Reforming the Informed Consent Process and Embedding Key Cultural Aspects

A Research Paper submitted to the Department of Engineering Science

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Jordan Giles

Spring 2024

On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Advisor

Garrick Louis, Department of Systems and Information Engineering

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Signature_____Jordan Giles_____5/7/24

Approved_____Garrick Louis, Department of Systems and Information Engineering___5/7/24

1. Introduction

Healthcare practitioners and researchers conduct medical procedures and research studies all the time. However, before these procedures and studies can be carried out, they must ensure that the potential participants they will be working with for their experiments give informed consent. Informed consent is essential to the efficacy of ethical research. It is a process that takes place before a patient undergoes a medical procedure or research study. Its purpose is to inform the patient of all aspects of a potential study or procedure they may engage in, so they are able to make an educated, voluntary decision to participate or not (Nijhawan et al., 2013). The two primary actors in this process are the healthcare practitioner, who plays the role of the educator, and the patient.

The entire process from conception to completion first begins with the creation of a consent form by the site investigator, or one is provided by the sponsor with research protocol. Next the consent form is personalized for the specific case including relevant names, contacts, and numbers. Then the consent form must be reviewed by the Institutional Review Board (IRB). The IRB is a group constituted under the Food and Drug Administration to review and monitor scientific research involving human participants. The IRB is able to approve, reject, or require modifications to submitted research. Their purpose is to ensure the rights and welfare of potential participants is protected ("Institutional Review Board", 1998).

2. Informed Consent Components

Informed consent is not simply a suggestion, but a legal requirement. It is necessary that the patient feels they are both adequately informed about every aspect of the study they may engage in, and that their decision to participate is voluntary and not forced in any way.

Therefore, there are rules specifying exactly how healthcare practitioners should carry out informed consent. The Joint Commission, a national healthcare-organization accreditation organization, requires documentation of every step of the informed consent process, with five essential elements: "(1) the nature of the procedure, (2) the risks and benefits and the procedure, (3) reasonable alternatives, (4) risks and benefits of alternatives, (5) and assessment of the patient's understanding of elements 1 through 4" (Shah et al., 2023, p.1). While these are the basic requirements for documentation, there are also standards, which are essentially a specific focus of the informed consent process that vary from state to state. There is the subjective standard, which asks what the patient needs to know and understand to make an informed decision. The reasonable patient standard, which asks what the average patient needs to know to be an informed participant in the decision. Lastly, the reasonable physician standard asks what a typical physician would say about the procedure (Shah et al., 2023). Most states refer to the reasonable patient standard, as the role of patient understanding is imperative to the ethics of the study. Furthermore, the practitioner has an obligation to employ one of these standards as best fit for the procedure or study.

The informed consent process is a federally governed requirement mandated by the US Department of Health and Human Services and the US Food and Drug Administration. Their regulations require six general requirements of the process. First, consent is required from participants. There are special circumstances in which exceptions for waivers of consent may be made, however these situations are highly regulated and outside of the scope of this project. Next, participation must be voluntary. The potential participant must not be coerced or influenced by any outside factors to offer their participation. The language used in the consent documentation must also be understandable to the study participant. Furthermore, consent

documentation cannot include language that would force the participant to waive their legal rights or releases any parties from the healthcare organization from liability for negligence. The information presented in the form must be concise, focused on the target goal of assisting the potential patient in understanding why they should or should not consider participating in the study. This information should be comprehensible and organized. There should be a particular emphasis on presenting information that does not just list facts, but gives the potential participant a true understanding of what the study entails and allows them to make an informed decision ("Informed Consent Guidance", 2022).

3. The Conflict

3.1. Inconsistent

While informed consent is meant to maintain a patient's autonomy and allow them to make an educated, informed decision, it often fails to meet that obligation. One of the key factors of success for informed consent is the practitioner-patient relationship. There is a heavy burden on the physician to thoroughly and accurately explain the nature of the procedure or study. The Joint Commission has found that if there is inefficient communication and poor quality decision-making between the two parties, this can negatively affect the informed consent process. Furthermore, they found that many physicians lacked awareness of patients' base-level health literacy, therefore leading them to develop consent forms significantly above the understanding of the patient ("Quick Safety 21", 2022).

Physicians operate on very busy schedules therefore making it difficult for them to devote the necessary time to truly ensure the patient understands the nature, risks and benefits of the potential study or procedure. Physicians also receive limited training on conducting informed

consent. In fact, a study found that only 9% of 2553 surveyed patient-practitioner interactions met the requirements for informed decision making (Hall et al., 2012). Lastly, the role of human nature plays a part in the integrity of the healthcare practitioner. Although this is not the case for every healthcare practitioner, some may take shortcuts to speed up the informed consent process, leaving out crucial information or distorting information that may negatively influence a patient's decision to participate in a study. While the inconsistency of each healthcare practitioner in leading the informed consent process is a significant issue, the documentation itself lacks uniformity as well. A research study found that the first four elements required in documentation by the Joint Commission only appeared in consent forms 26.4% of the time ("Quick Safety 21", 2022). Another study involved 200 patients who were given an informed consent form and then assessed based on their understanding of the information presented. The results indicated that only 34% of patients felt informed of the risks, and an even lower 26% reported being informed of possible alternatives (Vikas et al., 2021).

3.2. Inadequate

As it currently stands, the informed consent process does not always lead to patients making a completely autonomous, informed decision. Often, the form is not written in such a way that it could be understood by someone from a non-medical background. The jargon is often overly technical. ("Common Problems", 2014). This should not be the case, since informed consent documentation is meant to replicate an open conversation rather than a legal document. This only works to the detriment of the patient who is meant to benefit from the process. One study conducted by the American Journal of Surgery investigated the degree of understanding of different aspects of the informed consent process by potential patients. The results of the experiment provided sufficient evidence that more attention needs to be placed on patients'

understanding of information presented to them, the amount of information presented, and the understanding of benefits and risks of the surgery (Falagas et al., 2009). If patients are not adequately informed about a possible medical procedure they may take part in, it can lead to a host of serious consequences. These consequences range "from low patient satisfaction with care, increased patient regret, poor adherence to treatment plans, both underuse and overuse of the health system, and patient litigation against medical practitioners" (Sherman et al., 2021, p.2).

3.3. Inaccessible

While these are general issues with the informed consent process, there are also more that arise specific to cultural communities. The informed consent process fails to capture specific cultural differences of minority communities that may influence decision making. One of the key differences is language barriers. Individuals who do not speak English as their first language may struggle to understand the information presented in documentation, especially if it is already wordy or heavy in technical jargon. The role of the family in decision-making also comes into play. Different cultures have varying attitudes towards healthcare decision-making, autonomy, and disclosure of medical information. In some cultures, decisions about healthcare may be made collectively by the family rather than by the individual patient alone. This can create conflicts with the individualistic approach emphasized in the informed consent process. It is important that practitioners are culturally sensitive to these differences. Healthcare providers may not be adequately trained to communicate effectively with patients from diverse cultural backgrounds. Failure to recognize and respect cultural norms, values, and communication styles can hinder effective information exchange and shared decision-making ("Quick Safety 21", 2022).

Another cultural factor that researchers found affected the efficacy of informed consent is the knowledge and perception of research protocol. Historical injustices, discrimination, or disparities in healthcare access and treatment may lead individuals from certain cultural backgrounds to distrust healthcare providers or institutions (Halkoaho et al., 2016). This mistrust can undermine the effectiveness of the informed consent process if individuals are skeptical about the information provided or the motivations behind it.

4. The Proposal

In order to combat these issues, I propose an application that will resolve the inconsistency, inadequacy, and inaccessibility of informed consent documentation. I elect for a digital form of administration as it allows for incorporation of various forms of media such as video and audio components. There is previous research investigating the success of a digital platform for informed consent. The informed consent documentation was administered via iPad in this experiment. The study consisted of 90 individuals between the ages of 18 and 80 who were literate in written and spoken English. They were presented with an introductory video to a chemotherapy neuropathy clinical research study, then video and audio summaries of an informed consent form, along with an option to read the document online or in printed form. They were then given an interactive multiple choice comprehension quiz on the material. The control group interacted with the same research study, but were given the standard paper informed consent documents. The results indicated that those in the iPad group scored significantly higher on the comprehension test than those in the control group (compare mean of 57% to mean of 77%). Furthermore, those who read the paper consent form spent only 13.2 average minutes viewing the content compared to those in the iPad group who spent an average

of 22.7 minutes. Additionally, the iPad group reported overall higher enjoyment and satisfaction with the process (Rowbotham et al., 2013). My application follows a similar format, but incorporates key cultural aspects that have stood as potential barriers or drawbacks to a completely autonomous and informed consent process.

I propose an application with video and audio components over the paper format as this format forces patients to spend longer engaging with the content, it increases interest, and it increases comprehension. Furthermore, a digital platform can be accessed from anywhere with an internet connection, allowing patients to review and complete informed consent documents remotely. This is particularly advantageous for patients with mobility issues or those who live in rural areas with limited access to healthcare facilities. Therefore, I am able to increase accessibility to informed consent for a subset of the population that may have been overlooked and underserved. This application is marketed to patients and healthcare practitioners in the United States, as the informed consent process varies across the world. Furthermore, I want to be specific with the population I hope to serve as cultural factors differ extensively from country to country. It would not be feasible or within the scope of this project to incorporate every factor into the application.

Digitizing the informed consent process also has benefits for hospitals and research facilities. Patients can electronically sign consent forms using digital signatures, eliminating the need for printing, scanning, or mailing paper documents. This streamlines the consent process and reduces administrative burdens for both patients and healthcare providers. A digital platform offers secure encryption, authentication, and access controls to protect patient privacy and confidentiality. The data collected in the application is stored securely in electronic health record systems, reducing the risk of loss or unauthorized access. Furthermore, this electronic data

maintains detailed audit trails of consent activities, including timestamps, user actions, and changes made to consent documents. This provides transparency and accountability in the consent process, which may be useful for legal or regulatory compliance purposes.

This format will also remove a heavy burden from the healthcare practitioner as they will no longer be the one primarily responsible for verbally communicating expectations. That way, no key information can be manipulated or intentionally or unintentionally left out. Although the physician should still be on-call to answer questions as the patient navigates the application, this should free up more time in their schedule and ease stress surrounding communication of protocol. Much of the content in the video such as the nature of the study, risks, benefits, and alternatives is usually communicated verbally by the healthcare practitioner. Since this content must first be reviewed and approved by the IRB before it is implemented into the application, there will be a smaller margin of error than if it was being communicated verbally. Through the application, there is no longer a requirement for physician competency in order for patients to navigate informed consent documentation.

My application follows a similar format to the iPad study detailed at the beginning of the proposal. However, it is more fleshed out as shown in Figure 1 below. Before beginning the introductory video, I ask preliminary questions to get to know the patient so that the experience can be tailored to best serve their identity and background. Next they will be asked to watch the introductory video which provides a background on the study or procedure they may choose to engage in. Next they are quizzed on the information in the video. They are told if their answer is correct immediately after answering the question. If they are incorrect, they will have to try the question again until they are correct. After completing the quiz, they watch a video on the informed consent process. Once again they take a multiple choice quiz on the content of this

video where each sequential question must be answered correctly in order to move onto the next. Lastly, the user will be prompted to provide an electronic signature giving their consent for participation if they chose to do so after reviewing all previous content.

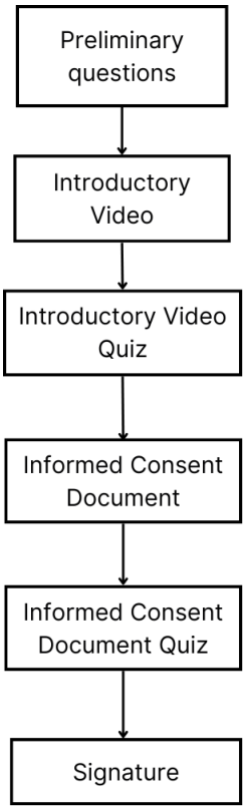

Figure 1. Basic Components Overview

4.1. Getting Started

Upon opening the application, the user is presented with the home screen which lists the name of the study, name of the healthcare practitioner, and a “Get Started” graphic that they must push to start the process. At all times, there is a graphic in the top right corner with the word “MENU”. If the user selects this, they will see a drop-down menu with every step of the informed consent process as listed in Figure 1. Items that they have not completed yet will appear in gray text with a lock next to them to indicate that they cannot be viewed yet. However,

any completed items appear in colored text and the user is able to select these and scroll through content they previously completed. That way they always have access to information so they can reference it any time or refresh their memory. At the bottom of the screen is the video progress bar. A small circle on the bar will indicate at what point in the video the user is. By pressing down on and dragging this circle left and right, the user can go forward and backward to any point in the video that has already been watched. It is important to note that the user cannot scroll to any point in the video that has not been viewed yet. This prevents the user from skipping crucial content. The user can also select different video speed options: x.25, x.5, x1.5 and x2 speed. This will be helpful for users who comprehend content at a slower or faster pace than usual.

4.2. Preliminary Questions

The preliminary questions serve as a way to embed key cultural factors into the informed consent process. They gather information regarding the user's background and identity so that the rest of the experience on the app is as advantageous as possible. The preliminary questions follow the format of the flowchart shown in Figure 2. Some key questions that were included based on previous research is a request for users to select their language. Since users who do not speak English as their first language had previously struggled to benefit from informed consent in the same way, this will bridge the gap. Users will also be prompted to answer their race/ethnicity. As historical mistrust of researchers has led some minority groups to be apprehensive about informed consent, this information will be helpful in later portions of the application. One of the biggest differences between this application and previous forms of digital informed consent is the consideration of the role of the family. In the questionnaire, there is a section where the participant can indicate if they would like to invite a collaborator for the

informed consent process. The text associated with this decision will appear as follows: “Would you like to invite anyone as a collaborator during this process? You are granting them permission to be present while completing every part of this application. They will also have access to every answer you provide for this form”. For cultures where family or spouses play a heavy role in decision making, this will allow the participant to partake in their cultural norms without denying them access to the informed consent process.

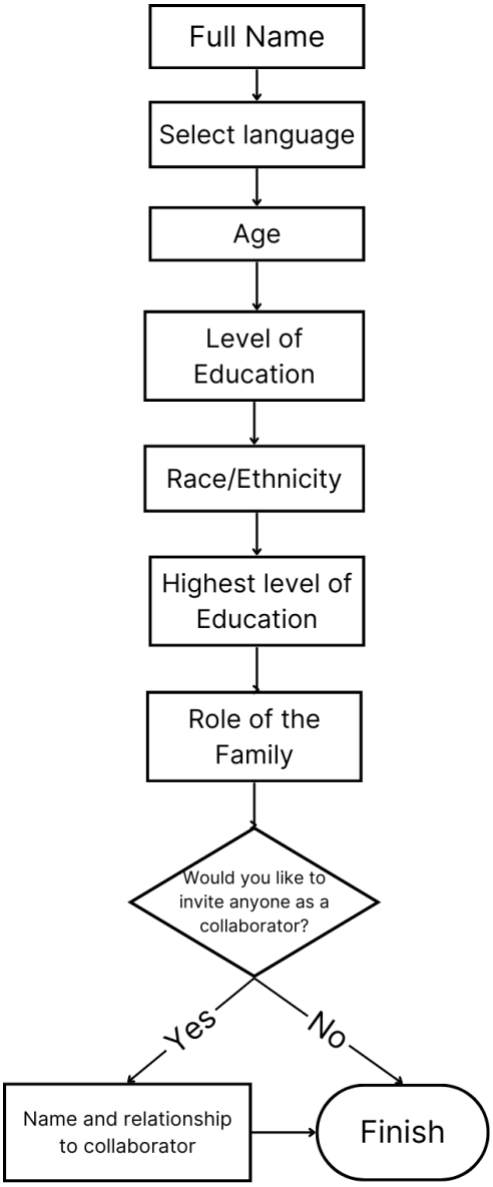

Figure 2. Preliminary Questions

4.3. Introductory Video

The introductory video offers a background and overview of the study or procedure. It explains exactly what the procedure or research study is, how it will be done, and what it seeks to accomplish. The language is overall clear and simple, and any relevant technical terms used are defined in this video. The video will feature cartoon characters that act out what is narrated in the video. For example, if the steps of a surgery are being outlined, the graphics will match each step of the surgery process. There will also be a transcript to accommodate for deaf or hard of hearing users, or those who prefer to read rather than watch the content. As historical mistrust and negative experiences with researchers may influence some minority group's comfort level with engaging with informed consent, any physician characters present in the video will be the same race as what the patient selected in their preliminary questionnaire. The introductory video is rather short and simply aims to give the patient a basic overview of what to expect.

After watching this video, users will move on to take the quiz on the content from the introductory video. The quiz, although different for each individual research study or medical procedure, shares a common goal of assessing the patient's understanding of the content presented to them. The questions require basic knowledge of the science behind the study or procedure, just to the extent that the user knows what may be done to their body if they partake. Users will not be required to regurgitate information that would be expected of a scientific researcher, unless it is necessary for their well-being in the experiment.

4.4. Informed Consent Documentation

This section of the application will follow the Code of Regulations outlined by the Food and Drug Administration. First participants will watch a video that details the risks and benefits of the procedure or study outlined in the Introductory Video. This video will also contain

possible alternatives as well as the risks and benefits of these alternatives. Like the format of the previous video, this one will be acted out by cartoon characters matching the specified race of the participant. Once again, a live transcription of the script of the video will also be included on screen with the graphics.

The video will contain the following information as regulated by the FDA (U.S. Food and Drug Administration, 2023; ”Informed Consent Checklist”, 2016):

1.1. Research purpose statement

1.2. Description of procedures that will be followed

1.2.1.1. Description of any experimental procedures

1.3. Description of any possible risks or discomforts to the patient

1.3.1.1. If research involves more than minimal risk, a description of any compensation or medical treatments offered to treat injury, what the treatment entails, and where to find more information about it

1.4. Description of benefits that can be expected from participation

1.5. Disclosure of alternative procedures or treatment options that may be advantageous to the participant

After this, the participant will be prompted to take a multiple choice quiz to ensure their comprehension of this section of the documentation. As with the previous quizzes, users cannot move onto the next question until they answer the previous one correctly. After the quiz is completed, users will be presented with the standard informed consent document outlined by the FDA in video format. This video will not include characters, but simply graphics with each statement appearing on screen.

This section will include the following information (U.S. Food and Drug Administration, 2023; “Informed Consent Checklist”, 2016):

1.1. Statement that the study involves research

1.2. Time length for participation

1.3. Statement describing the extent (if any) to which confidentiality will be maintained

1.4. For research governed by the FDA, a statement acknowledging that the FDA may inspect records

1.5. If research involves collection of identifiable private information or identifiable biospecimens, either of the following statements will be included depending on the nature of the research:

1.5.1.1. Identifiers might be removed from this information or biospecimens, and then used for future research or distributed to another investigator without request for further consent

1.5.1.2. Information or specimens collected will not be used or distributed for future use even if identifiers are removed

1.6. Contact information

1.6.1.1. Name of healthcare practitioner, phone, address, and any other relevant parties

1.6.1.2. Regarding participant’s rights (Research Compliance Services)

1.6.1.3. Who to contact in the event of injury related to the study (Research Compliance Services)

1.7. Statement acknowledging participation is voluntary

1.8. Refusing to participate will not incur penalty or loss of benefits to which the participant is entitled

1.9. Participation can be discontinued at any time with penalty or loss of benefits

1.10. Statement that subject may keep copy of the consent form

4.5. Signed Consent

Lastly, a document with a written version of each statement will become available after watching the video. Once the user scrolls to the bottom of the document, they will be able to select a button at the bottom right corner of the screen "Continue to Sign" which brings them to a page where they will be able to provide their electronic signature indicating they are fully aware of the nature of the study, the risks, benefits and alternatives, and that they would like to participate in the study or procedure. The text for this section will appear as follows:

> I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in [the contact information section of the previous video]. I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study (University of Michigan Medical School, 2024, p. 9).

4.6. Additional Features

The bottom left corner of the app screen contains a graphic with the word “HELP”. If the user selects this at any time, a drop-down menu with two options will appear: “Ask a question” and “Meet with my physician”. By selecting “Ask a question”, a text box will appear where the patient can type a question which will be sent to the healthcare practitioner conducting their procedure or research study. If the patient has a more involved question or prefers talking over typing, they can select “Schedule a meeting with my physician”. Selecting this option will then prompt the user to select if they would like to meet virtually or in person. After selecting either option, they will be given a list of times that correspond with the physician’s availability. They can then select one that matches their availability as well, and a message is sent to the physician alerting them of the meeting. It is important to note that the physician should always be available while the patient is completing the informed consent form. Although they have less of a burden in administering informed consent because of the app, it is still important they are involved in the process. The schedule exists to assist patients who may be completing the form remotely who would like to meet with their physician in person. It is also helpful for patients who would like to talk to their physician, but have a present obligation and cannot meet immediately.

5. Conclusion

In conclusion, the current landscape of informed consent within healthcare presents a myriad of challenges, ranging from inconsistency and inadequacy in communication to accessibility issues, especially within culturally diverse communities. The fundamental purpose of informed consent, to empower patients in making autonomous and informed decisions about their healthcare, is often compromised due to these shortcomings.

The proposal for an application to address these challenges is a promising step forward. This application would standardize the informed consent process, ensuring that information is communicated clearly and comprehensively, regardless of the healthcare practitioner's communication skills or the patient's cultural background. By providing easily accessible, culturally sensitive, and more engaging content, this application has the potential to bridge the existing gaps in understanding and comprehension.

However, the successful implementation of such a solution would require collaborative efforts from healthcare institutions, practitioners, policymakers, and technology developers. It's crucial to prioritize patient-centered care and actively involve patients in the development and refinement of this application to ensure that it truly meets their needs and preferences. Furthermore, ongoing training and education for healthcare professionals on effective communication, cultural competency, and the importance of informed consent are still necessary to support the implementation and utilization of this application effectively. Ultimately, by addressing the challenges and limitations of the current informed consent process, this proposed application has the potential to enhance patient autonomy, improve healthcare outcomes, and foster trust between patients and healthcare providers from a wider range of cultural backgrounds and identities.

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