Journal of Medical Ethics 1999;**25**:263–267

Can the written information to research subjects be improved? - an empirical study

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Abstract

Objectives—*To study whether linguistic analysis and changes in information leaflets can improve readability and understanding.*
Design—*Randomised, controlled study. Two information leaflets concerned with trials of drugs for conditions/diseases which are commonly known were modified, and the original was tested against the revised version.*
Setting—*Denmark.*
Participants—*235 persons in the relevant age groups.*
Main measures—*Readability and understanding of contents.*
Results—*Both readability and understanding of contents was improved: readability with regard to both information leaflets and understanding with regard to one of the leaflets.*
Conclusion—*The results show that both readability and understanding can be improved by increased attention to the linguistic features of the information.*
(*Journal of Medical Ethics* 1999;**25**:263–267)

Keywords: Research ethics; patient information language

Introduction

It has for a number of years been generally accepted that informed consent is a necessary condition for enrolling patients or healthy volunteers in medical research projects.[1] Informed consent is also a requirement of many national legislations and of the harmonised ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) good clinical practice guidelines regulating clinical pharmaceutical research in the European Union, the USA, and Japan.[2] The purpose of the information component of the informed consent process is that the patient is informed about the project in a way which makes it possible for the patient to understand what participation in the project entails. The information is given both in written and in oral form, although the extent of the oral information can be very variable.

A number of studies have been made of the readability of information leaflets, and a few studies have looked at how much patients understand after having read the leaflets.[3–13] For a recent general review of the literature on written patient information see Arthur.[14] In many of these studies it is suggested that both readability and understanding can be improved if the information leaflets and consent forms are checked and/or written by a professional language user (journalist, communication specialist etc).

We have found it of interest to study whether this suggestion can be given empirical support.

In this study we therefore investigated whether linguistic analysis and appropriate changes in written information leaflets can change the perceived difficulty of the consent form, and the understanding of the content of the form.

Materials and methods

We obtained ten written patient information leaflets currently or recently in use in different randomised controlled trials (RCTs) run by Astra Danmark A/S, a pharmaceutical company. From these, two were selected because they: a) concerned subjects who were not in any current treatment, b) were concerned with diseases/conditions which are both commonly known and not very severe. The two leaflets are furthermore intended for use in two different age groups. One of the leaflets describes a RCT testing of a new drug for hypertension in people above 75, whereas the other describes a rather complicated RCT testing the effect of a new local anaesthetic in connection with the sterilisation of women between 25 and 45 years of age.

The two leaflets were analysed with regard to layout, style, language, and picture of the receiver (ie the implicit representation of the author's ideas about the type of person reading the text). A number of problems were identified in all of these categories, and these formed the basis for a revision of the leaflets with the purpose of increasing understanding in four areas: a) the intersubjective understanding which exists

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between the sender and the receiver; b) the understanding of the graphic symbols; c) the cognitive understanding of the subject matter, and d) the understanding of the message itself.[15]

It is not enough for the receiver to understand the signs of the text and to have a cognitive understanding of the subject matter. He/she must also "get the message", ie arrive at an understanding of the intentions of the sender with regard to the text.

In order to be able to test the original and the revised leaflet against each other in an unbiased way no changes where made in the content of the revised leaflet, ie the revised leaflet did not contain more items of information than the original. The changes were thus limited to changes in language, style, and layout.

The text was restructured with the aim of reaching a sequence which was logical seen from the point of view of the interests of the receiver (this may differ from the point of view of the sender). The text was broken down into smaller segments and these were given subheadings. Long sentences were divided into smaller sentences, and professional language was replaced by lay language. Two examples of the changes that were made are given below:

Example 1

Original leaflet:

INFORMATION TO THE PARTICIPANTS

Long-term treatment of elevated blood pressure with drug A and hydrochlorthiazide in older patients.

Revised leaflet:

Patient information:

Do You want to participate in a test of a new drug?

Example 2

Original leaflet:

The course of the trial

You will take 2 or 3 tablets every morning during a period of 30-34 weeks. 2/3 of the patients will be treated with drug A and 1/3 will be a control group and will be treated with hydrochlorthiazide. It is decided by chance to which group you will belong. Neither you nor your doctor will know which treatment you are receiving. It is only when the whole trial is finished, that you and your doctor will get to know, which treatment you are receiving.

In order to assess the results of the drug treatment as correctly as possible all patients will receive placebo (non-active drug) for a short period during the trial.

Revised leaflet:

Plan for the course of the trial

Time: The trial lasts 30-34 weeks.

The treatment: 2/3 of the participants will be treated with the new drug A and 1/3 will be treated with the known drug Dichlotride. It is decided by drawing lots to which of the treatment groups you will belong. Neither you nor your doctor will know which of the two treatments you are receiving. It is only when the whole trial is finished that you are told which treatment you have received. In order to perform the trial as correctly as possible there will be a short period during the trial during which all participants receive non-active drug (placebo).

Medicine: You will take 2 or 3 tablets every morning during the whole trial period.

For each of the two leaflets (hypertension and sterilisation) a separate questionnaire was developed in order to test each of the four areas of understanding. The questionnaires also contained questions about the demographic characteristics of the respondents and their previous experience with medical research and general attitudes towards medical research. As far as possible the questions where identical in the two questionnaires. Answers to questions were presented in multiple choice format.

The questionnaires were tested in a pilot study and modified accordingly.

The respondents for the test of the hypertension leaflet were recruited at centres and clubs for pensioners, and although the actual hypertension study only recruits persons older than 75 years of age, we allowed persons older than 60 years of age to participate in the present study. Appointments were made with groups of respondents who were given both written and oral information about the present study. Each person was then randomised to receive either the original or the revised information leaflet. All were told that they could use whatever amount of time they found necessary to read and understand the leaflet. Immediately after having read the leaflet they filled in the questionnaire.

The respondents for the test of the sterilisation leaflet were recruited in a similar way at a number of work-places where most of the work-force is female.

The results where analysed using non-parametric statistics and log-linear models.[16] The analysis was performed using the program CSS Statistica for PC.

Each questionnaire contained a number of questions aimed at testing the cognitive understanding of the respondents. From this group of questions a simple summative scale was formed of

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Table 1 Demography of respondents

Study	*Hypertension*	*Sterilisation*
N*:	135	100
Sex:		
Male	34	
Female	101	100
Age:	74 (62-92)**	35 (25-45)
Education after primary school:		
None	51	9
1-2 years	14	25
3-4 years	35	37
5-6 years	13	19
> 6 years	17	10

* n may be less than N in any sub-tabulation due to missing data.
** median (range).

the informative questions (ie questions where more than 10% of the respondents answered wrongly).

Results

The demography of the respondents can be seen in table 1. Twenty-seven per cent of the respondents receiving the hypertension leaflet were already receiving treatment for hypertension. There were no statistically significant differences betwen those already receiving treatment and other respondents.

There was a general positive attitude towards medical research, and most perceived the study described in the information to be "very important" or "important". There are no significant differences between respondents receiving original and revised leaflets concerning general attitude, but respondents receiving the revised sterilisation leaflet find the study more important (table 2).

The results with regard to perceived readability and comprehensibility show that the revision of the leaflets in general increases these parameters (table 2).

There were no differences between the groups given the original leaflets and the revised leaflets with regard to their willingness to participate in the study described in the leaflets, although the respondents find that the revised leaflets give a more open choice as to whether one wishes to participate in the study. This difference is statistically significant in the hypertension study ($p<0.005$), but not significant in the sterilisation study ($p=0.089$).

One of the questions concerning cognitive understanding is worded: "Who decides which treatment you will receive if you participate in the trial" with the three possible answers:"The responsible doctor", "Chance (drawing lots)", and "The pharmaceutical company". In response to this question in the hypertension study, most respondents answered: "The responsible doctor" even though the leaflets clearly stated that allocation of treatment would be by chance. The correct answer was given by 26% receiving the original hypertension leaflet, and by 42% receiving the revised hypertension leaflet. In the sterilisation study most respondents answered this question correctly.

Irrespective of the study and of the leaflet they received more than 90% of all respondents answered correctly questions about the voluntary nature of research participation, and about the possibility of withdrawing at any time during the trial.

The summative cognitive understanding scale for the hypertension leaflet contained five questions (table 3). Univariate statistical analysis showed that understanding increased with both level of education and with having received a revised leaflet. Log-linear analysis with backwards elimination of insignificant interactions showed that the best model contained positive interactions between level of education and comprehension, and between type of leaflet and understanding (Maximum Likelihood $X^2=.984$, df=6, p=.986). Both level of education and type of leaflet thus independently influence understanding.

Table 2 Attitude towards research: perceived importance, readability, and comprehensibility

	Hypertension		*Sterilisation*	
	Original	*Revised*	*Original*	*Revised*
What is your general attitude towards medical research?				
Very positive	6	6	4	4
Positive	43	34	33	29
Negative	7	13	11	11
Very negative	3	2	0	2
How important do you think the study is?				
Very important	21	14	7*	12
Important	31	31	27	28
Less important	4	9	11	7
Don't know	9	10	6	2
Is the leaflet easy to read?				
Very easy	12**	19	4***	15
Easy	38	43	21	34
Difficult	14	0	20	0
Very difficult	1	0	6	0
How much of the leaflet do you think you understand?				
All of it	27	31	14***	21
Most of it	28	28	24	18
Half of it	7	2	12	0
A smaller part	3	1	1	0
Are there words or concepts in the leaflet that you don't understand?				
No	30***	48	27***	44
Yes, a few words	20	11	15	5
Yes, a number of words	8	0	8	0
Yes, a lot of words	4	2	1	0

* $p < 0.05$ (Mann-Whitney U-test).
** $p < 0.005$ (Mann-Whitney U-test).
*** $p < 0.001$ (Mann-Whitney U-test).

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Table 3 Understanding in the hypertension study

Number of correct answers	*Original*	*Revised*
0	13*	14
1	7	4
2	13	6
3	22	19
4	14	17
5	4	12

* $p < 0.05$ (Mann-Whitney U-test).

The summative cognitive understanding scale for the sterilisation leaflet contained seven questions. There was no connection between comprehension measured with this scale and any of the background variables.

For both versions of both leaflets there is a significant positive correlation between perceived comprehensibility and understanding ($p<0.05$ in both cases, Spearman rank correlation).

Discussion

A potential problem in this study is that the respondents are not in exactly the same situation as patients considering whether or not they should consent to participation in a trial. This is, however, probably not a major problem since the two conditions in question (hypertension and sterilisation) are well known by the general public. The results as to whether or not the respondents would consent to participation are probably influenced by the artificial situation, but there is no reason to believe that the results as to understanding are influenced to any substantial degree.

A second potential problem is that the present study only investigates the effects of modifying the written information given to patients. In real life patients receive both written and oral information and their understanding of the trial depends on both kinds of information. Based on the present study it is thus not possible to say whether modification of information leaflets will increase total understanding in real-life situations. Taken at its extreme this argument could imply that we have no reason at all to improve written information, since any deficiency can be remedied through oral information. This extreme version of the argument is clearly problematic, and we therefore do have independent reasons to be concerned with the quality of the written information. There is also evidence suggesting that in some cases the oral information may be less than comprehensive.[17]

A third problem is that it is difficult to measure some kinds of understanding through a questionnaire. It is especially difficult to measure the respondents' understanding of the intended message, ie what the sender of the information really wants to convey. A full study of this aspect of the communication would probably require a different research design, for instance a design incorporating qualitative interviews.

The results concerning the comprehension of the information about randomisation are interesting because most respondents in the hypertension study give the incorrect answer that "the responsible doctor" will decide which treatment they are going to get, even though both the original and the revised information leaflets contain clear statements of the fact that allocation was going to be by chance or the drawing of lots. This seems to indicate that randomisation is an idea which is so alien to the conception of the normal doctor-patient relationship in this group of older people, that many persons in this group cannot comprehend it. The finding that the same question is answered correctly by the younger respondents in the sterilisation study could indicate either a pure age-effect or a cohort effect. (A cohort effect occurs if a given age-segment of people have been exposed to specific factors in childhood or youth which have formed them and which determine their present attitudes etc.) The present study is unable to distinguish between these two possibilities, but a cohort effect seems most plausible.

The results show that the perception of the readability and comprehensibility of a standard information leaflet can be improved by professional linguistic revision of the leaflet. This result is not surprising since a number of studies have shown that the average information leaflet is difficult to read and understand.[14 18] It is interesting that there is a correlation between the respondents' own assessment of the comprehensibility of the form, and their actual comprehension. This indicates that it may be useful simply to ask whether or not a prospective research subject has found the information leaflet easy or difficult. The answer to this question could be used as a rough indication of the person's level of understanding. This result empirically supports the advice given by Wager *et al* that it is useful to test the understanding of prospective research subjects after giving information but before eliciting consent.[19]

In one of the studies (hypertension) presented here the revision of the information leaflet leads to an increase in understanding, whereas there is no statistically significant increase in the other study (sterilisation). This difference can probably be explained by differences in the complicated research design which has to be explained to the readers of the information leaflet. The hypertension study is a straightforward randomised controlled clinical trial, whereas the sterilisation study simultaneously tests a new local anaesthetic and a new

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method of applying local anaesthetics during the operation. The understanding of the sterilisation study is further complicated by the fact that the respondents have to keep three different forms of pain control medication/procedures (general anaesthetic, local anaesthetic, analgesic tablets) separate in their mind if they are fully to understand the study. The sterilisation study is therefore rather difficult to explain and understand, especially within the constraints of an information leaflet of no more than four A4 pages (including the actual consent form). One possible interpretation of our results concerning understanding is therefore that one of the trials could only have been made comprehensible if more extensive modifications had been made to the information leaflet, including modifications of content.

The study was based on original information leaflets prepared by a pharmaceutical company. The perception of many members of research ethics committees is that the average quality of leaflets written by pharmaceutical companies is higher than the quality of leaflets written by individual researchers. If this is true it only reinforces the conclusion that considerable gains could be made in the perception and understanding of consent forms if these routinely had to pass a linguistic service check.

Acknowledgements

The study was funded in its entirety by a joint grant from the Danish Health Sciences and the Danish Humanities Research Councils. We thank Astra Danmark A/S for permission to access and use their consent forms as the basis of this study.

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