

Readability of patient information can be improved

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ABSTRACT

INTRODUCTION: The number of participants in medical experiments has declined and consent often rests on perilous ground because the participant information sheet (PIS) on which informed consent rests preserves identification with the expert environment. This study explores to which extent research ethics committee (REC) members appreciate this problem.

MATERIALS AND METHODS: A retrospective analysis of ten REC applications were subjected to a naïve reading followed by structural analysis to generate themes and subthemes to guide structured REC member focus-group interviews. This analysis informed a prospective survey where REC members registered terms and phrases posing comprehension barriers to lay receivers.

RESULTS: Main barriers of comprehension were aspects of contents presentation and specialised terminology. Problematic terms centred mainly on epidemiology, design, descriptive and topographic anatomy and physiology, diagnostic procedures and medicines. Contents problems centred on irrelevant and superfluous information and poor presentation.

CONCLUSION: The language, structure and format of the PIS should be improved. Avoiding technical jargon or explaining it when it is used, using more common words when they are available and a clearer structure were identified as potential targets of intervention.

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Medical experiments involving test participants must comply with the Helsinki Declaration which demands consent. Consent must be informed which implies that participants can understand what the investigator tells them and can find and understand important aspects of the trial in relation to purpose, personal engagement as well as safety, the expected efficacy, and practical details before they sign the consent document prior to their participation. These details are communicated via the participant information sheet (PIS).

Regional research ethics committees (RECs) assess ethical aspects of the medical experiments on the basis of a lay person summary (LPS) that closely mirrors the PIS in tone, style and format and which, for all practical purposes, is equivalent to the PIS in terms of contents and wording of the key aspects of trial participation, even if the PIS de facto handed out to trial participants

may be more lengthy and offer more practical details than the LPS. The REC is obliged to bar a medical experiment if, among others, the PIS is thought to pose comprehension problems. Serving as “a linguistic sounding board” [1], an important role of lay REC members is to check the readability of the PIS based on the LPS. We assume that this responsibility, given by law, is taken very seriously by REC members at large and that, if in doubt, they will not give an LPS or PIS posing any comprehension problems the benefit of the doubt.

Clinical trials reportedly generally fail to achieve adequate recruitment [2]. In Danish clinical research, a 20% decline in the number of subjects in phase I-IV trials was seen from 2008 to 2009 [3]. Why this is so has not been established. One reason could lie in the communication. The UK National Research Ethics Service thus has voiced concern that PIS's are becoming too long and complex and that this may hamper recruitment [4]. The process of informed consent in clinical practice is also reported often to be inadequate [5] and consent not to be sufficiently “informed” [6] because potential participants often do not fully understand the documents on which consent rests. Several studies have accordingly suggested that the purpose of the PIS would be better served if more attention was paid to its form [7, 8] and language [9-11], as demonstrated for example by a prior study in the Danish setting [12].

To our knowledge, no studies have yet explored Danish REC members' general perception of the PIS and LPS readability. This explorative case study aims to fill this gap by exploring REC members' evaluation of the readability of a sample of PIS's with a view to informing an intervention geared to enhance their comprehension in general.

We assume that the PIS does not serve its purpose well in the eyes of REC members because it preserves identification with the expert environment in which it is born at the expense of serving the communicative purpose in the lay environment for which its use is intended.

MATERIAL AND METHODS

The study was conducted from September 2008 to June 2009. A *retrospective* analysis combined observation with a structured survey to obtain knowledge of the nature of the problem and REC members' “index” appreciation of this problem. Ten PIS summaries were randomly

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 FIGURE 1

Questionnaire template featuring research ethics committee members identification of comprehension problems of contents, style and structure and design in lay person summaries.

Summaries: 64	Time spent: median 13.6 min (range 2-35)
Members: 15 (10 lay, 5 prof.)	Tenure: median 2 y (months-range 7 y)
List of too technical words: 268 words	
Contents (no. 137)	
53 Irrelevant or superfluous information. "Far too much information"; "Too longwinded"	
45 Poor presentation of contents. "Poor presentation"; "Clearer presentation needed"	
24 Repetitions. "Purpose stated several times"; "He's overdoing it"	
15 Lacking information. "No introduction is given"	
Style (no. 173)	
54 Technical and difficult words. "Too many drug names"	
33 Long or complicated sentences. "Incomplete sentences"; "Does not hang together"	
20 Agent-less passives	
19 Abbreviations	
9 Inconsistency in use of synonyms "Confusing"	
9 Confusing punctuation. "Many errors of punctuation and spelling"	
8 False friends. "Uses the wrong words"	
2 Negative instruction	
Structure and design (no. 30)	
25 Lack of heading/subheadings; too few paragraphs. "Muddled, needs paragraphs"	
5 Lack of illustrations	
Other problems: "Headings in English"; "State purpose early"; "Wrong use of terms"	

extracted from applications submitted to the RECs of the Central Denmark Region. The investigator (MP) subjected these texts to a naïve reading to arrive at a non-judgmental and open-minded understanding of their readability. This was further deepened by a structural analysis generating themes and subthemes to guide two structured focus-group interviews with REC members. First, open, general questions (e.g. "What problems do you see in lay summaries") gave REC members the opportunity to articulate their own initial understanding. Then, more closed questions determined to which extent the principal investigator's naïve reading and interpretation was shared by the REC members. These questions addressed four aspects of readability: contents, style, design and structure. This second series of questions aimed to establish a common ground and to discuss and reach agreement on concrete proposals for the prospective part.

A subsequent *prospective* part used a simple questionnaire template with 15 possible categories of problems of contents, style and structure and design (the last two collapsed into one) based on the retrospective findings and the focus-group interviews. Inter-rater rating consistency was pilot-tested before rating began and differences were discussed and resolved at a brief consensus meeting to ensure inter-rater homogeneity in rating and categorization of problems. No attempt was made to check and to control for subsequent intra-rater consistency. An open category designated "other problems" allowed room for description of problems outside the

agreed pre-specified problem categories. All REC members read one or more PIS's consecutively submitted to the REC. For each PIS summary they read, they filled in one questionnaire checklist. For each checklist, entries were summed.

The *prospective* part aimed to inform the process of designing the intervention, wherefore its findings were not quantified using statistical analysis. We aimed not to suggest reasons for differences observed between the participants, so multivariate analysis of each participant's knowledge base with relevant socio-demographics was not performed. Basic sociodemographic data (profession, years of committee tenure) and time spent on reading the LPS were obtained. Minutes from the focus-group meetings were taken by the principal investigator and an associate, their minutes were compared and adjusted at a consensus meeting, and the minutes were approved by the REC members.

Trial registration: not relevant.

RESULTS

During the study period sixty-four applications were received by the REC, each with an enclosed PIS and LPS. All REC members were invited to fill in a questionnaire for each application read. A total of 200 filled in questionnaires equivalent to a median 3.1 (range 1-8) for each application were returned and REC members identified 268 different terms which they found too technical.

REC members singled out terms that were both

highly specialized, belonging to experimental sub-domains (specialties) and more general medical terms (Figure 1). The terms spanned all parts of speech with nouns accounting for about 90% of the words. Most nouns related to epidemiology and design (e.g. "intervention" intervention, "placebo" placebo), descriptive and topographic anatomy and physiology (e.g. "epigastriert" epigastrium, "blastocytter" blastocytes) diagnostic procedures (e.g. "aplanationstonometri" applanation tonometry, "ekkokardiografi" echocardiography), and medicines (e.g. "ACE-hæmmer" ACE inhibitors, "angiotensin II antagonist" angiotensin-II antagonists). Standard epidemiological terminology and terms denoting design were frequently and consistently identified as potential barriers to lay comprehension as also reported by others [12, 13]. The texts contained relatively few Latin and Greek terms, probably because the writers knew that they could bar the lay receiver's comprehension. The REC members' observations thus confirm the prevailing understanding that most problems of comprehension are rooted in difficulty of understanding lexical nouns. This indicates that conceptual factors rather than syntactic ones were responsible for perceived difficulties in comprehension. The REC members also identified "sub-technical" (or academic) vocabulary as problematic and identified Danish words that have a special meaning in medicine (e.g. "studiet", "reagens", "bisidder", "administration", "kontraststof). Finally, compound nominal phrases appeared to be a prominent medical register marker. Only few verbs and adjectives were identified.

The range of terms selected may reflect both REC members' variable educational background and their highly idiosyncratic approach and understanding of "the nature of the problem". There was little congruence between committee members reviewing the same LPS and PIS on which terms were difficult; and there was much variation in the number and nature of terms identified by individual members as "difficult". However, when presented with the total list, the REC members were largely unanimous that the terms on the list all needed to be "translated" into lay terms.

Seventy-four questionnaires were returned with the message "no comments to this lay summary" and were excluded from the analysis. Ranked by order of frequency, the main contents problems noted in filled-in questionnaires centred on irrelevant and superfluous information and poor presentation. The main problems of style concerned lexis and syntax (Figure 1).

Differences between lay and professional committee members showed only weak trends. Lay members tended to spend a little more time reading the LPS and PIS than the professional members, tended to make slightly more comments and ticked off more problem categories. Twelve of 15 REC members returned the

questionnaire with "no comments" a number of times (range 1-16 times); three lay members did not on any occasion return questionnaires without comments.

Agreement between lay and professional REC members' filled in questionnaires could only be assessed in those lay summaries that had been read by both one of each (n = 53). Eleven applications were read only by one respondent and were not included in this analysis. Agreement between lay and professional raters was high (75-100% agreement between ticked off categories) in six (11%), fair (50-75% agreement) in 29 (55%) and poor (0-50% agreement) in the remaining 18 (34%) lay summaries.

DISCUSSION

The main finding is that the qualitative case data back the assumption that sparked the present study. Serving as proxies for the intended lay receiver of the PIS, the lay REC members identified as principle barriers of comprehension aspects of contents presentation and style. Interestingly, their evaluations were much in line with professional members' evaluations; notably as far as the excessive use of specialized terms denoting design and methodology.

The problem of poor comprehension of the PIS among its end users is well-known [14-16]. Yet, the present study was conducted among largely well-educated members of a REC quite familiar with the language of medicine, i.e. among trained readers. We must therefore expect these texts to pose considerable comprehension obstacles to lesser-skilled readers.

Comprehension is, of course, contextual in the sense that it arises from an interaction between features that characterize both the text and its reader. In the reader, features affecting readability are prior knowledge, reading skills, interest and motivation, among others. In the text, features affecting readability are contents, style, design and structure. Such could not be controlled for in the present set-up; indeed, should not be controlled for given the purpose of the study. Moreover, how the investigator explains information about research should, of course, not be equated with how the subject actually processes and interprets that information. We therefore used REC lay members, in their capacity as competent ignorants, as a proxy for lay persons who participate in experimental research even though their sociodemographic characteristics suggest that their readability skills may lie above those of the average lay person. However, lay persons presumed competent to make an informed choice about participation in an experiment relevant to their disease often have prior subject matter knowledge. All things equal, the above-average subject matter knowledge of the lay person was therefore assumed largely to balance the

Do test participants in medical research understand what happens to them when and how?



above-average reading ability of the committee lay members. Finally, even in research projects comprising patients with a chronic disease, the individual person's knowledge will vary considerably and the PIS should provide sufficient information despite these differences. Therefore, the lay REC members act as general lay-person representatives and must be assumed to "rate" the readability of the lay summaries with this in mind and, if suspecting comprehension problems, not to give the text at hand the benefit of the doubt.

The present findings lend support to the argument that poor comprehension could have a bearing on recruitment, either directly as evidenced by the above-average literate respondents unanimous identification of key concepts as incomprehensible or, indirectly, because the recognition among the medical specialists that lay person readers would find the lay person summaries difficult to understand could affect their recruitment effort "by anticipation". The latter argument finds support in the conclusions of a study on facilitators and barriers to enrolment reporting that accrual problems were rooted mainly in physician-related factors like concern over patients' ability to comprehend information and that patient- and system-related factors accounted for the lesser part of the accrual problems [16]. We may therefore assume that communication both directly and indirectly affects recruitment.

A second main finding was that we identified two possible language intervention targets: contents presentation and style. The structural problems echo findings in another recent study of PIS advocating a clear structure and a short PIS [15]. As to language, our respondents unanimously identified technical jargon as a main problem with nouns accounting for about 90% of the words identified. The semantic categories representing the highest barriers were epidemiology and design, descriptive and topographic anatomy and physiology, diagnostic procedures and medicines. Our results confirm other studies' conclusions on the difficulty of understanding the meaning of core concepts of epidemiology

and design (terms like *double-blinding*, *randomisation*, etc.) [12]; yet, it is, to our knowledge, the first study that takes the description of the issue of comprehension problems in the PIS to a deeper level of semantic categories and parts of speech. This problem of "scientific literacy" is not restricted to health and experimentation in clinical trials, but ours and others' findings [12, 17] make a strong case for targeted linguistic intervention.

The main *strength* of the present study is that we chose a real setting with a relatively large sample of authentic texts and a mixed respondent group as proxy for the intended target reader. The study proceeded through a series of steps to arrive at a non-judgmental, deeper understanding of the nature of the problem. The interactive approach allowed us to explore REC members' attitudes and allowed us to design a template for a *prospective*, explorative part.

The main *weakness* of the present study lies in its data. They must be interpreted with caution given the study's design. Selection bias in the form of volunteer bias may play a role and we did not analyze how lay REC members differed from those they represent (the general lay man). Further, we performed no non-response analysis. However, we have no reason to believe that respondents differed in ways from non-respondents that would affect the findings since REC members were unanimous in their evaluation of the nature, relevance and pertinence of the problems. We may be facing a social desirability bias that may have caused REC members to err in measuring data toward the expected outcome, i.e. the texts were poorly written. However, given the nature of their job, social desirability is expected to play no major role in this context.

CONCLUSION

Both lay and scientific REC members found that there is much room for improvement of the language, structure and format of the PIS. Simple things as avoiding technical jargon or explaining it when it is used, using more common words when they are available and having a clearer structure were identified as principle targets of intervention.

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