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Development and Validation of a Low-Literacy Opioid Contract

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Abstract: Opioid contracts (OPCs) are often used to outline the criteria and circumstances for which opioid medications are prescribed. The purpose of this study was to develop and validate an English-language, low-literacy OPC. Specifically, the low-literacy OPC was designed to outline proper administration of prescribed medication(s) as well as highlight patient responsibilities and expectations. A 4-step process was used to develop and validate the low-literacy OPC, including: (1) content identification; (2) attention to low-literacy guidelines; (3) evaluation based on Suitability Assessment of Materials (SAM) criteria; and (4) pilot testing with patients ($n = 18$) to assess comprehension. Final OPC content, presented largely in bulleted format, was based on current literature and consensus of the first 3 authors. The 4-part OPC was formatted on $8\frac{1}{2} \times 11$ inch paper using 16- to 24-point size Arial-style font. The 6-page OPC, written at the 7th reading grade level, included 12 recognizable clipart-type illustrations to supplement written text. Two reviewers scored the OPC in the superior range based on total SAM percentage scores. Nineteen ($n = 19$) of the 26 statements were comprehended by all patients completing the pilot testing. Overall, the low-literacy OPC is comprehensive, valid, readable, and formatted according to established low-literacy guidelines.

Perspective: This study describes the development and validation of a low-literacy, English-language OPC. The OPC was formatted using low-literacy guidelines and validated with a sample of patients to confirm understanding of content. Accordingly, the low-literacy OPC is suitable for use in routine clinical practice.

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

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

Chronic noncancer pain is 1 of the most frequent reasons people seek medical care.^{6,29,32} For instance, musculoskeletal pain accounted for almost 10% of office-based visits in the United States between 1980 and 2000.⁴ Consequently, primary care physicians (PCPs) often prescribe opioids in an attempt to alleviate patients' symptoms and improve their overall functioning. Despite a sharp and steady increase in opioid prescribing over the past 10 to 20 years,^{4,22} many PCPs are uneasy prescribing opioids due to lack of training and

concerns regarding drug abuse, addiction, adverse outcomes, and tolerance.^{2,24,32}

Opioid abuse, accounting for almost 10% of all drug abuse in 2002,¹¹ has escalated in recent years.⁵ The societal and economic costs—healthcare, criminal justice, and workplace productivity—of opioid abuse are significant.³ Further, illicit drug abuse in patients with chronic pain receiving opioids is common,^{13,17} and emergency departments often maintain lists of nontherapeutic drug-seeking patients.¹⁰

Given the potential adverse outcomes related to opioid abuse and misuse on both individual and societal levels, an Opioid Contract (OPC) could potentially serve as a vehicle in outlining the criteria and circumstances for which opioids are prescribed.^{9,14} In a recent study of English-language OPCs used by American Pain Society members, Roskos et al²⁵ found that all OPCs required advanced health literacy skills to fully comprehend. However, as highlighted in national reports by the Institute of Medicine,²¹ American Medical Association Foundation,²⁶ and National Assessment of Adult Literacy²⁰ only a small proportion of American adults have proficient

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health literacy skills. Further, similar to the reading demands of OPCs, patient education materials^{33,34,38} and informed consent documents^{19,23} are typically written at levels beyond the actual reading abilities of the majority of American adults. In light of these findings, the purpose of this study was to develop and validate an English-language low-literacy OPC. Specifically, the low-literacy OPC was designed to outline proper administration of prescribed medication(s) as well as highlight patient responsibilities and expectations.

Materials and Methods

Design and Procedures

Development of the low-literacy OPC included 4 sequential steps, each with a specific aim. The aim of Step 1 was to identify content to be included in the OPC. The aim of Step 2 was to develop the OPC based on low-literacy guidelines. The aim of Step 3 was to critically evaluate the OPC based on established criteria for low-literacy patient education materials. The aim of Step 4 was to pilot test the OPC with a convenience sample of patients to assess comprehension of content. The 4 steps are described in detail below. The institutional review board at the University of Tennessee Graduate School of Medicine-Knoxville approved the procedures for this study.

Step 1: Identification of OPC Content

The aim of Step 1 was to identify content to be included in the OPC. First, after a MEDLINE literature search to locate studies related to OPC content, a review article by Fishman et al⁹ was identified. The first author generated initial content for the low-literacy OPC based on Fishman's⁹ content review of OPCs from 39 academic pain centers throughout the United States. Next, both physician authors reviewed the content proposed by the first author to ensure that all pertinent material was included. Based on consensus of the first 3 authors, final OPC categories and content were agreed on.

Step 2: Development of OPC Based on Low-Literacy Guidelines

The aim of Step 2 was to develop the OPC based on low-literacy guidelines, including recommendations for suitable reading grade level and formatting characteristics.

Reading Grade Level

Pertinent content identified during Step 1 was organized to construct complete sentences. Sentences were written and continually revised to make each statement as straightforward as possible without taking away from the intended content. Further, one- or two-syllable words were used when possible.

The Flesch Reading Ease (FRE) was used to calculate the reading grade level of the OPC. The formula is $206.835 - (1.015 * ASL) - (84.6 * ASW)$, where ASL is the average sentence length (total number of words/total number of sentences) and ASW is the average number of syllables per word (total number of syllables/total number of

words). Scores on the FRE range from 0 (very difficult to read) to 100 (easy to read).³¹

Formatting Characteristics

On completion of sentence construction, text was organized according to similar content. Next, the OPC was formatted based on suggested low-literacy guidelines in the literature,³⁶ including: (1) font ≥ 12 point; (2) consistent font style; (3) combination of uppercase and lowercase text; (4) adequate amount of white space; (5) use of headers and separators; (6) use of bullets; and (7) use of recognizable illustrations. Further, the Institute for Healthcare Advancement's English-version of the California Advance Health Care Directive was reviewed to garner ideas regarding formatting of a low-literacy contract.¹²

Step 3: Evaluation of OPC Based on Established Criteria for Low-Literacy Materials

The fourth author and an independent rater separately assessed the OPC using the Suitability Assessment of Materials instrument (SAM).⁸ Both reviewers were provided the OPC, detailed SAM scoring instructions and a SAM evaluation form.

The SAM is comprised of 6 main categories (Content [content about behaviors, scope is limited, summary or review included], Literacy Demand [reading grade level, writing style/active voice, vocabulary uses common words, context given first, learning aids via "road signs"], Graphics [type of graphics, relevance of illustrations, lists/tables explained, captions used for graphics], Layout and Typography [layout factors, typography, subheadings used], Learning Stimulation and Motivation [interaction used, behaviors are modeled and specific, motivation—self efficacy], and Cultural Appropriateness [match in logic/language/experience, cultural image and examples]) with 22 criteria. We did not include the SAM criteria related to cover graphic, as this criteria was not applicable to the OPC. Therefore, a total of 21 criteria were analyzed. The SAM and scoring criteria are available at: <http://www.hsph.harvard.edu/healthliteracy/doak.html>.

Using the SAM point system, each criteria is given a rating of 0 (not suitable), 1 (adequate), 2 (superior), or NA (not applicable). An overall percentage score is then calculated by dividing the sum of the ratings by the total possible score (OPC total possible score = 42). Total SAM suitability percentage scores are grouped as follows: 0% to 39% (not suitable), 40% to 69% (adequate), and 70% to 100% (superior).

Interrater reliability for total SAM score was assessed using an intraclass correlation coefficient (ICC), validated for use with multiple raters, and calculated in a 2-way random model based on absolute agreement. The Statistical Package for the Social Sciences (SPSS+; SPSS, Chicago, IL) for Windows Version 14.0 was used calculate the ICC.

Step 4: Pilot Testing of OPC to Assess Patient Comprehension of Content

Setting and Participants

Two convenience samples of patients were recruited to assess the utility of the OPC. Data were collected in 2 waves to allow the researchers to revise and improve clarity of the OPC if necessary. A total of 18 patients, 9 in each wave, evaluated the OPC.

Data Collection Procedures

Data collection procedures were identical during both waves as 1 research assistant completed all interviews. After patients had registered with the designated clinic nurse, the research assistant asked eligible patients (≥ 18 years of age, English speakers) if they were interested in partaking in the study. Patients were told that they would be asked to complete an oral interview and that all responses would be anonymous. Patients received \$10 cash to compensate them for their time.

After each patient had provided written informed consent, the research assistant administered a brief demographic questionnaire and assessed patients' health literacy skills using the valid and reliable Newest Vital Sign (NVS).³⁷ The NVS is a nutrition (ice cream) label (http://www.pfizerhealthliteracy.com/pdf/FH_vitalsigns_040605.pdf) accompanied by 6 yes-no

questions (http://www.pfizerhealthliteracy.com/pdf/FH_vitals_quest8X10_040605.pdf). Briefly, patients are presented with a laminated copy of the NVS and then asked 6 questions about how they would decipher the information contained on the ice cream label (eg, "If you eat the entire container, how many calories will you eat?"). Based on total NVS score, patients are categorized as follows: 0 to 1 (high likelihood of limited literacy), 2 to 3 (possibility of limited literacy), and 4 to 6 (almost always indicates adequate literacy).

Patients were also presented with a laminated copy of the OPC. The research assistant asked each participant to (1) read aloud each statement and (2) state "in their own words" what each statement meant. Each oral interview was taped using a digital voice recorder.

Data Analyses

The first or second author independently listened to and scored each oral interview. To assess interrater reliability (using Kappa index [κ]), the first and second author each reviewed a randomly selected interview during each wave of data collection. We thought that this strategy was sufficient for 2 reasons, including: (1) each oral interview was selected at random; and (2) scores on 26 statements were compared. Specifically, each statement ($n = 26$) was assigned 1 of 3 designations based on the criteria developed by Sen-

PART 2 THINGS I AGREE TO DO

I will

- only get my pain medicine from Dr. _____'s office. 
- take my pain medicine as listed in Part 1.
- tell my other doctor(s) that I am taking pain medicine.
- tell Dr. _____ about ALL of the medicines (over-the-counter, herbs, vitamins, those ordered by other doctors) I am taking. 
- tell Dr. _____ about all of my health problems.
- allow Dr. _____ to talk with other doctors about my health problems. 
- only ask for refills during an office visit (Monday to Friday from 8:00 am to 5:00 pm).

Go to the next page 

2

Figure 1. Sample page from Low-Literacy Opioid Contract. The complete low-literacy opioid contract can be obtained from the first author.

Table 1. Suitability of Materials Assessments (SAM) of Low-Literacy Opioid Contract

SAM CATEGORY/CRITERIA	REVIEWER 1 SAM RATING*	REVIEWER 2 SAM RATING*
Content		
Clearly stated purpose	2	2
Content topics	2	2
Scope	2	1
Summary/review	1	1
Literacy demand		
Reading grade level	1	1
Use of active voice/conversational style	2	2
Vocabulary	2	2
Context given first	1	1
Use of headers/road signs	2	2
Graphics		
Graphic/illustration type	2	2
Relevance of illustrations	2	2
Explanation of lists/charts/tables	2	2
Use of captions for graphics	2	1
Layout and typography		
Layout factors	2	2
Typographical features	1	2
Use of subheadings	1	2
Learning stimulation and motivation		
Use of interaction	2	2
Modeling/specificity of behaviors	2	2
Motivation	2	2
Cultural appropriateness		
Match in logic, language, and experience	2	2
Cultural image and examples	2	1
Total SAM score†	88.1%	85.7%

*Each criteria is given a rating of 0 (not suitable), 1 (adequate), 2 (superior), or NA (not applicable).

†An overall percentage score is calculated by dividing the sum of the ratings by the total possible score: 0% to 39% (not suitable), 40% to 69% (adequate), and 70% to 100% (superior).

tell and Ratcliff-Baird²⁷: (1) unable to read; (2) insufficiently or incorrectly paraphrased; or (3) comprehended.

The Statistical Package for the Social Sciences (SPSS+) for Windows Version 14.0 was used to calculate interrater reliability (K) as well as basic statistics (eg, mean, standard deviation, percentages, frequencies) to describe patients' demographic characteristics, health literacy skills and comprehension of OPC statements.

Results

Step 1: Identification of OPC Content

Using Fishman's⁹ review as a guide, a 4-part OPC was created (Please contact the first author to obtain a full copy of the low-literacy OPC). Part 1 included a medication schedule template. Part 2 included statements pertaining to activities that the patient agreed to do.

A total of 19 bullet points (20 sentences) were included in Part 2. Part 3 included 2 sections outlining things that could happen if the patient did not comply with the things described in Part 2. Part 3 included 3 bullet points (3 sentences) and 3 complete sentences. Part 4 included a section for both the patient and physician to sign the form. The second page of the OPC is displayed in Fig 1.

Step 2: Development of OPC Based on Low-Literacy Guidelines

Reading Grade Level

The FRE score of the OPC was 80.99, which corresponds to a 7th reading grade level.

Formatting Characteristics

The 6-page low-literacy OPC was formatted on 8½ × 11 inch paper using Arial-style font. Font point size ranged from 16 for bulleted text to 24 for section headers (eg, PART 1, MY PAIN MEDICINE). With the exception of 1 word (ALL) in Part 2, uppercase text was used exclusively for section headers. Headers, separators, and bullets were used throughout the OPC. To maximize the amount of white space, quadruple line spacing was used to separate bullet points. Twelve (n = 12) recognizable clipart-type illustrations (eg, pill bottle, physician, hospital, pharmacy, police officer, pen) were used to supplement written text.

Table 2. Demographic Characteristics and Newest Vital Sign Scores of Study Participants

SOCIODEMOGRAPHIC CHARACTERISTIC	SAMPLE 1 (N = 9)	SAMPLE 2 (N = 9)
Age in years (mean ± SD, [range])	55.0 ± 18.6 (21–79)	46.3 ± 22.8 (18–85)
Sex (n)		
Female	8	8
Male	1	1
Race (n)		
Caucasian	8	8
African-American	1	1
Educational Attainment (n)		
Some high school or less	3	3
High school graduate or GED	2	1
Some college	3	3
College graduate	1	2
Newest vital sign scores* (n)		
0–1	2	0
2–3	7	3
4–6	0	6

*Health literacy assessment based on Newest Vital Sign (NVS) raw scores: 0 to 1 (high likelihood of limited literacy), 2 to 3 (possibility of limited literacy), and 4 to 6 (almost always indicates adequate literacy).

Step 3: Evaluation of OPC based on Established Criteria for Low Literacy Materials

Both reviewers scored the OPC in the *superior* range based on total SAM percentage scores (ICC = 0.98) (Table 1). Individually, most criteria were rated as superior (Reviewer 1 = 16 of 21 criteria; Reviewer 2 = 15 of 21 criteria) by both reviewers.

Step 4: Pilot Testing of OPC to Assess Patient Comprehension of Content Demographic Characteristics of Patient Samples

Eighteen (n = 18) patients, 9 in each wave of data collection, reviewed the OPC. The demographic characteristics and health literacy assessments of both groups are presented in Table 2.

Revision of Materials After the First Wave of Data Collection

After completion of the first wave of data collection, 2 revisions were made to the OC. First, "street" was replaced with "illegal" drugs. After completion of the oral interview, the research assistant asked each patient whether "street" or "illegal" was a better term to use. All (n = 9) patients recommended using "illegal" in place

of "street" drugs. Second, the OC was formatted so that section headers were located at the top of each page (eg, I will).

Interrater reliability for the randomly selected interview during the first wave of data collection was K = 0.92, indicating almost perfect agreement.^{15,16} Interrater reliability for the randomly selected interview during the second wave of data collection was K = 0.88, indicating almost perfect agreement.^{15,16}

Patient Comprehension of OPC Content

Overall, 19 of the 26 statements were comprehended by all (n = 18) patients (Table 3).

Discussion

Patients often struggle to read materials such as educational pamphlets and informed consent documents routinely disseminated in health care settings. Although some low-literacy educational information is available, only recently have investigators described the development and validation of such materials. For instance, as part of larger studies, the creation and validation of pediatric injury prevention materials³⁰ and patient satisfaction instruments^{28,35} have been described.

Roskos et al²⁵ evaluated 162 English-language OPCs used by *American Pain Society* members and found the average readability to be at the 14th grade level. In re-

Table 3. Patient Comprehension of Low-Literacy Opioid Contract Statements (n = 18)

OPIOID CONTRACT STATEMENT (N = 26)	CORRECTLY PARAPHRASED % (N)
I will only get my pain medicine from Dr. ___'s office.	100.0 (18)
I will take my pain medicine at listed in Part 1.	100.0 (18)
I will tell my other doctor(s) that I am taking pain medicine.	100.0 (18)
I will tell Dr. ___ about all of my health problems.	100.0 (18)
I will allow Dr. ___ to talk with other doctors about my health problems.	100.0 (18)
I will tell Dr. ___ if I get pain medicine from another doctor or emergency room.	100.0 (18)
I will keep my pain medicine in a safe place AND away from children.	100.0 (18)
I will get my pain medicine from only ____.	100.0 (18)
I will bring all of my unused pain medicine in their pharmacy bottles the next time I come to see Dr. ____.	100.0 (18)
He/she may count the number of pills in my bottle(s).	100.0 (18)
I will allow Dr. ___ to check my urine (pee) or blood to see what drugs I am taking.	100.0 (18)
I will NOT share, sell, or trade my pain medicine with anyone.	100.0 (18)
I will NOT use someone else's medicine(s).	100.0 (18)
I will NOT change how I take my medicine(s) without asking Dr. ____.	100.0 (18)
I will NOT ask Dr. ___ for extra refills if I lose or misplace mine.	100.0 (18)
If I do not do all of the things listed in Part 2, Dr. ___ will no longer order pain medicine for me.	100.0 (18)
If I do not do all of the things listed in Part 2, Dr. ___ may send me to drug abuse treatment.	100.0 (18)
I know if I drive while taking pain medicine, I can be charged with driving under the influence (DUI).	100.0 (18)
If I am charged with DUI while taking pain medicine, Dr. ___ is not to blame.	100.0 (18)
I will tell Dr. ___ about ALL of the medicines (over-the-counter, herbs, vitamins, those ordered by other doctors) I am taking.	94.4 (17)
I will NOT use illegal drugs (crystal meth, marijuana, cocaine).	94.4 (17)
I will NOT ask Dr. ___ for extra refills if I use up my supply before my next appointment.	94.4 (17)
If I do not do all of the things listed in Part 2, Dr. ___ may stop giving me medical care.	94.4 (17)
I will call Dr. ___'s office at least 24 hours in advance if I need to cancel my appointment.	88.9 (16)
Dr. ___ and my pharmacy may work with the police to look at any misuse or sale of my pain medicine.	88.9 (16)
I will only ask for refills during an office visit (Monday to Friday from 8:00 AM to 5:00 PM).	83.3 (15)

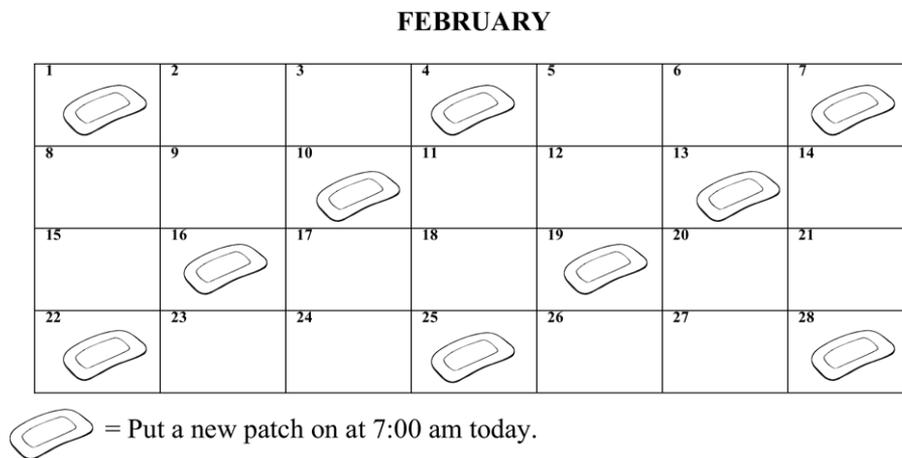


Figure 2. Sample patient instructions for an adhesive pain medication.

sponse to these findings, we used 4 discrete steps to create and validate a low-literacy OPC for use in routine clinical practice. Via this comprehensive process, we created an OPC written at the 7th reading grade level. The word “medication” adds complexity to the reading level because it is a multisyllabic word. Replacing “medication” with “drug” throughout the OPC would decrease the reading level to 6th grade, which is generally recommended for low-literacy educational materials.³⁶

Reading grade level is often used as a proxy to gauge patient understanding of written materials. Although reading grade level is a starting point for estimating the likelihood of patients’ comprehension of written materials, there are some potential pitfalls—use of jargon, underestimation of reading grade level via computer software packages—to consider.¹⁸ Importantly, when developing the OPC we not only calculated reading grade level, but followed established low-literacy formatting guidelines and evaluated the OPC using recognized standards. For instance, both reviewers scored the OPC in the superior range based on SAM criteria.

Last, we confirmed understanding and interpretation of each of the 26 statements with a group of 18 diverse patients. One third (n = 16) of patients had not completed high school and 2 scored in the 0–1 range on the NVS. Overall, regardless of educational attainment of NVS score, patients’ understanding of OPC content was excellent (all patients comprehended 19 of the 26 statements). Because 3 patients insufficiently or incorrectly paraphrased the following statement: “I will only ask for refills during an office visit (Monday to Friday from 8:00 AM to 5:00 PM),” we recommend perhaps quantifying this statement slightly (eg, do not call for refills when the office is closed).

Explicit samples of opioid medication scheduling to facilitate proper patient use are presented in Figs 2 and 3. For example, the monthly calendar depicting when to replace an adhesive pain medication is clearer than instructing the patient to simply “Apply a new patch every 72 hours.” Explicit directions are critical to ensure medication misuse because patients often have difficulty following and interpreting dosing schedules. For instance,

although 71% of patients with limited literacy skills correctly stated the instructions, “Take two tablets by mouth twice daily,” only 35% could demonstrate the number of pills to be taken daily.⁷

Limitations

Our findings should be interpreted in light of several potential limitations. First, the NVS was used to assess patients’ health literacy skills. The NVS is a quick screening tool designed to gauge patients’ health literacy skills (eg, high likelihood of limited literacy, possibility of limited literacy, or almost always indicates adequate literacy), not measure them directly. However, the NVS is highly correlated with the extensive Test of Functional Health Literacy in Adults.^{1,37} Second, just 2 of the patients completing the oral interview were men. However, we see no reason why patient sex should make a difference in interpreting OPC content. Third, the study was conducted in 1 clinical setting in the Southeastern United States. Finally, the OC is only available in English at the present time.

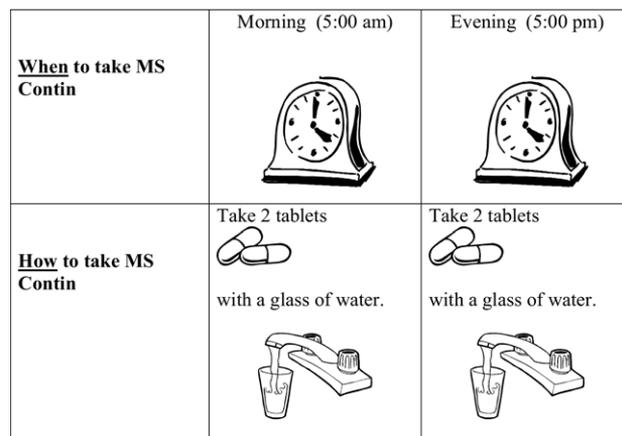


Figure 3. Sample patient instructions for an oral pain medication.

Conclusions

The low-literacy OPC is comprehensive, valid, readable, and formatted according to established low-literacy guidelines. Accordingly, the low-literacy OPC is suitable for use in routine clinical practice and ideally as an educational tool for patients.

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