Bundled Consent in US Intensive Care Units

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Background Bundled consent, the practice of obtaining anticipatory consent for a predefined set of intensive care unit procedures, increases the rate of informed consent conversations and incorporation of patients' wishes into medical decision-making without sacrificing patients' or surrogates' understanding. However, the adoption rate for this practice in academic and nonacademic centers in the United States is unknown.

Objective To determine the national prevalence of use of bundled consent in adult intensive care units and opinions related to bundled consent.

Methods A random sample of US hospitals with medical/surgical intensive care units was selected from the *AHA [American Hospital Association] Guide*. One intensive care unit provider (bedside nurse, nurse manager, or physician) from each hospital was asked to self-report use of per-procedure consent versus bundled consent, consent rate for intensive care unit procedures, and opinions about bundled consent.

Results Of the 238 hospitals contacted, respondents from 100 (42%) completed the survey; 94% of respondents were nurses. The prevalence of bundled consent use was 15% (95% CI, 9%-24%). Respondents using per-procedure consent were more likely than those using bundled consent to self-report performing invasive procedures without consent. Users of bundled consent unanimously recommended the practice, and 49% of respondents using per-procedure consent reported interest in implementing bundled consent.

Conclusions Bundled consent use is uncommon in academic and nonacademic intensive care units, most likely because of conflicting evidence about the effect on patients and surrogate decision makers. Future work is needed to determine if patients, family members, and providers prefer bundled consent over per-procedure consent.

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Informed consent is the process by which clinicians promote patient autonomy and shared decision-making by discussing the indications, risks, benefits, and alternatives of medical treatments with patients or their surrogate decision makers.[1] When seeking to obtain informed consent in the intensive care unit (ICU), clinicians often face special challenges because patients frequently lack decisional capacity and are unable to consent to urgent invasive procedures. In these situations, if clinicians are unable to identify or contact a designated surrogate decision maker, procedures may be performed without consent as emergency procedures to avoid patient harm. Because of decisional incapacity and other factors, nearly half of common invasive ICU procedures are performed without consent.[2]

The use of bundled consent, a practice in which permission is sought for a set of commonly indicated procedures in advance of a specifically identified need (eg, at the time of ICU admission or before the first indicated procedure), offers a possible solution to the high volume of procedures performed without consent. Bundled consent, in contrast to traditional per-procedure consent, was shown in a controlled trial to dramatically increase the rate of informed consent before procedures (from 53% to 90%) without compromising patients' or surrogates' understanding of the relevant procedures.[3] Bundled consent may serve as a prompt for an early family meeting with the attending ICU physician that would not occur otherwise or would occur in a hurried manner because of the urgency of a patient's condition. Additionally, its use in the ICU enhances physicians' communication with patients and families and improves families' satisfaction with and understanding of the care their loved ones receive.[4] Potential problems with bundled consent include undue stress for new families in the ICU, the omission of important details in a shorter informed consent conversation, and a lack of sufficient training for clinicians who will obtain the consent.[5] Patients might have difficulty making decisions about procedures that are not currently indicated, and their goals of care might change if their condition worsens. Bundled consent has both benefits and possible adverse consequences, and the national implementation of this practice is unknown. Previous surveys have been limited by focusing solely on academic centers[6] or hospitals within a single state.[7]

> Bundled consent dramatically increases the rate of informed consent before procedures without compromising patients' or surrogates' understanding of the relevant procedures.

In this study, we aimed to determine the national prevalence of use of bundled consent in adult ICUs. We further sought to identify clinician and hospital factors that might predict or influence the implementation of a bundled consent policy, to assess the impact of a bundled consent policy on rates of procedural consent, and to assess current perceptions of the practice of bundled consent among ICU clinicians.

Methods

Survey Design and Measures

We designed a brief survey (provided as a Supplement to this article) to assess how procedural informed consent is used in adult ICUs in the United States. Respondents indicated whether their units used bundled or per-procedure consent and used a 5-point scale (never, rarely, sometimes, often, or always) to estimate how often procedures were performed in their ICUs without documented

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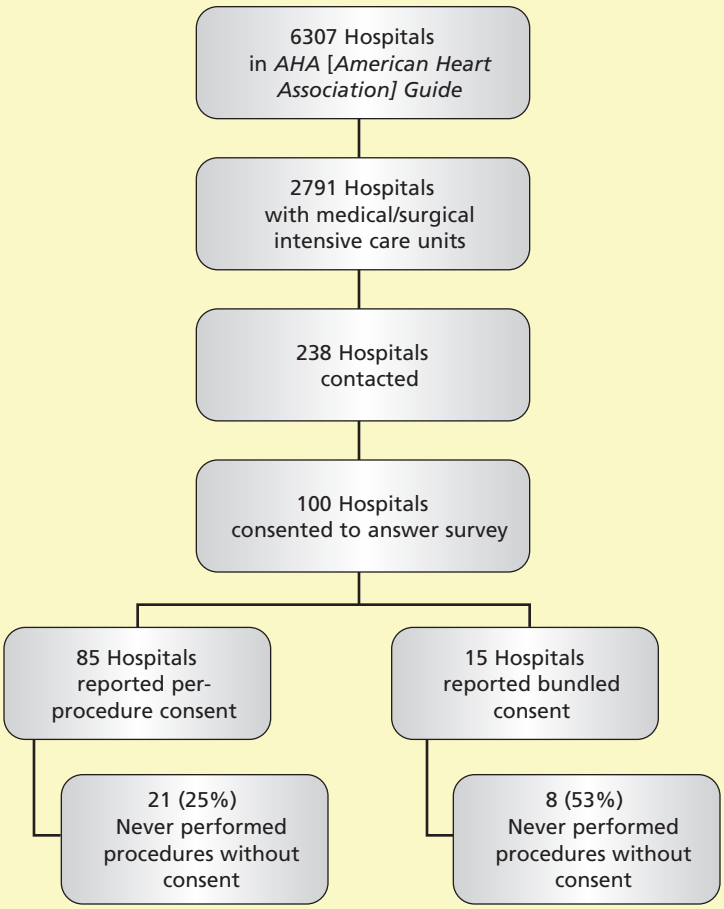

Figure 1 Study flow diagram illustrating participant selection and consent type. Survey sample displayed according to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[11]

informed consent. We specified a priori that our principal measure of consent rate would be a self-report of never performing ICU procedures without consent.

Survey respondents also reported whether an intensivist was the attending physician of record in their ICU, which team members routinely obtained consent, and why procedures were performed without prior informed consent in their units. Respondents who indicated that their ICUs used bundled consent were asked a series of follow-up questions to assess why their units adopted this practice and if they would recommend the practice to other ICUs. Respondents whose units used per-procedure consent were asked if they would be interested in implementing bundled consent and, if not, to indicate the reason.

Survey Sample and Administration

We prospectively surveyed a nationally representative sample of US hospitals from June 2017 through May 2018. We randomly selected hospitals with medical or combined medical/surgical ICUs from the 2017 edition of the *AHA [American Hospital Association] Guide* to reach providers at both academic and nonacademic institutions.[8] We gathered additional provider and hospital information for each of the ICUs from the AHA Annual Survey Database.[9]

We administered the survey by calling ICUs and requesting to speak to an intensivist physician, bedside nurse, medical director, or nurse manager. We intended to select providers who had direct knowledge of informed consent practices in their unit, spent significant time providing real patient care, and routinely participated in bedside procedures. When we reached appropriate individuals, we asked them to participate in the study. Respondents who agreed received the survey either by telephone or in an email with a personalized link to an online form. We collected and managed study data with electronic data capture tools (REDCap, hosted at the University of Chicago).[10] We obtained informed consent for participation either by telephone or electronically. The study protocol and all materials were deemed exempt by the institutional review board at the University of Chicago (IRB170284).

Statistical Analysis

We powered our study to generate a sufficiently precise estimate of the cross-sectional prevalence of bundled consent use. Assuming that the national prevalence was 15% on the basis of the findings of Stuke et al,[6] we calculated that surveying 100 hospitals would produce a 95% confidence interval of approximately 10% to 20%. We determined the univariate associations between bundled consent use and various hospital and provider factors, including type of hospital (teaching affiliation, critical access status, and ownership), total number of hospital beds, and number of medical/surgical ICU beds. We compared differences between groups by using *t* tests of means for normally distributed continuous variables, quantile regression for medians of non-normally distributed continuous variables, and 2-tailed Fisher exact tests for categorical variables. All data analysis was performed with statistics software (Stata 15, StataCorp LLC), and *P* less than .05 was considered significant.

Results

Survey Respondents

Of 6307 hospitals in the *AHA Guide,* 2791 had medical/surgical ICUs and were therefore eligible to be surveyed. We randomly selected 238 hospitals, and respondents from 100 completed the survey (42% response rate; see Figure 1 for flow diagram).

Table 1
Demographics of survey respondents and nonrespondents

Variable	Nonrespondents[a] (n = 138)	Respondents[a] (n = 100)	P[b]
No. of full-time-equivalent medical/surgical intensivists, mean (SD)	6 (12.6)	6.2 (7.9)	.92
No. of hospital beds, mean (SD)	219.6 (207.5)	254.5 (192.3)	.19
No. of medical/surgical intensive care unit beds, mean (SD)	14.7 (13.6)	17.9 (12.8)	.07
Region			.84
Northeast	28 (20)	18 (18)	
Midwest	31 (22)	24 (24)	
South	58 (42)	39 (39)	
West	21 (15)	19 (19)	
Intensivists provide care			.08
Yes	52 (38)	54 (54)	
Critical access hospital[c]			.40
Yes	9 (7)	4 (4)	
Teaching affiliation			.11
None	90 (65)	52 (52)	
Minor teaching	36 (26)	38 (38)	
Major teaching	12 (9)	10 (10)	
Hospital ownership			.79
Government, nonfederal	21 (15)	17 (17)	
Not for profit	96 (70)	66 (66)	
For profit	18 (13)	16 (16)	
Government, federal	3 (2)	1 (1)	

[a] Values are number (percentage) unless otherwise indicated in the first column.
[b] Fisher exact tests (2 tailed) were used for categorical variables and quantile regression was used for medians. No statistically significant differences between the 2 groups were found.
[c] Designation is given to selected rural hospitals by the Centers for Medicare and Medicaid Services to improve access to care and reduce financial vulnerability.

Of the respondents, 94% were nurses, 3% were physicians, and 3% were other clinicians. Participating and nonparticipating hospitals were similar in terms of mean number of ICU beds, geographical location, hospital ownership, and teaching affiliation (Table 1).

Bundled Consent Use and Associated Hospital Characteristics

Of the 100 participating hospitals, respondents from 15 reported using bundled consent in their ICUs (prevalence, 15%; 95% CI, 9%-24%). Hospitals using bundled consent had more medical/surgical ICU beds than did hospitals using per-procedure consent. We found a nonsignificant trend toward more total beds in hospitals using bundled consent than in those using per-procedure consent. Number or presence of full-time intensivists, geographic location, critical access status, teaching affiliation, and hospital ownership did not differ according to type of consent (Table 2). Respondents from both groups agreed on the common ICU procedures that require informed consent (Figure 2). When asked to indicate all of the possible providers who routinely obtained informed consent, respondents most often reported the attending physician of record (68%), followed by bedside nurses (58%), physician assistants and nurse practitioners (30%), and trainees including residents and fellows (27%). Formal training for clinicians on how to discuss informed consent was rarely reported for all ICUs but was more common among units using bundled consent (53% vs 24%, $P = .02$).

Impact of Bundled Consent on Patients and Providers

Of respondents using per-procedure consent, 75% self-reported performing invasive procedures without consent, as compared with only 47% of respondents using bundled consent ($P = .02$; Figure 3). For both groups, the most common reason for performing a procedure without consent was the urgent nature of the procedure (63%). Other reasons were inability of patient to consent with no surrogate available (9%) and unavailability of personnel with necessary skills and credentials to obtain consent (1%).

Respondents from all 15 hospitals using bundled consent said they would recommend the practice to other hospitals. Four common reasons given for using bundled consent were "more efficient for practitioners," "more efficient for patients/surrogates," "concern about procedures being performed

Table 2
Characteristics of hospitals using per-procedure consent and hospitals using bundled consent[a]

Variable	Per-procedure consent[b] (n = 85)	Bundled consent[b] (n = 15)	*P*[c]
No. of full-time-equivalent medical/surgical intensivists, median (IQR)	5 (2-8)	4 (0-5)	.31
No. of hospital beds, median (IQR)	166 (99-373)	322 (116-463)	.07
No. of medical/surgical intensive care unit beds, median (IQR)	14 (8-24)	24 (8-34)	.04
Region			.80
Northeast	14 (16)	4 (27)	
Midwest	21 (25)	3 (20)	
South	34 (40)	5 (33)	
West	16 (19)	3 (20)	
Intensivists provide care			.26
Yes	43 (51)	11 (73)	
Critical access hospital[d]			>.99
Yes	4 (5)	0 (0)	
Teaching affiliation			.39
None	45 (53)	7 (47)	
Minor teaching	33 (39)	5 (33)	
Major teaching	7 (8)	3 (20)	
Hospital ownership			.09
Government, nonfederal	16 (19)	1 (7)	
Not for profit	57 (67)	9 (60)	
For profit	12 (14)	4 (27)	
Government, federal	0 (0)	1 (7)	

Abbreviation: IQR, interquartile range.
[a] Data were obtained from the 2017 *AHA [American Hospital Association] Guide*.[8]
[b] Values are number (percentage) unless otherwise indicated in the first column.
[c] Median values of continuous variables were compared by using quantile regression. Categorical variables were compared by using Fisher exact tests (2-tailed).
[d] Designation is given to selected rural hospitals by the Centers for Medicare and Medicaid Services to improve access to care and reduce financial vulnerability.

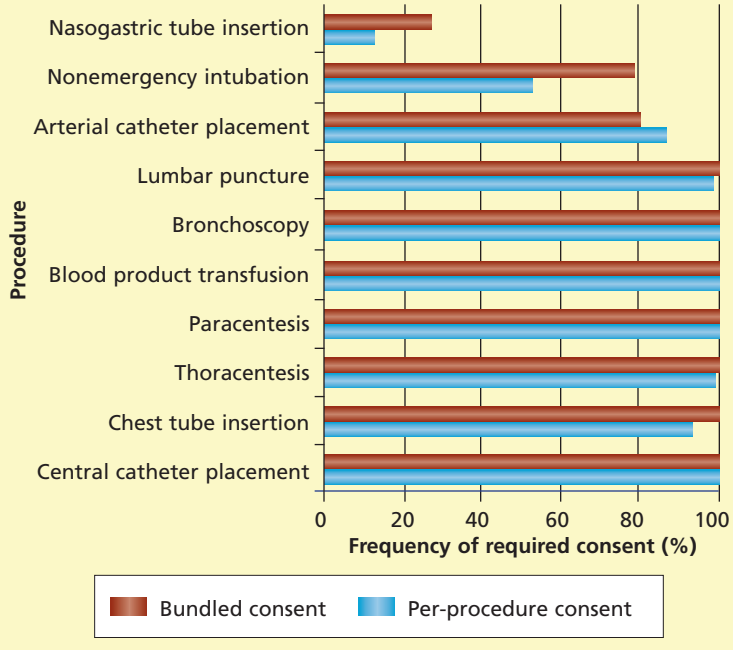

Figure 2 Frequency of required consent by procedure. Respondents were asked whether their intensive care units required for consent for several common procedures. The frequency with which units sought consent for each procedure did not differ according to type of consent.

without consent," and "belief that this practice is better for physician-patient/surrogate communication" (Table 3). Seven of 15 hospitals using bundled consent had been using it for more than 5 years. Of the respondents using per-procedure consent, 39 of 80 (49%) reported interest in implementing bundled consent (5 respondents using per-procedure consent did not answer this question). Some reasons for lack of interest were "belief that separate consent should be obtained for individual procedures," "concern that practice may negatively affect physician-patient/surrogate communication," and "concern regarding legal risk/liability."

Discussion

To our knowledge, our study is the first to use a nationally representative sample of both academic and nonacademic adult ICUs to assess the prevalence of bundled consent use for common ICU procedures. We found that bundled consent was used infrequently, with only 15% of US adult medical and combined medical-surgical ICUs using the practice, and that this prevalence has not changed significantly in the past decade. Respondents using bundled consent were less likely than those using per-procedure consent to self-report performing invasive procedures

without consent. Notably, all survey respondents using bundled consent recommended the practice to other ICUs, and almost half of respondents using per-procedure consent expressed interest in implementing bundled consent at their institutions.

There are several potential reasons why bundled consent has not been used more widely despite the interest in bundled consent expressed by our survey respondents who were using per-procedure consent. First, providers may worry that bundling together several procedures would reduce a patient's or surrogate's understanding of a given procedure. This concern is a reasonable one that has contradictory reports in the literature. One study indicated that bundled consent leads to families missing out on critical updates,[12] and in another study, only 11% of residents conducted a complete informed consent discussion for each procedure in a bundled consent protocol.[5] Other single-center studies found that bundled consent did not reduce comprehension by individuals who provided consent[3] and even increased family satisfaction with the ICU.[4] Another advantage of bundled consent over the per-procedure approach is that ICU clinicians need not delay or defer diagnostic or therapeutic procedures that do not meet the criteria for emergency need or implied consent. By enhancing efficiency of the informed consent process, bundled consent may reduce these risks to patients and promote patient autonomy. This factor is of particular relevance considering the increasing use of ICUs without a concomitant increase in the number of critical care providers.[13]

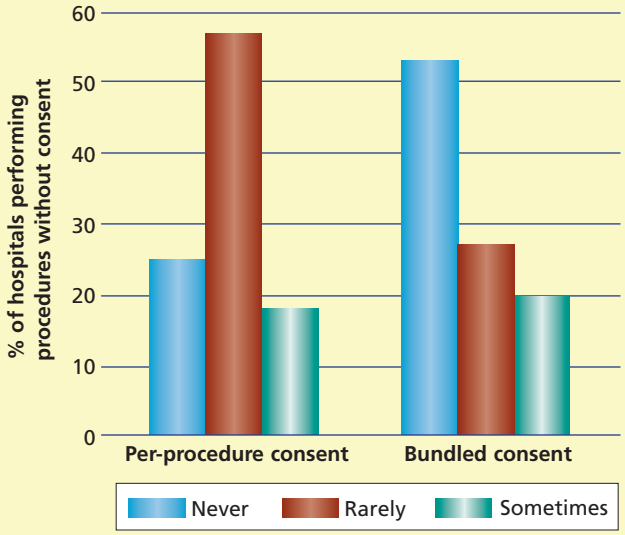

Figure 3 Frequency of invasive procedures performed without consent according to consent protocol.

Second, a major ethical concern is that bundled consent could result in bombarding the patient or surrogate decision makers at the time of admission with a lengthy and involved conversation about procedures that may need to be done at some point during the patient's stay. A recent study assessing residents' perceptions of bundled consent showed that 88% felt there were too many procedures to discuss and that 78% of residents thought bundled consent was awkward and stressful for families.[5]

Third, several respondents using per-procedure consent cited unease regarding legal liability if their hospitals were to adopt bundled consent. We found

Table 3
Opinions on bundled consent

Question	Response	Percentage
	Respondents using bundled consent	
Would you recommend bundled consent to ICUs at other hospitals?	Yes	100
Why does your ICU use bundled consent?	More efficient for practitioners	66
	More efficient for patients/surrogates	66
	Concern about procedures being performed without consent	60
	Belief that this practice is better for physician-patient/surrogate communication	40
	Recommended by an accrediting body	13
	Respondents using per-procedure consent	
Would you be interested in implementing bundled consent in your ICU?	Yes	49
Why does your ICU not use bundled consent?	Belief that separate consent should be obtained for individual procedures	44
	Concern that practice may negatively affect physician-patient/surrogate communication	17
	Concern regarding legal risk/liability	7
	Concern that ICU's patient population would not approve of the practice	7

Abbreviation: ICU, intensive care unit.

that respondents using bundled consent were unanimous in recommending the practice to other institutions and that almost 50% of these users had been using bundled consent for more than 5 years. This strong endorsement may suggest that these ICUs have not encountered significant medical-legal issues or dissatisfied patients and families, but additional work is needed to identify the precise legal challenges that may be state specific.

We found that respondents from ICUs that used bundled consent were markedly more likely to self-report obtaining informed consent before invasive procedures were performed. Respondents using per-procedure consent were 1.6 times as likely as those using bundled consent to report performing procedures without consent. This observed effect size is consistent with results of the single-center study by Davis et al,[3] in which switching from per-procedure to bundled consent increased the rate of consent for procedures. However, this finding from our study is exploratory because it is based on providers' self-reports. In addition, we did not directly measure the quality of informed consent conversations. Users of bundled consent may have been more inclined to self-report improved consent out of desire to please regulatory agencies and demonstrate that this protocol improves hospital compliance.

Use of bundled consent for ICU procedures may increase rates of informed consent in ICUs and incorporate patients' wishes into medical decision-making.

Finally, we demonstrate a clear need to enhance clinician training on how to engage in the process of informed consent. Only 30% of respondents in our study reported that their ICUs had a formal training process. This finding aligns with the moderate resident readiness reported in an academic institution using bundled consent. In that study, residents self-rated their comfort level as 3.3 on a scale of 1 to 5 for conducting a consent conversation.[5] Given the increasing premium placed on patient self-determination and the central role of informed consent within that paradigm, mechanisms to train and assess clinicians' competency in informed consent practices should not be an afterthought.

Study Limitations

Although our response rate was acceptable for this type of survey research, our results may be subject to response bias. Self-reported procedural consent rates might be subject to social desirability bias, which could skew the reported rates higher than the actual rates. However, we would expect hospitals using per-procedure consent and those using bundled consent to experience this bias equally, so it should not invalidate the observed differences between groups.

Although we set out to survey a mix of provider types, most respondents were bedside nurses, and we believe that this is an unexpected strength of our data. Nurses participate in almost all bedside procedures in the ICU and have more direct contact with patients than physicians do.[14,15] The physician explains the risks, benefits, and alternatives of a procedure, whereas the nurse ensures that the consent conversation occurred and, more importantly, acts as an advocate for patients.[15-18] Nurses routinely follow checklists to maintain hospital protocols, such as informed consent, and are able to indicate whether or not informed consent is routinely obtained before procedures. They are ideally positioned to state how often procedures are performed without consent because they are more likely to report what is actually happening in routine clinical care. In our survey, 58% of respondents reported that nurses routinely obtained informed consent in their ICUs, highlighting nurses' involvement in the informed consent process.

Conclusions

The use of bundled consent for ICU procedures is uncommon in the United States and has not changed since 2010, when it was assessed in academic centers.[6] Intensive care unit providers, mostly nurses, expressed interest in implementing bundled consent in their units, and respondents using bundled consent unanimously recommended it to other institutions, suggesting a need to provide more information about the practice. Many ethical challenges are involved with bundled consent, including the potential to overwhelm patients and family members by front-loading informed consent conversations or by asking for opinions on procedures that might change if the patient's condition worsens. However, bundled consent may be effective for increasing rates of informed consent and incorporating patients' wishes into medical decision-making if better training is provided to the clinicians obtaining informed consent. Future work is needed to assess whether patients, family members, and health care providers prefer bundled consent over individual per-procedure consent.

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Respondent demographics

1. Type of provider (select one)
   a. Physician
   b. Nurse
   c. Other
2. Name of hospital
3. Contact information + preferred means of communication:

Part 1 – Informed consent for procedures in the ICU

1. Which providers take care of patients in your ICU (select all that apply)?
   a. Residents
   b. Fellows
   c. Physician assistants/nurse practitioners
   d. General internists
   e. Intensivists
   f. Other:
   g. Don't know
2. Is an intensivist the attending of record for patients in your ICU?
   a. Yes
   b. No
   c. Don't know
3. Which member or members of the care team routinely obtain(s) informed consent for procedures in your ICU (select all that apply)?
   a. Trainees (includes residents, fellows)
   b. Attending of record
   c. Physician assistant/nurse practitioner
   d. Bedside nurse
   e. Medical students
   f. Other:
   g. Don't know
4. For which procedures is informed consent routinely obtained?

a. Central venous catheter placement	Yes	No
b. Arterial catheter placement	Yes	No
c. PA catheter placement	Yes	No
d. Nasogastric (NG) tube placement	Yes	No
e. Chest tube placement	Yes	No
f. Thoracentesis	Yes	No
g. Paracentesis	Yes	No
h. Nonemergent intubation	Yes	No
i. Blood and blood product transfusion	Yes	No
j. Bronchoscopy	Yes	No
k. Transthoracic echocardiography (TTE)	Yes	No
l. Transesophageal echocardiography (TEE)	Yes	No
m. Lumbar puncture	Yes	No
n. Other(s):		

5. Think of only procedures for which you feel procedural consent is necessary. In your ICU, how often are procedures performed without prior documentation of informed consent?
   a. Never
   b. Rarely
   c. Sometimes
   d. Often
   e. Always
6. What is the most common reason that procedures are performed without prior documentation of informed consent?
   a. Urgent nature of procedure
   b. Patient is unable to consent and there is no surrogate available
   c. Personnel with necessary skills/credentials to obtain consent are unavailable
   d. Other(s):
7. Does your institution provide targeted training for practitioners who will be obtaining procedural consent?
   a. Yes
   b. No
   c. Don't know

Continued

Supplement Survey questions.

8. ***Bundled consent*** is a process by which consent for multiple, potentially necessary procedures is sought in advance of a specifcally identified need, eg, at the time of admission to the ICU or first indicated procedure. This practice often involves the use of a single, standardized document. Do you currently or has your institution ever used a bundled consent policy in your ICU?
   a. Yes → please skip to Part 2 of the survey
   b. No → please answer #9. *You may skip Part 2*
   c. Previously used, but not at present → please skip to #11. *You may skip Part 2*

9. Would you be interested in implementing bundled consent in your ICU?
   a. Yes → *End of Survey*
   b. No → Please answer #10

10. If you answered "No" to #9, why are you not interested in bundled consent (select all that apply)?
   a. Belief that separate consent should be obtained for individual procedures
   b. Concern re: legal risk/liability
   c. Belief that our patient population would not agree with such a practice
   d. Concern that this practice may negatively affect physician-patient/surrogate communication
   e. Other(s):

11. Why did your institution de-adopt bundled consent (select all that apply)?
   a. Belief that separate consent should be obtained for individual procedures
   b. Concern re: legal risk/liability
   c. Belief that our patient population would not agree with such a practice
   d. Concern that this practice may negatively affect physician-patient/surrogate communication
   e. Other(s):
   f. Don't know

Part 2 – Users of Bundled Consent

1. How long has your ICU utilized this practice?
   a. Less than 1 year
   b. Between 1-5 years
   c. Between 5-10 years
   d. Greater than 10 years
   e. Don't know

2. Why does your ICU use a bundled consent (select all that apply)?
   a. Concern about procedures being performed without consent
   b. More efficient for practitioners
   c. More efficient for patients/surrogates
   d. Recommended by an accrediting body
   e. Belief that this practice is better for physician-patient/surrogate communication
   f. Other(s):

3. Since adopting bundled consent, has the number of procedures being performed without documented informed consent been reduced?
   a. Yes
   b. No
   c. Don't know

4. Would you recommend bundled consent to other ICUs?
   a. Yes
   b. No

Supplement *Continued.*

Abbreviations: ICU, intensive care unit; PA, pulmonary artery.