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Development and Usability Analysis of a Multimedia eConsent Solution

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Abstract. *Background:* More and more medical data is being stored digitally in routine care. The secondary use of patient data is only possible to a limited extent for data protection reasons. In order to enable a long-term and far-reaching use of secondary data, a possible approach is to obtain "broad consent" from patients, e.g. on research projects whose purpose is still unknown at the time of consent. *Objective:* To develop and evaluate an interactive eConsent prototype that presents the extensive contents of the "broad consent" in multimedia form for the purpose of a successful and resource-efficient information and consent process. *Methods:* The eConsent prototype was designed on basis of a literature review and in accordance with the goals of the German medical informatics initiative. User tests and subsequent questionnaire surveys using the System Usability Scale (SUS) were carried out with patients from a university hospital to assess the prototype's usability. The study was conducted in a quasi-experimental, one-group posttest-only design. *Results:* The created interactive prototype can present the contents acoustically and visually and offers the possibility to retrieve additional information. With a SUS score of 84,1/100 the results indicate a very good usability of the prototype. *Conclusion:* The next steps will include further refinements of the prototype based on the feedback received and a subsequent study with a broader user group aimed at introducing an eConsent tool as part of a patient portal.

Keywords. Informed consent, multimedia, patient portals, patient participation

1. Introduction

Several national initiatives, for example the German medical informatics initiative (MI-I) [1] or the German Biobank Alliance [2], have emerged to utilise the increasing possibilities of digitisation in medicine in the best possible way for care and research. In order to enable a long-term and far-reaching use of secondary data, treatment- or study-specific consent seems no longer sufficient. Obtaining a "broad consent" to allow data to be used for research projects, whose purpose is still unknown at the time of consent, might be a possible solution [3]. However, such a “broad consent”, which includes patient information and a consent text, can be quite extensive according to the

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circumstances. The usual consent procedure with paper forms and personal explanations on site would be extremely time-consuming and labor-intensive due to the detailed content and the many patients involved. Current research on electronic consent tool (eConsent) approaches shows that a multimedia presentation of educational content can help to improve understanding and make the consent process more pleasant for patients [4]. Furthermore, eConsent approaches can facilitate an interactive educational process and provide additional information [5]. In addition, eConsent solutions may have the potential to increase the economic efficiency of consent processes [6].

The aim of this work is to describe the development and evaluation of an eConsent prototype that can digitally communicate the contents of the patient information of a "broad consent". Subsequent steps such as a digital signature or the digital documentation of the consent were not within the scope of this prototype. The conception of a tool with a modular structure, multimedia processing, interactive elements, a high usability as well as optional access to further information should enable a successful and resource-efficient consent process. The usability of the prototype was tested and assessed by patients of the University Hospital Erlangen (UKEr). Moreover, the findings of this work are intended to lay the groundwork for further iteration steps for developing an eConsent tool tailored to the patients' need.

2. Methods

Preceding the development of the prototype, a literature research was carried out with regard to comparable studies and projects as well as ergonomics of human-system interaction. The conceptual design was based on those findings and set up in accordance to the requirements of the MI-I. Furthermore, the "Mustertext Patienteneinwilligung" [7], consented within the MI-I, served as specification for the mandatory content of the patient information tool. The implementation ideas were then concretised and adapted in a prototype using Microsoft PowerPoint®. The resulting initial design was refined in line with feedback obtained by conducting a pre-test with potential users.

Thereafter, the actual study was conducted in a quasi-experimental, one-group posttest-only design at the UKEr, a hospital of maximum care level. User tests and subsequent questionnaire surveys with patients from two different departments of the UKEr (Department of Paediatrics and Adolescent Medicine and Department of Urology) were carried out to assess the prototype's usability. Only patients who were unable to carry out the test due to physical or mental limitations were excluded. In the Paediatrics Dept. the parents participated as caretakers for their children.

The System Usability Scale (SUS) [8] was used as the primary outcome measure for the evaluation of usability. In addition to the SUS items, the questionnaire contained further statements on digital patient education, which could be rated on a five-part Likert scale. Moreover, the respondents were asked to indicate whether or not they would be willing to agree to the "broad consent" on the basis of the information provided. Finally, they could document a positive as well as a negative aspect of the tested prototype as free text. In the Department of Paediatrics and Adolescent Medicine, the volunteers were recruited from a waiting room, where the user test and questionnaire survey were subsequently carried out. In the Department of Urology, in-

patients were asked in written form to participate, and in case of a positive feedback, the test and survey were carried out in the patient's room.

3. Results

The prototype offers the possibility to present the content in two modes, text mode and audio mode. In audio mode (Figure 1), the content is presented by a speaker and illustrated in parallel by animated pictograms. Pictograms, which are displayed with a blue background at the end of a module (1.), can be clicked to call up further and summarising information. It is also possible to switch between modes during the presentation.

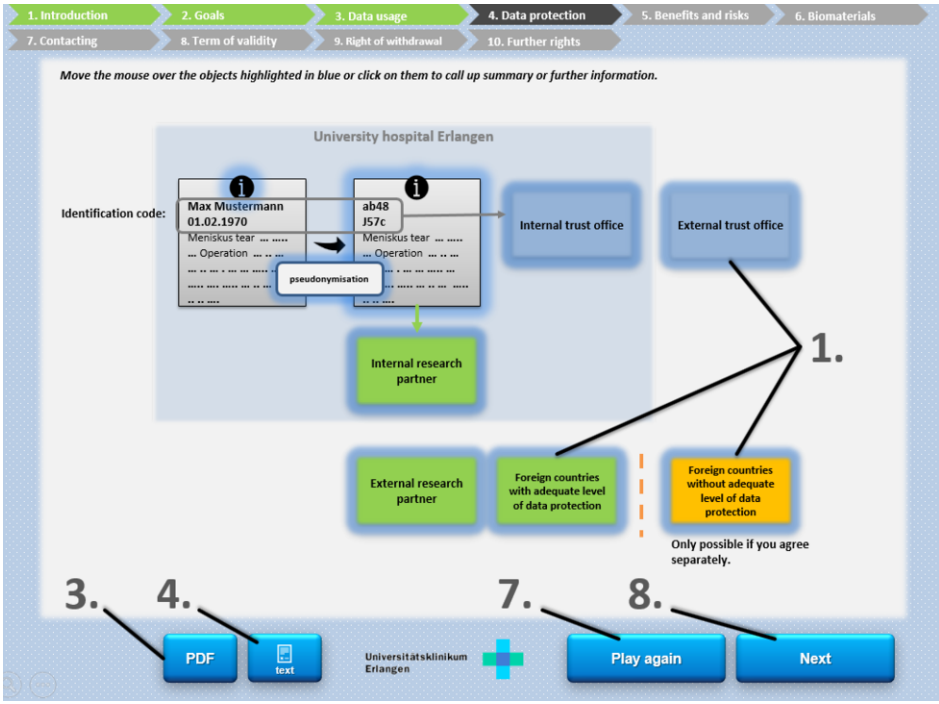

Figure 1. The audio mode of the prototype.

The text mode (Figure 2) displays the content in written form and with hyperlinks (2.) that allow access to summary and further content. Users go through both modes module by module while their progress is indicated by the bar at the top of the screen. Regardless of the selected mode, there are several buttons to interact with at the bottom of the screen. Clicking the "PDF" button (3.) displays the complete patient information in PDF format. This serves as an alternative to the interactive presentation by the prototype. Next to the “PDF” button there is a button for switching between text and audio mode (4.). Using the two buttons "Next" (5.) and "Back" (6.) (text mode) or "Next" (7.) and "Play again" (8.) (audio mode) at the bottom right of the screen, subsequent modules can be started and previous ones repeated.

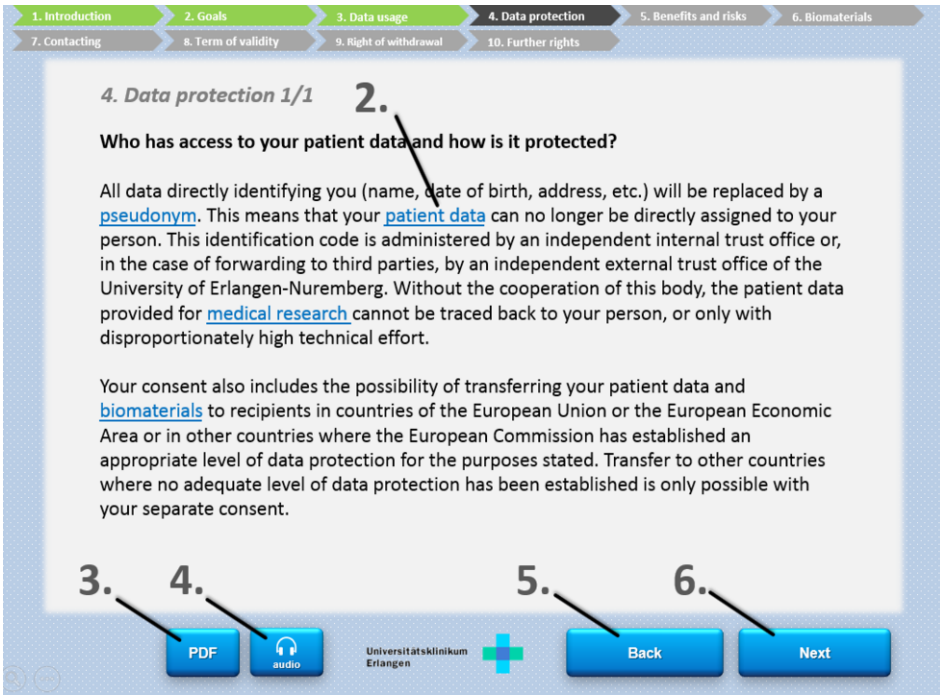

Figure 2. The text mode of the prototype.

3.1. Usability analysis

A total of 47 participants, 42 from the Department of Paediatrics and Adolescent Medicine and 5 from the Department of Urology, were included in the study. As an extract of the results, Table 1 shows the number of participants, the age, the SUS score, and the number of participants willing to agree to the "broad consent" per clinic.

Table 1. Number of participants (n), age, SUS score and number of participants agreeing to "broad consent" per clinic.

	n	age (mean)	SUS score (mean)	agreed to “broad consent”
Department of Paediatrics and Adolescent Medicine	42	41,6	85,4	29 (69%)
Department of Urology	5	65,4	73,5	4 (80%)
total	47	44,1	84,1	33 (70,2%)

In 22 of 47 questionnaires, the free text field was used to name positive and negative aspects of the prototype. The most frequent negative aspect was the extensive content (9/22), the most frequent positive aspect the good comprehensibility (6/22) as well as the simple operation (5/22) of the prototype. 78,7 % of the participants chose the text mode and didn’t try the audio mode at all.

4. Discussion

During hospitalisation, a large amount of patient-related data is routinely collected and digitally stored in the hospital's EHR and then transferred to a data warehouse. However, this data pool has so far hardly been used for research purposes. A crucial factor in changing this circumstance is the patients' willingness to allow the use of their data for secondary purposes. In this context, the four funded MI-I consortia have cooperated in the MI-I consent working group and defined a template for a "broad consent" patient information and consent form. This template comprises four modules differentiating between (1) reuse of data documented during a hospital care process, (2) reuse of biomaterial for research, (3) linking hospital care data with health insurance-based outpatient data, and (4) allowing for re-contact. Unfortunately, this template now has a length of 9 pages, which is seen as a major barrier to inclusion in the traditional paper-based information as part of the normal patient admission process. Thus, based on international experiences, the application of a user-friendly eConsent tool to better engage the patient in the process might be a possible solution [5]. Harle et al. [5] found that some patients wished to receive even more information than required by standard consent regulations. For these high-information-seeking users, the optional access to supplementary information within an eConsent application represents a great advantage, without overwhelming low-information-seeking users with additional information. This option was implemented in the prototype and is regarded as an important component for a successful eConsent application by the authors. The concept of the audio mode should be further investigated as it has only been tested by a few participants and, in contrast to the text mode, less comparable approaches can be found in the literature.

There are some studies that compared paper-based patient information with digital patient information by eConsent prototypes. Tan et al. [9] and Rowbotham et al. [10] showed that approaches with digital elements can improve patient understanding, but also take more time and are perceived as more monotonous than paper-based approaches. Nevertheless, the digital implementation and the media used in these studies can only be compared to the prototype of this work to a limited extent, since content, scope and purpose differ. Rowbotham et al. worked with patient information on a specific clinical study and Tan et al. used a photo story as a medium. Both approaches are strongly aimed at communicating medical facts, which is not the case with "broad consent".

The high validity even for small samples, the technology independence as well as the relatively simple application of the SUS [11, 12] were decisive for its selection by the authors. For the interpretation of normalised SUS scores (0 = lowest usability and 100 = highest usability), a translation into a curved grading scale from A+ (84.1-100) to F (0-51.6) can be done [13]. Consequently, the prototype's SUS score of 84,1 constitutes an A+ and was rated far above average by the participants, indicating a high degree of usability. This assumption is also supported by the free text comments provided by the study participants. The extensive content, the most frequent negative aspect mentioned by the participants, is the result of the given contents of the "broad consent" template and could not be changed or shortened within our electronic consent prototype.

Nevertheless, this study has a few limitations that need to be mentioned. On the one hand, as mentioned above, only 10 of the 47 subjects tested the audio mode. This might be due to the fact that the participants could freely choose the mode. However, the audio mode does not appear to be suitable for use in a waiting room, which is also

illustrated by its low level of use by the participants in the Paediatrics Department. The usage in a quiet environment, such as the patient's room or home, seems to be more appropriate. On the other hand only 5 participants of the urological clinic could be included in the study. The SUS score therefore relates primarily to the text mode and cannot give a reliable indication of the usability of the entire prototype. Furthermore, the study participants had an average age of 41.6 years. This is due to the high proportion of young parents who were included in the study from the children's and youth clinic and the lower number of participants from the urological clinic. This limitation needed to be accepted in our study as the time frame for the first author's master thesis was limited. It should be noted that a maximum care provider treats patients of all ages and the preference to use an eConsent tool may differ between these age groups. Even though the low number of participants in the Urology Department does not allow any significant statement, the lower SUS score (73.5 vs. 85.4) in this subpopulation might indicate that the patients´ age and eHealth literacy should be further considered in the design of an enhanced multimedia eConsent application.

In contrast to studies [9, 10] with control groups and tests to evaluate the effectiveness of the interventions, the data of this study do not allow an assessment of the patients' understanding using the developed prototype. In order to assess the prototype in terms of its didactic capabilities and the media used, further evaluation studies must be carried out. However, the fact that a total of 70.2% of the participants stated that they agreed to the "broad consent" was assessed positively by the authors. Although, it should be considered that the social desirability may have positively influenced the consent rate.

5. Conclusion

In summary, the authors draw the following conclusions from the results. Although the significance is impaired by the limitations described above, the results indicate that the prototype is very user-friendly, especially in text mode. The next steps will include further refinements of the prototype based on the feedback received and a subsequent study with a broader user group. Within the scope of such an extended study, the aspects regarding didactic capabilities of an eConsent tool and a comparison with a paper-based version should be addressed. In the last step, the eConsent tool is intended to be implemented and evaluated as part of a patient portal, which would allow its provision to patients in a quiet and more comfortable pre-admission situation at home.

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Conflict of Interest

The authors state that they have no conflict of interests.

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