CORRESPONDENCE

The Quality of Informed Consent Forms—A Systematic Review and Critical Analysis

by Julia Lühnen, Prof. Dr. med. Ingrid Mühlhauser, and Prof. Dr. phil. Anke Steckelberg in issue 22/2018

Validity of Evaluation Criteria Is Not Clear

As an author of patient consent forms and as a clinician I am disappointed by the non-transparent study report and its summary employing stereotyped scientific jargon (1). What is the old standard? The authors provide only a summarized evaluation. Was there not a single qualified information leaflet? The authors' conclusion, that their quality assessment of the explored consent forms may be generalized, is presumptuous. The validity of the "relevant evaluation criteria" remains completely opaque.

In contrast to evidence-based health information, the main function of consent forms lies in providing information for enhancing the mandatory pre-procedure patient-doctor communication; supporting an individually adequate decision; strengthening the relationship between doctor and patient; and minimizing the risks and adverse effects of a recommended medical procedure. Pre-procedure communication therefore does not merely aim at providing evidence-based information, but also at eliciting from the patient crucial information about individual risks and values, attitudes or previous medical experiences which may be relevant for their decision. Thus, pre-procedure communication encompasses an important relationship aspect, which may outweigh the delivered evidence-based information in the patient's decision-making process. Cognitive processing of evidence-based information will be curbed by concurrent threatening affects. If the consent form intensifies a patient's anxiety, his/her ability to use the delivered evidence-based information for an adequate decision will be hampered. The same is true when the consent form is used in a manner that triggers feelings of anger or helplessness. A consent form therefore has to be conceptually different from a predominantly litigation-avoiding package leaflet. If a consent sheet induces negative emotions, then a patient's decision against a medical procedure may not be based on a sound informed consent and on patient autonomy, but may be due to poor communication, even if all the quality criteria of evidence-based health information have been met.

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Conflict of interest statement

Dr Kappauf is the author of three oncological consent forms that were not investigated in the study. He receives licensing fees/royalties from Thieme for these forms.

Time Expenditure as a Quality Criterion

Pre-procedure discussions relating to consent always consist of two parts. The first part concerns the technical/factual content of the consent form, as was explained and evaluated in detail in the article (1). The second part relates to the patient's competence to give consent.

The question therefore is: is the patient able to understand/comprehend the consent form, and is s/he able to act on her/his understanding of their own free will? Competence to consent is taken for granted by the legislator in medical law, in the same way as legal competence is in the civil code. The lack of such competence has to be proved, for example, in geriatric or palliative medicine. In the article, I found only one place where this was referred to: in *Table 2* (item 5, line 6): "[...] that the patient has understood the information."

A patient's ability to consent needs to be documented in the consent form. This does not require input from a psychiatrist—common sense usually suffices.

Another question is: how much time does the completion of a consent form take the doctor? The less time spent, with the result being equal, the better the consent form. The necessary time taken to achieve this is a crucial quality criterion.

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The author declares that no conflict of interest exists.

In Reply:

We thank our correspondents for their critical discussion of our article (1). We will address some of the issues raised in detail.

Ascertaining the competence to give consent is an important component of the pre-procedure discussion and should be documented in the consent form. If the patient does not have competence, the pre-procedure discussion involves their legal representative, and the decision will have to be made by proxy.

The subject of our analysis comprised the written materials and not the entire consent process. For this reason we were not able to consider the aspect of time expenditure. From the patient's perspective, time expenditure matters far less than a comprehensive and comprehensible pre-procedure discussion. Consent forms that meet the criteria for evidence-based health information can—in our opinion—help to put this aspiration into practice more easily, since crucial information for the pre-procedure discussion is already available in a comprehensible format.

There is no validated instrument for the purpose of evaluating consent forms that might make classification feasible. For this reason we presented our results in a purely descriptive form. The criteria we applied were defined on the basis of an evidence-based and consensus based guideline for evidence-based health information. According to these criteria, the consent forms we investigated were not suitable for enabling an informed decision. In spite of certain differences in quality, we would not rate any of the consent forms as very good. In all forms, sources of information were not cited, and an appropriate numerical presentation of harms and benefits was missing. Our analysis does not allow for any general conclusion about the quality of all consent forms, but it is fair to assume that the results are generalizable to a certain extent.

In a process of shared and informed decision-making, patients should weigh up on the basis of the

best available evidence which options meet their own preferences and ideas best. We therefore agree that the pre-procedure discussion should consist of more than evidence-based facts. But the facts cannot be omitted because they form the basis of the individual weighing-up process. Especially numerical data can help to assess the probabilities for the possible benefits and harms of a medical measure more realistically (2, 3). It was also shown that anxiety or uncertainty do not increase if more information is provided in the context of the pre-procedure discussion (4).

With regard to the package information leaflets mentioned, it was recently ascertained that even those working in the healthcare professions do not understand the information on adverse effects (5). For this reason, we would not use such package leaflets for comparison if appropriate and comprehensible risk communication is needed. Consent forms are probably in many cases used only for the purposes of consent that is legally valid. However, the objective should be an informed decision. For this reason, we make a plea for new standards, in order to ensure that patients receive, at the right time, the information they need in order to make an individual informed decision.

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The author declares that no conflict of interest exists.