



Research Briefs

Innovative use of a standardized debriefing guide to assist in the development of a research questionnaire with low literacy demands

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ABSTRACT

Prevalence and impact of low literacy has resulted in greater attention to developing written materials at lower reading levels for both patient education and research. The purpose of this study was to develop and evaluate how well a research questionnaire about self-management preferences, intentionally developed as a tool for individuals with low literacy skills, performed. The investigators created a standardized debriefing guide to evaluate comprehension and ease of instrument completion to accompany the administration of the Conventional and Alternative Management for Asthma (CAMA) instrument. The use of a standardized debriefing guide following cognitive interviewing techniques, allowed for the identification of problematic words, unclear meanings and confusion over scaling despite a deliberate attempt to develop a tool with low literacy demands. Such approaches might be considered critically important to insure the accuracy of patient-reported outcomes when self-administered tools are used to collect research and clinical data.

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1. Introduction

Although global rates of illiteracy are decreasing, one in five adults still cannot read and write and many more do not possess the skills needed to meet work demands, social responsibilities and health requirements (Richmond, Robinson, & Sachs-Israel, 2008). In recognition of the impact of literacy on health knowledge and status, leaders in the field have advocated for the development of patient education materials at low reading grade levels (Nielsen-Bohlman, Panzer, & Kindig, 2004). Less attention however, has focused on research materials such as self-administered questionnaires.

According to the 2003 National Assessment of Adult Literacy, 14% of the American population has below basic literacy skills (White & Dillow, 2005). Of the adults with low literacy, a disproportionate number live in poverty and/or are racial or ethnic minorities in their country of residence. Lower literacy in these groups is due, in large part, to lower educational attainment (Kutner, Greenberg, & Baer, 2005, Kutner et al., 2007). Perhaps unsurprisingly, low literacy is associated with lower completion rates of preventative health

measures, less self-management, and increased risk of hospitalization (DeWalt et al., 2004), medication errors and other adverse health outcomes, even after controlling for other relevant variables (Kripalani et al., 2006; Lee, 1999; Sudore et al., 2006; Williams, Baker, Honig, Lee, & Nowlan, 1998). In fact, low literacy can be a more significant factor in predicting health disparities than education or race/ethnicity (Sentell & Halpin, 2006).

Recognition of the prevalence and impact of low literacy has resulted in greater attention to developing written materials at lower reading levels for both patient education (Mayeaux et al., 1996; Townsend, 2011) and research (Paasche-Orlow, Taylor, & Brancati, 2003; Sugarman & Paasche-Orlow, 2006). Unfortunately, much of the focus on research materials has been directed towards the development of informed consent forms suitable for those with lower literacy skills and not self-administered health-related research instruments. The latter are frequently developed to answer questions of clinical interest to scholars or to the pharmaceutical industry and their reliability and validity are established using prototypical research subjects: White adults with higher educational attainment. Later, without further testing or modification, these questionnaires are deployed in new studies with subjects who may be distinctly different than the population in which the psychometric properties were first established, without appropriate modification and re-testing. Under such circumstances, instruments with higher literacy demands may be subject to misreporting. Specifically, individuals with lower literacy make more nonresponse errors, exhibit more inconsistent responses, and improperly follow skip

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instructions (Al-Tayyib, Rogers, Gribble, Villarroel, & Turner, 2002). There is also some evidence to suggest that people with low reading skills are reluctant to complete written surveys from the outset due to a sense of shame (Al-Tayyib et al., 2002; Olson, Smyth, Wang, & Pearson, 2011; Williams & Swanson, 2001).

In chronic diseases like asthma, self-management is necessary (Bodenheimer, Lorig, Holman, & Grumbach, 2002) but may be suboptimal due to many factors, including limited health literacy (Apter et al., 2006; Thai & George, 2010) and unconventional preferences for care (George, Freedman, Norfleet, Feldman, & Apter, 2003; George, Campbell, & Rand, 2009). Health care providers' understanding of culturally-derived preferences for care is as critical to the practice of evidence-based medicine as is the knowledge gleaned from randomized clinical trials and clinical expertise (Haynes, Devereaux, & Guyatt, 2002; Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). To that end, the purpose of this study was to systematically develop and evaluate how well a research questionnaire about culturally relevant self-management preferences, intentionally developed as a tool for individuals with low literacy skills, performed. To assist in this appraisal, the investigators created a standardized debriefing guide to evaluate comprehension and ease of completion to accompany the administration of the *Conventional and Alternative Management for Asthma (CAM-A)* instrument. The CAM-A questionnaire was developed, as part of a larger study, following traditional instrument development steps.

2. Sample

A convenience sample of adults with persistent asthma, defined as having been prescribed a daily inhaled corticosteroid, was enrolled from their primary care office. These sites included two internal medicine group practices, two family medicine practices, and one federally qualified health clinic. No formal testing of participants' literacy was conducted.

3. Procedure

3.1. Instrument development

A questionnaire was created following conventional instrument development steps and piloted between February 2009 and June 2011. The initial version consisted of 39 items written at a 5.7 grade reading level (calculated to include the written instructions for instrument completion).

3.2. The development and use of a standardized debriefing guide

To evaluate the performance of the CAM-A instrument, the authors developed a standardized debriefing guide based on cognitive interviewing techniques grounded in cognitive psychology and information processing theory. The cognitive interview techniques were developed to improve the quality of survey data by reducing response error that can occur if questions are not interpreted in the way they were intended (Rosal, Carbone, & Valentine Goins, 2003). To that end, the authors developed a standardized debriefing guide to query subjects about question flow, reading difficulty and clarity as these techniques have been considered valuable in developing new instruments or adopting instruments for use in different populations (Carbone, Campbell, & Honess-Morreale, 2002). However, the authors extended these techniques to also examine the cultural relevance and literacy demands of each question which is a novel application of conventional cognitive interviewing approaches.

All study-related forms (informed consent, health privacy, demographic and medical history) were first read to the subjects. Then research assistants (RAs) oriented the subjects to the instructions for instrument completion, as well as to the scale and anchors and asked

the subjects to complete the instrument independently. Possible responses ranged from 1 to 7 with verbal anchors only at the endpoints (1 = strongly disagree, 7 = strongly agree). The first 14 items also included a "not applicable" option, which on the survey was designated as "N/A". The RAs then observed the subjects as they completed the instrument and made notes indicating which items subjects paused at, skipped or omitted. The subject was stopped after every 10 questions to allow the RA to administer the standardized debriefing guide (Table 1) to evaluate comprehension, ease of instrument completion, literacy demands and cultural relevance. Since the instrument had 39 items, each subject was stopped four times; each time they answered the standardized debriefing guide questions, as noted in Table 1.

3.3. Ethical considerations

This study was approved by the Institutional Review Boards of the University of Pennsylvania and Thomas Jefferson University, Philadelphia, PA. Subjects were enrolled after the informed consent had been read to them and after they had all their questions adequately answered. Subjects received \$20 cash and transportation expenses (\$6 cash or four mass transit tokens).

4. Results

The standardized debriefing guide was completed for all 210 subjects enrolled (88% female; mean age 48; 76% Black; 20% White; 62% with ≤ 12 years of schooling). On average, subjects completed the CAM-A instrument in <5 minutes. Three subjects requested the questionnaire be read to them; one was legally blind. Feedback from subjects can be divided into two categories.

4.1. Subjects reporting reading and comprehension difficulties

Eight subjects (4%) had difficulty using the Likert scale. Specifically, these subjects either stated that they did not understand how to use the scale, requested help from the RA to select their desired answer or changed their answer from one extreme to the other during the RA review. Importantly, the subjects who experienced difficulty implementing the scale were more highly educated: two had 13 years of schooling (some college), one had 14 years, one had 16 (university degree) and one had attained a post-graduate degree after a 4-year university. Four subjects (2%) requested help in reading one or two unfamiliar words. None of these four individuals were the same as those who had difficulty with the scaling. Two of these individuals read the word *severe* as *sever* and therefore were unable to answer the question without assistance. An additional two subjects requested that the RA provide a definition for the word *tolerance*. Of these four individuals, three subjects had completed 12 years or fewer of schooling (no university) and one had completed 16 years (attained university degree).

Most commonly, subjects asked for clarification. Thirty-one subjects (15%) asked for clarification on the wording of 15 distinct items; the most commonly requested clarification was for the term *natural*

Table 1

Standardized debriefing guide for assessing item comprehension and ease of completion.

1. Did you have any difficulty reading any of the items? If yes, which ones and why?
2. Did you have any difficulty understanding the words used or their meaning? If yes, which ones and why?
3. Did you find any of the items culturally insensitive or irrelevant (thoughtless; inappropriate)? If yes, which ones and why?
4. Did the questions flow smoothly (i.e., make sense)? If not, which ones and why?
5. Are there other things that you believe about asthma, or its management, that were not included in this survey? If yes, please tell us what they are.

therapies. An additional 22 subjects (10%) did not understand the colloquial expression *open pores*. This term is part of the Black vernacular used to describe periods of perceived susceptibility to germs following bathing, cold temperature or rain exposure. Of the 159 subjects who self-reported their race as Black, only 7 (4%) did not understand this term compared to 13 of 42 Whites (31%), one Asian, and one subject who only reported their ethnicity (Latino).

Thirty-eight subjects (18%) described 15 of the 39 items as having confusing wording but did not offer suggestions for improvement. In addition, 77 subjects (37%) added qualifying remarks about 21 items, such as 21 individuals who reported they could not answer questions about their prescribed inhaled corticosteroids because they were intentionally non-adherent.

4.2. Subjects reporting item selection difficulties

Thirty one subjects (15%) characterized 14 items as inappropriate; 21 of these 31 (68%) reported that it was wrong to ask about CAM due to its lack of scientific evidence. Twenty-eight subjects (13%) said that they hesitated in answering a question because they were uncertain if the statement was true or false. Sixteen subjects (7%) did not feel it was relevant to ask them about the role of prayer in their asthma control. Lastly, 20 subjects (10%) expressed displeasure with the item concerning God's role in their asthma management; one because she was Muslim and thought that the word "God" should be described using vocabulary representing the three monotheistic religions including "Allah". Only one of the 39 items elicited no comments.

5. Discussion

Despite a deliberate attempt to develop an instrument for individuals with low literacy skills, problematic words, unclear meanings and confusion over scaling were evident from analysis of the standardized debriefing guide. These difficulties were not confined to those with less schooling suggesting that a lower reading level alone is not sufficient to remove the potential for misreporting when instruments are self-administered. This is important because few studies describe a standardized approach to the piloting of new questionnaires and many studies employ research instruments in new clinical populations without re-piloting or reestablishing reliability and validity. The use of a standardized debriefing tool, such as the one used in this study, offers a novel method to address literacy demands not currently addressed by conventional instrument development approaches.

Although there is a relative paucity of data on reading ease and comprehension of research instruments, our study is consistent with others' findings. For example, other research has demonstrated that despite inadequate comprehension, individuals with low literacy answer questions on surveys (Al-Tayyib et al., 2002) or omit answers altogether (Kimble et al., 2001). In addition, in a study of 194 rheumatology patients, 13.4% were unable to read the two-syllable word *symptom* on an arthritis-specific literacy screening test (Swearingen et al., 2010). This is particularly interesting given that 76% of the Swearingen subjects read above an eighth grade level. This rate of reading difficulty is much higher than in our study where only two subjects (1%) could not read the two-syllable word *severe*. In another study, poor performance of a pain screening instrument was attributed to the use of words such as "pain" when "discomfort" might be more precise (Krebs, Carey, & Weinberger, 2007). This likely has bearing on this study as we found much confusion over the term "natural therapies".

This study also corroborated previous findings in which low literacy subjects experienced difficulty in using Likert scaling, specifically related to the direction of the scale (Bernal, Wooley, & Schensul, 1997) and comprehension of the response choices (DeWalt et al., 2004; Sentell & Ratcliff-Baird, 2003). What was most interesting

was that 63% of the subjects reporting scaling difficulties in our study had 13 or more years of education.

Although higher educational attainment is usually associated with higher literacy, years of schooling tends to over predict literacy skills in countries like the United States (Somers, 2005). This is because most individuals attend public schools that provide a free but sometimes substandard educational experience. To that end, two-thirds of children who complete 12 years of schooling (achieve a high school degree or its equivalent) perform at below proficiency levels in reading and writing and fail to achieve basic literacy (Sedita, 2010). Poor performing schools are not the only reasons why students graduate with insufficient skills. There is also great pressure for "social promotion" over mastery learning, that is, to promote a child to the next grade so they remain with children their own age.

The findings of this study must be considered in the context of several limitations. First, this study used a convenience sample and as such, may not be representative. In addition, subjects may have denied any difficulty with reading comprehension or scaling due to shame (Wolf et al., 2007), leading to a potential for underreporting. Alternatively, subjects may have provided feedback on items to please the researcher, leading to over reporting. Most importantly, items identified as confusing likely did require clarification due to imprecision in the instrument's development.

5.1. Implications for practice and research

If it is true that people have difficulty understanding materials with low literacy demands and struggle with scaling, then it is likely that we are collecting inaccurate information in both clinical and research settings. This speaks to the need to do more extensive and systematized piloting of materials. It also makes clear the need to further explore the utility of alternative data collection methods, using sophisticated technology such as interactive voice response systems and computer-based audio programs, as well as "low-tech" techniques employing visuals to augment or replace words (Leiner, Rescorla, Medina, Blanc, & Ortiz, 2010; Shea et al., 2008; Townsend, Corry, Quigley, & George, 2012; Wengreen, Munger, Wong, West, & Cutler, 2001).

6. Conclusions

The findings from this study suggest that a significant amount of data collected by self-administration may be inaccurate due to errors in answering scaled items or unclear wording, despite purposeful development of materials for low literacy populations. This has the potential to lead to misreporting that in turn, can contribute to misunderstanding and miscommunication in research settings and in clinical encounters, where important health appraisals depend on accurate information. This study provides compelling data that a more deliberate and standardized approach to assess understanding of patient reported information is a critically important component of any data collection process.

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