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## Methods

Using the Delphi technique, panelists rated levels of agreement with statements describing how analgesics and sedatives should be given to dying ICU patients and how palliative care should be distinguished from euthanasia. Participants were drawn from 3 panels: 1) Canadian Academic Adult Intensive Care Fellowship program directors and Intensive Care division chiefs (N = 9); 2) Deputy chief provincial coroners (N = 5); 3) Validation panel of Intensivists attending the Canadian Critical Care Trials Group meeting (N = 12).

#### Results

After three Delphi rounds, consensus was achieved on 16 statements encompassing the role of palliative care in the intensive care unit, the management of pain and suffering, current areas of controversy, and ways of improving palliative care in the ICU.

### Conclusion

Consensus guidelines were developed to guide the administration of analgesics and sedatives to dying ICU patients and to help distinguish palliative care from euthanasia.

### Background

Intensivists are confronted with a difficult balance in providing analgesia and sedation for dying patients. If they administer too little to control distress, they provide inadequate palliative care and patients suffer [1-7]. If they administer too much for life to continue, they may risk prosecution for committing euthanasia [6,8-15]. With recently increasing legal scrutiny, fear of prosecution may continue to grow and perpetuate the undertreatment of pain and suffering at the end of life [1-3], [7-16].

The alleviation of pain and suffering is crucial to the provision of quality end-of-life Care [17]. While the US Society for Critical Care Medicine (SCCM) has published practice parameters[18] for the provision of analgesia and sedation in critically ill ICU patients, no guidelines exist for analgesic and sedative use in dying patients. In Canada, the Chief Coroner of Ontario has defined palliative care [19] to help coroners distinguish palliative care from euthanasia; however, these guidelines are not specific to the ICU and give no specific guidance on how to determine whether the doses given were commensurate with patient distress.

The purpose of this study is to develop consensus guidelines on the use of analgesia and sedation in dying ICU patients. Clear guidelines will help develop a standard of care, diminish the risks of under-medication (inadequate palliative care) and over-medication of pain and suffering (possible euthanasia), and thereby improve the overall quality of end-of-life care in the ICU.

#### Methods

#### Participants

Three panels were used in this study: The first Delphi panel was formed by approaching the Adult and Pediatric Critical Care fellowship program directors from all of the Canadian academic centers; in academic centres without a Critical Care fellowship program, the Intensive Care Division Chief was approached. Fellowship program directors and division chiefs were chosen since they represent an easily identifiable group of Intensivists who usually act as opinion leaders in Critical Care medicine in their academic centres. The continuing medical education literature has shown the importance of opinion leaders in changing current practice [20]. By using opinion leaders to develop these guidelines, we hoped to increase the likelihood of their eventual dissemination and use. Intensivists in non-academic centres were excluded in order to ensure panelists were "experts" in critical care medicine. In Canada, non-academic ICUs frequently combine Intensive Care/Coronary Care Units (ICU/CCU) and may be staffed by physicians who have not been formally trained in Critical Care Medicine. Out of a possible 27 panel members (13 adult, 14 pediatric), 19 (9 adult, 10 pediatric) agreed to participate. Refusals to participate were predominantly attributed to difficulty in fulfilling the time commitments needed to participate in the study (n = 2 adult, n = 3 pediatric); no reasons were provided in the remaining cases (n = 2 adult, n = 1 pediatric). As the results from the second Delphi round were analyzed, it became clear that a simple consensus statement was not appropriate for both adult and pediatric patients. This paper reports on the adult consensus statement based on the responses of the 9 adult Intensivists: 2 Anesthetists, 4 Respirologists, 2 Internists, and 1 Surgeon; it included 7 men and 2 women.

The second Delphi panel was formed by approaching all of the provincial Deputy Coroners/Medical

Examiners. Of a possible 14 panel members, 5 (all men) agreed to participate. Reasons for refusal included lack of time (n = 5), and lack of knowledge required to answer the initial Delphi questionnaire (n = 1); no reason was given in the remaining cases (n = 3). Coroners/medical examiners were consulted to build understanding between the Intensivists and coroners regarding what constitutes good palliative care in the ICU setting and because upon review of a patient's death, coroners/medical examiners are expected to be able to distinguish palliative care from euthanasia in all clinical settings.

Because our goal was to develop consensus guidelines to guide physicians ordering analgesia and sedation for dying patients – and thereby improve the quality of end-of-life care they prescribe – ICU nurses and other allied health professionals were not used in the development of these guidelines.

The third panel was composed of a convenience sample of the 12 academic Adult Intensivists who attended the End-of-Life (EOL) Day of the national Canadian Critical Trials Group (CCCTG) meeting in April 1999. These Intensivists, composing the validation panel, all have an interest in researching the care received by dying patients in the ICU. All 12 EOL Day attendees volunteered to participate. Their responses were used to validate the consensus statements obtained from the original two panels described above. The validation panel was composed of 6 Internists, and 6 Respirologists; it included 8 men and 4 women.

#### Consensus process

This study used the Delphi method to develop a consensus statement on the appropriate use of analgesics and sedatives in dying ICU patients. The Delphi method involves several iterations ("rounds") of a questionnaire until consensus is achieved within the chosen panel of "experts" [21-27].

Panelists were provided with background information on the problems of pain control in the ICU; problems in the provision of quality end-of-life care; the importance of a consensus statement on the use of analgesics and sedatives in dying ICU patients; and definitions of palliative care, euthanasia and assisted suicide based on a MEDLINE review of the literature from 1970–1999, prepared by the authors. While definitions of euthanasia and assisted suicide were provided, our goal was not to debate whether these practices should be legalized and literature to support either side of this current debate was not presented to panelists. Responses to the initial Delphi questionnaire were based on this review of the literature and on the "expert" knowledge of the panel members.

In the first Delphi round, the Intensivist panel was asked a series of 9 open-ended questions describing how analgesics and sedatives should be given to dying ICU patients and how palliative care should be distinguished from euthanasia (Table <u>1</u>). The coroner/medical examiner panel was asked 8 questions; their questionnaire was the same as the Intensivists', but the first question was omitted because it required "expert" clinical knowledge that the coroners would not possess. Responses to all Delphi rounds were obtained via mail, fax and e-mail.

Table 1. Initial Delphi Questionnaire ---- Intensivists

Since our goal was to develop Intensivist-based consensus guidelines, the second Delphi round involved the Intensivist panel only. The questions and concerns raised by the coroner panel in the first Delphi round were inserted into the appropriate section of the document that had been generated by the Intensivist panel. Intensivist panelists were then asked to comment on the document generated in the first round, clarify any obscurities, and raise any questions not adequately addressed. They were asked to respond to new questions that were generated from either the qualitative analysis of their previous responses, or from the responses of the coroner panel in the first Delphi round. They were also asked to rate their level of agreement with each section and the overall document on a Likert scale ranging from 1 (complete disagreement) to 7 (complete agreement).

The third Delphi round involved both adult Intensivist and coroner panels. A summary of each section of the document generated in the second round – which represented the proposed consensus statement for that section – was inserted as an italicized statement at the beginning of each section. Panelists were then asked to rank their agreement with each consensus statement on a Likert scale, and were asked to identify modifications that would allow them to agree completely with each statement. They were also asked to rank their overall agreement with the document and, again, identify changes that would allow them to agree completely with the document. Median scores from the second round were then presented to panelists in the third Delphi round, enabling individual panel members to compare their level of agreement with that of other panelists. A fourth Delphi round was not required since consensus was achieved in the third round.

The third panel (validation panel) was presented with the final consensus statements obtained after the third Delphi round. They were also asked to rate their agreement with each statement on the same Likert scale. If they gave any statement a score less than 5, they were again asked to identify modifications that would allow them to agree completely with that statement.

### Data analysis

The responses of the Intensivists and coroner panels were analyzed separately. Qualitative analysis was performed by content analysis in each round [27]. Initially open coding was used to give conceptual labels to randomly selected panelist responses [27]. These conceptual labels generated the formation of categories (or sections) [22,23,27]. Subsequently, the properties of each category were delineated [27]. The responses of all panel members carried equal weight [22,27].

Since a normal distribution could not be assumed, the median score obtained from each section was used to determine agreement among panelists. It was stipulated that consensus was determined as 80% agreement (a median Likert score of 5.6 on 7 point scale) within the initial 2 panels (Intensivists and coroners) [21,22]. It was decided *a priori* that statements which did not achieve a Likert score of 5.6 would be discarded.

No modifications were made to the statements as a result of the validation panel's comments. No statements were discarded.

#### **Research ethics**

This study was approved by the University of Toronto's Research Ethics Committee. Informed consent was obtained from each panel member. Responses were kept confidential and, after responses were received by the principal investigator; all identifying information relating to the individual panel member was removed.

#### Results

In the third round, consensus was obtained in both Delphi (Intensivist and coroner) panels on 16 statements. These statements can be organized into 4 categories (tables 2,3,4,5). The first category (table <u>2</u>) discusses 1) how palliative care is different in the ICU than in other settings, 2) the role of palliative care in the ICU, and 3) the difficulties in assessing pain and suffering that are specific to the ICU.

Table 2. Palliative Care in the ICU

Table 3. Management of Pain and Suffering

Table 4. Current areas of Controversy

Table 5. Ways of Improving Palliative Care in the ICU

The second category of consensus statements (table <u>3</u>) describes the management of pain and suffering in the ICU. These guidelines provide practical guidance on what clinical factors to consider when selecting an initial starting dose of analgesics and sedatives and how to judge whether an effective level of palliation was achieved. In view of the high doses of drugs used in the ICU, the guidelines emphasize that a maximum dose does not exist but rather, the palliation of pain and suffering must be individualized to each dying patient and drugs administered in accordance with clinical need.

The third category of consensus statements (table <u>4</u>) focuses on areas of controversy in the current literature. These statements discuss the role of palliation in persistently vegetative patients, and describe how dying patients paralyzed with neuromuscular blockers should be managed. According to participants, terminal sedation represents another means of alleviating pain and suffering at the end of life and is not euthanasia. The principle of double effect whereby analgesics and sedatives may be administered to alleviate distress even though death may be hastened by their administration was seen to be useful in allowing physicians to achieve an effective level of analgesia. The physician's intent when administering these drugs was seen as the distinguishing factor between palliative care and euthanasia. Documentation of the reasons for withholding/withdrawing life-sustaining treatments and the ways pain and distress will be alleviated is important. This not only ensures that the physician's intent in ordering and administering analgesics and sedatives is clear, but improves the quality of end-of-life care within the ICU by detailing a clear and comprehensive treatment plan.

Finally, the fourth category of consensus statements (Table <u>5</u>) discusses how palliative care in the ICU can be improved in the future through research and ongoing education of the staff. The guidelines explore the role of emotional and psychological support of the ICU staff to help them deal with the frequency of deaths in critically ill patients. Such support will hopefully increase their abilities to cope with the emotional and psychological stress in caring for critically ill patients and allow them to provide consistently good palliative care. The guidelines propose increasing ties with Palliative Care Medicine. Traditionally considered to be the polar opposite field in the spectrum of care, Palliative Care Medicine may be invaluable in helping to improve the quality of end-of-life care in the ICU setting.

All guidelines achieved high degrees of consensus. The final median Likert scores of all three panels are provided in table  $\underline{6}$ .

Table 6. Median Likert Agreement Scores ----- Final Delphi Round

#### Discussion

The goal of this study is to develop consensus guidelines on analgesia and sedation that consider the unique challenges encountered when palliating dying ICU patients, and help distinguish palliative care from euthanasia in the ICU setting. The guidelines are not intended to argue for or against the legalization of euthanasia. Our hope is that the guidelines will decrease the confusion and anxiety regarding the use of opiates and sedatives at the end of life and thereby improve the quality of care received by dying patients. To meet this goal, we have divided the guidelines into sections describing palliative care in the ICU setting, management of pain and suffering, areas of controversy, and ways of improving palliative care in the ICU.

A recent review of the literature by Ostermann et al. [28] revealed the paucity of good randomized controlled trials on sedation in ICU patients. Research has revealed problems in alleviating pain even among skilled palliative care providers [1-4,29,30] and there is no proof in the current literature that Intensivists are better at relieving their dying patients' distress than other physicians [3]. Healthcare providers withdrawing treatments from dying patients frequently encounter apprehension and concern from surviving family members about how their loved one's pain and distress will be treated. In these situations of withdrawal of life-sustaining treatment, both healthcare providers and family members hope for a speedy, comfortable death in which pain

and other distressing symptoms are well controlled and the process of dying is accomplished in peace with loved ones at the bedside [<u>17</u>]. However, questions by family members often reveal concern that their loved one's final moments will be filled with suffering, or, alternatively, that drugs such as opiates and benzodiazepines given by the healthcare team will unduly hasten the dying process and/or kill their loved one [<u>1-3</u>],[<u>7-16,32,33</u>].

Cases of euthanasia committed by healthcare providers have occurred and receive widespread media attention [9-15]. These highly publicized cases of euthanasia, restrictive prescribing legislation, and increased scrutiny by coroners, licensing bodies, families and the public, lead healthcare providers to under-treat the pain and symptoms of their dying patients [1-16,32,33]. Furthermore, fears of being misunderstood – of having their intent to palliate mistaken for an intent to kill – are currently being exacerbated by debates/articles in the medical literature [34-37]. The authors of these articles seek to promote the legalization of euthanasia by misappropriating ethical principles such as the Principle of Double Effect in order to confuse their colleagues and diminish the fundamental and very real differences between the practices of palliation and euthanasia [34-37]. An unintended consequence may be to increase the reluctance on the part of health care providers to administer adequate analgesia and sedation to dying patients.

The US Society for Critical Care Medicine practice parameters [18] and in Canada, the Ontario Chief Coroner's memo on palliative care [19], have established practice parameters on analgesia and sedation. Unlike our guidelines, the SCCM practice parameters [18] do not discuss the use of opiates and sedatives in dying patients, while the Ontario Chief Coroner's guidelines[19] do not relate to the ICU. Brody et al. [38] also developed guidelines for compassionate management in withdrawing intensive life-sustaining treatments; however, these guidelines were based on a literature review, did not use consensus methodology or involve a national panel of Intensivists and only represented the authors' opinions. Furthermore, Brody et al. [38] do not attempt to address how palliative care can be distinguished from euthanasia in the ICU.

To our knowledge, our consensus guidelines on analgesia and sedation in dying ICU patients are the first of their kind developed using consensus methods and involving coroners. The use of consensus methodology and the participation of coroners will hopefully serve to clarify the areas of controversy, their nature and help us resolve these dilemmas in the future. As well, participation by coroners will hopefully result in increased understanding of the difficulties faced both by those caring for the dying and for those asked to review the care received – for it is only through open dialogue that we can ever hope overcome any doubts about intent – to palliate or to kill – and thereby improve the quality of end-of-life care.

This study has three main limitations. First, our guidelines use a small group of expert Intensivists and Coroners to focus attention on how pain and suffering ought to be palliated at the end of life. While our panel sizes were small, saturation of responses occurred in each Delphi round, a sign of credibility (internal validity). Although we attempted to validate our consensus statements by using an independent panel of Intensivists, this panel was also small. While the validation panel was a convenience sample, panelists were representative of Intensivists across the country and agreed with all of the developed consensus statements, a sign of transferability (external validity).

Second, our consensus guidelines are physician-based. They represent an initial attempt to improve the quality of end-of-life care in the ICU by describing best practice in regards to the administration of analgesics and sedatives to dying patients. In order to improve the overall quality of end-of-life care in the ICU, these consensus guidelines need to be incorporated into an overall program to educate the ICU staff in caring for dying patients. These guidelines can then be discussed and modified as needed by other members of the ICU team

Third, our consensus guidelines are developed from a professional and not a patient's perspective. Intensivists' assumptions on how to best treat pain and suffering at the end of life may differ markedly from patients' and families' lived experiences. More research is needed to explore the patient's and family's perspective on how palliative care can be improved in the ICU.

# Conclusion

We have developed a set of guidelines that can be used by critical care societies, training programs, and coroners alike to guide the provision of analgesia and sedation in the ICU. Application of our guidelines should minimize the twin risks of under-treatment (and its resultant pain and suffering) and over-treatment (and its resultant risk of prosecution for euthanasia) for dying patients in the ICU.

# Competing interests

None declared.

# Authors' contributorship

LAH: involved in research planning, design, data collection and analysis, writing of paper, revising of paper, and approving final draft. WRCH: research project design, interpretation of results, critical appraisal of paper drafts, and approval of final draft. LLC: research methods, design, data analysis, critical appraisal of paper drafts, and approval of final draft. PAS: research project concept, design, methods, interpretation of results, actively involved in writing/revising drafts of paper, and approval of final draft.

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