The Journal of Pain, Vol 8, No 10 (October), 2007: pp 753-758
Available online at www.sciencedirect.com

ELSEVIER

ORIGINAL REPORTS

Literacy Demands and Formatting Characteristics of Opioid Contracts in Chronic Nonmalignant Pain Management

Steven E. Roskos, Amy J. Keenum, Lindsay M. Newman, and Lorraine S. Wallace
University of Tennessee Graduate School of Medicine, Department of Family Medicine, Knoxville, Tennessee.

Abstract: Chronic nonmalignant pain affects a significant number of adults, with many requiring opioid medications to manage their symptoms. Although the content of typical opioid contracts (OCs) has been explored, no studies have examined the literacy demands and formatting characteristics of OCs currently used throughout the United States. We evaluated 162 English-language OCs submitted to us by current American Pain Society members residing in the United States. OCs were evaluated for reading grade level and formatting characteristics. The mean readability of OCs was at grade level 13.8 ± 1.3 (range = 10–17), whereas the average text point size was 11.0 ± 1.4 (range = 6–16). Active voice was used exclusively in almost half of OCs (n = 79, 48.8%). Most OCs contained not only sophisticated medical language but multisyllable, nonmedical terms and vocabulary not used in typical everyday conversation. Overall, most OCs reviewed presented information at much too high a reading grade level, and with formatting characteristics that probably would make these documents difficult for the average patient to fully comprehend.

***Perspective:** This study indicates that there is a mismatch between the reading demands of most OCs and the actual health literacy skills of American adults. Accordingly, those developing OCs should be cognizant of the actual literacy abilities of their patient population and design and evaluate OCs accordingly.*

***Key words:** Chronic opioid therapy, chronic pain, contract, nonmalignant pain, opioids.*

Editor's Note: Please see the related Editorial by Christopher L. Edwards and Lesco Rogers, page 824.

As documented in population-based studies, chronic nonmalignant pain affects a large proportion of both young[12] and older adults.[21] Despite the efficacy of opioids in managing chronic pain and improving patients' quality of life,[5,17,24] physicians are often reluctant to prescribe opioids for chronic nonmalignant pain for fear of regulatory scrutiny and/or the potential for patient dependence and abuse.[19,20,23,26] Given the ramifications of improper opioid use, it is imperative that the physician and patient reach a mutual understanding regarding the specific circumstances for which opioids are prescribed.

An opioid contract (OC) has been recommended by some pain specialists and primary care physicians as a key component in outlining instructions and expectations for appropriate opioid use and patients' rights and responsibilities.[1,3,7,9] However, there is some controversy about the value of OCs in certain patient populations, the nature of the information included, and their ability to accomplish positive outcomes. Nonetheless, guidelines have been offered regarding the content and tone of the OC.[7,9]

For an OC to be effective in outlining the conditions of treatment, it must be presented in a format that facili-

Received September 18, 2006; Revised December 5, 2006; Accepted January 5, 2007.
Supported by the Department of Family Medicine at the University of Tennessee Graduate School of Medicine-Knoxville.
Address reprint requests to Dr. Lorraine S. Wallace, University of Tennessee Graduate School of Medicine, Department of Family Medicine, 1924 Alcoa Highway, U-67, Knoxville, TN 37920. E-mail: lwallace@mc.utmck.edu
1526-5900/$32.00

doi:10.1016/j.jpain.2007.01.005

tates patient understanding and ultimately the informed consent process. Unfortunately, much of the patient education literature[2,8,10,11,28-30] and informed consent documents[15,18] are written at a reading level requiring advanced literacy skills. This trend is problematic given that approximately one third of all adults in the United States have below basic or basic health literacy skills.[16]

Although the content characteristics of typical OCs (ie, terms of treatment, patient responsibilities, emergency issues, legal considerations) has been previously described,[7] no studies have specifically assessed the readability and formatting characteristics of these documents. To address this gap, we examined the literacy demands and formatting characteristics of OCs currently used in clinical practices throughout the United States.

Materials and Methods

Design and Procedures

The researchers provided the American Pain Society (APS) with an overview of the study, which was subsequently approved. As per the researchers' request, the APS generated a simple random sample of 1000 current members (representing approximately one third of the current membership) during March 2006. Sixty-one (n = 61) of the current members identified were currently residing outside of the United States and were excluded from our analyses. The Institutional Review Board at the University of Tennessee Graduate School of Medicine-Knoxville approved the study protocol.

We sent each APS member residing in the United States (n = 939) a packet through the United States Postal Service via first-class mail. A brief, hand-signed cover letter describing the purposes and objectives of the study was enclosed. We also enclosed a response form in which each APS member indicated (check-box) whether or not they currently used an OC in their clinical practice. For those indicating that they currently used an OC in their clinical practice, we requested that they send a copy to us. Respondents were provided a self-addressed, stamped envelope in which they could send a copy of their OC to the researchers. As an incentive to participate, a $1.00 bill was enclosed in each packet, and respondents were entered into a random drawing for a 30 Gig Ipod (retail value, $300.00).

Evaluation Process

We calculated the readability (reading grade level) of each OC by using McLaughlin's Simplified Measure of Gobbledygoop (SMOG) formula.[13] We also assessed formatting characteristics—derived from the Suitability of Materials Assessment[6] and User-Friendliness Tool[2]—including typographical and layout features.

Calculation of Readability

The SMOG has been used extensively in assessments of readability of health-related materials.[8,14,28,30] First, 3 groups of 10 consecutive sentences at the beginning, middle, and end of a document are selected. Then, all words with 3 or fewer syllables are identified and the total summed. Next, the square root of the total is rounded to the nearest integer. Last, the reading grade level of the document is obtained by adding 3 to this integer. A modified SMOG formula was used to assess the readability of documents with less than 30 sentences.[31]

Formatting Characteristics

The total number of pages of each OC was tallied. Text point size of the main body of each OC was determined by measuring the distance from the ascent line (top of the capital letters) to the descent line (bottom-most descender, eg, lowermost portion of the lower case letter p or y) with a C-Thru Ruler (C-Thru Ruler Company, Bloomfield, CT). Language used throughout each OC was categorized as active voice, passive voice, or a combination of active and passive voice.

Table 1. Representative List of States Represented and Not Represented

States Represented (n = Contracts Reviewed)	States Not Represented
Alabama (n = 3)	Alaska
Arizona (n = 3)	Arkansas
California (n = 17)	Maine
Colorado (n = 4)	Mississippi
Connecticut (n = 1)	Nebraska
Delaware (n = 2)	New Mexico
Florida (n = 7)	North Dakota
Georgia (n = 6)	Oklahoma
Hawaii (n = 1)	Rhode Island
Idaho (n = 2)	South Dakota
Illinois (n = 9)	West Virginia
Indiana (n = 7)	Wyoming
Iowa (n = 1)	
Kansas (n = 1)	
Kentucky (n = 2)	
Louisiana (n = 4)	
Maryland (n = 5)	
Massachusetts (n = 2)	
Michigan (n = 6)	
Minnesota (n = 5)	
Missouri (n = 3)	
Montana (n = 2)	
Nevada (n = 1)	
New Hampshire (n = 1)	
New Jersey (n = 7)	
New York (n = 5)	
North Carolina (n = 4)	
Ohio (n = 5)	
Oregon (n = 5)	
Pennsylvania (n = 6)	
South Carolina (n = 1)	
Tennessee (n = 3)	
Texas (n = 8)	
Utah (n = 2)	
Vermont (n = 3)	
Virginia (n = 10)	
Washington (n = 3)	
Wisconsin (n = 5)	

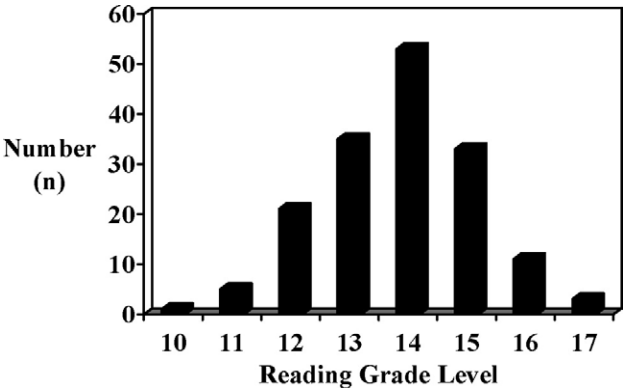

Figure 1. Distribution of reading grade levels of opioid contracts (n = 162).

Last, we assessed each OC on the following features: Font style for reading ease (ie, avoidance of all-capital letters, italics, and specialty fonts), use of ample white space, paragraph length (less than 4 to 5 lines), sentence length (ie, short), use of common words (ie, words are common or defined), use of headers/separators, visual presentation of information (eg, bullets, boxes), and whether information was limited to "need to know." Each OC was evaluated on each of the aforementioned features as follows: 2 (superior), 1 (adequate), or 0 (poor). Because of the subjective nature of this evaluation method, the last author reviewed all OCs (n = 162), whereas the first author reviewed 20 randomly selected OCs. For 92% of these features, both reviewers assigned the same score.

Statistical Analyses

All data were entered and analyzed with the use of the Statistical Package for the Social Sciences (SPSS+) for Windows, Version 14.0 (SPSS, Chicago, IL). Descriptive statistics (percentages, frequencies, means, standard deviations) were calculated to describe the literacy demands and formatting characteristics of OCs.

Results

Response Rate

Of the 939 packets mailed to APS members residing in the United States, 27 were returned to the researchers because of incorrect/incomplete mailing addresses. Therefore, of the 912 packets mailed to APS members, a total of 367 responses were received, yielding a corrected response rate of 40.2% (367/912). Two hundred five (n = 205) APS members indicated that they currently did not use an OC in their clinical practice, whereas 162 included a copy of their OC with their response. We received OCs from APS members representing 38 states (Table 1).

Readability

The mean SMOG reading grade level of OCs was 13.8 ± 1.3 (range = 10–17). Most OCs (n = 100, 61.7%) were written at or above the 14th reading grade level, whereas none were written at or below the recommended reading level of 6th grade[6,32] (Fig 1).

Examples of text extracted from OCs written at or above the 14th reading grade level are presented in

Table 2. Selected Text From Opioid Contracts Highlighting Patient Responsibilities*

Additional Treatment	
	"Medications are given as part of an overall treatment program, and I will do all in my power to cooperate and participate in the range of non-medicinal efforts to be undertaken."
Guarding Medication	
	"It must also be safeguarded from inadvertent use by other adults or intentional use by those who abuse drugs."
Legal Considerations	
	"If the medication was stolen and I can provide legitimate police reports to substantiate the circumstances surrounding the medication theft, special exceptions may be made."
	"All of these drugs have the potential for abuse or diversion and, accordingly, rather strict accountability is necessary when use is prolonged."
	"The Pain Center staff may confer with my pharmacist(s) regarding my medication profile."
Points of Termination	
	"I am aware that failure to abide by any of these conditions will be considered a breach of this contract and may result in the termination of the patient-provider relationship."
Prohibited Behavior	
	"I understand that I am absolutely prohibited from abusing alcohol, marijuana, or other street or recreational drugs."
	"I will not consume excessive amounts of alcohol in conjunction with narcotics, nor will I use, purchase, or otherwise obtain any illegal substances."
Terms of Treatment	
	"I will communicate fully with my doctor about the character and intensity of my pain."
	"Unannounced urine or serum toxicology screens may be requested and your cooperation is required."
	"I agree to carry only the needed amount of medicine on my person."
	"Most patients on this type of regime find that the amount of improvement they experience in a level of pain and their overall function outweighs the side effects and risks, but the degree of improvement varies between individuals, as do the occurrence and severity of the side effects, making it impossible to predict who will and who will not benefit as expected."

*Extracted from opioid contracts written at or above the 14th reading grade level.

Table 3. Selected Text From Opioid Contracts Highlighting Precautionary Considerations*

Abuse
"The majority of deaths attributed to opioids occur in nonpatients who deliberately abuse a combination of substances."
"Patients can endure this residual pain, as long as their dose of opioids is titrated up to a level where they can function."
"Opioid medication may be hazardous or lethal if inadvertently taken by someone who is intolerant to the medication (especially children) or by a person different from whom they were prescribed or in a manner different than they were prescribed."
Risk Factors
"I understand that these are potentially dangerous medications and that, if taken improperly, may lead to excess sedation, respiratory depression, and death."
Side Effects
"I understand that these medications may cause drowsiness and/or diminish my ability to think clearly, and it is my responsibility to monitor myself and make judgments on a moment-to-moment basis about my ability to operate a motor vehicle."
Tolerance
"I understand that with gradual titration and continued use I will develop tolerance, which will allow me to take dosages of opioids that would kill an opioid-naive individual."
"I am aware that tolerance to analgesia means that I may require more medicine to get the same amount of pain relief."
"While physical dependence is to be expected after long-term use of opioids, signs of addiction and psychological dependence shall be interpreted as a need for weaning or slowly discontinuing the opioid medication."
Use during Pregnancy
"I understand that any medicine has at least some potential for injuring a fetus."
"I am aware that, should I carry a baby to delivery while taking these medications, the baby will be physically dependent on opioids."
Withdrawal
"Abrupt withdrawal symptoms may include sweating, irritability, tremors, and extreme discomfort."

*Extracted from opioid contracts written at or above the 14th reading grade level.

Tables 1 and 2. Sample text highlighting patient responsibilities (additional treatment, guarding medications, legal considerations, points of termination, prohibited behavior, and terms of treatment) are displayed in Table 2. Precautionary considerations (abuse, risk factors, side effects, tolerance, use during pregnancy, and withdrawal) associated with opioids are depicted in Table 3.

Formatting Characteristics

Most OCs contained 1 to 2 pages (range = 1 to 8). Text point size ranged from 6 to 16 (mean = 11.0 ± 1.4). Active voice was used throughout 79 (48.8%) OCs, whereas passive voice was used in 48 (29.6%). A combination of active and passive voice was used in 35 (21.6%) OCs.

Table 4 depicts typographical and layout features of the OCs. Overall, very few OCs scored in the superior range on any typographical/layout feature. Most OCs scored in the adequate range for font style (n = 128, 79.0%), use of headers/separators (n = 99, 61.1%), and paragraph length (n = 93, 57.4%). A significant number of contracts scored in the poor range for use of common words (n = 150, 92.6%), limiting information to "need to know" (n = 136, 84.0%) and use of ample white space (n = 117, 72.2%).

Discussion

The most important finding of our study was that all OCs reviewed exceeded the recommended 6th reading grade level, with most requiring the patient to have proficient health literacy skills. This finding is problematic because only 12% of American adults have proficient health literacy skills.[16] Most OCs contained not only sophisticated medical language (eg, toxicology, titrated, analgesia) but multisyllable, nonmedical terms (eg, conjunction, inadvertent, vigilance, substantiate) and vocabulary not used in typical everyday conversation (eg, "character of my pain," "should I carry a baby to delivery").

As presented in Table 5, complex text can be revised to comply with recommended literacy guidelines and ultimately improve patient comprehension. Ideally, OCs should be revised to meet low-literacy formatting guidelines.[6,32] Once OCs have been developed in accordance with low-literacy recommendations, they should be evaluated in the patient population in whom they will be delivered. Specifically, patient understanding and comprehension of the content included in the OC needs to be

Table 4. Typographical and Layout Features of Opioid Contracts (n = 162)

Typographical/Layout Feature*	Evaluation, N (%)		
	Superior	Adequate	Poor
Font style for reading ease (avoidance of all-capital letters, italics, and specialty fonts)	3 (1.9)	128 (79.0)	31 (19.1)
Use of ample white space	0	45 (27.8)	117 (72.2)
Paragraph length (<4 to 5 lines)	10 (6.2)	93 (57.4)	59 (36.4)
Sentence length (ie, short)	2 (1.2)	45 (27.8)	115 (71.0)
Use of common words (ie, words are common or defined)	0	12 (7.4)	150 (92.6)
Use of headers/separators	3 (1.9)	99 (61.1)	60 (37.0)
Information limited to "need to know"	0	26 (16.0)	136 (84.0)

*Based on established criteria.[19,25,28]

Table 5. Current Versus Revised* Text From Opioid Contracts

Current Text	*Revised Text*
"The Pain Center staff may confer with my pharmacist(s) regarding my medication profile."	"The Pain Center staff may talk to my pharmacist about all of the medicines I am taking."
"I know that any medicine has at least some potential for injuring a fetus."	"My baby could be harmed if I take this medicine while I am pregnant."
"Abrupt withdrawal symptoms may include sweating, irritability, tremors, and extreme discomfort."	"If I stop taking the medicine too quickly, I may have bad side effects. I may sweat, lose my temper, or shake."
"It must be safeguarded from inadvertent use by other adults or intentional use by those who abuse drugs."	"I will keep my pain medicine in a safe place. I will make sure that I am the ONLY person to take this medicine."
"Unannounced urine or serum toxicology screens may be requested and your cooperation is required."	"Dr. ___ will ask me to take random urine (pee) and blood tests to make sure that I am taking my medicine the right way."

*Based on established criteria.[19,25,28]

assessed directly—having patients read and explain in their own words what each statement means—to ensure that patients truly understand the benefits, risks, and the reciprocal responsibilities related to opioid administration. This systematic approach has been shown to be effective in documenting patient understanding of advance directive informed consent documents[25] and injury prevention materials for children.[27]

Exceeding high reading demands was not the only factor that may impede patient comprehension and the informed consent process. Overall, most OCs were text-dense, with little white space and smaller-than-recommended text size.[6,32] Sentences tended to be lengthy, with uncommon words used throughout without definition. Many OCs used solely passive voice, which is generally more difficult for the patient to understand than active voice. Similar to other patient education materials,[2] most OCs contained significantly more information than the patient really "needed to know."

Despite the shortcomings of the OCs reviewed, many formatting characteristics matched recommended low-literacy guidelines.[6,32] For instance, font style was usually adequate, with avoidance of unusual font styles or all capitals. Paragraph length was often sufficient (less than 4 to 5 lines), whereas headers and separators were used routinely throughout OCs. Those developing OCs should build on these formatting strengths and be cognizant of additional formatting characteristics that may improve patient comprehension (ie, larger text size, greater white space, use of active voice).

Limitations

Our study has several limitations that should be considered when interpreting the results. Although we reviewed 162 contracts from 38 states, our response rate was approximately 40%. Although this response rate is typical of similar populations,[4,22] the possibility of selection bias remains. Second, our review was limited to OCs currently used in the United States. We did not contact APS members residing outside of the United States because we were only able to adequately review and calculate readability on OCs written in the English language. Three US respondents included OCs written in the Spanish language; however, we did not review these documents. Third, our evaluation of some of the typographical and layout features was subjective. However, we did have high inter-rater reliability. Last, it is unlikely that an OC is simply distributed to the patient without further assistance or explanation by clinical personnel. Unfortunately, there was no way for us to evaluate verbal explanations provided to supplement the OC itself. However, we would argue that the OC should be easily understandable to the majority of patients without additional verbal explanation or clarification.

Conclusions

In conclusion, most OCs reviewed presented information at much too high a reading grade level, and with formatting characteristics that probably would make these documents difficult for the average patient to fully comprehend. Physicians who elect to use OCs to assist their treatment of chronic nonmalignant pain should develop OCs in compliance with generally accepted low-literacy standards for patient education materials.[6,32] Future directions for research could include the development and pilot testing of low-literacy OCs, followed by measuring the effect of low-literacy OCs on quality of care for patients with chronic nonmalignant pain.

References

1. Adams N, Plane M, Fleming M, Mundt M, Saunders L, Stauffacher: Opioids and the treatment of chronic pain in a primary care sample. J Pain Sympt Manage 22:791-796, 2001

2. Arnold CL, Davis TC, Frempong JO, Humiston SG, Bocchini A, Kennen EM, Lloyd-Puryear M: Assessment of newborn screening patient education materials. Pediatrics 117:S320-S325, 2006

3. Arnold R, Han P, Seltzer D: Opioid contracts in chronic nonmalignant pain management: Objectives and uncertainties. Am J Med 119:292-296, 2006

4. Cowan AE, Winston CA, Davis MM, Wortley PM, Clark SJ: Influenza vaccination status and influenza-related perspectives and practices among US physicians. Am J Infect Control 34:164-169, 2006

5. Devulder J, Richarz U, Nataraja SH: Impact of long-term use of opioids on quality of life in patients with chronic, non-malignant pain. Curr Med Res Opin 21:1555-1568, 2005

6. Doak C, Doak L, Root J: Teaching Patients with Low Literacy Skills. 2nd ed. Philadelphia, Pa, JB Lippincott Company, 1996

7. Fishman S, Bandman T, Edwards A, Borsook D: The opioid contract in the management of chronic pain. J Pain Sympt Manage 18:27-37, 1999

8. Freda MC: The readability of American Academy of Pediatrics patient education brochures. J Pediatr Health Care 19:151-156, 2005

9. Jacobsen P, Mann J: The valid informed consent-treatment contract in chronic non-cancer pain: Its role in reducing barriers to effective pain management. Compr Ther 30: 101-104, 2004

10. Kaphingst KA, Rudd RE, DeJong W, Daltroy LH: Literacy demands of product information intended to supplement television direct-to-consumer prescription drug advertisements. Patient Educ Couns 55:293-300, 2004

11. Kirksey O, Harper K, Thompson S, Pringle M: Assessment of selected patient educational materials of various chain pharmacies. J Health Commun 9:91-3, 2004

12. Mallen C, Peat G, Thomas E, Croft PR: Severely disabling chronic pain in young adults: Prevalence from a population-based postal survey in North Staffordshire. BMC Musculoskel Disord 21:42-47, 2005

13. McLaughlin G: SMOG grading: A new readability formula. J Reading 12:639-646, 1969

14. Meade CD, Smith CF: Readability formulas: Cautions and criteria. Patient Educ Counsel 17:153-158, 1991

15. Molina L: Readability of education materials and informed consent forms for women seeking surgical sterilization. Int J Gynaecol Obstet 73:177-178, 2001

16. National Center for Education Statistics. National Assessment of Adult Literacy: A First Look at the Literacy of America's Adults in the 21st Century. NCES Publication No. 2006470. December 2005

17. Nicholson B: Responsible prescribing of opioids for the management of chronic pain. Drugs 63:17-32, 2003

18. Paasche-Orlow M, Taylor H, Brancati F: Readability standards for informed-consent as compared with actual readability. N Engl J Med 348:721-726, 2003

19. Ponte CD, Johnson-Tribino J: Attitudes and knowledge about pain: an assessment of West Virginia family physicians. Fam Med 37:477-480, 2005

20. Potter M, Schafer S, Gonzalez-Mendez E, Gjeltema K, Lopez A, Wu J, Pedrin R, Cozen M, Wilson R, Thom D, Croughan-Minihane M: Opioids for chronic nonmalignant pain: Attitudes and practices of primary care physicians in the UCSF/Stanford collaborative research network. J Fam Pract 50:145-151, 2001

21. Reyes-Gibby CC, Aday LA, Todd KH, Cleeland CS, Anderson KO: Pain in aging community-dwelling adults in the United States: Non-Hispanic whites, non-Hispanic blacks, and Hispanics. J Pain 8:75-84, 2007

22. Rothschild JM, Fang E, Liu V, Litvak I, Yoon C, Bates DW: Use and perceived benefits of handheld computer-based clinical references. J Am Med Inform Assoc 13:619-626, 2006

23. Scanlon MN, Chugh U: Exploring physicians' comfort level with opioids for chronic noncancer pain. Pain Res Manage 9:195-201, 2004

24. Simon S: Opioids and treatment of chronic pain: Understanding pain patterns and the role for rapid-onset opioids. Med Gen Med 23:54, 2005

25. Sudore RL, Landefeld CS, Williams BA, Barnes DE, Lindquist K, Schillinger D: Use of a modified informed consent process among vulnerable populations: A descriptive study. J Gen Intern Med 21:867-873, 2006

26. Trescot AM, Boswell MV, Atluri SL, Hansen HC, Deer RT, Abdi S, Jasper JF, Singh V, Jordan AE, Johnson BW, Cicala RS, Dunbar EE, Helm S, Varley KG, Suchdev PK, Swicegood JR, Calodney AK, Ogoke BA, Minore WS, Manchikanti L: Opioid guidelines in the management of chronic non-cancer pain. Pain Physician 9:1-39, 2006

27. Trifiletti LB, Shields WC, McDonald EM, Walker AR, Gielen AC: Development of injury prevention materials for people with low literacy skills. Patient Educ Couns 64:119-127, 2006

28. Wallace LS, Lennon ES: American Academy of Family Physicians patient education materials: can patients read them? Fam Med 36:571-574, 2004

29. Wallace LS, Rogers ES, Turner LW, Keenum AJ, Weiss BD: Suitability of written supplemental materials available on the Internet for nonprescription medications. Am J Health Syst Pharm 63:71-8, 2006

30. Wegner MV, Girasek DC: How readable are child safety seat installation instructions? Pediatrics 111:588-591, 2003

31. Weinrich SP, Boyd MD, Power BD: Tool adaptation for socioeconomically disadvantaged populations, in Frank-Stromborg M, Olsen SJ (eds): Instruments for Clinical Health Care Research. 2nd ed. Sudbury, MA, Jones & Bartlett, 1997

32. Weiss BD: Health Literacy: A Manual for Clinicians. Chicago, IL: American Medical Association Foundation, 2003