Quality Improvement Project to Increase Patients' Knowledge About Their Impending Procedures During the Consent Process

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DESCRIPTION OF THE PROBLEM

For the past century, informed consent has been a cornerstone of medicine [1]. It has gradually developed over the years with the advancement of medicine [2]. Before undergoing image-guided interventions, a patient and his or her provider engage in a discussion regarding the procedure and its details. This dialogue is referred to as informed consent. As a part of the informed-consent process, the patient signs a document to verify that he or she has participated in this dialogue [3]. In addition to educating the patient about the procedure itself, essential elements of informed consent include potential risks, benefits, and alternatives [3-5]. Physicians are also required to allow patient questions with regard to the aforementioned details [6]. Consent must provide adequate information such that a patient would be able to make a knowledgeable decision about the treatment plan [4].

All adult patients giving consent should be of intact mental status. In the case of minors, consent should be obtained from their parents or legal guardians. When a patient has an altered mental status, consent should be obtained from the legal guardian, power of attorney, or next closest family member [4].

Informed consent can be sought for research or clinical purposes [3]. This quality improvement project examines the role of informed consent in a clinical setting. Informed consent is one of the foundations of the patient-physician relationship. A primary goal of the consent process is to create a level of comprehension that allows patients to make, to the best of their abilities, informed judgements about their own clinical care. For a multitude of reasons, patients may not achieve an ideal level of comprehension during the consent process.

At our institution, we have anecdotally noticed a trend in which patients, in casual conversation immediately before or after procedures, demonstrate what seems to be an inadequate degree of knowledge about their own procedures. In response, we set out to verify this finding and then to attempt to improve the quality of our consent process by implementing a new video-aided consent process.

WHAT WE DID

This quality improvement project was determined by our institutional review board not to constitute human subjects research. This project complied with HIPAA guidelines. All patients who provided consent for interventional radiologic procedures at a single hospital were offered voluntary surveys from March to June 2017. A total of 80 patients participated in this quality improvement project.

For the initial phase of the study, the consent process was performed unaltered. After a patient arrived to the preprocedural area, a physician or physician extender engaged in a face-to-face consent discussion. After the consenting physician left the preprocedural area, a member of the nursing staff approached the patient and asked him or her to voluntarily fill out a quality survey. The survey consisted of circling which procedure the patient was about to undergo, noting whether the patient had previously undergone this same procedure or if it was the first time. The patient was asked to rate on a scale ranging from 1 to 10 his or her degree of understanding of the procedure, benefits of the procedure, risks of the procedure, and alternatives to the procedure.

After the initial period of surveys was completed, the video-aided consent process was implemented. In this process, after arrival to the preprocedural area, the patient was presented with a tablet device containing the relevant educational consent video for the procedure he or she was about to undergo (Interventional Radiology Patient Education Video Package; Holvan Group,

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San Luis Obispo, California). After video consent was completed, the patient was then approached by a member of the nursing staff and asked to voluntarily fill out the quality survey. After the survey was refused or completed, a physician or physician extender engaged in a face-to-face discussion with the patient about the procedure and addressed any remaining questions the patient may have had. Survey data were recorded and stored on a secure server, and data analysis was performed.

OUTCOMES

Because this was a quality improvement initiative, no patient demographics were recorded. Face-to-face consent and video consent groups were compared. Thirty-seven patients completed surveys after face-to-face consent, and 43 patients completed surveys after video consent. Means and standard deviations were calculated for each of the four degrees of understanding categories in each group, and analysis was performed using a one-tailed t test comparing the degree of understanding after face-to-face consent versus video consent (Table 1).

Our data suggest possible improvement of patient procedural understanding after implementation of the video-aided consent process. Prior studies have also demonstrated benefit from implementing video consent in addition to verbal consent and have also seen significantly improved patient understanding, analogous to our study [7-9]. We agree with Tompsett et al [2] that methods such as video and written consent should serve as complementary add-on tools and not entirely replace the existing verbal consent process. In our improvement surveys, an across-all-questions average of 7.9 of 10 suggests that there is still room for improvement for the current verbal consent processes.

With new advancements in medicine, physicians are often required to explain more complex procedural details to patients [2]. Because procedures in interventional radiology are quite complex and much of our imaging capabilities and medical devices are foreign to patients, a comprehensive understanding may be difficult to obtain. Patients undergoing a thorough consent process may still be inadequately knowledgeable about their procedure. In addition, physicians may not always thoroughly communicate consent to the degree that the capacity for patient understanding is maximized. A potential contributor to this inefficiency may be physicians' inability to explain complex medical terminology in a simple, understandable way. Physicians often operate at a level that is far above patient comprehension. They may overlook this aspect during their discussion, using vocabulary and procedure details that are unfamiliar to patients [9].

Informed consent in patients with disabilities as well as those with lower reading and writing skills must not be overlooked. Comparative studies show increased levels of comprehension in video groups versus verbal groups in patients with learning disabilities or cognitive impairments [2,9-11]. Video-aided consent improves comprehension for patients who have difficulty reading the written consent form [7].

In the 21st century, online and other information platforms have made it easy for patients to gain knowledge about their operative procedures and treatment course. Although these utilities at first glance are useful, they sometimes lead to confusion, incorrect perceptions, and the need for further clarification about the procedure during the consent process [12]. An information overload from multiple sources may be confusing and/or contradicting to the patient in the consent process.

Video consent shows promise in beginning to bridge this gap. Across all categories, there was an increase in understanding (from 7.3 of 10 to 8.1 of 10, $P < .05$) after the initiation of our video consent process. Additionally, although not captured in these data, there was anecdotally a significant decrease in time spent during the face-to-face portion of the consent process after video consent, during which patients still had the opportunity to have all of their questions and concerns addressed. A very recent ruling in the Pennsylvania Supreme Court has mandated that all procedural consents be obtained by physicians and invalidates procedural consents obtained by physician extenders, including physician assistants and nurse practitioners [13]. This will drastically alter workflow in many practices, and one can easily imagine that the time saved with video-aided consent will become even more valuable.

Table 1. Self-reported understanding, scale of 1 to 10 (highest comprehension = 10)

Category of Understanding	Standard Consent, Mean ± SD	Video-Aided Consent, Mean ± SD	Significance
Procedure	7.42 ± 1.75	8.07 ± 1.99	$P = .06$
Benefits	7.54 ± 1.87	8.36 ± 1.87	$P = .03$
Risks	7.43 ± 1.89	8.45 ± 1.77	$P = .007$
Alternatives	6.81 ± 2.44	7.52 ± 2.82	$P = .12$

We do note, however, that patients still reported decreased understanding of the procedural alternatives compared with the other categories. From informal discussion among the providers at our institution, this is not surprising, as the nature of the procedure, the risks, and the benefits are foremost in our own minds. This belies an opportunity for improvement in the way we tailor our consent process, with a moment taken to emphasize the alternatives of our intended intervention.

There were limitations to our evaluation. The validity of our survey, or of any official questionnaire to test understanding of informed consent in interventional radiology, has not been established. We are unaware of any other questionnaires regarding supplemental video consent in interventional radiology. The number of participants was small, and in combination this makes the results of our small pilot study unreliable. Further evaluation of this potentially beneficial aid is recommended.

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