

Parent Comprehension of Polio Vaccine Information Pamphlets

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ABSTRACT. *Background.* Medical information pamphlets often are written using language that requires a reading level higher than parents of many pediatric patients have achieved. Anecdotal reports suggest that many parents may not readily understand the federally mandated Public Health Service vaccine information pamphlets prepared by the Centers for Disease Control and Prevention (CDC) in 1991. The level at which the pamphlets need to be written for low-reading-level parents is undetermined, as is whether parents reading at higher levels will accept low-reading-level materials.

Methods. To determine whether a simple pamphlet prepared at a low reading level using qualitative and adult education techniques would be preferable to the available CDC polio vaccine information pamphlet, we conducted an integrated qualitative-quantitative study. We compared the parent reading time and comprehension of a simplified pamphlet (Louisiana State University, LSU) comprising 4 pages, 322 words, 7 instructional graphics, and a text requiring a 6th grade reading ability with the equivalent 1991 CDC vaccine information pamphlet comprising 16 pages, 18,117 words, no graphics, and a text requiring a 10th grade reading level. We measured the reading ability of 522 parents of pediatric patients from northwest Louisiana seen at public clinics (81%) and in a private office (19%). Of the entire group, 39% were white, 60% African-American, and 1% Hispanic; the mean age was 29 years; the mean highest grade completed was 12th grade 3 months; and the reading level was less than 9th grade in 47% of parents and less than 7th grade in 20%. After parents were given one of the pamphlets to read, their reading time, comprehension, and attitude toward the pamphlet were measured.

Results. Mean comprehension was 15% lower for CDC than for LSU (56% vs 72% correct; $P < .001$) and reading time was three times longer for CDC than for LSU (13 minutes 47 seconds vs 4 minutes 20 seconds; $P < .0001$). These trends were significant for parents reading at all but the lowest levels. Mean comprehension and reading time did not differ among parents reading at the third grade level or less. However, mean comprehension was greater and reading time lower for LSU among parents at all reading abilities greater than the third grade. Parents in the private practice setting took the longest time to read the CDC (20 minutes 59 seconds vs 5 minutes 46 seconds, LSU), yet their comprehension on the LSU

was significantly higher than on the CDC (94% vs 71%; $P < .0001$). Two focus groups of high-income parents were unanimous in preferring the LSU.

Conclusions. A short, simply written pamphlet with instructional graphics was preferred by high- and low-income parents seen in private and public clinics. The sixth grade reading level appears to be too high for many parents in public clinics; new materials aimed at third to fourth grade levels may be required. The new 1994 CDC immunization materials, written at the eighth grade level, may still be inappropriately high. The American medical community should adopt available techniques for the development of more effective patient-parent education materials. *Pediatrics* 1996;97:804-810; *adult literacy, patient education materials, patient comprehension, polio vaccine information pamphlet, informed consent.*

ABBREVIATIONS. CDC, Centers for Disease Control and Prevention; LSUMC-S, Louisiana State University Medical Center in Shreveport; LSU, Louisiana State University; REALM, Rapid Estimate of Adult Literacy in Medicine.

The National Childhood Vaccine Injury Act of 1986 requires that individuals who administer a vaccine included in the Act must give parents the appropriate Public Health Service vaccine information pamphlet prepared by the Centers for Disease Control and Prevention (CDC) or develop pamphlets that meet the requirements of the Act.^{1,2} Three pamphlets prepared in 1991 became available in April 1992; one for the diphtheria, tetanus, and pertussis vaccines; one for the polio vaccine; and one for the measles, mumps, and rubella vaccines.

The CDC estimates it will take 15 to 20 minutes for an adult who reads at the ninth grade level to read each pamphlet.² Frequently voiced complaints about the 1991 pamphlets are that they are too long, too detailed, and too difficult to read thoroughly, particularly in a physician's office or a public health clinic.²⁻⁴ In response to these concerns, Public Law 103-183, passed in 1993, includes the requirement that the pamphlets be simplified. In early 1994 the CDC began releasing vaccine materials written at an eighth grade reading level. These are not yet available in final form.²

A previous study found that only 35% of parents and caretakers of pediatric patients cared for in public clinics had reading levels at or above a ninth grade level, despite the fact that 95% had received at least a ninth grade education.⁵ The reading abilities of most adult patients in public family practice, internal medicine, and obstetric clinics, and of parents of pediatric patients in public hospitals have been

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shown to be much lower than the required reading levels of written materials, such as the vaccine information pamphlets.⁵⁻¹⁰

The purpose of this study was to develop a simplified polio vaccine pamphlet using state-of-the-art qualitative research and adult education methods and then to compare the available 1991 CDC polio vaccination informational pamphlet to the simplified pamphlet with regard to comprehension, reading time, and perception of parents of both high and low socioeconomic status.

METHODS

Study Locations

The pamphlet comprehension study was conducted at three clinic sites in Shreveport: the pediatric clinic of Louisiana State University Medical Center in Shreveport (LSUMC-S), a large public university hospital serving predominantly the indigent and Medicaid populations of northwest Louisiana; the Caddo Parish Health Unit; and a three-physician private pediatric office.

Development of Louisiana State University (LSU) Polio Pamphlet Using Focus Groups

The authors conducted a series of focus groups among parents of high and low socioeconomic status with varied reading skills. An adult learning center, two job training facilities, and the office of the Shreveport Junior League were used. The groups helped the authors develop and evaluate their pamphlet and develop a quantitative questionnaire. The Junior League focus groups also helped evaluate whether high-income parents would accept low reading level materials. The participants agreed that they wanted a vaccine pamphlet with bright colors, color graphics, and portrayals of ethnically diverse people.

The authors then simplified and condensed the text of the CDC pamphlet, following published guidelines for developing patient education materials for readers with low literacy skills.¹⁰⁻²³ The goal was to produce a simplified pamphlet that was short, colorful, and appealing, while containing the essential behavioral information the physicians believed parents needed to know. The pamphlet was not designed to give all the information included in the 1991 CDC polio pamphlet, nor was it designed to meet the needs of special interest groups or to tell parents everything about polio. In the LSU brochure parents are encouraged to have their children vaccinated on time, and they are informed of the basic risks. The objectives of the content and illustrations were both behavioral and instructional. The pamphlet was designed with the additional objective of being practical and appealing to parents in both public and private settings. The final version contains instructional graphics using developmentally accurate, racially neutral figures (Fig 1).

Description of Polio Vaccine Pamphlets

The 1991 CDC polio pamphlet is a black and white, nonillustrated, 8-1/2 by 5-1/2 inch booklet. The title is "Polio, What You Need to Know." The pamphlet has a total of 18,117 words printed on 16 pages (including the cover). Readability calculated using Grammatik IV²⁴ software revealed a Fog Index²⁵ of a 10th grade reading level and a Flesch-Kincaid²⁶ of 8th grade.

The final version of the LSU polio pamphlet is bright yellow with a full-color graphic of a mother and child on the cover. The title is "Take Care of Your Child & All Children Need the Polio Vaccine." The pamphlet is 8-1/2 by 5-1/2 inches and consists of 322 words printed on four pages (including the cover). The pamphlet contains seven instructional graphics. Readability calculated using Grammatik IV software revealed a Fog Index of a sixth grade reading level and a Flesch-Kincaid of fourth grade.

Study Population

The study population consisted of a convenience sample of 522 parents or adult patients seen in private and public pediatric clinics during July 1993. The adults waiting in the clinic were interviewed by a research assistant in a private room and invited to participate in the study. All adults who were accompanying

1. What is polio?

Polio is a disease. It is caused by a virus. Some children and adults who get polio may be paralyzed. There is no medicine to make people with polio better.

2. Take care of your child.

Get your child vaccinated for polio. Polio vaccine is the best way to keep children from getting polio.

3. Your child needs **4 doses** of the polio vaccine. The best times are:

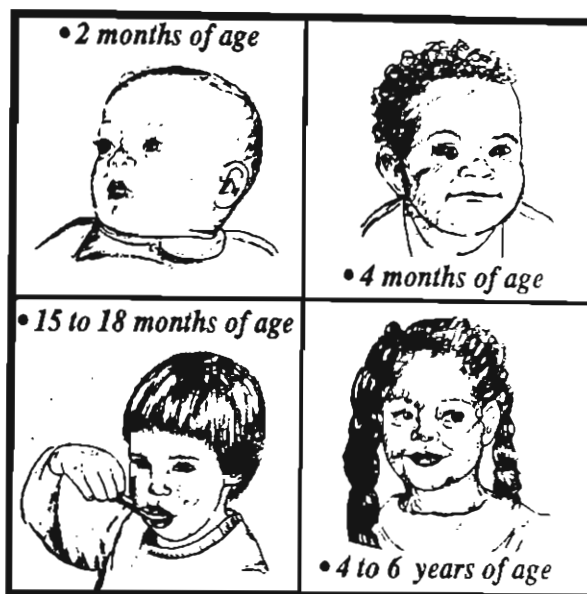


Fig 1. Instructional graphics from a Louisiana State University polio pamphlet.

children were tested with the children in the room. Testing was done by one of five research assistants (4 medical students and 1 college student), each of whom had training and at least one month's experience in test administration and interviewing. The entire protocol took approximately 20 minutes per patient.

Refusal

Of 568 potential subjects, 32 (6%) refused to participate, and in an additional 14 (2%) testing was not completed because the nurse or physician was ready to see the patient. Twelve (7%) of adults in LSU clinics, 18 (7%) in the public health clinic, and 2 (2%) in the private practice refused to participate. The primary reason given for refusal was that the parents were tired of waiting or too preoccupied with their children.

Pamphlet Comprehension Study Overview

The testing phase of the study was completed in 14 days during June to July 1993. After written consent was obtained, the adults were given a reading test, the Rapid Estimate of Adult Literacy in Medicine (REALM),^{27,28} and either the LSU or CDC to read. The research assistants then administered a questionnaire that included demographic questions and assessed parents' comprehension and attitudes about the pamphlet they had just read. To avoid contamination of results by previous exposure to a vaccine pamphlet, testing was done in staggered 7-day intervals. On the first 7 days of the study, the research assistants gave subjects the CDC polio vaccine pamphlet and during the second 7 days the simplified LSU pamphlet. Parents who had obtained immunization for children within the previous 2 weeks were excluded.

The research assistants asked the adults to read silently either

the CDC pamphlet or the LSU pamphlet and answer a few questions concerning their thoughts about the material. The research assistants recorded the length of time the subjects took to read the pamphlet. They then administered the structured questionnaire.

TESTING INSTRUMENTS

Questionnaire

The structured questionnaire included 9 demographic items written in standard national survey format, 9 questions assessing parents' comprehension of the pamphlet they received, and 10 assessing their attitudes about the pamphlet. Comprehension questions were open ended and graded as correct or incorrect. Four comprehension questions focused directly on risk (eg, "What are the risks of polio drops?"). Attitude questions (eg, "If someone gave you this pamphlet in a clinic, what are the chances you would read it?") were written on a five-point Likert Scale (responses ranged from "excellent" to "poor," with "don't know" as a sixth option). The nine comprehension questions assessed information that the pediatric infectious disease author (J.A.B.) believed were essential to parent education about the polio vaccination and informed consent and were consistent with mandates of the National Childhood Vaccine Act of 1986.

REALM Reading Test

The REALM^{27,28} is an individually administered screening instrument designed specifically for use in busy public health clinics. It is unique among reading recognition tests because all test words are commonly used lay medical terms, allowing it to be particularly useful in estimating literacy levels as they apply to medical settings. The 66-word test correlates highly with other standardized reading tests and can be administered and scored in 1 to 2 minutes by personnel with minimal training. The REALM identifies individuals with low reading ability and provides a reading grade range estimate for those who read at a ninth grade level or below.

Statistical Analysis

PC-SAS 6.04²⁹ was used to calculate descriptive statistics, correlation coefficients, χ^2 , and Student's *t*-test scores to determine significant difference on parents' reading time, comprehension, and attitude scores. Mean reading times and percentage of comprehension between groups were compared using Student's *t*-test, whereas differences in proportions reporting dichotomized attitudes/preferences were compared using χ^2 .

RESULTS

The 522 subjects tested ranged in age from 13 to 70 years, with a mean age of 29 years. A small minority were not the parents of the child brought to the clinic. Eleven percent of the caretakers were teenagers. The race of the subjects, last grade completed in school, insurance status, and other population characteristics are noted in Table 1. Twenty-eight percent of all parents had private health insurance for their dependents. There is no significant difference in the

demographic data of the caretakers who received each of the pamphlets.

Population Reading Levels

The mean REALM raw score of all subjects tested was 54, or seventh to eighth grade reading level. Forty-seven percent of all subjects were reading below a ninth grade level and 20% below a seventh grade level. A much larger percentage of parents seen in public clinics were reading below a ninth grade level (57%) compared with only 4% of parents seen in the private setting (Fig 2). The mean education level (last grade completed in school) was 12 years 3 months (Table 1). Sixty-five percent of subjects did not graduate from high school, although only 8% of subjects were younger than 19 years. Subjects' total comprehension scores were significantly correlated with total REALM scores (Pearson correlation coefficient 0.53, $P < .001$). Reading time was significantly correlated with REALM score, but the Pearson correlation coefficient was weak (0.14, $P < .01$).

Reading Time and Comprehension

The mean reading time was significantly longer ($P < .0001$) for the CDC than for the LSU pamphlet (13 minutes 47 seconds vs 4 minutes 20 seconds). Comprehension on the CDC was 56% in comparison to 72% on the LSU ($P < .0001$). When we examined reading times and comprehension within stratified reading groups, these trends remained stable (Figs 3 and 4). Among subjects who were reading on a high school level (ninth grade or above), the mean CDC time was 16 minutes 0 seconds vs 4 minutes 21 seconds for the LSU ($P < .0001$) and comprehension was 67% vs 83% for the LSU ($P < .0001$). Of the subjects who were functionally illiterate (reading on a sixth grade level or below on the REALM), there were similar differences in reading time for the CDC versus the LSU (9 minutes 39 seconds vs 4 minutes 57 seconds; $P < .0001$) and comprehension scores (CDC 37% vs LSU 51%; $P < .002$). Of the 31 subjects who were reading on a third grade level or below, there was a trend in comprehension scores (CDC 29% vs LSU 45%; $P < .07$) but no significant difference in time (CDC 7 minutes vs LSU 5 minutes 23 seconds; $P = .64$).

Parents in the private practice setting took signif-

TABLE 1. Demographics of Study Population (n = 522)

Age	Mean	29 years (+9.7)
	Range	13 to 70 years
Last grade completed	Mean	12.3 years (+2.1)
	Range	2 to 20 years
REALM reading level		Raw score (grade range)
	Mean	54 (7th to 8th grade)
	Range	1 to 66 (\leq 3rd grade to \geq high school)
Race	Black	60%
	White	39%
	Hispanic	1%
Site	Number of parents (%)	Percent privately insured
Private clinic	100 (19)	83
Hospital clinic	170 (33)	7
Public health unit	252 (48)	20
Total	522	28

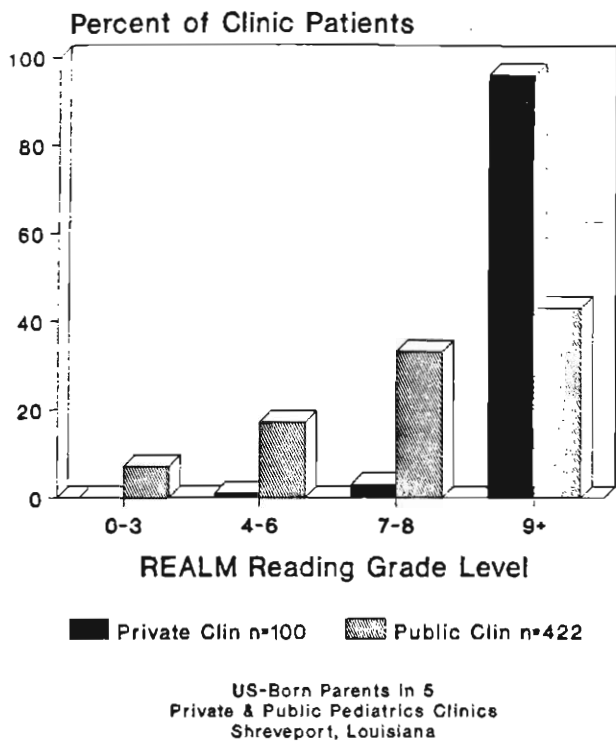


Fig 2. Reading grade levels of parents in private and public pediatric clinics.

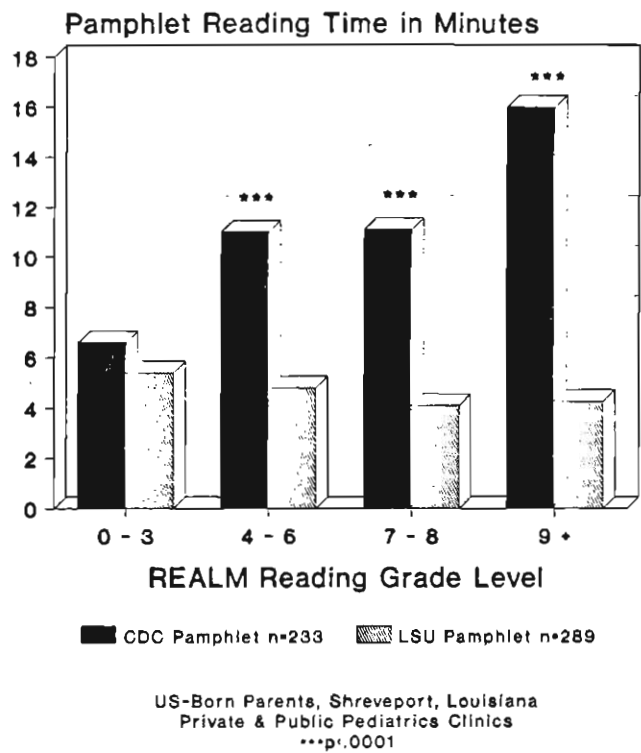


Fig 4. Mean reading time for parents given one polio vaccine pamphlet.

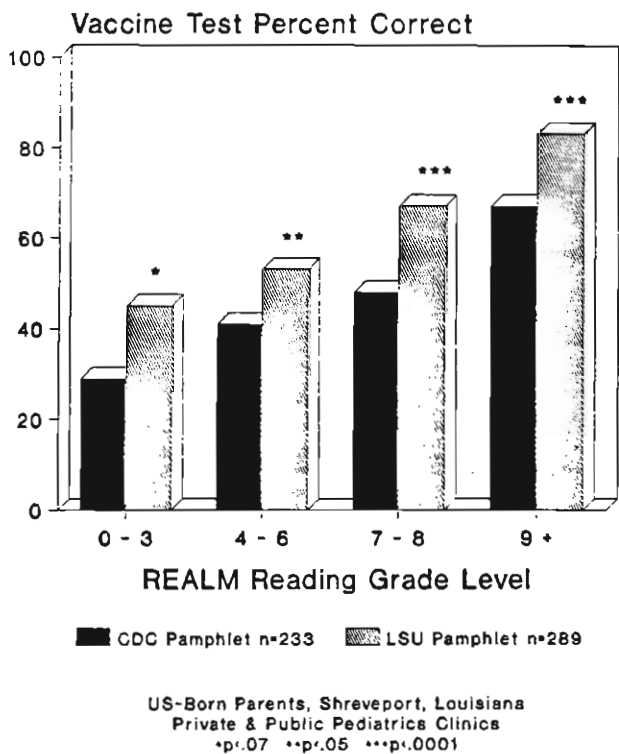


Fig 3. Mean polio vaccine test comprehension after reading one vaccine pamphlet.

icantly longer to read the CDC than the LSU (20 minutes 59 seconds vs 5 minutes 46 seconds; $P < .0001$) and their comprehension on the LSU was significantly higher on the LSU compared with the CDC (LSU 94% vs CDC 71%; $P < .0001$).

Parents had significantly higher comprehension of

questions dealing with informed consent after reading the LSU when compared with those who read the CDC (Table 2). On the four questions that dealt with the risks of the vaccine, in only one ("If your babysitter has not had the polio vaccine, what should you do?") was there a significant difference between the LSU and the CDC in the parents reading below a seventh grade level.

Attitude and Pamphlet Preference

High-income Junior League focus group participants were unanimous in preferring LSU over CDC. Quantitative results validated the qualitative findings. Ninety-nine percent of parents in the private office reported that if someone gave them the LSU pamphlet they would likely or very likely read it compared with 63% who reported the same for the CDC. Three percent of the parents given the LSU pamphlet said they were not likely to read it compared with 25% of the parents given the CDC. Ninety-two percent of parents seen in the private office who were given the LSU pamphlet said that their understanding of it was "very good" to "excellent," compared with 34% who read the CDC. Eighty-eight percent of private parents said the LSU pamphlet did a very good to an excellent job of encouraging them to have their child immunized compared with 65% of those who read the CDC.

A significantly higher proportion of all parents rated the LSU pamphlet (79%) as very good to excellent in explaining polio than the CDC (59%) ($P < .001$). Significantly fewer (3%) rated the LSU as fair to poor than the CDC (11%) ($P < .001$). Eighty-one percent of parents who were given the LSU pamphlet said that the chances they would read it if

TABLE 2 Comprehension of Informed Consent Questions (After Reading CDC or LSU Pamphlet)

		Parent Reading Level				
		All	≤3	4 to 6	7 to 8	≥9
What is the risk of getting the polio shot?	LSU	79%*	69%	64%	77%†	86%‡
	CDC	64%	28%	61%	57%	74%
Which vaccine is given to a child or someone at home who is taking prednisone or cancer medicine?	LSU	47%‡	15%	28%	41%†	59%
	CDC	33%	0	19%	21%	48%
If you are worried that your child has a problem after getting the vaccine, what should you do?	LSU	96%*	92%	89%	97%*	98%†
	CDC	87%	66%	87%	80%	93%
If your babysitter has not had the polio vaccine, what should you do?	LSU	43%*	15%	20%†	31%*	60%*
	CDC	5%	11%	3%	5%	5%

* $P < .0001$; † $P < .05$; ‡ $P < .01$.

it were given to them in a clinic were very good to excellent, whereas 49% ($P < .001$) said the same of the CDC pamphlet. Eighty-two percent of the LSU pamphlet readers said their understanding of the pamphlet was very good to excellent compared with 48% ($P < .001$) of the CDC readers. Concerning the appeal of the brochure, 71% (LSU) and 26% (CDC) reported high ratings for looks and 5% (LSU) and 42% (CDC) reported negative ratings. All differences cited were significant at the $\alpha < 0.05$ level. The ratings of the LSU pamphlet were similar for parents reading on a ninth grade level or above and parents who were functionally illiterate (reading at less than a seventh grade level on the REALM). In fact, all reading groups gave the LSU significantly higher approval ratings than the CDC. There was no significant difference in the approval ratings of the LSU pamphlet between private clinic parents and those seen in the public clinics.

DISCUSSION

The vaccine information pamphlets developed by the CDC in 1991 were designed to provide information about vaccines and enable informed consent. However, because of the length of the pamphlets, the amount of information provided, and the reading level, many physicians were concerned about their effectiveness. To address these issues, CDC pamphlets have been revised. Although shortened and simplified, they are written at an eighth grade level (Fog level)² and have no instructional graphics.

The results of this study indicate that parent comprehension can be maintained or improved by a simpler, shorter pamphlet that incorporates instructional graphics and a limited number of concepts. Reading time is shortened as well. Readers at all levels, in both public and private medical settings, also preferred the colorful, simple pamphlet. Qualitative and quantitative findings indicate that high socioeconomic patients with high reading ability can comprehend the 1991 CDC pamphlet, but prefer a simpler one that is easier to understand and can be read in one fourth the time.

Implications for Informed Consent

In the area of informed consent (Table 2) most parents seem to have difficulty understanding some of the risks of the polio drops; only 33% given the CDC and 47% given the LSU pamphlet answered the

question about prednisone/cancer contraindications correctly. Of those reading on a ninth grade level or higher, only half of those given the CDC and 59% of those given the LSU pamphlet understood this same contraindication. The low-level readers struggled most to understand these risks (0% CDC vs 15% LSU). Comprehension of the risk of the polio shot was significantly higher ($P < .0001$) for all subjects at all reading levels. This may indicate merely good guessing based on previous knowledge about the side effect of any injection. Although the CDC reports that physicians who use the vaccine information pamphlets will have reduced chances of having a negative judgment brought against them if they follow the law, our findings indicate that many public patients will have a difficult time comprehending the 1991 CDC brochure and that low-level readers may also have difficulty with the shortened pamphlets. These findings indicate that both the CDC and LSU pamphlets must do a better job of communicating the risks of oral polio vaccine and raise the question of the level of comprehension a patient achieves by reading other consent forms.

Implications for Patient Education Materials

One of the important clinical findings of this study is that adults' comprehension of patient education materials can be two to three grade levels below their reading grade level. Patient reading level is generally determined by reading recognition tests such as the REALM^{27,28} or the Wide-Range Achievement Test-Revised 3.³⁰ Word recognition is a beginning reading skill; comprehension is a higher order skill.^{31,32} Lower-level readers may be able to pronounce words, yet not comprehend their meanings.³²

This study also demonstrated that pamphlet readability levels determined by the Flesch-Kincaid,²⁶ the Fog Index,²⁵ or any other readability formula³³ cannot be relied on to predict comprehension. The LSU pamphlet (sixth grade level according to the Fog Index; fourth grade Flesch-Kincaid) did not produce an 80% level of comprehension on the questionnaire administered to the adult subjects until they scored at a ninth grade level or greater on the REALM. This confirms both the discrepancy between tested reading level and actual comprehension and the lack of exactness of readability formulae.

The discrepancies between adults' reading recognition and comprehension may be even more pro-

nounced in medical settings in which adequate parent comprehension may require parents not only to understand medical information, but to apply it by implementing specific behaviors. Our comprehension test was pragmatic and applied directly to medical situations. Test questions such as "If your babysitter has not had the vaccine, what should you do?" require parents to both understand the risks of the vaccine and apply this knowledge in a real-life context.

The findings of this study and the information gained in the focus groups indicate that the American Academy of Pediatrics, physicians, and hospitals may need to reevaluate standards for educational brochures, pamphlets, and informed consent forms. Most American Academy of Pediatrics materials for parent-patient education are written at an eighth grade level or higher.⁵ Our findings suggest that simple, short, colorful materials written at even lower levels actually may be more appealing to all audiences, and that even simpler materials with more instructional graphics, coupled with oral instruction, may be needed for parents reading below a seventh grade level.

Our experience and that of patient education specialists^{10,18-23} indicate that current materials contain an excessive amount of information that most patients do not find useful. The number of concepts per pamphlet should be limited. Pamphlet authors should determine the key points that the patient (or parent) needs to know to achieve the behavioral objectives. Nonessential concepts can then be deleted. The key is to write for the desired health behavior,¹⁸ rather than for high-level knowledge.

Our work demonstrates the usefulness and beneficial outcome of using focus groups of the target populations to help design and evaluate patient education brochures and questionnaires. Further studies need to be conducted with short, simple material developed in partnership with parents.

Implications for National Immunization Activities

The results of a 1993 National Adult Literacy Survey, the first to provide accurate and detailed information about the skills of the adult population as a whole, found that literacy skills were deficient among 47% of the United States adult population. More troubling for pediatric health providers is the fact that most of the adults scoring at such low levels did not perceive themselves at risk and, in fact, described themselves as being able to read and write English well to very well.

Our findings make the National Adult Literacy Survey data more relevant to pediatric health providers and to efforts to effectively provide information to parents concerning immunizations and the diseases they prevent. All physicians and public health officials who work with low-income families should be aware of the low comprehension scores of parents with limited reading skills (less than seventh grade). Fewer than 37% of parents who read the CDC pamphlet could answer the question "How old should your child be when he gets his first dose of the vaccine?" and fewer than one fourth knew how

many dosages of the vaccine were necessary. These results indicate that an unacceptably low percentage of low-level readers are comprehending important information in the 1991 CDC pamphlet. Although these low-level readers performed better after reading the LSU pamphlet, their comprehension scores remained unacceptably low. This indicates an important area for future research in patient education and interventions to improve compliance with immunization recommendations. Materials for these parents may need to be written at lower than a third grade level, contain even more graphics, and be supplemented by videotapes or oral instruction.

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