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Source / Izvornik: **Patient Education and Counseling, 2006, 60, 294 - 300**

https://doi.org/10.1016/j.pec.2005.10.009

Kušec, S., Orešković, S., Škegro, M., Korolija, D., Bušić, Ž., Horžić, M. (2006) *Improving comprehension of informed consent.* Patient Education and Counseling, 60 (3). pp. 294-300.

http://www.elsevier.com/locate/issn/0738-3991

http://www.sciencedirect.com/science/journal/07383991

http://medlib.mef.hr/246

Improving comprehension of informed consent

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Abstract

Objective. To explore the way the doctor-patient communication process may be improved by adopting the patients' conversational style in the development of written materials for surgical patients. **Methods.** Written information prepared by doctors, specialists in abdominal surgery, was tested for comprehension on patients undergoing cholecystectomy, using the standard Cloze test procedure. At the same time, the patients were asked to describe in their own words all they knew about their illness and the treatment. The collected 150 patient narratives were analyzed, and a typical narrative for each educational level was selected based on average SMOG score, word count and sentence length. The patient-worded information was then tested for comprehension on new patients, selected from primary health care, using the same Cloze procedure as with doctor-developed information. Patient profile of best lay communicators was defined using also sociodemographic characteristics, and reported information seeking and decision making preferences. **Results.** Only 50% of patients completed Cloze test, of which over 40% showed poor comprehension. Analysis of transcribed narratives collected from 150 patients showed increasing complexity of style by educational level (average SMOG score 7, 8, and 9; sentence length 11, 13, and 15 words; for low, medium and high educational level, respectively). Cloze tests based on typical narratives, and tested on primary care patients, indicated to the style best understood by all. Dominant characteristics of patients producing a narrative of similar style to the best-understood narrative were observed: medium educational level, women over 60, urban workers, interviewed after surgery, informed by specialist at ultrasound, knowledge about illness from one to ten years, learned most about illness from lay people, those who wanted more information in both oral and written form, and preferred active role in decision making. **Conclusion.** Analysis of patient profiles with typical narratives that were best understood by other patients shows where to look for lay experts in doctor-patient communication. **Practice Implications.** Obtained findings indicate to the importance of patient participation in developing informed consent information, and to the possible method for improving comprehension of educational patient materials in general.

Keywords: Informed consent, Comprehension, Doctor-patient communication, Shared decision making, Cholecystectomy

1. Introduction

Effective communication plays the central role in doctor-patient relationship since it has been shown to influence positively patient satisfaction, compliance and medical outcomes, while reducing healthcare costs and thus increasing the overall quality of health care [1-4]. It is particularly important for informed consent where patients are expected to participate in the decision making process by weighing the benefits against the risks of recommended treatments [5]. To be able to become true and competent decision makers, patients need to understand what lies behind those recommendations and discuss them with their doctors appropriately. Only by becoming competent communicators as well will the patients be able to participate actively in that communicative interaction, and reach a mutual agreement with their doctors, the basis for shared decision making [6].

But there are numerous barriers to both communication and mutual understanding between the patient and the doctor – education and language are often mentioned and researched [4]. Patients' expectations cover also the wish for more information, in understandable language, about the medicines prescribed and the risks involved in the treatments [7]. In the hospital setting, recent accreditation and quality requirements are defined from patient's rights perspective as well, indicating 'the need to deliver culturally and linguistically appropriate services, recognizing that the delivery of these services is more than simply a patient's right, but is, in fact, a key factor in the safety and quality of patient care' [8]. The appropriate language would be the one familiar to patients, easy-to-understand, using common words from everyday language and tailoring the messages to individual patient needs [9]. And indeed, medical language and everyday language have been seen as two different languages [10], a fact only natural considering that patients and doctors live in two different worlds [3].

Studies have shown that doctors are well aware of the difficulties of translating their knowledge into language the patient can understand [3]. And although it is expected that doctors switch from medical language to everyday language while talking to patients, in the attempt to promote better understanding, patients usually do not perceive it as such and even they themselves attempt to adopt medical language for the sake of the doctor [10]. A recently suggested model of interactive communication loop [11] stresses the importance of checking comprehension and recall to achieve both effective communication and better medical outcomes, while clarifying and tailoring the message in the repeated cycles. Since many authors on clear writing suggest we should write the way we talk to be better understood, to use the conversational style [9], this study tried to build on the results of such previous research and make use of the spoken patients' words for development of written information for surgical patients.

So, it is the aim of this paper to show that shared vocabulary, seen from the patients' perspective, could contribute to doctor-patient communication in terms of better comprehension and shared decision making.

2. Methods and participants

For this study, as an example of a surgery that would require of patients to weigh its risks and benefits before signing informed consent, laparoscopic cholecystectomy was chosen, i.e. gall bladder surgery, as one of the very frequent surgeries around the world [12]. This decision excluded any concerns related to illnesses that either directly affect mental capacity of patients (mental illnesses), raise further delicate issues (cancer), are age-dependent (pediatric or geriatric conditions) or gender-dependent (reproductive system).

Educational levels were defined as: low (up to 8 years of schooling), medium (9 to 12 years of schooling), and high (13 and more years of schooling), corresponding to the educational system in Croatia (i.e. elementary school, secondary school, and college/university degree).

The study was carried out in two different settings, corresponding to two stages. Stage 1 covered hospital patients and Stage 2 patients in primary health care (PHC).

2.1. Stage 1 – Hospital patients

A total of 150 hospital patients scheduled for laparoscopic cholecystectomy were selected to participate in the study according to inclusion criteria: age 18-75 years, both genders, different educational levels. Age limits were set above 18 years to avoid the issue of minors and their right to consent, and below 75 years to avoid the mental capacity testing procedures, which are not performed routinely on hospital patients in Croatia. All patients who met the inclusion criteria were approached consecutively and interviewed by a trained interviewer (S. K.), either before or after surgery, irrelevant of the fact whether conversion to open cholecystectomy was done.

Patients were interviewed in clinical wards of two university hospitals in Zagreb, over the period of four months in 2004. Permission for the study was obtained from the hospital ethics committees, and all patients gave their signed informed consent for participation immediately before the interviews.

The interviews comprised several steps. First, an anonymous structured questionnaire was completed by the interviewer for each patient on sociodemographic data, and questions on: comprehension of explanations provided by a doctor, wish for more detailed information and the form of information, wish for active participation in the decision making process, information sources, and duration of their illness.

Second, the patients were asked to recount in their own words, as if telling another patient, all they knew about: their illness, causes, and symptoms; proposed and alternative treatments; risks and benefits of the treatments; and prognosis of their illness. Special attention to language was made in this particular step to avoid the use of technical terminology and thus the influence on patients' choice of words. Namely, after asking the patients why they were in hospital at that particular moment, they were asked the following questions using the same words the patients themselves used. For example: Why have you decided to do [...gall bladder surgery]? How is this [...surgery] done? What happens after [...the operation]? All statements were audio recorded and later transcribed.

Third, written information for patients in the form of a one-page text explaining all necessary informed consent issues (diagnosis, risks, benefits, treatment options, prognosis), which was developed by specialists at the clinic, served as the basis to develop a Cloze test [13], by which patients' comprehension of information was tested. A standard version of Cloze test [9] was made out of each hospital's written information, with every fifth word missing. The patients filled in the blanks in the text, and their words were later checked for corrrectness. Time needed for each patient to complete the test was recorded.

2.2. Stage 2 – PHC patients

A total of 45 patients from primary health care were selected with the help of primary care physicians, based on the inclusion criteria: age 18-75 years, both genders, different educational levels, no history of undergone cholecystectomy, no medical training. With the lack of the group's previous experience with this surgical procedure we wished to reduce the impact of knowledge and focus more on the style. Each of the three educational levels (low, medium, high) was represented by 15 PHC patients, of both genders and different ages. Patients were surveyed either in waiting rooms of doctor's offices or at patient homes. After collection of sociodemographic data, a Cloze test was given to patients to complete, respecting the procedure that each of the three types of Cloze tests would be completed by 5 patients in each educational group.

Three Cloze tests were developed for PHC patients, following the same standard procedure as in Stage 1, but the basis were typical texts made out of transcribed patient narratives obtained during Stage 1 with hospital patients. The definition of 'a typical text' for each educational level was: 1) average readability; 2) closest to average sentence length, combined with 3) closer to average total word count, in that particular order.

2.3. Measures and statistical analysis

Cloze test results, i.e. words written by each patient to fill in the blanks, were considered correct when identical to the original text, i.e. written information for patients in Stage 1, and transcribed typical narratives in Stage 2. Percentage of correct answers was calculated for each patient and the scores interpreted as follows: text not understood (below 40%), text requiring revision or respondent requiring assistance (40-59%), and text understood (above 60%) [9].

Readability of both written information for patients and transcribed patient narratives was calculated using Simple Measure of Gobbledygook (SMOG) test [14]. This test was used primarily because of its widespread use in the existing patient education literature, but also because of its simplicity of manual use [15]. Moreover, it has been easily modified for Croatian language by defining the words containing four or more syllables as ‘difficult’ words [16].

Average sentence length and total word count per patient narrative were calculated using Microsoft Word for Windows, and statistical differences using Statistical Package for Social Sciences for Windows, version 10 (SPSS Inc., Chicago, IL, USA) based on chi-square test.

3. Results

Table 1 shows sociodemographic characteristics of all study patients, hospital patients of Stage 1, and PHC patients of Stage 2.

3.1. Stage 1 – Interview and Cloze test of hospital patients

The sample of 150 hospital patients consisted mostly of women (70%), patients of over 60 years of age (47%) and of medium educational level (43%), i.e. having completed 9-12 years of schooling.

Questionnaire results on reported comprehension showed that 96.7% stated they had understood their doctor while explaining all about their illness and treatment, and 77% stated they had understood the doctor ‘a lot’ or ‘completely’. One patient, an elderly woman of only 4 years of schooling, could not decide and give a clear answer but stated ‘I don’t know’ to both questions. Analysis by educational level revealed that even more patients with low educational level stated they had understood the doctor ‘completely’ (68%) than those with medium (53%) or high (57%) educational level. A high 83% preferred more detailed information but preference for oral information (49%) prevailed over written (5%) or both forms combined (45%). When asked about the sources of information for that particular illness and treatment, statistically significantly greater proportion of patients with low educational level than the other two groups stated they had been provided that information by their general practitioner (75%) ($P = 0.049$), and most information (66%) by medical staff in general. On the other hand, significantly lower proportion (14%) ($P = 0.011$) of patients with low educational level stated they had read something about their medical condition or treatment, and not one patient from that educational group had the impression to have received most information from any of the media sources. Although 57% of all patients stated they wanted an active role in decision making, significantly more patients with low educational level (67%) ($P < 0.001$), and significantly more patients of the older group (59%) ($P = 0.001$), had rather left the decisions to their doctors.

A total of 75 (50%) patients completed Cloze test after interviewing. Of the remaining 75 who did not complete it, 29% were in pain and could not do it properly, 20% did not have the glasses necessary for reading, 19% refused, and the other 32% either complained of “too technical text” or “too small letters”, were incapacitated (illiterate, incapacitating illness) or did not complete it for organizational reasons (visits, hospital routine work, etc.).

Both texts developed at the two hospitals as informed consent information, and which served as the basis for the two Cloze tests, were of the same readability: SMOG readability score 12, indicating that a person should have at least 12 years of schooling to be able to read and presumably understand the text without difficulty; font Times New Roman 12; identical average sentence length (15 words per sentence). Cloze test results by patients'educational level (Table 2) showed distinct differences among the groups. Patients with medium educational level and Cloze test scores above 60% were medical nurses only. Completion time varied among patients and did not show any regular pattern by either gender, age or education. To the contrary, the results showed that some patients with high educational level needed much less or much more time than others while some patients with low educational level gave up completing after a short period of time, irrespective of test results.

Transcribed narratives of 150 hospital patients were analyzed by educational level (Table 3). Results showed clear differences in narrative style: patients with lower educational level expressed themselves with more easy-to-understand language as assessed by SMOG readability score and sentence length (number of words per sentence) but also had less to say about their illness and treatment as judged from narrative length (total number of words per narrative, i.e. word count). For all the three variables the results showed ascending trend proportional to educational level. In each educational level, an almost identical proportion of patients used the style that was typical for their group in terms of average SMOG score: 39%, 38% and 37% of patients with low, medium, and high educational level, respectively. Their profile, which combines sociodemographic characteristics with questionnaire results, is shown in Fig. 1.

3.2. Stage 2 – Cloze test of PHC patients

Cloze test results for 45 PHC patients are shown in Table 2, along with results from Stage 1, for comparison. One patient (6.7%) with low educational level scored above 40% but the same descending trend, inversely proportional with educational level, could be observed for poor comprehension, as in Stage 1.

3.3. Analysis of narrative style

The narrative out of which one of the Cloze test was developed, and that was best understood ($P = 0.002$) by all PHC patients during testing in Stage 2, was the narrative given by a patient with medium educational level (Table 4). Dominant characteristics of hospital patients with medium educational level who produced narratives of typical readability for that group (SMOG score 8) gave a clear profile: women over 60 years of age; urban workers; patients interviewed after surgery; patients who knew about their diagnosis from the specialist at ultrasound, knew about their illness from one to ten years, and learned most about it from other lay people; patients who wanted more information in both oral and written form; patients who preferred active role in decision making.

Furthermore, when an in-depth analysis of linguistic features was done, results showed that: 1) written information developed by specialists was problematic for patients in terms of professional terminology, because the patients were mostly unfamiliar with it, and Cloze test options given by patients were similar and sometimes synonymous but different to medical terms; and 2) transcribed patient narratives were problematic because of the syntax, since many broken phrases and sentences interrupted the logical flow and the meaning.

Finally, results of an in-depth analysis of the language used in written information and patient narratives show quite well the differences between professional and lay terminology but are expressed in Croatian language and for that reason the actual wordings could not have been presented here.

4. Discussion and Conclusion

4.1. Discussion

Since it is the idea of this paper to indicate to the method for improving informed consent information by using patients' words and building on patient expectations and perspective in terms of language as well, the analyzed patient profile was compared to comprehension test results and language/style used in patient narratives, primarily in view of patient educational levels.

Although many patients stated they had understood their doctor, a discrepancy between such a statement in very high percentages of patients with low educational level and the fact that they usually had not read anything about their condition, mostly did not complete the Cloze test for whatever reason, and preferred information in the oral form, indicated to their unrealistic perception of comprehension and communication competence. A more or less open insecurity of low educated patients in interactions with their doctors, in terms of fear, shame, lack of question-asking, etc. [3], was reinforced in this study by the fact that 67% of patients with low education had rather left the decision making process entirely to their doctors.

These findings are not surprising, and they are in line with the many studies that explored the effects of terminology on patients' recall and understanding. These studies show that patients actually recall or understand only a half of what is being said to them by doctors [11,17], revealing that patients reluctantly engage in discussions [3], and even though sometimes patients with lower education report more confusing terminology received by their doctor [18], the result is the same: inadequate comprehension is often left unnoticed or undealt with by doctors and the patients perform poorly [3,4]. Decision making preferences reported in this study only confirmed results of other researches – that patients with lower education and older patients usually prefer that their doctors take control over the decision making process [3,19,20].

Very similar results were obtained by Kriwanek et al. [21] in a study on recall of surgical information for patients undergoing laparoscopic cholecystectomy as well, where clarity of information was perceived as good by 74% of patients, compared to 77% of those who reported having understood 'a lot' and 'completely' in this study. Also, when recall was measured in that same study, 49% showed insufficient recall for procedures and 69% for risks, which could be compared to 41% of our patients who showed poor Cloze test results (below 40%) if we take that poor comprehension might lead to poor recall in the communication process.

Although written information developed by specialists showed relatively high readability score, SMOG score 12, the same high levels have been observed for other patient information in Croatian language [16] or other media [22]. Also, a growing body of evidence shows that informed consent forms written in other languages and for various purposes are written at readability levels far too high for average readers to understand [23]. However, patient narratives on surgical information obtained in this study showed an easier style – much lower readability levels and shorter sentences, which increased by educational levels (Table 3). This finding indicates: first, that surgical information could be expressed in an easier style, and second, that the complexity of expression increases with variables such as educational level. Such great differences were not found for age and gender, although slightly lower scores for readability and sentence length were observed in female and older patients.

However, when transcribed narratives were tested for comprehension on PHC patients, relatively surprising figures were obtained: none of the PHC patients scored above 60% on Cloze test but there were no medical staff among those patients to score that high as in Stage 1, and they did not have the experience of the surgical procedure as hospital patients. Furthermore, hospital patients with high educational level scored better than PHC patients but this may be interpreted by their familiarity with textbook-type information with clearer syntax, which means that perhaps a more detailed and more complex information may be suitable for those with at least 13 years of schooling.

On the other hand, patient narratives, which were used as a raw material in this study, could easily be further refined and revised for clearer syntax, and would still retain the patient perspective so valuable for effective communication. Moreover, certain frequent words, phrases and metaphors could be easily extracted, the misconceptions identified and corrected, and still the patients' expectations met. It means that beside the medical doctors responsible for the content of messages, other specialists should be involved in tailoring the messages for different patient groups:

sociologists, psychologists, and certainly linguists as well. Increased attention to linguistic features has already shown to improve both the readability and understanding of information for patients [24], so it might be a good advice to have a linguist among the hospital ethics committee members when assessing the suitability of informed consent documents.

Also, since we strongly advocate involvement of patients in developing any materials intended for their use, admitting they are experts as well [25], we find the dominant characteristics of patients producing narratives of similar style (Fig. 1), and especially the profile of the patient producing the best-understood narrative, a useful indicator where to look for lay experts in communication.

4.2. Conclusion

In conclusion, considering the profile of lay experts that emerged from this study, as far as communication is concerned, it seems we still have a lot to learn from 60-year-old ladies.

4.3. Practice implications

Obtained findings indicate to the importance of patient participation in developing informed consent information, and to the method for improving comprehension of educational patient materials in general.

Acknowledgements

The authors wish to thank all patients involved in this study for sharing with us their stories, even at the moments of their painful condition, hoping their words will be heard and remembered.

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Figures

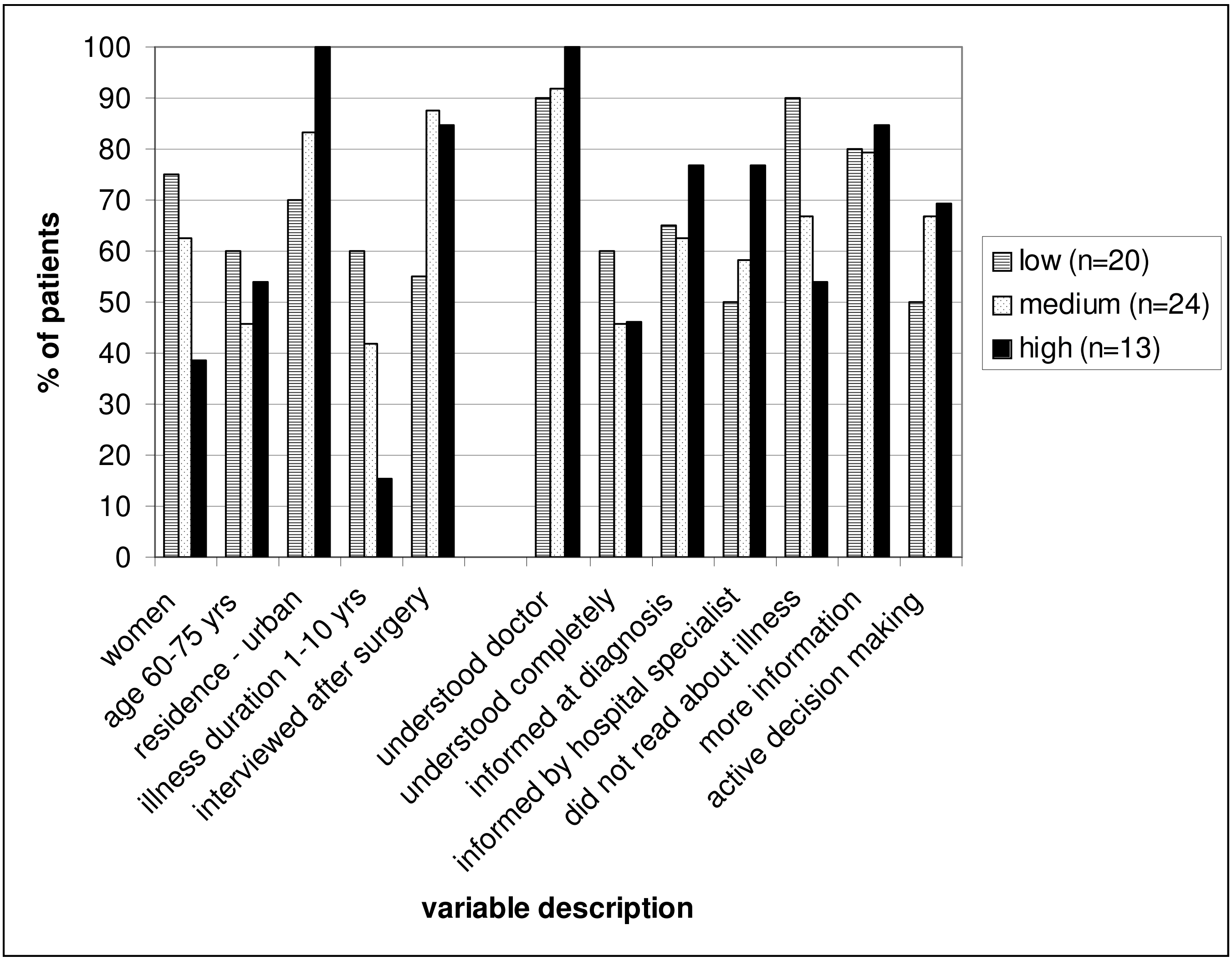

Figure 1
Dominant profile of study patients with narratives of average readability by educational level

Tables

Table 1

Sociodemographic characteristics of study patients

Characteristic			Stage 1 - hospital Total patients (n=150)	Stage 1 - hospital Cloze test completed (n=75)	Stage 2 - PHC PHC patients (n=45)
Sex	Female		105 (70 %)	48 (64 %)	31 (69 %)
	Male		45 (30 %)	27 (36 %)	14 (31 %)
Age groups	Younger	(20-39 yrs)	22 (15 %)	16 (21 %)	11 (24 %)
	Middle	(40-59 yrs)	58 (39 %)	37 (49 %)	22 (49 %)
	Older	(60-75 yrs)	70 (47 %)	22 (29 %)	12 (27 %)
	Mean age		55.7 yrs	51.6 yrs	48.4 yrs
Education	Low	(0-8 yrs)	51 (34 %)	13 (17.3 %)	15 (33.3 %)
	Medium	(9-12 yrs)	64 (43 %)	39 (52.0 %)	15 (33.3 %)
	High	(13+ yrs)	35 (23 %)	23 (30.7 %)	15 (33.3 %)

Table 2

Cloze test results by educational level

Comprehension level		Educational level (%) low	medium	high	Total
Not understood	Stage 1	100.0	43.6	4.3	41.3
	Stage 2	93.3	66.7	40.0	66.7
Requiring assistance/revision	Stage 1	0	46.2	73.9	46.7
	Stage 2	6.7	33.3	60.0	33.3
Understood	Stage 1	0	10.3	21.7	12.0
	Stage 2	0	0	0	0

Table 3

Analysis of patient narratives by SMOG score, mean sentence length and word count for each educational level

Variable		Educational level		
		low	medium	high
SMOG	median	7	8	9
	range	(5-9)	(6-11)	(7-12)
Sentence length		11.2	13.3	15.1
Word count		385	503	595

Table 4

Cloze test results by text type serving as the basis for Cloze test

Comprehension level	Text type (%)			Total
	1 (low education)	2 (medium education)	3 (high education)	
Not understood	93.3	33.3	73.3	66.7
Requiring assistance/revision	6.7	66.7	26.7	33.3
Understood	0	0	0	0