

# Informed consent for procedures in the intensive care unit: ethical and practical considerations

Lucy J Modra, Andrew Hilton and Graeme K Hart

For many years it was accepted that when a patient was admitted to the intensive care unit for treatment, they had implicitly consented to any procedures necessary for the delivery of intensive care.<sup>1,2</sup> This presumption is now being questioned, with some commentators suggesting that informed consent should be obtained before all invasive procedures performed in the ICU.<sup>3</sup> The College of Intensive Care Medicine (CICM) of Australia and New Zealand recommends that patients and/or their legally recognised representatives have a right to “Give verbal or written consent for a procedure, after explanation and before treatment, unless precluded by an emergency”.<sup>4</sup>

We review the literature on informed consent for ICU procedures (procedural consent), and show that obtaining consent before common ICU procedures is not yet standard practice. We explore reasons for the disjuncture between the official position of the CICM and current practice, and consider logistical and ethical aspects of procedural consent in the ICU, which is different to consent in other health care environments. Most notably, ICU patients need multiple procedures and are often not competent to consent, so consent is obtained from surrogate decisionmakers. A robust ICU procedural consent process must accommodate these limitations, rather than simply transposing the familiar model of informed consent for elective surgery to the critical care environment. From an ethical standpoint, the consent process should balance the interests of patients and families (promoting their understanding and involvement in decision making) with the interests of clinicians (primarily medicolegal protection).

## Informed consent

The concept of informed consent to medical treatment emerged in the second half of the 20th century, against a background of increasing emphasis on patient autonomy in health care interactions.<sup>5</sup> Beauchamp and Childress set out seven elements of informed consent:<sup>6</sup>

- patient competence
- disclosure of relevant information
- patient understanding of that information
- doctor’s recommended course of action
- voluntariness of the decision
- patient decision
- formal authorisation of the plan.

## ABSTRACT

There is increasing interest in procedural consent (informed consent for invasive procedures) in the intensive care unit. We reviewed studies of procedural consent and show that it is not yet routine practice to obtain consent before performing invasive procedures on ICU patients. We considered logistical barriers to procedural consent in the critical care environment and the ethical implications of introducing routine procedural consent to the ICU.

Crit Care Resusc 2014; 16: 143–148

Patient understanding includes understanding of the proposed treatment, including its risks and benefits, alternative treatments and the expected outcome if they had no treatment. Voluntariness refers to the extent to which a patient feels free to choose between the given options, unburdened by coercive influences. This process has a legal dimension, with the patient formally authorising the doctor to perform the procedure.

This model of informed consent is criticised for being extremely difficult to attain in practice.<sup>7,8</sup> Studies of informed consent in the coronary care setting show significant problems with ensuring patient understanding.<sup>9,10</sup> These difficulties are amplified in the ICU setting, as critical illness impairs or prevents patient understanding and involvement in decision making.<sup>11</sup> However, the intention of informed consent — to promote the patient’s autonomy in health care interactions, recognising that their values may be different from those of the treating clinician — is widely accepted as ethically sound in Western cultures.

ICU procedural consent is specifically about invasive procedures performed at the ICU bedside, including airway interventions, vascular access procedures, diagnostic and therapeutic aspirates and some endoscopic procedures (Table 1). The consent process may take place verbally or in writing.

This article focuses specifically on non-emergency ICU procedures rather than time-critical procedures. Time-critical procedures are those that occur when delaying the intervention to obtain consent may endanger the patient. In these situations, emergency consent applies: it is assumed that the patient would consent to urgent and potentially

**Table 1. Invasive procedures commonly performed in the intensive care unit**

- Airway interventions: endotracheal intubation, minitracheostomy and percutaneous tracheostomy
- Vascular access insertion procedures: central venous catheters, arterial lines, pulmonary arterial catheters, extracorporeal membrane oxygenation cannulae and peripherally inserted central catheters
- Diagnostic and therapeutic taps: lumbar puncture, abdominal paracentesis and thoracocentesis
- Intercostal catheter insertion
- Endoscopic procedures: upper gastrointestinal endoscopy, bronchoscopy and transoesophageal echocardiography
- Percutaneous endoscopic gastrostomy placement

life-saving interventions.<sup>5</sup> The distinction between time-critical and non-time-critical procedures is difficult to establish in the setting of critical illness, but many ICU procedures are not so time-critical as to preclude discussion with the patient or family.

**Current practice**

There are no published data on methods, indications or rates of procedural consent in Australian ICUs. It is our opinion that informed consent is not routinely obtained before invasive procedures in Victorian ICUs. One Victorian ICU director explained that consent to ICU core business and non-elective procedures is assumed for unconscious patients and more formal consent is not pursued from their next of kin; conscious patients have the procedure and risks explained whenever possible and documented in notes; and less urgent ICU procedures, eg, percutaneous tracheostomy, have consent obtained from the next of kin (personal communication, January 2012).

Another ICU director noted that formal consent was only expected for tracheostomies (personal communication, January 2012). Austin Health provides written information at the time of each admission about common procedures and

at the preadmission clinic for elective surgical admissions, and seeks formal consent for other procedures, such as tracheostomy and upper gastrointestinal (UGI) endoscopy. At the time of writing, Alfred Health is rolling out a new procedural consent process. An interactive multimedia program about ICU procedures, including videos and information in multiple languages, will be available on iPads in the ICU waiting room. The program prompts relatives to electronically schedule a meeting with their ICU medical team. At this first meeting, a consultant or senior registrar obtains formal written consent for ICU procedures. This is “blanket” pre-emptive consent for all ICU procedures as clinically indicated, including for tracheostomies and extracorporeal membrane oxygenation (ECMO) (Professor Carlos Scheinkestel, Director of Intensive Care and Hyperbaric Medicine, Alfred Hospital, personal communication, 14 February 2014).

Studies of ICU procedural consent from the United States and Europe reveal significant variation in practice, even within hospitals.<sup>1,12-14</sup> For example, a study of ICU program directors in the US found that procedural consent rates for central venous catheter (CVC) insertions ranged between 23% and 81%.<sup>14</sup> This depended on the setting, with medical ICUs reporting higher rates of procedural consent than surgical ICUs.

The greatest variation in consent practice is reported for non-emergency intubation and vascular access procedures, including CVC, arterial catheter and pulmonary artery catheter insertion (Table 2). Stuke and colleagues reported procedural consent rates of 31.1% to 93.1% for vascular access procedures and 21.1% to 46.2% for non-emergency intubation.<sup>13</sup> That study did not ask respondents to specify whether written or verbal consent was obtained. Davis and colleagues audited baseline rates of procedural consent before introducing a new consent process, and found that written consent was documented for 35% of CVC, 5% of arterial line and 10% of pulmonary arterial catheter insertions.<sup>1</sup> Vincent and colleagues surveyed members of the European Society of Intensive Care Medicine and found that 5% of doctors would obtain written

**Table 2. ICU procedural consent rates**

Study	Reporting methods	Respondents (response rate)	Vascular access procedures	Non-emergency intubation	UGI endoscopy	Tracheostomy
Manthous et al 2003 <sup>14</sup>	Survey of ICU program directors in US	88 (27%)	14%–87%	14%–48%	82%–100%	NA
Stuke et al 2010 <sup>13</sup>	Survey of ICU directors in US	70 (37%)	32%–93%	35%	NA	97%
Davis et al 2003 <sup>1</sup>	Written consent rates in a US tertiary ICU	292*	5%–35%	NA	96%	86%
Vincent 1998 <sup>12†</sup>	Survey of members of the ESICM	504 (40%)	37%–83%	NA	72%–100%	NA

UGI = upper gastrointestinal. ICU = intensive care unit. US = United States. NA = not applicable. ESICM = European Society of Intensive Care Medicine. \* Number of procedures performed in audit period. † Combined written and verbal consent rates reported.

informed consent before arterial line placement and between 38% and 68% would obtain verbal consent before arterial line placement.<sup>12</sup>

In contrast, most clinicians believe that informed consent should be obtained before UGI endoscopy, fibre-optic bronchoscopy, tracheostomy or percutaneous endoscopic gastrostomy (PEG) tube placement.<sup>1</sup> This is reflected in practice, with over 80% of respondent ICU directors reporting that consent is routinely obtained before UGI endoscopy and fibreoptic bronchoscopy,<sup>14</sup> and 97.1% reporting consent is routinely obtained for tracheostomy and PEG tube placement.<sup>13</sup> Davis and colleagues found that baseline consent rates were 95% for gastrointestinal endoscopy, 100% for bronchoscopy and 86% for tracheostomy.<sup>1</sup>

Consent may be particularly important for tracheostomies and PEG tube insertions because insertion of these long-term devices represents a decision to persist with intensive care treatment. The disparity between the high consent rates for UGI endoscopy and bronchoscopy and relatively low consent rates for non-emergency intubation or CVC insertion is more difficult to explain. The risks of these procedures in a critically ill patient are at least commensurate. Clinicians may obtain consent before endoscopic procedures because these are otherwise performed in the operating theatre, where informed consent is mandated by the World Health Organization safe surgery checklist. Davis and colleagues suggest "it is also possible that a different aura attends certain procedures that compel clinicians to make greater efforts to obtain consent".<sup>1</sup> This raises the question: do patients and families also value the informed consent process more highly in these particular procedures, or is this "aura" only visible to clinicians? Our consent practices should be shaped by the risks of the procedure and concerns of the patient and family, rather than evolving arbitrarily.

The piecemeal manner in which ICU consent practices evolve is well demonstrated by the example of consent for blood transfusion. The Australian Commission on Safety and Quality in Health Care requires informed consent for blood transfusion.<sup>15</sup> Blood transfusion is a special case, as some patients have religious objections to transfusion, and patients may be concerned about the well publicised but now extremely low risk of HIV or viral hepatitis transmission. These are important reasons to obtain consent. In the context of ICU care, blood transfusion is a low-risk procedure; it has a lower risk than many procedures for which informed consent is not normally obtained. ICU patients and families may mistakenly believe that it is a high-risk treatment because of the separate consent process. This shows the importance of developing a cohesive ICU procedural consent process. Otherwise, our consent practices

will continue to be shaped by policies that are primarily designed for non-critical care settings.

### Logistical factors in consent

There are some important limitations on informed consent for procedures in the ICU, compared with informed consent for a discrete elective surgical procedure. First, ICU patients are often not competent to make their own health care decisions due to sedation, analgesia, delirium or pain. The reported rate of proxy consent for ICU procedures varies between 65.6% and 73%.<sup>1,13</sup> The reliance on proxies has its own problems, with difficulties in locating an appropriate surrogate decisionmaker and ensuring the surrogate's familiarity with the patient's preferences and willingness to act as surrogate.<sup>5,16</sup> Most jurisdictions in Australia have legal provisions for proxy consent given by a relative or carer.<sup>17</sup>

Second, ICU patients require a series of procedures over days to weeks, many of which are completely unfamiliar to the patient and his or her family. The risk of these procedures will vary depending on the procedure, the patient's clinical state, and the experience of the proceduralist. During the stressful situation of critical illness, patients and their families may be overwhelmed by a large amount of information about procedures.<sup>16</sup> There are certainly limitations in the ability of patients to understand and recall information that is provided during critical care informed consent discussions,<sup>11,18</sup> but information should not be withheld for fear that it will be forgotten or misunderstood. Patients and families should be allowed to develop an understanding of procedures that they consider adequate. For many, this would involve a basic understanding that invasive procedures form part of ICU treatment and that there are risks associated with these procedures.

Finally, obtaining informed consent for procedures could be extremely time-consuming for ICU clinicians. Some may argue that obtaining consent would leave no time to actually perform the procedures, thereby compromising patient care. Against this concern, Marsillio and Morris found that the median time taken to obtain specific procedural consent was only 5 minutes.<sup>3</sup> Standardised written information, online resources, videos or multimedia presentations would make the consent process more efficient. However, a verbal discussion in the patient's own language should be offered, as this is shown to improve patient understanding of the consent process.<sup>16</sup> Information can be reinforced by multiple ICU clinicians including resident medical staff, bedside nurses and allied health staff. A disadvantage of standardised information is that patients or families may be unnecessarily alarmed about procedures that the patient ultimately does not need.<sup>3</sup>

### Arguments in favour of procedural consent

Treatment decisions made in the setting of critical illness have far-reaching consequences for patients and families, therefore they should be involved as much as possible in decision making. Invasive procedures form a small component of the overall ICU treatment plan, but a procedural consent process would increase the amount of information conveyed to the patients and their families, leading to greater understanding and dialogue about treatment decisions. Informed consent for procedures could serve to demystify the tubes and machines attached to the patient, which can be distressing for families.

Importantly, introducing routine informed consent for ICU procedures would ensure that patients and families understand the risks and discomfort involved in ICU treatment. This may help families understand the true cost of persisting with treatment in the face of diminishing benefits in a deteriorating patient.

Informed consent is particularly important in the ICU because intensive care patients are among the most vulnerable of hospitalised patients.<sup>16</sup> ICU patients are often unable to communicate due to sedation, airway devices or neurological deficits, and have significant movement restrictions due to weakness and/or dependence on organ support devices. Schweickert and Hall describe ICU patients as “captive” in the unit, under the care of an on-duty intensivist who is previously unknown to them and unfamiliar with their preferences or values.<sup>16</sup> This highlights the importance of allowing family members to advocate for their relative in the ICU.

The informed consent process offers some legal protection for the treating doctor if there are complications from a procedure.<sup>19</sup> This is a central consideration in the discussion of ICU procedural consent. Proceduralists assess the risk of an adverse medicolegal outcome, and that affects the way they obtain informed consent. A study of the parents of paediatric ICU patients found that 54% believed that the primary purpose of the informed consent process was legal protection for doctors. One parent stated that informed consent was obtained, “In case anything happens, so it’s on my own risk”.<sup>3</sup> Most literature on ICU procedural consent originates from the US, which is a more litigious environment than Australia. This medicolegal backdrop has likely coloured the approach of American clinicians to informed consent, even when this is not overtly acknowledged by the authors. Nonetheless, the needs of doctors and patients are not necessarily at odds: an informed consent process that provides adequate information to patients or families and involves them appropriately in the decision making also provides for medicolegal defence in the event of complications.

### Arguments against procedural consent

Some argue that when patients are admitted to the ICU there is implied consent to the basic procedures necessary to deliver intensive care. However, in the absence of a formal consent process at the time of ICU admission, it is difficult to argue that consent is implied for all further care including subsequent semiurgent procedures. Implied emergency consent may be applied to insertion of a central line in a crashing septic patient. It is not as readily applied to the insertion of a new central line in the same, more stable, patient 5 days later. Consent is a process rather than a moment, and should be revisited in light of a patient’s changing condition and treatment requirements.

Seeking informed consent for routine procedures could lead to conflict if the patient or his or her surrogate refuses a recommended procedure, but wants ongoing critical care. Franklin and Rosenbloom explain, “... there are situations where, once the patient has consented to the general concept of treatment, negotiations over specific procedures and therapies can be counterproductive”.<sup>20</sup>

Certainly, the voluntariness of an ICU patient’s consent is limited by the fact that ongoing life-sustaining care is often contingent on invasive procedures occurring. The “choice” to undergo an intensive care procedure is, in many cases, an empty one. Marsillio and Morris found that 60% of procedures in a paediatric ICU were “strongly recommended”; a further 33% of procedures were considered “absolutely necessary”; and health care providers felt that parents had a genuine choice regarding the procedure in only 7% of cases.<sup>3</sup> This is a significant limitation of procedural consent in the ICU, but does not render the process worthless. Instead, in ICU procedural consent, the emphasis is on communication: providing information and presenting relevant options within the context of the patient’s illness.

Routinely obtaining informed consent for procedures in the ICU may inappropriately focus discussions between clinicians and families on procedures rather than on the patient’s overall treatment options and prognosis. This emphasis on technical details rather than the patient’s illness and prognosis can be misleading for families.

Patients and families may not want to engage in an informed consent process for procedures. Some patients prefer to be given very little information about proposed treatments or procedures, and defer their decision making to their treating doctor.<sup>21,22</sup> Research into consent for cardiac surgery suggests fairly stark divisions between patients who want to know “nothing” and patients who want to know “everything”.<sup>21,23</sup> However, it would be unreasonable to withhold information or discussions from all families in order to avoid giving unwanted information to some. A tiered approach to procedural consent, which allows patients and families to opt for more or less

information and discussion, could accommodate these varied expectations. The challenge lies in ascertaining how much information the patient or relative prefers. For example, they could be invited to ask for more or less detail as the consent discussion proceeds.

Patients and families from some cultures may not want to participate in an informed consent process, or at least not in its traditional form. The patient's sex, language and cultural background all shape expectations of the informed consent process.<sup>24</sup> The traditional or Western model of informed consent described by Beauchamp and Childress aims to accommodate patients' diverse cultural backgrounds by allowing them freedom to choose,<sup>6</sup> but this choice itself may be unwanted, or presented in a culturally inappropriate manner.

### The universal consent protocol

Some ICUs in the US have introduced a universal consent protocol<sup>13</sup> (UCP) as a way of expediting the procedural consent process. In this protocol, patients and families are given written information and a standardised consent form for several commonly performed procedures (eg, CVC insertion and endotracheal intubation) at the time of ICU admission.<sup>1</sup> Tracheostomy, PEG tube insertion and endoscopy are generally excluded from these forms. Patients and/or family members can consent to all the stated procedures, or consent to some but request specific discussion before nominated procedures, or not sign the consent form. If the form is not signed, specific consent is sought for each procedure. Davis and colleagues found that the use of such a UCP improved overall procedural consent rates in their ICU, without reducing the consenter's understanding of the procedures.<sup>1</sup> Stuke and colleagues found that 14% of respondent US critical care program directors reported that they were already using a UCP, and 78% were interested in introducing one.<sup>13</sup>

This protocol is strikingly efficient. It ensures that all patients and/or families receive a minimum amount of information about ICU procedures at the time of ICU admission. It is a tiered system, as families can choose a more in-depth procedural consent process by refusing to sign the form. The study of UCPs by Stuke and colleagues found that 4.4% of patients and/or families signed the form with some procedures excluded, and 5.2% of patients and/or families did not sign, preferring to be contacted about each procedure.<sup>13</sup> Conversely, families may opt out of detailed procedural information, consenting to the general concept of ICU care by simply signing the form.

However, this model of procedural consent places a premium on obtaining a signed consent form, prioritising medicolegal protection for the clinician ahead of respect for

patient autonomy. At worst, this blanket consent form may be little more than a waiver, with little recourse for discussion about procedures once it is signed. Manthous and colleagues found that hospitals that used a blanket consent form on hospital admission reported lower rates of procedure-specific informed consent.<sup>14</sup> This highlights the fact that audits of consent documentation do not necessarily reflect the quality or validity of the consent process.

It is not clear that a blanket consent form would serve its proposed legal purpose, as it cannot describe risk estimates for procedures in the patient's specific situation, nor how the harm–benefit ratio may change during the course of their illness.<sup>1</sup> This is a key problem with procedural consent for ICU patients; the same procedure may be performed repeatedly, with vastly different risks on each occasion. For example, risks associated with vascular access procedures increase in an increasingly coagulopathic patient. Also, the risks associated with a junior registrar performing a procedure are likely to be higher than when performed by an experienced proceduralist. A procedural consent process that allows ongoing discussion between clinicians, patients and families about invasive procedures in the context of the patient's illness would better serve patients and families, and also provide a more robust defence in the event of complications than a pre-emptive blanket consent form alone.

### Conclusion

Routinely obtaining consent for non-emergency procedures in the ICU would represent a significant change in practice. The ethical desirability of this change depends largely on the proposed consent process, ie, the extent to which the process accommodates the specific limitations of informed consent in the ICU and balances the interests of patients and clinicians (Table 3). Designing a process that achieves this balance represents a significant challenge. Blanket pre-emptive consent may not provide enough information for patients and families regarding specific procedures, espe-

**Table 3. An ideal intensive care unit procedural consent process**

- Efficiently provides information to patients and families, avoiding the need for repeated discussions or frequent overnight discussions
- Allows for ongoing discussion about procedures as needed
- Allows patients and families to choose to be more or less involved in decisions about procedures
- Avoids emphasising procedures ahead of prognosis and treatment aims, especially during valuable family-meeting times
- Does not delay timely interventions or disrupt patient care.

cially for procedures occurring several days after admission. Conversely, obtaining specific consent for each procedure could be unreasonably time-consuming for clinicians and families.

Procedural consent is a complex issue, worthy of further debate. It will be difficult to achieve consensus on which procedures require informed consent and how this should be obtained, partly due to significant variations in casemix, resources and patient demographics in Australian ICUs. Nonetheless, we should work to ensure that our policies address the unique challenges of procedural consent in the ICU, rather than simply being transposed, or imposed, from non-critical care environments.

### Competing interests

None declared.

### Author details

Lucy J Modra, Registrar, Intensive Care and Emergency Medicine

Andrew Hilton, Senior Intensivist

Graeme K Hart, Director, Department of Intensive Care

Austin Health, Melbourne, VIC, Australia.

Correspondence: lucy.modra@austin.org.au

### References

- 1 Davis N, Pohlman A, Gehlbach B, et al. Improving the process of informed consent in the critically ill. *JAMA* 2003; 289: 1963-8.
- 2 Raper RF, Fisher MM. Ethics of intensive care. In: Bersten AD, Soni N, editors. *Oh's intensive care manual*. 6th ed. Philadelphia, Pa: Butterworth Heinemann, 2009: 61-6.
- 3 Marsillio LE, Morris MC. Informed consent for bedside procedures in the pediatric intensive care unit: a preliminary report. *Pediatr Crit Care Med* 2011; 12: e266-70.
- 4 College of Intensive Care Medicine of Australia and New Zealand. Statement on the ethical practice of intensive care medicine. 2010. [http://www.cicm.org.au/cms\\_files/IC-9%20Statement%20on%20the%20Ethical%20Practice%20of%20Intensive%20Care%20Medicine.pdf](http://www.cicm.org.au/cms_files/IC-9%20Statement%20on%20the%20Ethical%20Practice%20of%20Intensive%20Care%20Medicine.pdf) (accessed Oct 2012).
- 5 Luce JM. Is the concept of informed consent applicable to clinical research involving critically ill patients? *Crit Care Med* 2003; 31 (3 Suppl): S153-60.
- 6 Beauchamp TL, Childress JF. *Principles of biomedical ethics*. 6th ed. New York: Oxford University Press, 2009.
- 7 Kirby MD. Informed consent: what does it mean? *J Med Ethics* 1983; 9: 69-75.

- 8 Sugarman J, McCrory DC, Powell D, et al. Empirical research on informed consent. An annotated bibliography. *Hastings Cent Rep* 1999; 29: S1-42.
- 9 Larobina ME, Merry CJ, Negri JC, Pick AW. Is informed consent in cardiac surgery and percutaneous coronary intervention achievable? *ANZ J Surg* 2007; 77: 530-4.
- 10 Astley CM, Chew DP, Aylward PE, et al. A randomised study of three different informational aids prior to coronary angiography, measuring patient recall, satisfaction and anxiety. *Heart Lung Circ* 2008; 17: 25-32.
- 11 Chenaud C, Merlani P, Ricou B. Informed consent for research in ICU obtained before ICU admission. *Intensive Care Med* 2006; 32: 439-44.
- 12 Vincent JL. Information in the ICU: are we being honest with our patients? The results of a European questionnaire. *Intensive Care Med* 1998; 24: 1251-6.
- 13 Stuke L, Jennings A, Gunst M, et al. Universal consent practice in academic intensive care units (ICUs). *J Intensive Care Med* 2010; 25: 46-52.
- 14 Manthous CA, DeGirolamo A, Haddad C, Amoateng-Adjepong Y. Informed consent for medical procedures: local and national practices. *Chest* 2003; 124: 1978-84.
- 15 Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. Sydney: ACSQHC, 2012. <http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf> (accessed Mar2014).
- 16 Schweickert W, Hall J. Informed consent in the intensive care unit: ensuring understanding in a complex environment. *Curr Opin Crit Care* 2005; 11: 624-8.
- 17 Skene L. *Law and medical practice: rights, duties, claims and defences*. 3rd ed. Sydney: LexisNexis Butterworths, 2008.
- 18 Williams BF, French JK, White HD; HERO-2 consent substudy investigators. Informed consent during the clinical emergency of acute myocardial infarction (HERO-2 consent substudy): a prospective observational study. *Lancet* 2003; 361: 918-22.
- 19 Douglas CD, McPhee JR. Informed consent: a review of the ethical and legal basis for medical decision-making for the competent patient. *ANZ J Surg* 2007; 77: 521-2.
- 20 Franklin C, Rosenbloom B. Proposing a new standard to establish medical competence for the purpose of critical care intervention. *Crit Care Med* 2000; 28: 3035-8.
- 21 Beresford N, Seymour L, Vincent C, Moat N. Risks of elective cardiac surgery: what do patients want to know? *Heart* 2001; 86: 626-31.
- 22 Curtis JR, Tonelli MR. Shared decision-making in the ICU: value, challenges, and limitations *Am J Respir Crit Care Med* 2011; 183: 840-1.
- 23 Ivarsson B, Larsson S, Lührs C, Sjöberg T. Extended written pre-operative information about possible complications at cardiac surgery -- do the patients want to know? *Eur J Cardiothorac Surg* 2005; 28: 407-14.
- 24 Clark PA. Intensive care patients' evaluations of the informed consent process. *Dimens Crit Care Nurs* 2007; 26: 207-26. □