Improving the Process of Informed Consent in the Critically Ill

Nicole Davis, BS
Anne Pohlman, RN, MSN
Brian Gehlbach, MD
John P. Kress, MD
Jane McAtee, JD
John P. Kress, MD
Brian Gehlbach, MD
Anne Pohlman, RN, MSN
Nicole Davis, BS
Jesse Hall, MD

Context Invasive procedures are often performed emergently in the intensive care unit (ICU), and patients or their proxies may not be available to provide informed consent. Little is known about the effectiveness of intensivists in obtaining informed consent.

Objectives To describe the nature of informed consent in the ICU and to determine if simple interventions could enhance the process.

Design, Setting, and Patients Prospective study of 2 cohorts of consecutively admitted patients (N=270) in a 16-bed ICU at a university hospital. All patients admitted to the ICU during the baseline period from November 1, 2001, to December 31, 2001, and during the intervention period from March 1, 2002, to April 30, 2002, were included.

Intervention A hospital-approved universal consent form for 8 commonly performed procedures (arterial catheter, central venous catheter, pulmonary artery catheter, or peripherally inserted central catheter placement; lumbar puncture; thoracentesis; paracentesis; and intubation/mechanical ventilation) was administered to patients or proxies. Handouts describing each procedure were available in the ICU waiting area. Physicians and nurses were introduced to the universal consent form during orientation to the ICU.

Main Outcome Measures Incidence of informed consent for invasive procedures at baseline and after intervention; whether the patient or proxy provided informed consent; and understanding by the consenter of the procedure as determined by the responses on a questionnaire.

Results Fifty-three percent of procedures (155/292) were performed after consent had been obtained during the baseline period compared with 90% (308/340) during the intervention period (absolute difference, 37.4%; P<.001). During baseline, the majority (71.6%; 111/155) of consents were provided by proxies. This was also the case during the intervention period in which 65.6% (202/308) of consents were provided by proxies (absolute difference, 6.0%; P=.23). Comprehension by consenters of indications for and risks of the procedures was high and not different between the 2 periods (P=.75).

Conclusions Invasive procedures are frequent in the ICU and consent for them is often obtained by proxy. Providing a universal consent form to patients, proxies, and health care clinicians significantly increased the frequency with which consent was obtained without compromising comprehension of the process by the consenter.

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process. In some states in which a delay in obtaining consent increases the risk of patient harm, physicians may perform procedures without obtaining explicit consent. Implied consent assumes that most individuals would assent to be treated in this situation; however, forgoing the usual dialogue that is the underpinning of the consent process represents another potential encroachment on patient autonomy.

Despite the difficulties presented by critical illness and the vulnerability of patients in the ICU environment with regard to consent for treatment, there is a paucity of medical literature concerning this topic. We recorded the number of invasive procedures, along with the frequency with which they were performed with informed consent, performed on all patients admitted to our ICU during a 2-month period. We also analyzed the understanding by the individual granting consent of the risks and benefits of these procedures. We repeated these analyses during a subsequent 2-month period after changing the process of informed consent via (1) adoption of a universal consent form for procedures, (2) implementation of an educational initiative directed toward ICU clinicians, and (3) implementation of formal proxy education through use of a handout. We hypothesized that although consent for invasive procedures is not obtained universally, a set of simple interventions would decrease the number of procedures performed without informed consent, while preserving consenter understanding.

METHODS

Setting and Participants
The study was conducted in a 16-bed medical ICU at a tertiary care teaching hospital. This ICU is a closed unit, with all care directed by critical care specialists. The physician team changes monthly and consists of 2 attending physicians (each for 2 weeks) and 8 to 10 resident and fellowship trainees.

Data Collection
To survey opinions of the medical ICU team (nurses, house staff, and attending intensivists), a baseline questionnaire covering 25 commonly performed procedures was administered. For each procedure, team members were asked if written consent was currently expected, as well as whether it should be mandatory in the answering individual’s opinion.

From November 1, 2001, until December 31, 2001, we identified all procedures performed during the first 21 days of each patient’s medical ICU stay. Procedures recorded included placement of arterial catheter, central venous catheter (CVC), pulmonary artery catheter (PAC), and peripherally inserted central catheter; bronchoscopy; thoracentesis; paracentesis; lumbar puncture; gastrointestinal tract endoscopy; blood transfusion; human immunodeficiency virus testing; chest tube placement; and tracheostomy. Procedures were identified daily through review of nursing and physician charting, query of physicians and nurses, and direct examination of patients, seeking evidence of new procedures performed (eg, a new catheter in place). The individual performing each procedure was recorded. We also sought a written consent form in the medical record, as well as the relationship to the patient of the person providing consent. Finally, for all procedures without a written consent form, the reason for this was solicited from the operator.

Individuals who gave consent were asked to complete a multiple-choice questionnaire assessing comprehension of the consented procedure in 4 domains: (1) the indication for the procedure; (2) a description of what the procedure entailed; (3) the right to refuse the procedure; and (4) potential complications. Adequate comprehension was prospectively defined as the consenter being able to indicate (1) at least 1 reason the procedure was indicated; (2) a description of what the procedure entailed; (3) knowledge of the right to refuse the procedure; and (4) at least 3 potential complications associated with the procedure.

Demographic information obtained included age, sex, race, ICU diagnosis, ICU length of stay, hospital length of stay, disposition after discharge from the ICU, Acute Physiology and Chronic Health Evaluation II (APACHE II) score,11 use of mechanical ventilation, and mortality. This study was approved by the institutional review board at the University of Chicago, Chicago, Ill.

Intervention
Following the initial 2-month baseline period of data collection, a 2-month intervention period ensued from March 1, 2002, to April 30, 2002. During this time, we developed a 3-part intervention process, which included a universal consent form that was approved by the institutional review board, the forms committee, and the legal and ethics staff of the hospital (form available from author on request). With this universal consent form, a patient or proxy was able to give advanced written permission for 8 commonly performed procedures (arterial catheter, CVC, PAC, or peripherally inserted central catheter placement; lumbar puncture; thoracentesis; paracentesis; and intubation/mechanical ventilation) in the ICU if necessary during the course of treatment. The second part of the intervention was an attachment to the universal consent form describing each procedure along with commonly associated complications. This information was derived from current patient handouts available from the American Thoracic Society, and sought to improve the education of patients and proxies regarding these commonly performed ICU procedures.12 These same informational handouts were available in the waiting area of the ICU. If a patient or proxy refused to sign the universal consent form, the standard practice of obtaining consent for each individual procedure was followed. We prospectively defined improvement in the process of informed consent as a higher incidence of documented informed consent with similar or improved consenter comprehension.

For the third part of the intervention, new residents and fellows were introduced to the universal consent form as part of an orientation to the ICU that oc-
curred on their first day. The universal consent form was also discussed with all nursing staff and was available for each new patient to the ICU. This third part of the intervention—the clinician educational component—consisted of a 15-minute discussion of the new consent form and the rationale for its implementation. For the house staff, this was performed by the ICU attending physician each month; for the nurses this was implemented by one of the authors (A.P.), who is a clinical nurse educator. We subsequently collected data on all admissions and procedures performed over another 2-month period (March 1, 2002, until April 30, 2002). All data were collected daily by 2 of the investigators (N.D., A.P.). These investigators were not privy to the results of the data analyses until the study was complete.

**Statistical Analysis**

Continuous demographic data were recorded as the mean (SD) or median (interquartile range), as appropriate. Continuous demographic data from the baseline and intervention periods were compared using the t test or the Mann-Whitney rank sum test, as appropriate. Categorical data were compared between the baseline and intervention periods using the χ² analysis or the Fisher exact test. For those patients with multiple ICU admissions, only the first ICU admission was analyzed. Based on our preliminary observations before the study began, we noted that informed consent was obtained for approximately 50% of procedures performed. With a goal of a 20% improvement to 70%, with an α of .05, and a desired power of 90%, we estimated that a sample size of 134 patients would be needed during each period; for the nurses this was estimated that a sample size of 134 patients would be needed during each period. All statistical analyses are 2-tailed and were performed using SPSS statistical software (Version 8.0, SPSS Inc, Chicago, Ill). A P value of less than .05 was considered significant.

**RESULTS**

**Clinicians’ Attitudes Toward Informed Consent for Procedures**

Seventy-three physicians and nurses were queried regarding opinions of those procedures requiring written informed consent. Of those queried, 45 (62%) believed consent was required for arterial catheters; 71 (97%) for CVCs; and 70 (96%) for PACs. Only 19 (26%) believed replacing an existing arterial catheter (37 [51%] for a CVC) via a new procedure at a different site required new written informed consent (Table 1).

**Participant Characteristics**

One hundred twenty-five consecutive patients admitted to the medical ICU were evaluated during the baseline period, while 145 consecutive patients were evaluated during the intervention period. There were no significant differences in any of the demographic variables collected except for a higher incidence of mechanical ventilation in the baseline group (49.6% [62/125] vs 34.5% [50/145]; absolute difference = 15.1%; P = .02). Participant characteristics are summarized in Table 2.

**Percentage of Procedures Performed With Written Consent**

During the baseline period, 53.1% (155/292) of procedures were performed with written informed consent. Written consent was provided by 98 individuals, including 27 patients who consented for themselves. The distribution of the procedures and incidence of informed consent are shown in Table 3. Although blood transfusion (46/47; 98%), gastrointestinal tract endoscopy (21/22; 95%), and bronchoscopy (11/11; 100%) all had high percentages of written consent obtained, they only accounted for 80 (27.4%) of 292 procedures performed. Of the 137 procedures performed with...

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**Table 1. Responses by Physicians and Nurses Regarding Informed Consent**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. (%) of Physicians and Nurses (n = 73)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Believe Procedure Requires Informed Consent</td>
</tr>
<tr>
<td>CVC insertion</td>
<td>71 (97)</td>
</tr>
<tr>
<td>Replacing CVC</td>
<td></td>
</tr>
<tr>
<td>New site</td>
<td>37 (51)</td>
</tr>
<tr>
<td>Over wire</td>
<td>16 (22)</td>
</tr>
<tr>
<td>Arterial catheter</td>
<td></td>
</tr>
<tr>
<td>Insertion</td>
<td>45 (62)</td>
</tr>
<tr>
<td>Replacement</td>
<td>19 (26)</td>
</tr>
<tr>
<td>PICC insertion</td>
<td>69 (95)</td>
</tr>
<tr>
<td>Peripheral intravenous insertion</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Placing a chest tube</td>
<td>69 (95)</td>
</tr>
<tr>
<td>Lumbar puncture</td>
<td>73 (100)</td>
</tr>
<tr>
<td>Tracheostomy placement</td>
<td>69 (95)</td>
</tr>
<tr>
<td>Inserting a bladder catheter</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Placing warming/cooling blankets</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Intubation (nonemergent)</td>
<td>33 (45)</td>
</tr>
<tr>
<td>Inserting nasogastric feeding tube</td>
<td>14 (19)</td>
</tr>
<tr>
<td>Esophagogastroduodenoscopy</td>
<td>72 (99)</td>
</tr>
<tr>
<td>PEG placement</td>
<td>71 (97)</td>
</tr>
<tr>
<td>Endoscopy</td>
<td>71 (97)</td>
</tr>
<tr>
<td>Placing patients in prone position</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Inserting rectal tube</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Blood transfusions</td>
<td>72 (99)</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>72 (99)</td>
</tr>
<tr>
<td>PAC insertion</td>
<td>70 (96)</td>
</tr>
<tr>
<td>Paracentesis</td>
<td>72 (99)</td>
</tr>
<tr>
<td>Thoracentesis</td>
<td>73 (100)</td>
</tr>
<tr>
<td>Elective intubation</td>
<td>50 (68)</td>
</tr>
</tbody>
</table>

*Abbreviations: CVC, central venous catheter; PAC, pulmonary artery catheter; PEG, percutaneous endoscopic gastrostomy; PICC, peripherally inserted central catheter.*
out written consent, 127 (93%) were for arterial catheters, CVCs, or PACs, despite the baseline opinions expressed in our survey that it was expected and reasonable for consent to be obtained (Table 1).

Of the procedures performed without written consent during the baseline period, the most common explanations ICU physicians gave were emergency (n = 34); consent not deemed necessary for a given procedure (n = 35); and no proxy present (n = 11). Additionally, 20 procedures were performed without a note in the medical record and we were unable to determine the reason for forgoing written consent.

During the intervention period, with the availability of the universal consent form, 90.5% of procedures (308/340) were performed with written consent. This represented a significant difference compared with the baseline period (53.1% vs 90.5%; absolute difference = 37.4%, P < .001). Written consent was provided by 125 individuals, including 33 patients who consented for themselves (P = .03 vs baseline period). Table 3 outlines the details for procedures performed.

Of the 32 procedures performed without written consent during this time, the most common explanations were emergency (n = 7) and no proxy present (n = 5). Additionally, 16 procedures were performed without a note in the medical record and we were unable to elicit the reason for waiving consent.

Of the 125 consenters, 83 received the universal consent form and 82 signed it. Of the 82 patients for whom universal consent was obtained, 75 actually underwent at least 1 procedure covered by this consent form.

**Patient and Proxy Understanding of Procedures**

Sixty (61.2%) of 98 consenters completed the procedure questionnaire during the baseline period. The reasons the questionnaire was not completed included death of patient (n = 6), participation refusal (n = 13), failure to return the questionnaire after receiving it from the research team (n = 14), and inability of the research team to locate the proxy consenter (n = 5). Of the 60 persons completing the questionnaire, all demonstrated knowledge of the indication for the procedure; the description of what the procedure entailed; and the option to refuse. Forty-nine (81.7%) of the 60 respondents were able to recognize at least 3 potential complications related to the procedure. Accordingly, we noted an 81.7% comprehension rate. Proxies consented for 71.6% (111/155) of procedures.

Fifty-nine (71.0%) of the 83 individuals who received the universal consent form also completed the procedure questionnaire. The reasons the questionnaire was not completed in the other 24 included death of patient (n = 2); participation refusal (n = 9); not returning questionnaire after receiving it from the research team (n = 8); proxy not located (n = 3); and language barrier (n = 2). Of the 59 persons completing the questionnaire, all demonstrated knowledge of the indi-
COMMENT

This investigation represents the first detailed description of the process of informed consent for invasive procedures during the care of critically ill patients. Proxies of ICU patients often experience anxiety and depression. Precise, widely accepted guidelines for providing consent in this environment do not exist, and there is diversity of opinion among clinicians as to which procedures require consent. This diversity was reflected in our survey data. Few clinicians thought that warming/cooling blanket use, peripheral intravenous insertion, or bladder catheter placement required consent, yet all of these procedures have indications, risks, and benefits. It is likely that most clinicians view these procedures as a part of the general management occurring in the ICU for which implicit consent exists. Our hospital policy states that informed consent is required for “all invasive procedures performed outside the operating room where there is more than minimal risk to the patient.”13,14 Certainly not all clinicians will agree on what constitutes “more than minimal risk.” Perhaps such vagaries partly explain the varying viewpoints and behaviors we noted.

Other procedures, such as blood transfusion, CVC insertion, thoracentesis, lumbar puncture, and endoscopy, are viewed as almost invariably requiring informed consent by our study clinicians. However, obtaining consent for these procedures during our baseline study period was quite variable. This may relate to a number of factors operative in the ICU environment. The first factor is the frequent inability of the critically ill patient to participate in the informed consent process due to the high incidence of delirium. In our study, patients gave consent for only 34% of all procedures for which informed consent was obtained. Although not statistically significant, a greater percentage of procedures were consented to by patients during the intervention period, which is consistent with a greater number of patients participating in the consent process. Thus, procedures such as CVC insertion, which is often performed on an emergent basis, may afford the clinicians a relatively short period to contact and obtain consent from proxies. Without this consent, clinicians in our study performed the procedure as a “medical emergency.” Nevertheless, our intervention substantially increased the incidence of consent obtained for arterial catheters, CVCs, and PACs. This is particularly germane given the high percentage of clinicians who deemed consent for such procedures to be appropriate in our baseline questionnaire. It is also possible that a different aura attends certain procedures that compel clinicians to make greater efforts to obtain consent. This might be true of blood transfusions, given medical and public concerns about risks therein related.

Regardless of the potential explanations for infrequent consent for certain procedures, we thought that the observed rate of consent for certain procedures was much lower than desired. We hypothesized that this might be improved by instituting a standardized, comprehensive approach to the consent process. We developed a universal consent form and procedure information handout, seeking to improve patient and proxy comprehension without increasing ICU physicians’ burden. In considering the nature of the ICU environment, a prospective approach to the potential need for invasive procedures seemed appropriate. We reasoned that providing patients and proxies with information about procedures at the time of admission to the ICU and obtaining consent for some of the procedures that might be performed would facilitate their understanding of these potential elements of care and would allow a greater number of proxies to participate in important decisions regarding care.

Interestingly, the universal consent form was discussed with and signed by only 57% of all proxies. Nevertheless, the majority of the actual procedures performed during the intervention period were performed under the auspices of this form. This suggests that physicians may be able to predict which patients will require invasive procedures and thus are able to anticipate the need for informed consent. Nevertheless, 36 procedures (20 baseline and 16 intervention) occurred with neither consent nor documentation of the procedure. Perhaps increased attention toward the importance of procedure documentation may reduce this number further.

Given the limitations imposed by patient incapacity, the unpredictability of critical illness, and the often complex mix of family members, friends, and partners seeking to represent the patient’s wishes, and assuming explicit laws regarding substituted judgment even exist in the state in question, how can informed consent in the ICU be used in the most effective manner? Our intervention significantly increased the number of procedures for which written consent was obtained, while preserving patient and proxy comprehension as assessed by questionnaire. Our intervention was multifaceted in that it
included a universal consent form, proxy education, and clinician education. However, it is not possible to know the individual impact of each intervention. Nevertheless, this multifaceted approach was relatively simple, requiring a brief didactic session with clinicians and written information for proxies. The universal consent form, once constructed, was simple to use and well received by most patients and/or proxies. Because it is conceivable that the universal consent form could discourage some physicians from participating in regular communication with the patient's proxy by removing the requirement for discussing each procedure individually, data regarding patient and proxy satisfaction with the process would have been interesting. It is notable, however, that only 1 of the 83 individuals presented with the universal consent form refused to sign it. A potential limitation of anticipatory consent is that it does not allow for alterations in the risk-to-benefit ratio of particular procedures as the patient's condition changes. In these situations—for example, when a procedure ordinarily contraindicated in the patient's present condition should, in the treating physician's judgment, be performed anyway—one should ideally obtain consent again.

Our study has several important limitations. Since it was conducted at a single center, the practice of informed consent and the attitudes of clinicians toward this process may be dissimilar to those of other institutions, particularly in other countries in which the process of informed consent may be different than in the United States. Our study design also did not allow us to determine precisely the cause of the increased rate of informed consent during the intervention period. Although the increase in rate of procedures associated with the universal consent form suggests that this instrument was responsible for the improvement, increased awareness through the educational initiative or even a Hawthorne effect are also possible explanations. Similarly, our study design may not be as rigorous as a randomized controlled trial. However, the latter design could conceivably increase the Hawthorne effect because the same clinicians would participate in 2 different consent processes simultaneously. In our design, each period comprised at least 2 different physician teams, allowing for a diverse array of clinicians participating in the consent process. Lacking validated instruments for assessing patient and proxy comprehension of procedures performed in the ICU, we cannot be certain that our tools possessed the sensitivity to detect differences in understanding. Further studies are needed to more reliably develop and validate tools for assessing consent comprehension. Finally, future studies that would include assessment of patient or proxy satisfaction with the consent process are warranted.

We have shown that education of clinicians, patients, and proxies regarding the process of informed consent can improve this process in critically ill patients. In addition, by providing physicians and nurses with a standard consent form and encouraging routine distribution of this form to patients and/or proxies at admission to the medical ICU, we were able to significantly increase the frequency with which informed consent was obtained for invasive procedures. A patient or proxy's understanding of procedures was excellent at baseline and was not compromised by routine distribution of this new instrument for guiding informed consent.

Author Contributions: Study concept and design: Davis, Pohlman, Gehlbach, Kress, McAtee, Hall. Acquisition of data: Davis, Pohlman, Gehlbach, Kress, Herlitz. Analysis and interpretation of data: Davis, Gehlbach, Kress, Hall. Drafting of the manuscript: Davis, Gehlbach, Kress, Hall. Critical revision of the manuscript for important intellectual content: Pohlman, Gehlbach, Kress, McAtee, Herlitz, Hall. Statistical expertise: Gehlbach, Kress, Hall. Obtained funding: Hall, Kress. Administrative, technical, or material support: Davis, Pohlman, Kress, McAtee, Herlitz. Study supervision: Pohlman, Kress, Hall.

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REFERENCES