

Defining Futile and Potentially Inappropriate Interventions: A Policy Statement From the Society of Critical Care Medicine Ethics Committee

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Objectives: The Society of Critical Care Medicine and four other major critical care organizations have endorsed a seven-step process to resolve disagreements about potentially inappropriate

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Dr. Kon disclosed other healthcare professional organization activities (President-elect, American Society for Bioethics and Humanities), disclosed government employment, and disclosed serving as an expert witness. Dr. Swoboda disclosed other healthcare professional organization activities (Surgical Infection Society, American Association of Critical-Care Nurses, Society for Simulation in Healthcare, International Nursing Association for Clinical Simulation and Learning member). Dr. Marshall disclosed relationships with providers of healthcare services (Consult for National Institutes of Health, and Academic Health Centers on Issues of Clinical and Research Ethics) and other healthcare professional organization activities (Consultant, National Institute of Allergy and Infectious Diseases, National Heart, Lung, and Blood Institute, and American Society for Bone and Mineral Research). Dr. Rincon disclosed relationships with providers of healthcare services (Otsuka, Bard), disclosed other healthcare professional organization activities (Neurocritical Care Society, American College of Chest Physicians), and received grant support (Genentech Research Grant). The remaining authors have disclosed that they do not have any potential conflicts of interest.

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treatments. The multiorganization statement (entitled: An official ATS/AACN/ACCP/ESICM/SCCM Policy Statement: Responding to Requests for Potentially Inappropriate Treatments in Intensive Care Units) provides examples of potentially inappropriate treatments; however, no clear definition is provided. This statement was developed to provide a clear definition of inappropriate interventions in the ICU environment.

Design: A subcommittee of the Society of Critical Care Medicine Ethics Committee performed a systematic review of empirical research published in peer-reviewed journals as well as professional organization position statements to generate recommendations. Recommendations approved by consensus of the full Society of Critical Care Medicine Ethics Committees and the Society of Critical Care Medicine Council were included in the statement.

Measurements and Main Results: ICU interventions should generally be considered inappropriate when there is no reasonable expectation that the patient will improve sufficiently to survive outside the acute care setting, or when there is no reasonable expectation that the patient's neurologic function will improve sufficiently to allow the patient to perceive the benefits of treatment. This definition should not be considered exhaustive; there will be cases in which life-prolonging interventions may reasonably be considered inappropriate even when the patient would survive outside the acute care setting with sufficient cognitive ability to perceive the benefits of treatment. When patients or surrogate decision makers demand interventions that the clinician believes are potentially inappropriate, the seven-step process presented in the multiorganization statement should be followed. Clinicians should recognize the limits of prognostication when evaluating potential neurologic outcome and terminal cases. At times, it may be appropriate to provide time-limited ICU interventions to patients if doing so furthers the patient's reasonable goals of care. If the patient is experiencing pain or suffering, treatment to relieve pain and suffering is always appropriate.

Conclusions : The Society of Critical Care Medicine supports the seven-step process presented in the multiorganization statement. This statement provides added guidance to clinicians in the ICU environment. (*Crit Care Med* 2016; 44:1769–1774)

Key Words: decision making; end-of-life care; ethics; ethics consultation; medical futility

In June 2015, the Society of Critical Care Medicine (SCCM), American Thoracic Society (ATS), American Association of Critical Care Nurses (AACN), American College of Chest Physicians, and European Society of Intensive Care Medicine (ESICM) published the ATS/AACN/ACCP/ESICM/SCCM Policy Statement on Responding to Requests for Potentially Inappropriate Treatments in Intensive Care Units (multiorganization statement) (1). The multiorganization statement defines futile interventions as those that simply cannot accomplish the intended physiologic goal. It defines proscribed treatments as those that are prohibited by applicable laws, judicial precedent, or widely accepted public policies (e.g., organ allocation strategies). It defines legally discretionary treatments as those for which there are specific laws, judicial precedent, or policies that give physicians permission to refuse to administer them. The multiorganization statement states that clinicians should not provide futile or proscribed interventions, and may choose to not provide legally discretionary treatments, and in such case clinicians should carefully explain the rationale for the refusal and may consider an ethics consultation if disagreements persist. In some cases, patients or families believe that clinicians are providing treatment that is inappropriate; however, such cases are not the subject of the multiorganization statement or the current statement.

The multiorganization statement defines “potentially inappropriate” treatments as those that have at least some chance of accomplishing the effect sought by the patient, but clinicians believe that competing ethical considerations justify not providing them. The statement also provides details regarding communication strategies and other methods to minimize conflict so that patients, surrogate decision-makers, and clinicians can reach mutually agreeable decisions about appropriate goals of care. The statement recommends that requests for potentially inappropriate treatment that remain intractable despite intensive communication and negotiation should be managed by a seven-step process: 1) Enlist expert consultation to continue negotiation during the dispute-resolution process; 2) Give notice of the process to surrogates; 3) Obtain a second medical opinion; 4) Perform review by an interdisciplinary hospital committee; 5) Offer surrogates the opportunity to transfer the patient to an alternate institution; 6) Inform surrogates of the opportunity to pursue extramural appeal; and finally 7) Implement the decision of the resolution process. The statement further specifies, “when time pressures make it infeasible to complete all steps of the conflict-resolution process and clinicians have a high degree of certainty that the requested treatment is outside accepted practice, they should refuse to provide the requested treatment and endeavor to achieve as much procedural oversight as the clinical situation allows” (1), that is, they should complete as much of the seven-step process as is practicable.

The multiorganization statement provides examples of potentially inappropriate treatments; however, a clear definition is not provided. The SCCM Ethics Committee believes that patients, families, and clinicians will benefit from a more consistent understanding of what generally constitutes inappropriate treatment, particularly in cases that involve time pressures that make it infeasible to complete all seven steps. Such a common understanding should decrease unwanted variability in patient care, although some variability will certainly persist. The SCCM Ethics Committee determined that a policy statement addressing this specific issue, based on empirical data and consensus opinion, is necessary. This statement was developed to broadly cover all ICUs, including, but not limited to, medical, surgical, trauma, neurologic, burn, cardiac, pediatric, pediatric cardiac, and neonatal ICUs. Because ICUs are highly variable, the committee focused on universal concepts in ICU care.

METHODS

A priori categories of potentially inappropriate interventions were developed. Categories included situations in which respondents would consider either cardiopulmonary resuscitation (CPR) or ICU interventions (often reported as mechanical ventilation) as inappropriate or futile, and similar situations in which respondents would not personally want CPR or ICU interventions (for complete details, see Appendix 1, Supplemental Digital Content 1, <http://links.lww.com/CCM/B979>).

Systematic review of publications in PubMed presenting data on futility or inappropriate interventions/treatments was performed. Inclusion criteria were English language reports of empirical research. Exclusion criteria were research performed in Asia or the Middle East (because these populations tend to have different standards of futility, including concepts of death by neurologic criteria) and research performed in third-world countries (because in these regions, decisions regarding appropriate and inappropriate interventions are often heavily influenced by limited resources). Abstracts for all reports were reviewed for primary screening, and full papers for all reports of empirical data were reviewed by two members of the writing committee. Recommendations were discussed by the full SCCM Ethics Committee throughout the writing process, and only those recommendations for which there was consensus were included.

DEFINING POTENTIALLY INAPPROPRIATE INTERVENTIONS

When asked to define potentially inappropriate interventions, physicians, nurses, and other healthcare staff appear to agree that life-prolonging interventions (or in some cases, interventions that merely prolong the dying process) are inappropriate when the patient will not survive outside the acute care setting or when the patient has irreversible severe neurologic injury (2–5). (nota bene: we use the term “potentially inappropriate” interventions for reasons articulated in the multiorganization statement. Empirical research assessing how physicians, nurses, patients, and family members define such interventions has

generally used the term “futile interventions.” As such, the data presented here regarding how individuals define potentially inappropriate interventions are based on research regarding how individuals define futile interventions and/or futility.) Three studies reported that when physicians were asked what they themselves would want, over 95% stated that they would not want CPR or mechanical ventilation if they had severe neurologic injury (persistent vegetative state [PVS], permanent coma) (6–8). In one study, approximately 90% of physicians stated that they would not want CPR or mechanical ventilation if they were unable to recognize people or to speak understandably (9). When asked about preferences in the case of advanced dementia, one study reported that 98% of physicians would not want CPR; another reported that 95% would not want mechanical ventilation and 76% would not want CPR (7, 8). One study reported that 87% of physicians would not want mechanical ventilation if they would not recover to survive outside the ICU (7).

These findings are consistent with the position statements of medical professional organizations. In 1991, the ATS asserted that an intervention is futile if it is highly unlikely to result in “meaningful survival” for that patient, and stated that such interventions could be withheld or withdrawn without consent of the patient or surrogate decision-maker (10). In 1995, the Canadian Medical Association advocated that health-care facilities develop policies to ensure a multidisciplinary approach to conflict resolution in cases of futile and nonbeneficial interventions. The statement asserted that interventions are nonbeneficial if there is no reasonable hope of recovery or if the person is permanently unable to experience any benefit (11). In 1997, the SCCM advocated a process-based approach for interventions that are not medically advisable and provided examples such as a patient in PVS (12). In 1999, the American Medical Association advocated a process-based approach to conflicts over futile interventions noting that such an approach should be enacted in cases when interventions merely prolong the dying process or when the patient is in PVS (13). In 2011, the California Medical Association issued a white paper and model policy that defined nonbeneficial interventions as those that “in a physician’s professional judgment, produces effects that cannot reasonably be expected to be experienced by the patient as beneficial or to accomplish that patient’s expressed and recognized medical goals, or has no realistic chance of returning the patient to a level of health that permits survival outside of the acute care setting” (14).

Fewer studies have assessed patient and family perceptions of inappropriate interventions. In one study, 90% of patients agreed that physicians need not offer mechanical ventilation if the physician judges it to be futile (15). Another study demonstrated wide agreement among patients that merely keeping organs alive is not appropriate (16). In another study, when patients with chronic obstructive pulmonary disease were given a scenario where they themselves were in permanent coma, 91% stated that they would not want CPR and 94% would not want to be on a ventilator; when given a scenario where they had advanced dementia, 82% would not want CPR

and 85% would not want to be on a ventilator (8). In the same study, when homeless individuals were given a scenario where they were in permanent coma, 67% would not want CPR and 58% would not want to be on a ventilator; when given a scenario where they had advanced dementia, 77% would not want CPR and 68% would not want to be on a ventilator (8). Two studies suggest that Caucasians are generally more inclined to refuse life-prolonging interventions than their non-Caucasian counterparts; however, even among minority groups, the majority appear to generally agree with the statements above (6, 8). These data suggest that a majority of patients and family members may be in general agreement with healthcare professionals regarding what constitutes potentially inappropriate treatment.

Based on these data and consensus opinion of the SCCM Ethics Committee, the primary goal of ICU care is to provide treatment to patients for whom there is a reasonable expectation of survival outside the acute care setting with sufficient cognitive ability to perceive the benefits of treatment. “ICU interventions should generally be considered inappropriate when there is no reasonable expectation that the patient will improve sufficiently to survive outside the acute care setting, or when there is no reasonable expectation that the patient’s neurologic function will improve sufficiently to allow the patient to perceive the benefits of treatment.” This definition should not be considered exhaustive; there will be cases in which life-prolonging interventions may reasonably be considered inappropriate even when the above criteria are not met. As evidenced by the data presented above, it is expected that some patients and families will object to decisions to limit or withdraw life-prolonging interventions. When the patient or surrogate decision maker(s) does not agree with the clinician’s decision, the clinician should follow the seven-step process outlined above before limiting or withdrawing life-prolonging interventions (1). As noted in the multiorganization statement, retrospective review, reporting, and tracking of such cases and outcomes are important to ensure fairness and equitability, and to follow for any unintended consequences (1). When time pressures make it infeasible to complete all seven steps and there is no reasonable expectation that the patient will improve sufficiently to survive outside the acute care setting with sufficient neurologic function to perceive the benefits of treatment, clinicians should refuse to provide the requested treatment and should complete as much of the seven-step process as the clinical situation allows (1). Such a decision is consistent with professional standards and good medical practice.

Some providers and institutions may believe that they should never overrule a patient or surrogate decision maker who is requesting life-prolonging interventions. These providers and institutions may support providing ICU care to a patient even when the above definition is met (17). Nothing in this statement should be construed as restricting the ability of such providers and institutions to provide such care. The purpose of this statement is to provide guidance that may be used by providers and institutions in cases in which they believe specific interventions are potentially inappropriate,

particularly in time-limited situations. The guidance provided in this statement should be considered neither exhaustive nor obligatory.

At times, it may be appropriate to provide time-limited ICU interventions to a patient when the above definition is met if doing so furthers the patient's reasonable goals of care (17). For example, a patient with end-stage cancer who will not survive outside the acute care setting may have a strong desire to be kept alive long enough to say "goodbye" to her daughter who is travelling to the hospital from far away. In such a case, although the default decision would be that ICU interventions are not appropriate, providers may agree that providing ICU interventions for a period of time to allow the patient to see her daughter is appropriate. Such decisions should be made on a case-by-case basis.

In some ICUs, it may be appropriate to admit patients for specific palliative interventions or for end-of-life care that provides comfort through the dying process. Such admissions, however, may not be appropriate in other ICUs. When the patient is experiencing pain or suffering, palliative interventions (i.e., treatments to ameliorate pain and suffering) are always appropriate. Although providing life-prolonging interventions may be deemed inappropriate in some cases, patients have a right to high-quality holistic care to relieve pain or suffering if they are experiencing such symptoms.

CONSIDERATIONS IN PROGNOSTICATION

When determining whether ICU interventions are appropriate in a specific case, clinicians must establish the prognosis in regard to survival outside the acute care setting and recovery of cognitive ability sufficient to perceive the benefits of treatment. Such prognostication, however, can be difficult. Objective scoring systems have been developed, and have demonstrated high reliability in specific disease and injury states (18–27). Data suggest that for some specific categories of patients, clinicians can accurately predict those who will not survive outside the acute care setting and/or will not regain meaningful cognitive ability (28–44). Such data must be reevaluated periodically in light of ever-improving diagnostic and prognostic ability and as advances in medical and surgical treatments improve outcomes (45–49).

Although prognostication is highly accurate and reliable in some specific disease and injury states, our ability to accurately predict survival and neurologic outcome for many patients remains suboptimal, and healthcare professionals are often overly pessimistic (50–53). Although providers with more experience are generally more accurate in their prognostic predictions (54, 55), neither available scoring systems nor providers are highly accurate for many patients (50, 56, 57). There are some data to suggest, however, that over the course of the patient's ICU stay, prognostication does improve (58, 59). In the case of infants and children, clinicians must consider the potential for cognitive development over time, and should assess the likelihood that the child might develop sufficient cognitive ability to perceive the benefits of treatment in the future.

Data further suggest that patients' and families' confidence in providers' abilities to prognosticate is suboptimal. One study assessed family members' belief that doctors' predictions of survival are accurate and their willingness to withdraw life-prolonging interventions based on such predictions. The investigators found that 40% of family members did not believe that doctors can accurately predict 0% survival, and most did not trust the doctor's statement of 0% survival. In this study, 32% of family members stated that they would continue life-prolonging interventions even if the doctor stated that there was less than 1% chance of survival, and 18% stated that they would continue life-prolonging interventions even if the doctor stated that there was a 0% chance of survival (60). As suggested in the multidisciplinary statement, specific strategies are essential to build trust and optimize communication. Such strategies include active listening during family meetings, provision of emotional support and trust-building techniques, presentation in clear language that is free from medical jargon, and actively eliciting and attending to the patient's values and preferences (see the multiorganization statement for complete recommendations) (1).

Such data suggest that providers should be cautious in survival and neurologic prognostication. To improve prognostic certainty, providers should consider the patient's course over time as well as the opinions of other experts in critical care medicine, neurocritical care, and/or other specialties.

RECOMMENDATIONS

1. Appropriate goals of ICU care include:
 - a. Treatment that provides a reasonable expectation for survival outside the acute care setting with sufficient cognitive ability to perceive the benefits of treatment.
 - b. Palliative care that provides comfort to patients through the dying process may be an appropriate goal of care in some ICUs.
2. ICU interventions should generally be considered inappropriate when there is no reasonable expectation that the patient will improve sufficiently to survive outside the acute care setting, or when there is no reasonable expectation that the patient's neurologic function will improve sufficiently to allow the patient to perceive the benefits of treatment.
3. The above definition should not be considered exhaustive. There will be cases in which life-prolonging interventions may reasonably be considered inappropriate even when the above definition is not met.
4. Decisions regarding whether specific interventions are inappropriate should be made on a case-by-case basis (1).
5. The term "futile" should be used only in the rare circumstance that an intervention simply cannot accomplish the intended physiologic goal. Clinicians should not provide futile interventions and should carefully explain the rationale for the refusal (1).

6. As detailed in the ATS/AACN/ACCP/ESICM/SCCM Policy Statement on Responding to Requests for Potentially Inappropriate Treatments in Intensive Care Units (1), a process-based approach should be used whenever an intervention is considered potentially inappropriate yet the patient or surrogate decision maker(s) requests the intervention.
7. When time pressures make it infeasible to complete all seven steps and the above definition is met, clinicians should refuse to provide the requested treatment and endeavor to complete as much of the seven-step process as the clinical situation allows (1). Such a decision is consistent with professional standards and good medical practice.
8. At times, it may be appropriate to provide time-limited ICU interventions to a patient even when the above definition is met if doing so furthers the patient's reasonable goals of care.
9. If the patient is experiencing pain or suffering, treatment to relieve pain and suffering is always appropriate.

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