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Audiovisual Modules to Enhance Informed Consent in the ICU: A Pilot Study

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Objectives: Obtaining informed consent for commonly performed ICU procedures is often compromised by variability in communication styles and inadequate verbal descriptions of anatomic concepts. The objective of this study was to evaluate the efficacy of an audiovisual module in improving the baseline knowledge of ICU procedures among patients and their caregivers.

Design: Prospective, observational study.

Setting: Forty-eight-bed adult surgical ICU at a tertiary care center.

Subjects: Critically ill surgical patients and their legally authorized representatives.

Interventions: An audiovisual module describing eight commonly performed ICU procedures.

Measurements and Main Results: Fifty-nine subjects were enrolled and completed an 11-question pre- and postvideo test of knowledge regarding commonly performed ICU procedures and a brief satisfaction survey. Twenty-nine percent had a healthcare background. High school was the highest level of education for 37%

percent of all subjects. Out of 11 questions on the ICU procedure knowledge test, subjects scored an average 8.0 ± 1.9 correct on the pretest and 8.4 ± 2.0 correct on the posttest ($p = 0.055$). On univariate logistic regression, having a healthcare background was a negative predictor of improved knowledge (odds ratio, 0.185; 95% CI, 0.045–0.765), indicating that those with a health background had a lower probability of improving their score on the posttest. Among subjects who did not have a healthcare background, scores increased from 7.7 ± 1.9 to 8.3 ± 2.1 ($p = 0.019$). Seventy-five percent of all subjects indicated that the video was easy to understand, and 70% believed that the video improved their understanding of ICU procedures.

Conclusions: Audiovisual modules may improve knowledge and comprehension of commonly performed ICU procedures among critically ill patients and caregivers who have no healthcare background.

Key Words: communication; health literacy; informed consent; intensive care unit; procedures; surgery

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More than 5 million patients are admitted to ICUs in the United States each year (1). Given the frequent need to perform several potentially life-saving procedures on short notice, many ICUs obtain bundled informed consent permissions from the patient or their legally authorized representative at the time of ICU admission (2, 3). The informed consent process is an early, important opportunity for clinicians to build trust and rapport with the patient and their caregivers by enhancing their understanding of the patient's illness severity, anticipated clinical trajectory, and need for diagnostic and therapeutic procedures, while ensuring that the care provided will be consistent with the patient's goals and values (4, 5).

Obtaining informed consent for commonly performed ICU procedures is often compromised by variability in communication styles and prolonged, complicated written and verbal descriptions of

anatomic concepts, especially when the patient and their caregiver lack a healthcare background, have cognitive and emotional impairments, or suffer from social and economic inequalities (6–8). Even after completing the informed consent process, patient and caregiver knowledge and comprehension are often poor (9, 10). Audiovisual aids have demonstrated efficacy in improving patient knowledge, engagement, and satisfaction in several non-ICU settings, gaining momentum as a worldwide healthcare prerogative (7, 11–14). However, the authors are unaware of any evidence that audiovisual modules affect the bundled informed consent process for ICU procedures. Audiovisual modules that enhance informed consent in the ICU may be particularly useful when contact and airborne infectious disease transmission precautions are necessary, as in the current coronavirus disease 2019 (COVID-19) pandemic.

To enhance the informed consent experience for critically ill patients and their caregivers, an audiovisual module describing commonly performed ICU procedures was developed and implemented in a 48-bed surgical ICU at a tertiary care center. This pilot study evaluated the efficacy and acceptability of the audiovisual module in improving baseline knowledge of ICU procedures among critically ill patients and their caregivers.

MATERIAL AND METHODS

Study Design and Subject Enrollment

This prospective, observational study was performed in a 48-bed adult surgical ICU at a tertiary care center during a 1-year period ending March 2020. At the time of ICU admission, all patients or their legally authorized representative were offered an audiovisual bundled informed consent module delivered on a wall-mounted television, followed by an informed consent discussion with a credentialed provider. Subjects who enrolled completed pre- and postvideo assessments of their knowledge regarding commonly performed ICU procedures, as well as a postvideo brief satisfaction survey. Subjects were ineligible for enrollment if they and their legally authorized representative were unable to provide informed consent, if it was necessary to perform ICU procedures emergently before obtaining consent, if consent was being obtained via telephone, or if the patient and their legally authorized representative were unable to comprehend the English language, as both the audio and visual components of the module were presented in English. Basic demographic information collected for each subject or legally authorized representative included age, sex, race, ethnicity, highest level of education, and whether they self-identified as having a healthcare background. Institutional Review Board approval was obtained prior to enrollment. All subjects or their legally authorized representatives provided written informed consent for participation in this study.

Audiovisual Module and Informed Consent

The audiovisual module (**Video 1**, Supplemental Digital Content 1, <http://links.lww.com/CCX/A420>) used plain language and concluded in 7 minutes and 33 seconds, consistent with expert recommendations for obtaining informed consent in ICU settings (8). The module presented eight procedures in a bundled consent, consistent with evidence that use of bundled consents can increase

the frequency of obtaining consent without compromising knowledge or comprehension of the patient or their legally authorized representative (3). The eight procedures included intubation and mechanical ventilation, sedation and analgesia, bronchoscopy, arterial catheter placement, central venous catheter placement, pulmonary artery catheter placement, chest tube insertion, and lumbar puncture. For these procedures, the module presented indications, risks, potential benefits, and alternatives means of achieving the same diagnostic or therapeutic objectives. The module was reviewed and approved by institutional legal representatives and confirmed as compliant with the HIPAA. ICU nurses accessed the module through orders integrated in the electronic health records and presented on wall-mounted televisions inpatient rooms. After the module was complete, a credentialed provider (i.e., doctor of osteopathic medicine or medical doctor, according to institutional protocols) returned to the room and completed the standard informed consent process by addressing any questions raised by the patient or their caregivers and obtaining written permissions, including the option to consent to some procedures while deferring others. The patient or legally authorized representative, the provider, and a hospital staff witness then each signed a paper informed consent document.

Development of the Knowledge Assessment

Content for the survey was developed through an asynchronous, two-round, modified-Delphi process with five ICU faculty, whereby these individuals listed five broad “need to understand” concepts regarding ICU procedures. The resulting concepts were formatted into questions that were reviewed by a multidisciplinary group consisting of nurse educators, surgical residents, critical care fellows, and ICU faculty, yielding 17 questions developed at a Flesch-Kincaid reading level of fourth to sixth grade. These questions were then piloted with 30 individuals in the general population to remove six questions that were answered correctly or incorrectly 100% of the time. The final survey consisted of 11 items, a first-time pass rate of 72%, and a Flesch-Kincaid reading level of fifth grade.

Knowledge and Satisfaction Assessment Administration

After enrolling in this study and before beginning the informed consent process, the patient or their legally authorized representative completed an 11-question test of their knowledge regarding commonly performed ICU procedures, as illustrated in **Figure 1**. The same 11-question test was performed again after being presented with audiovisual module, without reordering the questions. Subjects then completed a four-question satisfaction survey, which assessed the degree to which they agreed that 1) the video was easy to understand, 2) the video was too long, 3) their understanding was improved by the video, and 4) they understood the procedures listed on the consent form after watching the video. Responses to these questions were measured on a Likert scale, with answers ranging from 1 (strong disagreement) to 5 (strong agreement).

Statistical Analysis

The primary statistical objective was to determine whether subject knowledge regarding commonly performed ICU procedures

Knowledge Assessment

1. What is mechanical ventilation?
 - a. When a machine helps a patient to breathe by moving air into and out of the lungs.
 - b. When a tube placed through a small incision in the skin into the chest cavity.
 - c. When a catheter is placed into the heart to monitor blood pressure.
 - d. Medication to control pain.
2. What is a bronchoscope?
 - a. A tube placed through a small incision in the skin into the chest cavity between the lung and chest wall.
 - b. A camera scope used to evaluate the lungs.
 - c. A thin plastic cannula placed into the large venous system.
 - d. A breathing tube inserted into the windpipe to protect the airway.
3. What is the purpose of sedation?
 - a. Monitor blood pressure
 - b. Help a patient to breathe when they are unable to do so.
 - c. Keep a patient calm
 - d. Protect smaller veins from certain medication infusions
4. Which of the following is a side effect of sedation?
 - a. Injury to lungs
 - b. Blood clot formation
 - c. Infection
 - d. Low blood pressure
5. Where can arterial lines be placed?
 - a. The nose
 - b. The armpit
 - c. The fingertip
 - d. Through the mouth
6. Which of the following can be monitored with arterial lines?
 - a. Alertness
 - b. Breathing rate
 - c. Blood pressure
 - d. Urine output
7. Where can central venous lines be placed?
 - a. The foot
 - b. The groin
 - c. The wrist
 - d. The elbow
8. What is the name of a breathing tube that is placed into the mouth?
 - a. Endotracheal tube

Figure 1. Knowledge assessment and satisfaction survey. Before being presented with the audiovisual module, the patient or their legally authorized representative completed an 11-question assessment of their knowledge regarding commonly performed ICU procedures. The same 11-question assessment was performed again after being presented with audiovisual module. Subjects then completed a four-question satisfaction survey with responses measured on a Likert Scale.

would significantly improve after being presented with the audiovisual module. Therefore, pre- and posttest scores were compared with paired *t* tests and reported as mean values with SDs. The secondary statistical objective was to determine whether basic demographic factors (i.e., age, sex, race, ethnicity, highest level

of education, and having a health-care background) were associated with improvement in knowledge after being presented with the audiovisual module. Therefore, univariate logistic regression was used to assess whether demographic factors could predict improvement in knowledge, with plans to perform subgroup analyses to reassess the primary outcome based on the results of the regression analysis (i.e., if female sex was predictive of greater improvement in comprehension, then differences in pre- and posttest scores would be assessed for females and males separately). This pilot study did not include a comparison group and was exploratory in nature; therefore, a power analysis was not performed. All significance tests were two-sided, with *p* values of less than 0.05 considered statistically significant. Statistical analyses were performed with SAS Version 9.4 (SAS Institute, Cary, NC).

RESULTS

Subject Characteristics

Subject characteristics are listed in **Table 1**. Fifty-nine subjects were enrolled. The majority of subjects were White (88%), male (59%), and mean age was 55 years. High school was the highest level of education for 37% percent of all subjects. Seventy-one percent of all subjects did not have a healthcare background.

Knowledge and Comprehension of ICU Procedures

Of the 11 questions on the knowledge assessment, subjects completed 8.0 ± 1.9 questions correctly on the pretest and completed 8.4 ± 2.0 questions correctly on the posttest, for an average improvement of 0.4 ± 1.7 ($p = 0.055$). Scores improved from the pretest to the posttest for 51% of all subjects. There were no cases in which scores decreased from the pretest to the posttest. On univariate logistic regression, having a healthcare background

was a significant and negative predictor of improved knowledge (odds ratio, 0.185; 95% CI, 0.045–0.765), indicating that those with a health background had a lower probability of improving their score on the postvideo test. No other subject characteristics (i.e., age, sex, race, ethnicity, or education level) were significant

TABLE 1. Subject Characteristics

Subject Characteristics	Results
Age, yr, mean \pm SD	55 \pm 17
Sex, <i>n</i> (%)	
Female	24 (41)
Male	35 (59)
Other	0 (0)
Declined to answer	0 (0)
Race, <i>n</i> (%)	
White	52 (88)
Black or African American	4 (7)
American Indian or Alaskan Native	1 (2)
Asian	0 (0)
Native Hawaiian or other Pacific Islander	0 (0)
Declined to answer	2 (3)
Ethnicity, <i>n</i> (%)	
Hispanic/Latino	2 (3)
Non-Hispanic/Latino	55 (93)
Declined to answer	2 (3)
Education, <i>n</i> (%)	
High school	22 (37)
Some college	17 (29)
College graduate	12 (20)
Graduate degree	4 (7)
Doctorate degree	1 (2)
Declined to answer	3 (5)
Healthcare background, <i>n</i> (%)	
No	42 (71)
Yes	14 (24)
Declined to answer	3 (5)

predictors of knowledge on the posttest. In a subgroup analysis of patients and caregivers with no healthcare background, subjects completed 7.7 ± 1.9 questions correctly on the pretest and completed 8.3 ± 2.1 questions correctly on the posttest, for an average improvement of 0.6 ± 1.6 ($p = 0.019$).

Subject Satisfaction

Satisfaction survey results are listed in **Table 2**. Seventy-five percent of all subjects agreed or strongly agreed that the video was easy to understand. Seven percent of all subjects agreed or strongly agreed that the video was too long. Seventy percent of all subjects agreed or strongly agreed that their understanding improved with the video and that they understood the procedures described in the video. There were no technical failures of the audiovisual module

TABLE 2. Satisfaction Survey Results

Satisfaction Survey Statements	Responses
“The video was easy to understand.”	
Likert Scale Score, mean \pm SD ^a	3.9 \pm 0.9
Subjects who agree or strongly agree, <i>n</i> (%)	44 (75)
“The video was too long.”	
Likert scale score, mean \pm SD ^a	2.1 \pm 1.0
Subjects who agree or strongly agree, <i>n</i> (%)	4 (7)
“My understanding was improved by the video.”	
Likert scale score, mean \pm SD ^a	3.9 \pm 0.7
Subjects who agree or strongly agree, <i>n</i> (%)	41 (70)
“I understood the procedures after watching the video.”	
Likert scale score, mean \pm SD ^a	3.9 \pm 0.9
Subjects who agree or strongly agree, <i>n</i> (%)	41 (70)

^aScale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree.

and no cases in which the patient or their legally authorized representative requested that the module be prematurely ended.

DISCUSSION

In this study, an audiovisual informed consent module was associated with improved knowledge regarding eight commonly performed ICU procedures among patients and their caregivers who did not have a healthcare background. The module was generally well received and perceived as easy to understand. There were no technical failures or legal issues associated with use of the module. Although the amount of time that providers spent in patient rooms was not assessed, it seems reasonable to assume that use of the module would limit the amount of time that providers spend in rooms that are under contact and airborne infectious disease transmission, which have become more prevalent during the COVID-19 pandemic.

Previous studies using standardized processes and audiovisual modules to enhance informed consent for participation in research studies in non-ICU settings have had similar results. In two randomized trials, audiovisual modules increased understanding and retention of knowledge regarding trial protocols (11, 15). Evidence from multicenter research trials suggests that video consents may increase the frequency of enrolling older and non-White subjects.(16) The use of audiovisual modules to enhance preoperative informed consent for surgical procedures has yielded similar results. In two randomized trials, visual aids and video modules increased knowledge and comprehension of procedures (7, 13). The authors are unaware of any studies in which audiovisual informed consent modules were associated with negative results and recognize that the existing body of literature is likely influenced by publication bias (12). Regardless, evidence suggests that audiovisual modules can improve patient and caregiver knowledge and comprehension of research study protocols and invasive procedures, with few or no negative effects.

The ICU setting presents unique challenges in obtaining informed consent and building trust and rapport with the patient and their caregiver. Due to the high prevalence of patient sedation and delirium in the ICU, less than one quarter of all critically ill patients are able to provide informed consent during their ICU stay, even when considering postextubation phases of care (17). Therefore, legally authorized representatives are often needed to make decisions on behalf of the patient, which introduces emotional turmoil for the surrogate decision-maker. When obtaining research consent in the ICU, although patients and their caregivers only explicitly deny consent approximately 9% of the time, less than half of all opportunities to obtain informed consent are successful (18, 19). Given these low success rates and the frequent need to perform several potentially life-saving procedures in the ICU on short notice, many ICUs obtain bundled informed consent permissions from the patient or their legally authorized representative at the time of ICU admission. This may increase the frequency of obtaining consent without compromising knowledge or comprehension of the patient or their legally authorized representative (2, 3, 20). This study seeks to address the unique challenges associated with obtaining informed consent in the ICU—which are exacerbated during a viral pandemic—by providing evidence that it is feasible to deliver bundled audiovisual consent modules to patients and their caregivers. In addition, we wished to determine if the modules are associated with improved knowledge and comprehension of commonly performed ICU procedures among subjects with no healthcare background.

This pilot study was limited by a small sample size, the lack of a comparison group of subjects who received standard verbal-written informed consent without an audiovisual module, and its single-institution design. All nonessential clinical research ceased during the study period due to COVID-19, which prevented further enrollment. It seemed important to share findings from this study in a timely manner, rather than pursuing a second period of subject enrollment after full resumption of clinical research activities. Although the sample size was adequate to detect a statistically significant difference in pre and posttest scores among subjects with no healthcare background, it seems likely that this study failed to detect a statistically significant difference in scores for the total study population, and the clinical significance of these findings is subject to interpretation. In addition, the subjective data collected regarding participant satisfaction is low on the Kirkpatrick model of learning and must be interpreted as such. The rationale for this approach was that buy-in from stakeholders (particularly the patient population) is imperative for the successful implementation of any intervention. The lack of a comparison group and single-institution design are attributable to the exploratory nature of this pilot study. These findings may not be generalizable to nonsurgical ICUs. The survey used in this study was tailored specifically for the procedures described in the audiovisual module. The survey has not been validated in other studies, which further limits the generalizability of these findings. Finally, these results may have been influenced by the testing effect, in which knowledge is imparted through the process of testing (21). In addition to addressing the limitations of the present study, future research should clarify whether the use of audiovisual modules affects the efficacy of bundled consent relative to isolated consents for individual procedures

and investigate the impact of non-English audiovisual informed consent modules. Formal training for consenters may improve the ability of clinicians to achieve best practice objectives in obtaining informed consent (22). Human interaction remains an essential component of the informed consent process to build trust and rapport with the patient and their caregiver by enhancing their knowledge and comprehension of the patient's severity of illness and ensure that the care provided will be consistent with their goals and values. Therefore, formal training for consenters and preservation of face-to-face interactions should be emphasized in future investigations. Finally, future investigations should seek to understand which aspects of audiovisual consent modules effectively improve knowledge and comprehension, which aspects offer no advantage or are a detriment, and how these elements can be modified to enhance informed consent practices.

CONCLUSIONS

Audiovisual modules were associated with improved knowledge and comprehension of commonly performed ICU procedures among critically ill patients and caregivers who had no healthcare background. Further investigation is necessary to establish the external validity of these findings, investigate the impact of non-English audiovisual informed consent modules, and incorporate formal training for consenters to strengthen the human element of informed consent, which is an essential aspect of building trust and rapport with critically ill patients and their caregivers. Audiovisual modules that enhance informed consent in the ICU may be particularly useful when contact and airborne infectious disease transmission precautions are necessary, as in the current COVID-19 pandemic.

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