Consensus Guidelines on Analgesia and Sedation in Dying ICU Patients

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Consensus Guidelines on the Use of Analgesia and Sedation in Dying ICU Patients,

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BACKGROUND: Intensivists must provide palliative care to dying patients but risk prosecution for assisted death if they administer too much analgesia and sedation.

PURPOSE: To develop consensus guidelines on analgesia and sedation in dying ICU patients, and help distinguish palliative care from euthanasia.

METHODS: *Design*: Delphi technique. *Sample*: Three panels: 1) Academic Adult Intensive Care program directors and ICU directors in academic centres without a fellowship program 2) Deputy chief provincial coroners; 3) Validation panel of Intensivists from the 1999 'Canadian Critical Care End-of-Life' meeting. *Intervention*: Statements about analgesia and sedation. *Outcome measures*: A Likert scale indicating agreement with the statements, and indications of what modifications would increase agreement. *Analysis*: A median value of 5.6 (80% agreement) was stipulated a priori to indicate consensus.

RESULTS: Consensus was achieved on 16 statements.

CONCLUSIONS: We developed consensus guidelines on palliation in the ICU that will help distinguish palliative care from assisted death.

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Glossary of Terms

Assisted Suicide: "the act of killing oneself intentionally with the assistance of another who provides the means, the knowledge or both" (79).

Euthanasia: "the deliberate act undertaken by one person with the intention of ending the life of another person in order to relieve that person's suffering where that act is the cause of death" (78). Three categories are currently described in the literature: a) voluntary (in accordance with the wishes of the competent patient), b) nonvoluntary (when the wishes of the patient are not known) and, c) involuntary (done against the wishes of a patient) (78).

Neuromuscular Blockers: drugs which cause paralysis of skeletal muscle. Indications for use in the Intensive Care Unit include intubation, inability to oxygenate/ventilate on a mechanical ventilator despite heavy sedation, shivering in head injured patients (148).

Palliative Care: a "program of active and compassionate care primarily directed towards improving the quality of life for the dying. It is delivered by an interdisciplinary team that provides sensitive and skilled care to meet the physical, psychosocial and spiritual needs of both the patient and family" (18).

Principle of Double Effect: a principle used to justify why certain practices (acts of intervention or omission) are morally permissible while others are not (8,9). It is usually invoked in situations where it is impossible to avoid all harms (9). In order to apply the principle of double effect, four conditions must be met (8,9): 1) the act must not belong to a class of actions that are wrong even aside from their bad effects (e.g. killing except in self-defense, capital punishment and wars); 2) the good effect (e.g. pain relief) and not the evil effect (e.g. killing) must be intended; 3) the evil effect (killing) must not be a means to the good effect (pain relief); and 4) the good effect (pain relief) must outweigh the evil effects (killing).

Terminal Sedation: a continuous intravenous infusion of narcotics, benzodiazepines or barbiturates used, either alone or in combination, to sedate and relieve the patient's suffering until death ensues from the underlying disease (14).

AIM AND OBJECTIVES

- The goal of this project is to develop consensus guidelines for the use of analgesia and sedation in patients dying in Intensive Care Units (ICUs) and to help distinguish palliative care from euthanasia/assisted suicide.

LITERATURE REVIEW

1. STATEMENT OF THE PROBLEM:

Intensivists are confronted with a difficult balance in providing analgesia and sedation for dying patients. One the one hand, if they provide too little, they risk providing inadequate palliative care (as defined in glossary) and patients suffer (1-6,23). On the other hand, if they administer too much (overtreatment), they may risk prosecution for committing euthanasia (as defined in glossary) (6, 71-77). With recent increases in legal scrutiny, these fears of prosecution may continue to grow and perpetuate the undertreatment of pain and suffering at the end-of-life (7,71-77).

The ethically sanctioned "principle of double effect", which permits physicians and nurses to administer narcotics and sedatives to palliate dying patients, even though their administration may foreseeably hasten death, may be used in attempts to distinguish palliative care from euthanasia (6,8-11,13). However, the principle of double effect can be confusing to health care providers. Furthermore, while it was recognized in the US Supreme Court decisions in *Vacco v. Quill* and *Washington v. Glucksberg* (11,13), the principle of double effect has not been legally sanctioned in the Canadian Criminal Code despite the 1983 Law Reform Commission's recommendations (12).

Intensivists are sometimes unable to control their patients' pain and suffering with the intermittent intravenous administration of drugs. If intermittent administration is insufficient to provide palliation, continuous intravenous infusions of narcotics and sedatives may be used to sedate the patient until death ensues from the underlying disease state. This practice, known as "terminal sedation" in the current literature, can be prone abuse and is viewed with suspicion by healthcare professionals, lawyers and the public (14,145).

The alleviation of pain and suffering is crucial to the provision of quality end-of-life care (15). While the Society for Critical Care Medicine (SCCM) has published practice parameters (16) for the provision of analgesia and sedation in ICU patients, no guidelines exist for analgesic and sedative use in dying patients. Moreover, in order to help its coroners distinguish palliative care from euthanasia/assisted suicide, the Ontario Chief Coroner's office has issued a memo (17) defining "palliative care" which was subsequently circulated to all provincial coroners' offices. This definition of "palliative care" is not specific to the ICU and, while it recognizes that palliation must be given in proportion to pain and suffering, no help is given in determining if amounts were indeed commensurate with patient distress.

By developing clear consensus guidelines for analgesia and sedation in dying ICU patients, this study develops a standard of care, diminishes the risks of undertreatment (inadequate palliative care) and overtreatment (euthanasia/assisted suicide) of pain and suffering, and thereby improves the overall quality of end-of-life care in the ICU.

2. PALLIATIVE CARE.

Palliative Care is defined as: a "program of active and compassionate care primarily directed towards improving the quality of life for the dying. It is delivered by an interdisciplinary team that provides sensitive and skilled care to meet the physical, psychosocial and spiritual needs of both the patient and family" (18).

As emphasized by numerous commentators including the Law Reform Commission of Canada (12) and the Special Senate Committee (19), palliative care is ethical and legal.

2.1. Importance of Palliative Care in Critically Ill Patients.

Originating in the 1960s, ICUs were designed to use the most advanced, aggressive technology available to save lives, regardless of the cost (127). Since the primary goal of the Intensive Care Unit was (and still is) to save lives, Intensivists perceived death as a personal failure (20,21). Today, the limits of ICU technology are better recognized and the anticipated quality of life of surviving patients plays a much greater role in its use (20-22).

Currently, mortality rates in most ICUs range from 9-12% in adult units and 5 % in pediatric units (23). A large proportion of ICU deaths, in some studies 70% of deaths, are secondary to the withdrawal or withholding of life sustaining treatments (24). However, when the founding philosophy of Intensive Care Medicine is taken into account, it is not surprising that little attention has been given to exploring and meeting the needs of dying patients or their families in the ICU. Today, research continues to grow in this aspect of ICU medicine. This thesis is both a reflection of the current interest in end-of-life care in the ICU and a call for even greater efforts to discover and meet the needs of dying patients and their families.

Fears of a technological, prolonged, solitary death filled with pain and suffering has lead to public support of efforts to legalize euthanasia/assisted suicide (25). Death in the ICU would appear to epitomize all these fears and is often portrayed as the one of the most horrible deaths imaginable (20,21). Certainly, death in the ICU will always be different than death in other settings: the technology, the short time from diagnosis to death, the emotional and psychological burden of critical illness on patients and families cannot render it otherwise. These differences and legitimate fears of technology which was originally designed to save/prolong lives and now causes a prolonged, painful dying process, call for a concerted effort to ensure the best possible care is given to dying patients in the ICU.

While few studies exist, research has shown that families appreciate the continuing emotional and psychological support of the ICU staff as life-sustaining treatments are being withdrawn (Bowman K. unpublished data, University of Toronto). Whether, in these times of limited resources, patients should be permitted to die in the ICU or should be transferred to another location once it becomes clear that their death is inevitable, is, at least to some extent, a resource allocation question and will not be addressed here. Currently, patients do die in the ICU and the fact that Intensive Care Medicine involves caring for dying patients and their families cannot be ignored. Efforts must be made to overcome the fears and public perception of what death in the ICU entails.

As it becomes clear that life-sustaining therapies are not succeeding or if the therapies needed are too burdensome, the struggle to maintain life is replaced by a gradual acceptance of the inevitability of death. The goals of care then shift and, while maximizing the quality of (remaining) life is still as important as before, easing pain and suffering assumes an even greater importance. Thus, while both strive to maximize quality of life and ease pain and suffering, the primary goals of therapy in critical illness are on a continuum of care with ICU and palliative care units located at opposite ends of the spectrum. However, consideration of palliative care principles will hopefully improve the quality of end-of-life care provided to dying ICU patients and families. As suggested by commentators on the euthanasia/assisted suicide debate (12,25), perhaps by improving our care of these patients, the question of whether to legalize euthanasia/assisted suicide will cease. This argument and others in the euthanasia/assisted suicide debate will be explored in greater depth in subsequent sections.

2.2. Evaluation of Pain in the ICU.

Evaluating pain in the ICU is very difficult. Communication barriers imposed by the patients' underlying health, his/her acute critical illness, the effects of drugs on his/her level of consciousness and ability to concentrate, as well as the ICU environment, make assessments a challenge (26). While the patients' complaints of pain are usually the most important indicators, few ICU patients are able to communicate effectively with their healthcare providers (26-29). Since past experience with pain, and ethnic and cultural values play important roles in the patients' perception of pain, families may provide invaluable assistance in evaluating any current pain (26).

Communication barriers may oblige Intensivists to use descriptive tools such as visual analog scales (VAS), verbal descriptor scales (VDS), and numeric rating scales (NRS) to assess pain and the effectiveness of its relief (26,29). The main disadvantage of these tools is that they require some cognitive function and many ICU patients will be unable to use them (26). VAS may be used by healthcare providers to evaluate pain and some studies in burn patients have correlated nurses' and patients' assessments of pain (26). However, VAS are prone to observer bias and studies have shown 34.5% to 53.4% of nurses underestimate pain (26). No studies have examined the use of these scales in the assessment and relief of pain and/or suffering in dying patients.

Frequently, the ICU staff must therefore rely on insensitive, non-specific behavioral and physiological parameters (such as blood pressure, heart rate, etc.) to evaluate pain and suffering (26,29). Since anxiety and agitation may be a reflection of pain and/or suffering, Ramsay or similar scales may be used by the ICU staff to rate patients' distress (30-31). Unfortunately, many of these scales are too cumbersome to be practical outside of a research setting and many contain levels that are not clearly defined or mutually exclusive (26,30). ICUs do not routinely use these scales to record and evaluate pain resulting in a lack of consistency in their evaluations and a poor quality of care with respect to pain and symptom control (26-29,31). Again, none of these scales have been used or validated in dying patients.

Although pain and suffering are commonly discussed together in the literature, it is important to distinguish between them. Pain can occur without suffering; suffering can exist without pain (32,33). Suffering can be defined as the "distress brought about by the actual or perceived impending threat to the integrity or continued existence of the whole person" (32). Suffering is very individual in nature and it is difficult for one person to fully appreciate and understand the suffering of another (32,33). As with pain, problems in the assessment of suffering are exacerbated by the communication barriers imposed by critical illness and the ICU environment. Currently no scales to evaluate suffering in ICU patients exist.

2.3. Pain Relief in the ICU.

Few studies have explored whether we are successful in providing pain relief to ICU patients. Since 1979, studies have revealed that pain was the greatest source of worry and cause of sleep deprivation in ICU patients (28). The large multicentre SUPPORT study reported that 49.9% seriously ill patients complained of pain, 33% of whom had extremely severe pain (26,34). Using a numerical descriptive scale (NDS), Whipple et al. examined pain control in 17 trauma patients during their initial ICU course: 27% of patients rated their pain as moderate and 47% as severe (29). In contrast 95% of housestaff and 81% of nurses felt these patients had received good pain control (29). Puntillo examined the pain experiences in 24 surgical ICU patients after their transfer from the ICU (28). Although 7 patients did not recall pain (1 did not recall the entire ICU stay), 63% rated their pain as moderate to severe (28). Furthermore, the second most frequent recollection of patients of their ICU stay was pain which suggests that pain control remains an ongoing problem (28).

While life support technology may cause discomfort, it also plays an important role in alleviating distress caused by life-threatening illness. When a decision is made to withdraw life support, the amount of narcotics needed to relieve patients' pain and suffering increase markedly (27,35). Wilson et al. (35) explored the administration of sedatives and analgesics in 44 patients during the withholding/withdrawal of life support and found 75% of patients received drugs. Reasons for ordering drugs were cited by ICU staff as follows: to relieve pain (88%), anxiety (85%), decrease air hunger (76%), comfort families (82%) and, to hasten death (39%). Further exploration by the investigators revealed that health care providers were using "hasten death reasoning" according to the "principle of double effect"; i.e., they knew the administration of drugs may forseeably hasten death but their intention was to relieve suffering (35). No evaluation of the actual effectiveness of the ordering or administration practices was undertaken (35). To date, no studies have assessed our abilities to relieve pain and suffering in dying ICU patients.

Based on review of the current literature and consensus among 40 experts, the SCCM developed guidelines on the use of analgesia and sedation in ICU patients (16). These guidelines do not include any provisions for assessing the effectiveness of pain relief. Nor do they address how to use narcotics and sedatives as life support systems are being withdrawn. The SCCM practice parameters are thus unable to guide Intensivists in their efforts to palliate dying ICU patients.

2.4. Quality of End-of-Life Care.

Palliative care is essential to the provision of quality end-of-life care. Quality of care is "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (5). No studies have specifically explored the determinants of quality end-of-life care in the ICU. However, research in other settings has shown that dying patients fear pain, permanent unconsciousness, ventilator dependence and abandonment by their physicians and families (23). The Journal of the American Geriatric Society has suggested 10 determinants of good end-of-life care: 1) Relief of physical and emotional symptoms, 2) support of function and autonomy, 3) advance care planning, 4) avoidance of aggressive care near death, 5) patient and family satisfaction, 6) global quality of life, 7) minimizing family burden, 8) maximizing survival time, 9) provider continuity and skill, and 10) bereavement support (36). In the acute care setting such as the ICU, some of these determinants may assume greater importance, for example relief of pain and distress, relationships with families and friends, and avoidance of aggressive care near death. The number of determinants of quality end-of-life care may be much smaller. While these determinants may not be completely generalizable to the ICU, many ICU patients are elderly, and these determinants are thus suggestive of what quality of end-of-life care may entail within the ICU. Research is needed to explore the goals of quality end-of-life care in the ICU.

Since the quality of care a patient receives enables him/her to achieve "desired health outcomes"(5), quality of care directly affects a patient's quality of life. In the current literature, "quality of life" has two meanings: 1) an attribute of either biological or personal life, and 2) a qualitative relation between the patient's medical condition and his/her ability to pursue human values (37). Normative judgements of quality of life assume that some lives ought to be preserved while others have less value (37). The presence and severity of pain and suffering are important in normative assessments of our own quality of life and that of others. Thus some argue that a life full of pain and suffering is not worth living and use this argument to support the legalization of euthanasia and assisted suicide (25). The provision of quality end-of-life care, such as alleviating pain and suffering, is crucial in ensuring that dying patients continue to enjoy the best possible quality of life as their health deteriorates (5). As alluded to above, if the quality of life of dying patients can be improved, many feel support for the legalization of euthanasia/assisted suicide would diminish (38).

Thus, evaluation of the care provided at the end-of-life is important. Crucial to the provision of palliative care is the recognition of its dynamic nature: its goals are ever changing as death approaches (5). For example, as terminal illness progresses, being independent may be less important than strengthening relationships with family and loved ones (5, 15). The importance of accountability in end-of-life care has been recently emphasized (5).

While many measures of quality of care exist, few measures of quality of end-of-life care have been developed (5). Assessments of quality of end-of-life care have focused on three dimensions: structure, process and outcome (5). Structural dimensions have promoted the development of hospices, and institutional policies regarding the care of dying patients. Process dimensions such as pain management strategies and studies such as the SUPPORT study (39), suggest the need for research to improve health outcomes.

Outcome measures, or, in this situation, what it means to live well when dying, from the patient and family's perspective, are arguably the most crucial for quality assessments (5). Recent research has shown that patients' values in advance care planning differ from those of healthcare providers (39). What outcomes are most relevant to dying patients has been the subject of much controversy. No studies exist in ICU patients. However, recently, research has shown patients identify the following five areas as important in the provision of quality end-of-life care: 1) obtaining adequate pain and symptom management, 2) avoiding inappropriate prolongation of dying, 3) achieving a sense of control, 4) relieving burden and, 5) strengthening relationships with loved ones (15). Intuitively, in any setting, quality end-of-life care should facilitate all these endeavors.

Other problems specific to assessments of quality end-of-life care include the timing of assessments, the role of patient or surrogate as a source of patient information, and the importance of verbal reports versus numerical ratings of satisfaction with care, and ensuring the assessment tools are sensitive to the ever changing needs of the dying patients (5).

Unfortunately, palliative care research provides clear evidence of poor quality end-of-life care (3,40). Evidence that pain and suffering are undertreated at the end-of-life abounds (1-5,7,23,40). Studies have concentrated on exploring pain at the end-of-life and a paucity of literature exists on suffering especially in the ICU setting. This scarcity is due, in part, to the individual nature of suffering: it is very difficult for health care providers to recognize and assess, never mind teach (32,33, 41-49).

Many factors contribute to inadequate palliative care: communication barriers, lack of knowledge, fears of drug addiction, fears of adverse side effects, perceived lack of importance (on the part of healthcare providers) and a lack of palliative care facilities (3,4,14, 19,23,40).

Traditionally palliative care has not played an important role in the care of ICU patients (23). No studies assessing pain and suffering from the dying patient's or families' perspective exist in the ICU. Studies in surviving patients (28,29), alluded to above, suggest poor pain control. These studies and the lack of emphasis on this important aspect of ICU care raise frightening questions concerning our success at providing a "good death", which as most people would agree, should at least be one free of pain and suffering.

How can the quality of care be improved? Guidelines for clinical practice may help in several ways. By summarizing the research into effective processes of care at the end-of-life, guidelines can improve knowledge of palliative care (5). Guidelines can permit identification of problems and develop strategies for their resolution (5). They allow comparison of the quality of care between different institutions (5). Finally guidelines are important to improve communication within the health care team and between the healthcare providers, patients and families (5).

There is a lack of research upon which to base guidelines for the control of pain and suffering in dying ICU patients. Recognition of the urgent need to improve the care of these patients lead to the initiation of this project. The author's personal experience in palliating dying patients as well as the paucity of research in this area spurred the development of consensus guidelines based on the opinions of expert Intensivists with many years of experience in caring for dying patients. By detailing what good palliative care in the ICU should be and identifying current problems, these guidelines will facilitate and focus future research.

2.5. Principle of Double Effect.

Using analgesics and sedatives to provide relief of pain and suffering can sometimes hasten death by causing hypotension and respiratory depression. This fear of hastening death is one of the reasons for the reluctance of health care providers to administer narcotics and sedatives (4,19). As long as the health care provider's intent, when administering the analgesics/sedatives to dying patients, is solely to relieve pain and suffering, the *principle of double effect* can be used to justify such administration. The principle of double effect was first described in Roman Catholic theology by Thomas Aquinas to justify why certain practices (acts of intervention or omission) are morally permissible while others are not (8,9). It is usually invoked in situations where it is impossible to avoid all harms (9). In order to apply the principle of double effect, four conditions must be met (8,9):

1) The act must not belong to a class of actions that are wrong even aside from their bad effects (e.g. killing except in self-defense, capital punishment and wars);
2) The good effect (e.g. pain relief) and not the evil effect (e.g. killing) must be intended;
3) The evil effect (killing) must not be a means to the good effect (pain relief); and,
4) The good effect (pain relief) must outweigh the evil effects (killing).

The ethical principle of double effect is used by medical associations around the world to permit their members to administer narcotics and sedatives to palliate pain and suffering at the end-of-life, even if such administration will hasten death (50-51). The failure to alleviate pain and suffering is deemed to be a greater evil than the forseeable potential hastening of death. The principle of double effect does not however permit euthanasia or assisted suicide since they are the means to the good effect (8,9).

Abandoning the patient by leaving him/her suffering and in pain may furthermore be seen as a violation of the Hippocratic Oath (HO) and the Oath of Geneva (OG) by which physicians are sworn to "consider the benefit of the patient" (HO) and to keep "the health of my patient my first consideration...within the laws of humanity" (OG). The principle of double effect and the Hippocratic/Geneva Oaths have thus been helpful in increasing the comfort of healthcare providers when administering palliative care to dying patients.

Still, problems with the principle of double effect exist. It has its origins in 13th Century Roman Catholic theology. One could question whether it is valid to use this principle, imposing Roman Catholic thinking, in today's pluralistic and secular world (9). Even if we allow that most people are unaware of its origins and accept it as an ethical principle, significant problems remain.

The principle of double effect is a complex and confusing principle that uses intent to distinguish good acts from evil ones. What constitutes an evil act? If exceptions to killing are made in war, capital punishment and self-defense (8), is it evil to kill someone if death is the only way to relieve his/her intractable suffering? In surveys of public opinion, many people say no (9,52-54). So then how are evil and good effects weighed (8,9)? This central issue in the euthanasia/assisted suicide debate will be discussed in more detail below.

Intents are morally significant for several reasons: a) virtues are expressed through them, b) they shape the agent's character, c) they affect the quality of the agent's conduct in relation to others, and d) they reveal respect for intrinsic value and well-being of others (8). In the principle of double effect, a particular individual's intent is crucial to determine whether he/she is morally culpable of a particular evil act (8,9). Thus the subjectivity of intent is core to understanding how the principle of double effect determines moral culpability.

However, inherent difficulties exist in determining intent (8,9). Some theorists in the philosophy of mind have argued that intent is reflected in an individual's plans and subsequently, in their actions (8). However, these theorists admit that agents do not always intend every result they foresee (8). While intention can be judged to some extent by someone's actions, either of commission or omission, particular actions cannot always fully reveal someone's true intent. Intentions are unique to individuals (8). Many complex psychological motives may be involved in the formation of an intent (8,9). Someone's intent may therefore never be completely understood by another person or, for that matter, even by the person him/herself (8,9,147). In euthanasia ("mercy killing"), the agent intends to kill the patient in order to relieve intractable suffering. In criminal law, the agent has the mens rea of murder because he/she intended to kill. The motive, in this example, to relieve suffering, is sometimes referred to as "ulterior intent" (55). In criminal law, direct intents (in our example, to kill) determine guilt while motives (or "ulterior intents") go to sentencing (55).

A physician who intends to cause a terminally ill suffering patient's death with an overdose of narcotics and/or sedatives is committing euthanasia. Euthanasia or "mercy killing" is a form of murder under the Criminal Code of Canada since the intent is to kill the patient in order to relieve unmanageable suffering. Section 229 (a) of the Code makes this clear: "culpable homicide is murder (a) where the person who causes the death of a human being (i) means to cause his death, or (ii) means to cause him bodily harm that he knows is likely to cause his death, and, is reckless whether death ensues or not". While there are different standards of intention in civil law and criminal law in Canada[1] (55), I focus only on the subjective intent used in section 229 (a) (intentional homicide) and used in the principle of double effect. The reason why the accused is guilty of murder in criminal law in carrying out euthanasia is that he means (intends) to cause the death of the patient; the reason why the action is morally permissible under the principle of double

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[1] For the difference in the standards of intention in civil and criminal law, see, for example, John G. Fleming, The Law of Torts (4th ed., 1971) and Don Stuart, Canadian Criminal Law (2nd ed. 1982)

effect is that he intends to relieve suffering, and only foresees the death of the patient. To be found guilty of murder under section 229 (a) of the Code, the particular physician (the accused) administering the morphine, *not* a reasonable physician in the same situation, must be proven to have intended the death of his/her patient. Moreover, in criminal law, the mens rea (intent) can not always be inferred from the actus reus (criminal act). In other words, if a patient is overdosed and killed with morphine, it has to be proven that the physician administering the morphine intended to kill this patient: his/her intent cannot be inferred from the fact an overdose was given.

Confusion about the principle of double effect and the legal implications of euthanasia is seen among health-care providers (9,35). Healthcare providers have been found to be ignorant of the principle of double effect's determining conditions (9). Furthermore, healthcare providers may be mistaken in describing their own mental states due to the inherent difficulties in knowing our own intentions (147). However, some individuals may deliberately lie and abuse the principle of double effect by claiming their intent was solely to relieve pain, when it was really to kill. The lying health-care provider may be difficult to detect if analgesics or sedatives are used to kill since these drugs are traditionally ones used to relieve pain and suffering. In some, but not all, cases, the way the drugs were administered (actus reus), whether in response and in proportion to pain and suffering, or not (e.g. very high amounts of narcotics/sedatives given before the previous doses had time to take effect, i.e. administration contrary to the known pharmacology of the drugs), may be helpful in determining intent (mens rea).

Finally, some health care providers claim the principle of double effect is an artificial and hypocritical rationalization to permit the achievement of a goal we all (in all honesty) strive for: a quick, painless death (9).

Can the principle of double effect be saved? Some suggest it should be discarded in favor of a more fruitful line of thought in which efforts would be made to determine "which actions and effects are such that intending to realize them is wrong in all circumstances, which ones are such that intending them can be justified by the agent's reasonable and freely given consent, and which may be justified simply by appeal to the needs of others" (56). Still, many questions arise in this line of reasoning itself. Are we to determine which actions are always wrong from a teleological or deontological normative ethical perspective? Are we to determine which actions always have bad consequences? Under which interpretation or version of Utilitarian, Act or Rule? Should no limits exist on individual autonomy? (Section 14 of the Criminal Code states: " no person is entitled to consent to have death inflicted upon him.") Which needs of others could justifiably trump those of the individual? Answers to these questions are the subject of great debate and outside of the scope of this thesis. However, since consideration of virtue and care-based ethics (8) has been proposed to strengthen the principle of double effect, these theories will be explored briefly below.

The ethics of care considers moral reasoning and judgement in the context of our relationships with others (58-61). The particulars of a given situation are crucial. Emotions, such as concern, empathy and compassion and, consideration of the nature of our interpersonal relationships determines what is morally relevant and why (58,59). Care-based ethics emphasizes "feeling the right emotion at the right time" (61). To know which emotions are right at what time, a description of the character of the agent is needed, and the importance of virtue based ethics is thus revealed (58,59,62). Ethics of care broadens morality to include consideration of both the agent's reasoning (understood broadly to include his/her motives) and the manner (how) in which the action was performed (58). In this way care-based ethics are more deontological (both the ends and the means are important) than utilitarian (only the end is important). While, as suggested in other ethical theories, moral rules (deontology) and principles (principlism) may guide decisions, ethics of care dictates that they must be explored in context (of the current situation) rather than abstractly (58-60).

If the ethics of care are used to consider the propriety of the principle of double effect, compassion, insight into the nature and depth of the patient's pain and suffering, and consideration of the nature of the patient-physician relationship play a role in deciding whether euthanasia/assisted suicide are morally permissible practices or not. For example, if the physician has a dying patient with uncontrolled pain and suffering, compassion and the need to alleviate distress would require the administration of narcotics and sedatives. The way in which the physician expresses such caring (i.e. the way the drugs are administered) will determine if the action (giving the drugs) is morally wrong or not. If one considers the fiduciary nature of the physician- patient relationship captured in the motto "do no harm" (causing death being the traditional Hippocratic notion of ultimate harm), the ethics of care would recognize that compassion and the depth of the patient's distress and the need for relief may justify *hastening* death (if hastening death is a foreseeable side effect of the narcotics provided to alleviate pain). Administering an amount of narcotic and/or sedative out of proportion to the patient's pain, without waiting for the effects of previous doses to be seen and evaluated (i.e. failing to consider the pharmacology of the drugs), and, deliberately *causing* death is not permissible under the scope of the ethics of care. For in this latter scenario, any claims of compassion as justification for killing by the physician would be seen as overidentification with the patient (right emotion, at the wrong time).

How do we know if we feel the right emotions at the right time? Virtue based ethics "focuses on the agent; on his or her intentions, dispositions and motives; and on the kind of person the moral agent becomes, wishes to become, or ought to become as a result of his or her habitual disposition to act in certain ways" (63). Controversy exists over which character traits are required in order to be a virtuous physician. Proposed virtues include "fidelity to trust and promise, benevolence, effacement of self-interest, compassion and caring, intellectual honesty, justice and prudence" (64). It is not clear whether the possession of these traits are necessary and/or sufficient to be a virtuous physician. The virtuous person aims to do "good" in all situations (62,65). In the medical context, the virtuous physician's most important goal is to serve the patient's good, "to do no harm" (as in the ethics of care above) "unless pursuit imposes injustice upon his/her family, or requires a violation of her own conscious or professional standard" (66). In summary, the virtuous physician will recognize ethical dilemmas and have the right motives, the right intentions and be disposed to act in the right way in when confronted with any ethical problem (62,65).

Combining both ethics of care and ethics of virtue, the physician's intent can more clearly interpreted (both by others and by themselves) and such interpretations trusted. If a physician is virtuous and will always act for the patient's good with care and compassion, the physician's motives and intents will always be ethical. The good physician seeks a morally worthy end by morally worthy means. Their understanding and interpretation of the principle of double effect would be clear and unambiguous.

While the debate on the moral acceptability of euthanasia/assisted suicide is unlikely to be resolved soon, our society and the medical profession may, through consideration of ethical theories, decide that killing (euthanasia or assisted suicide) in certain situations, for example when pain and suffering are uncontrolled at the end-of-life, is morally acceptable. In this case, no appeal to the principle of double effect would be needed. However, care and virtue-based theories would still play a crucial role in determining the moral acceptability of each act of euthanasia/assisted suicide for it is the virtuous, caring physician who will know when the time has come to help end the life of the dying patient in uncontrollable pain and suffering.

This thesis will not argue the presence or absence of virtues and caring in today's physicians, nor their implications in terms any potential legalization of euthanasia/assisted suicide.

2.6. Terminal Sedation.

At times, it is impossible to relieve the dying patient's pain and suffering with intermittent administration of analgesics and sedatives. In these situations, a continuous intravenous infusion of narcotics, benzodiazepines or barbiturates can be used, either alone or in combination, to sedate and relieve the patient's suffering until death ensues from the underlying disease, in practice known as "terminal sedation" in the literature

(14,67-69,145). The frequency that terminal sedation is used isn't clear: estimates range from 15-50% of terminally ill patients (not solely ICU patients) (29,67-69). While many feel terminal sedation should be considered palliative care (67), others think it is tantamount to euthanasia (14,145).

Proponents of the view that terminal sedation is equivalent to euthanasia argue that the sedated patient dies both from the induction of unconsciousness and the withdrawal of food and hydration (14). In the ICU, life support systems are withdrawn, but hydration is rarely stopped. As many commentators, such as the Law Reform Commission (12) and Special Senate Committee on Euthanasia/Assisted Suicide (70) have stated, withdrawal of life support is ethical and legal. If one accepts the reasoning that in the withdrawal of life support, death occurs from the underlying disease, the same is true in terminal sedation. In dying ICU patients, the severity of their underlying illness is a more important cause of their inability to eat and drink than is terminal sedation. While terminal sedation may depress respiratory rate to a greater extent than intermittent doses of drugs, it is the dyspnea, pain and distress produced from the underlying illness that necessitates its use as the ventilator is being withdrawn. Thus the principle of double effect may be used to justify terminal sedation.

While patients may lose some control of the dying process (14,145) (since they lose awareness), they may still be able to control the time terminal sedation is initiated. If they are able to communicate with their family, loved ones and staff, terminally sedated dying ICU patients can still ensure there is adequate time to say goodbye, resolve disputes and reflect on their lives prior to the initiation of sedation (67). Most families are relieved once previously uncontrolled suffering is alleviated with terminal sedation and feel their loved one's dignity has been restored, not compromised as has been argued elsewhere (14). Terminal sedation, inasmuch as it removes pain and suffering, makes families more comfortable with an emotionally difficult prolonged dying process.

In *Vacco v. Quill* and *Washington v. Glucksberg*, the US Supreme Court endorsed terminal sedation as palliative care (14,67). The American Medical Association (AMA) also endorses terminal sedation (67). Healthcare providers may indeed have an obligation to provide terminal sedation, if it represents the sole way to alleviate the dying patient's pain and suffering (14,67). In fact, intravenous infusions of analgesics and sedatives are often used to relieve the pain and distress that all ICU patients experience as a result of their illness and the technology used to treat them, and are not solely used in dying patients (68,69).

Just as with the intermittent administration of analgesics and sedatives, terminal sedation may be abused: a high initial dose, quickly incremented may be suspicious of euthanasia. Clear parameters for its use, to diminish confusion with euthanasia/assisted suicide need to be elucidated.

2.7. Conclusion.

The above discussion has centered on the relief of pain and suffering in dying patients. It has not dealt with the spiritual or social aspects of palliative care nor has it discussed the care of the family during and after the patient's death. To date, even less emphasis has been placed on these components of palliative care in the ICU setting (21-23). More resources to remedy this problem and efforts to provide good comprehensive palliative care are needed. Research should then be undertaken to evaluate our effectiveness at providing palliative care and bereavement support for the family.

3. EUTHANASIA/ASSISTED SUICIDE.

Euthanasia is defined as "the deliberate act undertaken by one person with the intention of ending the life of another person in order to relieve that person's suffering where that act is the cause of death" (78). Three categories are currently described in the literature: a) voluntary (in accordance with the wishes of the competent patient), b) nonvoluntary (when the wishes of the patient are not known) and, c) involuntary (done against the wishes of a patient) (78). Since large doses of narcotics and sedatives are frequently administered to alleviate pain and distress during the withdrawal of life support, confusion may arise between palliative care and euthanasia/assisted suicide in this setting.

Euthanasia in all its forms is illegal and is not distinguished from murder under the Canadian Criminal Code s. 229 (a)(i), s. 222, & 231. The minimum sentence for murder is life imprisonment (s. 235).

The agent performing the act is used to distinguish euthanasia from assisted suicide: in the latter the patient commits the act causing his/her death; in the former, the act is performed by another. Assisted suicide is thus defined as "the act of killing oneself intentionally with the assistance of another who provides the means, the knowledge or both" (79). Assisted suicide is also illegal under the Canadian Criminal Code, section 241 of which states: " Every one who a) counsels a person to commit suicide or b) aids or abets a person to commit suicide, whether suicide ensues or not, is guilty of an indictable offense and liable to imprisonment for a term not exceeding fourteen years".

Euthanasia and assisted suicide have long been prohibited in medicine. The Hippocratic Oath clearly states: "I will give no deadly medicine to anyone if asked, nor suggest such counsel". Traditionally, this principle has been said to be a fundamental moral obligation of the medical profession. However, this belief is currently being challenged and, faced with our failure to relieve suffering at the end-of-life, many patients and physicians support voluntary euthanasia/assisted suicide in terminally ill patients (19,80-81,86,89,91).

When the debate to legalize voluntary euthanasia and assisted suicide is analyzed, the ethical arguments in favor of legalization are as follows:

1) Right to die: as autonomous, competent agents, people should have the right to chose the time and manner of their own death. Whether a terminally ill patient is truly autonomous is hotly debated (80-84,91);
2) Mercy and Compassion: no one should have to suffer a painful, horrible death. Patients should be assisted to die in the face of uncontrolled pain and/or suffering (84-86,91);
3) Consistency: patients who still have the ability to commit suicide are not committing a criminal offence, while those who are too ill to do so without assistance (i.e. those in greater need) are (89-91);
4) Gain in trust in the physician-patient relationship: patients will trust their physicians to provide them with relief and not abandon them to a painful death (87-91).

The arguments against legalization are:

1) Sanctity of life: life is a gift from God and not the property of the individual. It is therefore immoral to kill oneself or allow oneself to be killed (89-91). In today's secular society, the question of whether one's religious beliefs can be imposed on another arise (41,91);
2) Value of suffering: suffering enables patients and their loved ones to grow spiritually and morally. From a more religious viewpoint, suffering is perceived not only as an opportunity to grow, but also as a means of becoming closer to God (41-49). The secular view emphasizes the potential for personal growth that suffering provides (41-49);
3) Violation of the Hippocratic Oath: medicine has traditionally been devoted to preserving life; euthanasia and assisted suicide violate one of the most fundamental obligations of the profession (87-91);
4) Loss of trust in the patient/physician relationship: patients at the end-of-life will come to fear that physicians will assess their quality of life, and, if it is not deemed to meet that physician's preconceived notions of quality, patients will be euthanized. This is a legitimate fear since it is difficult not to impose one's own values and perceptions of quality of life on others (87-90);
5) Abuse of power: many people fear the gain in power the legalization of euthanasia/assisted suicide will give to physicians who already wield great influence in society (87-88,91);
6) Cessation of research in palliative care: confronted with difficult situations, physicians will want to "take the easy way out" and assist in their patients'deaths,

rather than provide them with good palliative care. Since there will no longer be a need to develop better palliative care, research will cease (86); and

7) Slippery slope: once voluntary euthanasia and assisted suicide are legalized, patients will feel coerced into asking for death in order to decrease the financial, and emotional burden their illness places on their family. Eventually, societies will begin to accept involuntary euthanasia of its disadvantaged, disabled members (81-91).

Certainly, the risk of coercion is already present in decisions to withhold/withdraw life sustaining therapies. Withholding and withdrawing therapies at the request of a competent patient or their valid surrogate is both ethical and legal. Since physicians are already comfortable with these decisions, they may be less questioning of withholding/withdrawing whereas, even if legalized, a certain unease with euthanasia/assisted suicide would persist and encourage more reflection and search for abuse. Still, there is no denying that some members of the profession may indeed abuse this power, impose their value judgements on the patients' quality of life and involuntarily euthanize them (80-90).

Due to public pressure, a Special Senate Committee was formed to study the question of legalization of euthanasia/assisted suicide. In their 1995 report, Of Life and Death, they recommended against legalizing these practices, largely in response to the slippery slope/abuse arguments (80,81). However, the Senate Committee did recognize a distinction between euthanasia and first or second degree murder. While, in euthanasia, the intent is still to kill, the motive is compassion. The Senate Committee recommended the Criminal Code reflect this motivation and therefore prosecute these crimes as "third degree murder" or "compassionate homicide" (80). This new class of murder would carry a lesser sentence than life imprisonment, again reflecting the motive for the crime, not one of hate but one of mercy and compassion (80). As yet, the Criminal Code has not been revised.

3.1 Canadian Cases.

In the past few years, murder charges have been laid against healthcare providers who have euthanized dying patients (71-77). Not all of these cases were tried in the courts: while some formed the basis for coroners' inquests, others were eventually dismissed due to a lack of evidence. Still, all generated much publicity and fueled the euthanasia and assisted suicide debate. While healthcare providers, in some cases, used potassium chloride (*Dr. Morrison 1997, R. v. Dr. De la Rocha 1993, R. v. S. Mattaya 1992, Dr. X. 1990)*, others have used massive doses of narcotics and sedatives *(R. v. Dr. Genereux, Dr. Graff 1991, R. v. Dr. Gal 1983).*

Since most patients in the ICU have high narcotic requirements and these increase during the withdrawal of life support, detection of euthanasia/assisted suicide can be particularly difficult in this setting. While the administration of large doses of narcotics and sedatives may reflect efforts to palliate the dying patients, the administration of potassium chloride is inconsistent with this goal since it only relieves suffering by hastening death (violating the principle of double effect since killing becomes the means to relief of pain and suffering). Moreover, perusal of newspaper articles (71-77) detailing the evidence presented during some of the trials *(R. v. Dr. De la Rocha, R. v. Mr. Mattaya, Dr. Graff)* confirm previous studies suggesting a deplorable lack of knowledge of appropriate means of controlling pain and suffering at the end-of-life.

The Canadian Medical Association has consistently opposed euthanasia and assisted suicide (51). In the cases detailed above, the provincial Colleges of Physicians and Surgeons have also enacted punishments for euthanasia/assisted suicide (71-77).

4. The IMPORTANCE OF CONSENSUS GUIDELINES ON THE USE of ANALGESICS AND SEDATIVES IN DYING ICU PATIENTS.

In order to aid coroners who, when reviewing deaths, have to distinguish palliative care from euthanasia, the Chief Coroner of Ontario issued a memo defining "palliative care" (17). This memo was later circulated to all provincial coroner offices. In this memo, palliative care is defined as:

1) care intended solely to relieve the patient's suffering,
2) care administered in response to symptoms or signs of suffering and commensurate with the suffering,
3) care that is not a deliberate infliction of death.

Unfortunately, no guidelines on how to determine whether the drugs administered are commensurate with suffering are provided. Moreover, these guidelines are not specific to the ICU where the distinction between palliative care and euthanasia/assisted suicide is more difficult. Our guidelines address both these problems.

The debate whether to legalize euthanasia/assisted suicide is unlikely to be resolved in the near future. The goal of this project is not to further the debate over the ethical and moral acceptability of these practices. Rather, our goal is to respond to the obvious need to improve quality of end-of-life care by developing a standard of care for dying ICU patients. Furthermore, our goal is to increase the comfort of the ICU staff by clarifying the border between palliative care and euthanasia/assisted suicide in the ICU, and thus encourage them to provide good palliative care while respecting the current laws banning euthanasia/assisted suicide.

Studies have not described what the needs of dying ICU patients are and how these needs can best be met in the ICU setting, nor have they assessed our abilities to alleviate these patients pain and distress during the withdrawal of life support. Our guidelines explore the appropriate use of analgesics and sedatives in palliating dying ICU patients. With the exception of the provision of relief from pain and suffering, our guidelines do not explore what the needs of dying patients and their families are, nor how these needs can be met.

METHODS

Design:

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 develops consensus in the following manner (91-93):

Round #1: A panel of individuals, "experts", are asked to answer specific questions based on their knowledge and experience. Their answers are qualitatively analyzed: the responses are coded, grouped into categories, and relationships between categories are developed. A Delphi document is thus drafted and resent to all the panel members.

Round #2: Panelists are given the opportunity to modify the statements in the Delphi document. They are also asked to rank their agreement with the document on a Likert scale. Their responses are reanalyzed (qualitatively), the rankings are summarized and provided to the panelists in the next round.

Round #3: Panelists are again given the opportunity to modify the document and rate their agreement. They are given the opportunity to compare their agreement (ranking) with that of other panel members.

Round #4: The re-rankings from the 3rd round are analyzed for consensus. If a pre-determined level of consensus is attained, the process ends. However, if consensus is not attained, the process is repeated until consensus is achieved. Consensus is generally anticipated in the 3rd or 4th round.

The Delphi method was chosen for this study because it does not require a face to face meeting in contrast to other consensus methods (92-94,96). The Delphi method permits repeated data collection by mail, fax and e-mail which allows participation by panelists across the country. The absence of face to face meetings also avoids any possible domination and/or coercion of the panel by one or two vocal members (94). Since the responses of panelists are known only to the investigator, their confidential nature may permit panelists to freely express their opinions, which may be difficult in a conference setting (94)

Disadvantages to the use of the Delphi method exist. The reproducibility of results increases with larger sample sizes and with the number of rounds. However, large panels are difficult to work with and expensive (92,95-97). As the number of rounds increases, so does the fatigue of panelists and investigators (95-97). Finally, too loose a definition of "experts" with a poor knowledge base decreases the value of the final consensus document (95-97).

Sample:

Two Delphi panels were used in this study. To form the first panel, we approached the Adult and Pediatric Critical Care fellowship program directors in all Canadian academic centers. In provinces without a Critical Care fellowship program, the academic center Intensive Care Division Chief was approached. Out of a possible 27 panel members (13 adult, 14 pediatric), 19 (9 adult, 10 pediatric) agreed to participate. Reasons for refusal were cited as 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). Since significant differences exist between adult and pediatric patients, it became clear that a single consensus statement was not feasible for both. Due to the current publicity of euthanasia/assisted suicide cases involving adults, both in

Canada (Dr. Morrison , Dr. Genereux) and the United States of America (Dr. Kevorkian) (71-77), a decision was made to concentrate on developing consensus guidelines for adult patients.

Intensivists in non-academic centers were excluded in order to ensure panelists were "experts" in critical care medicine. Experts were defined as physicians with formal training in Critical Care medicine, or physicians with extensive experience in tertiary level Intensive Care Units. In Canada, non-academic ICUs frequently combine Intensive Care/Coronary Care Units (ICU/CCUs) and may be staffed by physicians who have not been formally trained in Critical Care medicine. A final advantage of a panel of fellowship program directors was that since they had participated in the development of the guidelines, they were more likely to support their use (5). There was greater potential for wider dissemination and, perhaps, implementation of the consensus statements to physicians currently in training.

The second Delphi panel was formed by approaching the provincial Deputy Coroners/Medical Examiners. Out of a possible 14 panel members, 5 agreed to participate. Reasons for refusal included lack of time (n=5), lack of knowledge required to answer the initial Delphi questionnaire (n=1) and, no reason was given in the remaining cases (n=3).

There are two main reasons for the use of this second Delphi panel. First, the coroners/medical examiners are required by law to review deaths meeting certain well - defined criteria. They are therefore faced with the sometimes difficult task of determining whether the amount of narcotics or sedatives administered to the dying patient falls outside the boundaries of palliative care. In event of allegations of euthanasia/assisted suicide, they are (most often) the first to review the chart and decide whether any further investigations are needed. Therefore, coroners/medical examiners also qualify as "experts" in distinguishing palliative care from euthanasia/assisted suicide. Second, we anticipated that, in the future, this consensus statement may be used as a tool when deaths are reviewed in the ICU.

An independent panel, composed of the 12 Intensivists (4 women and 8 men) who attended the End-of-Life section of the Canadian Critical Care Trials Group Meeting in April 1999 was used to validate the consensus statements obtained from the original 2 panels described above. All Intensivists who attended this section of the Critical Care Trials Group meeting were asked and consented to participate.

Data Collection:

Panelists were provided with the research protocol which included background information detailing the problems of pain control in the ICU, the problems encountered in the provision of quality end-of-life care and the importance of a consensus statement on the use of analgesics and sedatives in dying ICU patients. The definitions of "palliative care", "euthanasia" and "assisted suicide" as defined by the 1995 Special Senate Committee's report, Of Life and Death (18,78,79) were also provided.

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/assisted suicide (Appendix I). The coroner/medical examiner panel was asked 8 questions—their initial questionnaire was the same as that given to the Intensivist panel with the exception of a question about what clinical parameters should determine how analgesia and sedation are needed to palliate dying patients (Appendix II). This first question required a response based on expert clinical knowledge that the coroners would not possess. Responses to all Delphi rounds were obtained via mail, fax and e-mail.

Panelists were encouraged to discuss all the ethical, legal and clinical issues (raised by the initial questions) that they felt were relevant to the provision of good palliative care in the ICU and its distinction from euthanasia/assisted suicide.

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 read the document generated from the first round and to comment on any perceived omissions, clarify any obscurities, and raise any questions they felt had not been adequately dealt with. They were asked to respond to new questions generated from either the qualitative analysis of their responses in the first round, or from the responses of the coroner panel in the first Delphi round. They were also asked to rate their level of agreement on a Likert scale ranging from 1 (complete disagreement) to 7 (complete agreement). Similarly, they were also asked to rank their overall agreement with the document. Since the responses of the adult and pediatric Intensivists were divergent, two separate consensus documents were formed at the end of the second round. In subsequent Delphi rounds, the adult and pediatric Intensivists formed two independent panels. As this project grew, and results from the second Delphi round were analyzed, it became clear that one consensus statement was not appropriate for both adult and pediatric patients. Recognition of these complexities in developing consensus guidelines lead to the decision to fully develop the adult consensus statement.

The third Delphi round involved both adult Intensivist and coroner panels. Both panels were asked to read the proposed consensus statements and subsequent text in each section. They were then asked to rank their agreement with each consensus statement on a Likert scale [from 1 (complete disagreement) to 7 (complete agreement)]. They were asked to state what modifications needed to be made for them to give each statement a score of 7 (complete agreement). They were also asked to rank (on a Likert scale) their overall agreement with the document and again, to state what changes needed to be made for them to give t he document a score of 7 (complete agreement). A fourth Delphi round was not required since consensus was achieved in the third round.

The independent panel of Intensivists was presented with the final consensus statements obtained after the third Delphi round. They were asked to rate their agreement with the statements on a 1 (complete disagreement) to 7 (complete agreement) Likert scale. If they gave any statement a score less than 5, they were asked to state what modifications needed to be made for them to give that statement a score of 7.

Data Analysis:

The responses of the Intensivists and coroner panels were analyzed separately by the author. Initially open coding was used to give conceptual labels to a randomly selected panelist's responses (98,99). These conceptual labels generated the formation of categories (or sections) (98,99). Each panelist's responses were subsequently coded in random order. The responses of each panel member carried equal weight. New codes

New questions were generated and guided data collection in the next round. In this way, the properties of each category were delineated (99). Any questions or concerns raised by the coroners were inserted into the appropriate section of the Intensivist document and addressed in the subsequent Delphi rounds.

Memos were used in order to help identify reactivity and bias and to help build the consensus document by identifying relationships between categories, subcategories and the central concept (98,99)

Responses in all subsequent Delphi rounds were qualitatively analyzed as described above. In the third round, an italicized statement was inserted at the beginning of each section. These were summaries of the subsequent section's text and were the proposed consensus statements.

In the second and third Delphi rounds, panelists were also asked to rate their agreement with each consensus statement and with the overall document on a Likert scale. Scores ranged from 1 (complete disagreement) to 7 (complete agreement). Since Normal distribution could not be assumed, the median score obtained from each section was used to determine the level of agreement among panelists. 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.

Consensus was predetermined to have occurred when 80% agreement (median Likert score of 5.6) was obtained among the initial two panels (Intensivists and coroners) (92,93). Consensus statements which did not achieve a Likert score of 5.6 were discarded from the final document.

(92,93). Consensus statements which did not achieve a Likert score of 5.6 were discarded from the final document.

Validation of the consensus statements was subsequently performed in April 1999 by an independent panel of Intensivists described above (98,99). Agreement with the generated consensus statements was rated on the same Likert scale as used by the original Intensivist and coroner panels. The validation panel was not presented with the final Likert score obtained in the third Delphi round. Median results were used, as described above, to determine consensus.

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. After responses to each round were received by the principal investigator, all identifying information relating to the individual panel member was removed.

RESULTS

The Adult Intensivist panel was composed of 2 Anesthetists, 3 Respirologists, 2 Internists, and 1 Surgeon; it included 7 men and 2 women. The coroner panel was composed of 5 men. The validation panel was composed of 6 Internists, 6 Respirologists; it included 8 men and 4 women.

The following results are the actual Intensivist panel's responses to the Delphi questionnaire after the third Delphi round. Where supporting evidence for their statements exists in the literature, references were inserted by the author. Both Intensivists and coroner panels were asked to rate their overall agreement with the responses to the Delphi questionnaire. In the third Delphi round, consensus was obtained: Intensivists' median agreement with the overall document rated a 7 (range 5 to 7) on the Likert scale, while the coroners' overall agreement was rated as 6.

Consensus was also obtained in both initial (Intensivist and coroner) panels on the 16 guidelines located at the start of each section. The median Likert scores (obtained in the third and final Delphi round) of the coroner and Intensivist panels are provided after each consensus guideline. Where ranges in these median scores occurred, they are presented. Where ranges are not provided, all members of the panel gave the consensus guideline the same score.

The median scores obtained from the validation panel for each consensus guideline are also provided.

CONSENSUS GUIDELINES ON THE USE OF ANALGESICS AND SEDATIVES IN DYING ICU PATIENTS.

PALLIATIVE CARE IN THE INTENSIVE CARE UNIT:

Good Intensive Care must promise relief of pain and suffering for ALL Intensive Care Unit (ICU) patients, not solely for those for whom death is inevitable. The palliation of dying patients in the ICU is different from palliative care in other settings since the dying process tends to be more dramatic and the time from withholding/withdrawing active disease treatment to death is much shorter. Ensuring good palliative care in the ICU is crucial.

Median Likert Score: Intensivist =7 (range 5 to 7); Coroner = 7 (range 5 to 7)

Validation panel = 6 (range 3 to 7).

Once it becomes clear that death is inevitable, Intensivists have an obligation, arising out of beneficence and non-maleficence, not to prolong their patients' dying by continuing active disease specific treatment (including life support). Moreover, once a decision has been reached, either at the request of, or with the agreement of the patient, family and staff, to withhold or withdraw life support, Intensivists have a duty to ensure that the best palliative care ("comfort measures") possible is given to that dying patient (23, 40,50). Often, death without further pain and suffering is the last promise we are able to make to our patients and their families.

Palliative Care in the Intensive Care Unit (ICU) has traditionally not been perceived as a continuum of care (20-22,100). When a decision is made to withhold or withdraw care, the Intensive Care team, patient, and family have traditionally changed their focus from a primarily interventional disease specific life-saving approach to a more intensively comfort-oriented treatment plan. However, the outcome of Intensive Care is often not obvious at the beginning of treatment and it is important to incorporate the teachings of palliative care into the care of all critically ill patients. Intensivists should always ensure their patients are comfortable and their pain well controlled, even during interventional disease specific treatment. Ensuring patient comfort solely during the pre-terminal phase of life must be de-emphasized. In fact, the main difference between disease specific treatment and palliative care is the goal: in disease specific treatment, the goal is to cure the patient; in palliative care, the goal is to support the patient. In both instances, comfort measures are very important.

Palliative care in the Intensive Care Unit differs significantly from palliative care in other settings. The dying process itself tends to be more dramatic. The time interval from withholding/withdrawal of active disease specific treatment (including life support) to death is generally much shorter. There is much less time available to prepare and accompany the patient and families through the dying process. This condensation of the grieving process means that it is often a more emotionally difficult one for everyone involved. Intensivists need to discuss all the goals, rationales, and limits of therapy with their patients and families (40,101). Discussions must include open communication about illness, prognosis, patient wishes and possible interventions including those aimed at palliation (40,101).

Ensuring good palliative care is important in the Intensive Care Unit (23,106,114). Since every patient is different, it is very important that the "comfort measures" that we administer be individualized. Pain and suffering should not be undertreated. Sometimes, the amounts of narcotics and sedatives needed to palliate, exceed what is thought to be “standard” doses for the chosen drugs. In recent times, the high amounts of analgesics and sedatives, required at the end-of-life, has given rise to fears (by lawyers, coroners, and public) that the drugs allegedly used to palliate, are really being used to assist in the death (euthanize/assist suicide) of patients (60,70,101,103).

The goals of this paper are therefore to respond to these concerns; to develop a consensus on the appropriate use of narcotics and sedatives in dying patients (both adults and pediatrics patients) in the ICU; and to distinguish palliative care from euthanasia/assisted suicide.

GOALS OF PALLIATIVE CARE IN THE INTENSIVE CARE UNIT.

The goals of palliative care in the ICU are: 1) relief of pain, 2) relief of agitation and anxiety, 3) relief of dyspnea, 4) psychological and spiritual support of patient and family and, 5) provision of comfort by changing the technological ICU environment to a more comfortable, peaceful one. Patients' wishes, including those expressed by advance directives, must be respected by the medical team.

Median Likert Score: Intensivist = 7 (range 6 to 7); Coroner = 6 (range 5 to 7)

Validation panel = 7 (range 4 to 7)

The goals of palliative care in the ICU are:

1) Relief of pain;

2) Relief of agitation and anxiety;

3) Relief of dyspnea;

4) Psychological and spiritual support of patient and family; and

5) Provision of comfort: by changing the technological ICU environment to a more comfortable, peaceful one (see below).

Patients' wishes, including those expressed by advance directives, must be respected by the medical team (23,103-109). Knowledge of advance directives may even preclude admission to the ICU, hence the proper communication of patients' wishes before ICU admission is crucial. All decisions regarding treatment or its withholding/withdrawal should respect the autonomy of the patient. Decisions should be made based on the known or reasonably perceived wishes of the patient, in consultation with their power of attorney for health care decisions and the family (107). Advance directives are useful in reflecting the values of individual patients and help in deciding which therapies would respect these values (106-108). Thus, they are useful in deciding when the goals of care should change from curative/supportive to palliative (i.e. wholly supportive).

Unfortunately, advance directives can cause problems when they are too vague or ambiguous. Difficulties may also arise when there is disagreement on the interpretation in regards to specific aspects of care. Open discussion is needed to resolve conflicts in interpretation if they arise.

Advance directives ought not demand that a physician violate his/her professional ethical principles.

While the psychological and spiritual support of the dying patient is undeniably an important aspect of palliative care, this paper will focus primarily on means to ensure relief of pain, dyspnea, anxiety/agitation and suffering. However, it is important to note that psychological support of patients may also require pharmacological intervention.

DIFFICULTIES IN THE ASSESSEMENT OF PAIN AND SUFFERING.

Pain and suffering are different. The ability to assess a patient's pain and suffering is crucial, yet these skills are poorly taught, if taught at all. In the Intensive Care Unit, pain assessment is rendered even more difficult by: 1) communication problems imposed by the ICU environment, 2) the severity of illness and the presence of multisystem organ failure, 3) decreased level of consciousness of patients as a result of illness and drugs, 4) our own lack of knowledge/difficulty in interpretation of clinical signs, and, 5) the unreliability of clinical signs. Suffering, because of its even greater individual nature, is harder to assess. Since the

assessment of suffering may not be easily amenable to teaching, what must be taught is respect for others' values; values through which individual suffering is perceived. Intensivists need to be aware of the abilities of their ICU staff in assessing and ensuring adequate relief of pain and suffering. Education, research and discussions with family members may be invaluable in improving the abilities of physicians and nurses to determine patient suffering.

Median Likert Score: Intensivist = 7 (range 6 to 7); Coroner = 7 (range= 4 to 7)

***Validation panel* = *6* (range *5* to *7*).**

First, it is important to distinguish pain from suffering. Suffering is the experience of emotional, physical, psychological or spiritual distress and incorporates the inability to remove oneself from a situation that is out of one's control. Therefore suffering can occur without pain; pain without suffering (32,33,110). At the bedside, it may not be possible to make this distinction. All that may be evident is that the patient is in distress and must be comforted through non-pharmacological or pharmacological means.

In the Intensive Care Unit, it is often difficult to assess pain because of:

1) Communication problems imposed by endotracheal tubes, ventilators, etc.;

2) The severity of illness and the presence of multisystem organ failure;

3) Decreased level of consciousness of our patients as a result of illness and drugs;

4) Our own lack of knowledge/difficulty in interpretation of clinical signs: for example, how much dyspnea is really felt by unconscious dying patients?; and

5) The unreliability of clinical signs (23,111).

Suffering, because of its individual nature, is even harder to assess (32,33). Family members may be helpful in aiding the physicians and nurses to determine patient suffering (33,135). Distress may occur in the absence of alertness (or full consciousness) and therapies need to be adjusted to eliminate this suffering which is then conveyed by facial expressions and body language (26).

The experience of pain and suffering is individual and varies according to situations and culture; however, education, in order to improve the abilities of all members of the health care team in assessing and relieving pain and suffering is very important (26,40). Unfortunately such skills are currently either not taught or not well taught at any level in our training (40,101,113-115). Experience currently plays a larger role than education in our ability to improve our skills in this area. Scales to estimate pain should be taught and used by students, nurses, and physicians in order to develop a common language. Intensivists must recognize that these scales are not perfect and limitations exist: the levels of these scales may not be mutually exclusive nor fully inclusive (30,31). Consideration should be given to provide all Intensivists with training in palliative care.

Great variability exists in the dosing of drugs among nurses and physicians during the withholding/withdrawing of life support based on different interpretations of suffering. Nurses may be better than physicians in assessing pain and suffering because of the amount of time they spend at the patient's bedside (28,29,111,118). Patients' families may also require education about the dying process to avoid misinterpretations (e.g. to prevent them from interpreting delirium as physical pain); however, they may provide invaluable guidance in regards to assessing suffering (26,116). In conclusion, while the assessment of suffering may not be amenable to teaching, what must be taught is respect for others' values, values through which individual suffering is perceived (41-49,116).

Emotions will always influence our interpretations, no matter how scientific we may want to be about the assessment of pain or, more so, of suffering. Still, more research is needed. Experience with pain and suffering in the ICU should be reported. Difficult cases should be discussed with all members of the medical team, the family and the patient if possible. The research in palliative care should be explored to see if it can be applied in the ICU setting (40,112,113).

RELIEF OF PAIN AND SUFFERING.

In order to relieve pain and suffering at the end-of-life, both pharmacological and non-pharmacological means should be used. Non-pharmacological interventions include ensuring the presence of family, friends and pastoral care (if desired), and, changing the technological ICU environment to a more private and peaceful one. Nursing interventions and accommodating patients' religious and cultural beliefs also play an important role in alleviating pain and suffering. Pharmacological interventions include any analgesics, sedatives or other adjuncts that will decrease discomfort. In general, narcotics are used for pain; benzodiazepines are used for agitation and anxiety. If the patient is experiencing pain and suffering, both analgesics and sedatives are used. This combination of drugs may provide better relief of pain and suffering at the end-of-life than either class of drug alone.

Median Likert Score: Intensivist = 7 (range 4 to 7); Coroner = 7 (range 6 to 7)

Validation panel = 7 (range 6 to 7)

In order to relieve pain and suffering at the end-of-life, both pharmacological and non-pharmacological means should be used.

Non-Pharmacological Interventions:

Non-Pharmacological interventions include ensuring family, friends and pastoral care (if so desired) are present. Efforts should be made to change the usual technological ICU environment to a more quiet, peaceful setting and to give the patient and family more environmental control (for example, providing access to music, lighting changes, increasing privacy (if possible), or offering a bed by a window (if available). Surrounding the patient with familiar well-loved possessions and having families recall memories of past events may help them during the dying process. Family involvement in personal care and their presence at the time of death may be particularly comforting. Other comfort measures such as ensuring a moist buccal mucosa, alleviating pressure areas, and using massage therapy may also be helpful (23,26,116,123-125).

These interventions should be used when caring for all ICU patients, not only for those for whom death is imminent.

Finally, efforts should be made to incorporate patients' cultural and religious beliefs and/or rites during the dying process. Patients and families must always be treated with compassion and respect (41-49,116).

Pharmacological Interventions:

Pharmacological interventions include any analgesics, sedatives or other drugs (such as butyrophenones and phenothiazines) that will decrease discomfort. In general, narcotics are used for pain; benzodiazepines are used for agitation and anxiety. If the patient is experiencing pain and suffering, both analgesics and sedatives are used. This combination of drugs may provide better relief of pain and suffering at the end-of-life then either class of drug alone (32,103,110,117,119,125).

The most commonly used narcotic is morphine although others, such as fentanyl may also be used in equipotent doses. The reason that narcotics such as morphine are so commonly used is that, besides its potent analgesic properties, it has several other effects which help palliate the dying patient. It decreases coughing and thus enables patients to better tolerate the endotracheal tube; it causes a general decrease in dyspnea and through its venodilating effects, it specifically decreases the dyspnea of congestive heart failure; and, finally, it has a soporific effect (23,31,32,112,119,125). If a patient develops side effects or is allergic to morphine, other narcotics such as hydromorphone (dilaudid) may be used.

In the Intensive Care Unit, during the withdrawal of life support, narcotics are most commonly administered intravenously or subcutaneously although oral, rectal or epidural routes may also be used.

Commonly used benzodiazepines include diazepam, lorazepam and midazolam. Diazepam may be preferred when palliating the dying patient due to its longer half-life. When continuous intravenous infusions are used, diazepam may not be the best choice due to its poor water solubility; therefore changing to lorazepam or midazolam ensures better drug delivery. Paradoxical reactions to benzodiazepines may occur and any worsening agitation in patients not previously exposed to these drugs requires re-assessment to determine whether more benzodiazepine is needed or whether an antipsychotic is required instead (23,112,119-121,125).

Intensivists should use the narcotics and benzodiazepines they are most familiar with since knowledge of the pharmacology and pharmacodynamics of these drugs ensures they will be used effectively (23,40,112,125).

Other drugs may be needed to palliate specific symptoms. Antipsychotics may be needed to treat delirium arising from either illness or from the side effects of the narcotics and benzodiazepines. Other agents are useful adjuncts for analgesia e.g. Nozinan. Antiemetics, e.g. metoclopramide, dimenhydrinate may be needed to alleviate nausea and vomiting (125). (N.B.: dimenhydrinate is usually inadequate).

There is no role for potassium chloride, or any other medication intended to cause death, in palliative care.

All other medications should be assessed in terms of their ability to alleviate pain and suffering. A balance between the need to use certain interventions to alleviate suffering and their ability to cause suffering must be achieved (40,50,101).

INITIAL DOSAGE.

Most ICU patients require narcotics and sedatives in order to ease the pain and suffering associated with their critical illness. The amount of drugs needed varies on an individual basis. As in active disease treatment, palliative care MUST be individualized. Considerations affecting the initial dose of narcotics and sedatives in palliation include: 1) the patient's previous narcotic exposure since tolerance develops quickly, 2) age, 3) previous alcohol or drug use and/or abuse, 4) underlying illness, 5) underlying organ dysfunction 6) the patient's current level of consciousness/ sedation, 7) level of available psychological/spiritual support, and, 8) patients' wishes regarding sedation.

Median Likert Score: Intensivist = 7 (range 4 to 7); Coroner = 7 (range 6 to 7)

Validation panel = 6.25[2] (range 5 to 7).

The majority of patients in the Intensive Care Unit are already on intermittent and/or continuous infusions of narcotics and intermittent and/or continuous infusions of sedatives in order to ease the pain and suffering associated with their critical illness (28,29,111).

Once the decision is made to withhold/withdraw life support, the dose of analgesics and sedatives required to ease pain and suffering at the end-of-life needs to be individualized. The importance of this individualization of palliative care cannot be over-emphasized.

In general terms, the required dose of narcotics and sedatives will depend on:

1) Patient's previous narcotic exposure since tolerance develops quickly;

2) Age: younger patients frequently need more than the elderly;

3) Previous alcohol or drug use and/or abuse;

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[2] Some validation panelists ranked their agreement as fractions on the Likert scale.

4) Underlying illness e.g. burn patients have high narcotic requirements and become quickly tolerant;

5) Underlying organ dysfunction e.g. renal and/or hepatic dysfunction; and

6) Patient's current level of consciousness/ sedation (23,112,125).

Other important factors may also influence the required dosage such as the availability of family, social and religious support. A young patient may need more drugs to control anxiety and distress when compared to an elderly patient; those without supports may experience more anxiety than someone with an extended family.

Palliative care in the ICU is different from that provided in other situations: the dying process is often not as prolonged and there is less time for the patient to reflect on their life, to discuss end-of-life issues and to grieve. Not being able to undergo this important reflective process may lead to higher narcotic/sedative requirements (23,122-124).

It is important for the Intensivist to remember that some patients will wish to be as awake as possible during the withholding/withdrawing process, while others will wish to be heavily sedated. These wishes must be respected and is yet another reason why palliative care must be individualized. When a patient is unable to communicate, families may provide an understanding of the degree to which the patient might wish to be sedated during the withholding/withdrawal process (116,41-49).

While families may play an important role in assessing pain and suffering, they are often physically and emotionally exhausted and may, inadvertently, attribute their own suffering to the patient. Objective assessment by the health care team is therefore important. If families do believe their loved one is in pain or is suffering, this perception should be alleviated either by an explanation (of the signs they are seeing) or by an increase in the analgesia/sedation for the patient. Intensivists must prepare families for the dying process by telling them what to expect. The family as well as the patient must be cared for; after all, it is the families who continue to grieve after the patient has passed away (40, 115,116).

Controversy exists over whether a patient may be more aware of their surroundings than is sometimes evident on clinical exam. Unfortunately, the clinical exam is all we have to assess awareness in dying patients. Ramsey scales may be useful despite their limitations (30-31). Intensivists should always err on the side of caution when assessing awareness and frequent re-assessments are needed. If true, this failure to adequately detect awareness further justifies the use of large doses of medication to ensure the patient is not suffering.

With the above stipulations in mind, palliative care may be initiated as follows *:

1) Intermittent Administration:

Initial doses of narcotics must always be individualized and depend on previous exposure. When the Intensivist communicates the goals of pain relief and sedation to properly trained Intensive Care Unit personnel, any need to set an hourly maximal dosage is precluded. However, when dealing with inexperienced personnel, setting an hourly maximum dose and ensuring frequent re-assessments encourages the physician to oversee the administration of narcotics/sedatives and may result in better end-of-life care.

Intensivists therefore need to be aware of the abilities of their ICU staff in assessing and ensuring adequate relief of pain and suffering.

For example, palliation may begin with 1-5 mg morphine IV q 15 min. prn.***, using dosages at the lower end of this spectrum if the patient has not been previously exposed to large amounts of narcotics ("narcotic naive"). Much higher initial bolus doses may be required if the patient is already receiving higher intermittent doses of morphine and has developed tolerance (23,125).

If the patient is anxious, agitated or dyspneic, benzodiazepines may be added. Initial doses again would depend on previous exposure. For example, midazolam may be started at 1-5 mg IV prn q 15 min *. However much higher doses may be used in a patient who has become tolerant. Again, there is no need for hourly maximum doses when dealing with properly trained personnel.* (23,117-119,125)

* The above mentioned doses are solely intended as examples and are NOT to be taken as strict recommendations.

2) Continuous Infusion:

Again, starting palliative doses will depend on previous exposure. For example, if patients have never been on narcotics previously, starting at 2-5 mg/hr IV of morphine may be appropriate *. Frequently, patients are already on infusions with average doses ranging from 2-10 mg/hr morphine, 50-150 ug/hr of fentanyl, and 2-10 mg/hr of midazolam *. When withdrawal of life support is begun, a bolus must be given and the rate of these infusions increased to ensure a faster rise to steady state concentrations. The balance between pain control and sedation level becomes irrelevant* (43, 47).

* The above mentioned doses are solely intended as examples and are NOT to be taken as strict recommendations.

TITRATION OF ANALGESICS AND SEDATIVES.

Once analgesics and sedatives are initiated, they are increased in response to 1) patient's request, 2) signs of respiratory distress, 3) physiological signs: unexplained tachycardia, hypertension, diaphoresis, 4) facial grimacing, tearing, vocalizations with movements, turns or other nursing care, and 5) restlessness. These clinical indicators, although crucial for graduated therapy, are imprecise. Ramsay or Likert scales, despite their limitations, may provide additional help in evaluating the patient's discomfort. The total amount of drugs required for any individual patient may far exceed any preconceived notions of "usual", in reality non-existent, doses.

Median Likert Score: Intensivist = 7 (range 6 to 7); Coroner = 7 (range 5 to 7)

Validation panel = 5.25[3] (range 4 to 7)

Once the patient's level of analgesia and sedation is thought to be adequate, ventilatory support is gradually removed. Currently, controversy exists in the literature over the "best" way to withdraw ventilatory support and many different approaches are used. For the purposes of this paper, two points should be made: 1) this withdrawal process should not be unduly prolonged, and, 2) it should be long enough to allow the health care team to ensure patient comfort (109, 119, 126-133).

Once analgesics and sedatives are initiated, they are increased in response to:

1) Patient's request*--(includes visual analog scales) occurs only in a minority of cases but any degree of discomfort, no matter how he or she defines it should be treated.

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[3] Some validation panelists rated their agreement as fractions on the Likert scale

2) Signs of respiratory distress** : (most important indication after patient's request)
includes tachypnea with accessory muscle use, gasping, patient-ventilator dysschrony.

3) Physiological signs: unexplained tachycardia, hypertension, diaphoresis suggest pain and/or suffering.

4) Facial grimacing, tearing, vocalizations with movements, turns or other nursing care.

5) Restlessness (23).

* The dying patient may not be able to respond to questions or verbal commands appropriately due to the severity of their illness, and the ICU environment.

* * Signs of respiratory distress need to be interpreted with some caution since with declining oxygen saturations, hypercarbia, decreasing lung volumes, cardiac output and the development of hypotension and acidosis all patients (narcotised or not) will become air hungry or tachypneic due to hypoxia and this may be interpreted as suffering when in fact the patient is in the preterminal phase just prior to death.

Ramsay (aim for score = 4-6) or Likert scales may provide useful tools to evaluate the effectiveness of the relief of the patient's pain and suffering (30-31).

The amount of drugs required for any individual patient will depend on the factors listed above. This amount may far exceed any preconceived notions of "usual" (in reality non-existent) doses.

It is important to remember that these clinical indicators, although crucial for graduated therapy, are imprecise. Unfortunately, there is no definitive way to evaluate pain and suffering in dying patients and interpretations vary from one caregiver to another, and from one family member to another.

Physicians and nurses demonstrate variable skill both in their ability to assess and their tolerance to patients' pain and suffering (28,29,111). Physicians are also known for underestimating the psychological needs of patients and their families (28). Years of experience may improve these abilities. These differences in interpretation, however, may explain some of the difficulties in determining how much medication is required to ease pain and suffering at the end-of-life.

During withdrawal of life support the goals and wishes of each individual patient need to be determined: aiming for an unconscious state may not always fit with these goals and light sedation, which may facilitate communication with family, may be more appropriate (23,116,123). However, light sedation may not be achievable in critically ill patients with multisystem organ failure and unconsciousness will supervene as oxygen levels decline.

SPECIAL SITUATIONS:

Neuromuscular blockers mask the clinical signs of pain and suffering delineated above. When possible, the withholding and withdrawal of life support should be started after their effects wear off in order to permit Intensivists to assess as accurately as possible the patient's pain and suffering and ensure good palliative care. If neuromuscular blockers were not in use, they should not be started in order to hide patient distress. The intent and justifications of Intensivists who fail to wait for neuromuscular blockers to wear off or who fail to reverse them must be carefully documented. Since patients in persistent vegetative states are deemed incapable of feeling pain or anxiety, sedatives and narcotics are usually not required during the withholding/withdrawal of life support. The family's perceptions of pain and suffering however may play a role in the use of narcotics and sedatives in these patients.

Median Likert Score: Intensivist = 7 (range 3 to 7); Coroner = 7 (range 5 to 7)

Validation panel = 6 (range 2 to 7)

a) Patients on Neuromuscular blockers.

The half-life of neuromuscular blockers may be affected by organ dysfunction. When properly titrated (1 twitch to train of four on a peripheral nerve stimulator), this prolongation of their half-life can be minimized (119, 141,142). When possible, the withholding and withdrawal of life support should be started after their effects wear off in order to permit Intensivists to assess as accurately as possible the patient's pain and suffering. If required, neuromuscular blockers can be reversed. Reversibility should be ensured with the use of a peripheral nerve stimulator using a train of four (119,141,142). Heavy sedation can then be used to provide relief of dyspnea and distress once the neuromuscular blockers are removed (23,119,142).

Sometimes due to their prolonged half-life, it is not possible to wait until neuromuscular blockers have worn off prior to initiating withholding/withdrawal of life support and sometimes patients have developed a profound polyneuropathy due to their prolonged use (119, 141). In these instances, heavy sedation should be used to ensure that patients have no awareness of being paralyzed and are not experiencing pain (indicative signs include heart rate, blood pressure response and diaphoresis). Intensivists, in these circumstances, should err on the side of over-sedation since the degree of pain and suffering is difficult to assess.

If neuromuscular blockers were not in use, they should not be started in order to hide patient distress (119,142). The intent of Intensivists who initiate neuromuscular blockers during the withholding/withdrawal of life support is suspect. The intent and justifications of Intensivists who fail to wait for neuromuscular blockers to wear off or who fail to reverse them must be carefully documented.

b) Patients in Persistent Vegetative States (PVS).

Clear goals of caring for these patients need to be established. PVS patients are thought to be unaware of their environment and not capable of feeling pain or anxiety (119,135-137). Sedatives and narcotics are usually not required during the withholding/withdrawal of life support. The family's perceptions of pain and suffering, however, may play a role in the use of narcotics and sedatives in these patients (119, 135-137,122).

DOES A MAXIMAL DOSE EXIST?

No maximum dose of narcotics or sedatives exist. The goal of palliative care is to provide relief of pain and suffering and whatever the amount of drugs that accomplishes this goal is the amount that is needed for that individual patient. By refusing to define a maximal dose of analgesics or sedatives, our goal is to ensure that Intensivists will use the required dose for each patient. If a maximal dose is ever declared, some patients will be in pain and will be suffering at the end-of-life because of the Intensivist's fears of litigation if this maximal dose is exceeded. Therefore, the intent of the physician administering the drugs becomes important in distinguishing between palliative care and assisted death (euthanasia/assisted suicide).

Median Likert Score: Intensivist = 7 (range 2 to 7); Coroner = 7 (range 5 to 7)

Validation panel = 6.5[4] (range 4 to 7)

There is NO maximal dose of narcotics or sedatives. There is NO dose that should not be exceeded in dying patients. The goal of palliative care is to provide relief of pain and suffering and whatever the amount of drugs that accomplishes this goal is the amount that is needed for that individual patient (23,125).

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[4] Some validation panelists rated their agreement as fractions on the Likert scale

The amount of drugs needed will vary widely in individual patients as already discussed above (23,112,125). There is no plateau in the dose-response curves of these drugs and the development of tolerance and the unpredictability of the duration of the dying process will also influence the total amount of drugs administered. In situations in which it is difficult to relieve the patient's pain and suffering, it is important to always check that the patient is indeed receiving the drugs administered i.e., that there is a good, patent IV line.

By not defining a maximal dose of analgesics or sedatives, our goal is to ensure that Intensivists will use the required dose for each patient. If a maximal dose is ever declared, some patients will be in pain and will be suffering at the end-of-life because of the Intensivist's fears of litigation if this maximal dose is exceeded. Therefore, the intent of the physician administering the drugs becomes important in distinguishing between palliative care and assisted death (euthanasia/assisted suicide).

No Institutional policies exist on the maximum doses of narcotics and sedatives that should be prescribed, nor should there be.

SHOULD ANALGESICS AND SEDATIVES BE ADMINISTERED IN RESPONSE TO SIGNS AND SYMPTOMS OF PAIN AND SUFFERING, OR BEFORE THEY BEGIN?

Support for both approaches exists among Intensivists on this panel. The treatment of signs and symptoms of pain and suffering is good palliative care. When appropriate doses of narcotics and sedatives are used and the intent of the physician is clear and well documented, preemptive dosing in anticipation of pain and suffering is not euthanasia nor assisted suicide but good palliative care.

Median Likert Score: Intensivist = 7 (range 6 to 7); Coroner = 7 (range 5 to 7)

Validation panel = 6 (range 4 to 7)

There is support for both approaches among Intensivists. Some physicians believe that narcotics and sedatives should be given in incremental doses once evidence of pain and suffering is present. Others felt that narcotics and sedatives should be administered before procedures known to cause pain and distress e.g. extubation (119). They argue that there is no need to make patients demonstrate suffering when we have the ability to ensure that death occurs in a peaceful, dignified manner. Anticipating pain and distress will avoid any gap in analgesia/sedation and it is well known that pain is much harder to control when it is not treated preemptively. Furthermore, Intensivists preemptively treat pain and suffering during active disease specific treatment and there is no reason why this approach to pain and suffering should change during the withholding/withdrawal of life support.

When appropriate doses of narcotics and sedatives are used and the intent of the physician is clear and well documented, pre-emptive dosing in anticipation of pain and suffering is not euthanasia or assisted suicide but good palliative care.

Most patients do not survive withdrawal of life support (129). However, if the Intensivist feels a patient may be able to breathe comfortably and maintain his or her oxygen saturation/gas exchange without ventilatory support, small doses of narcotics and sedatives may be tried initially and rapidly incremented if needed in response to pain or distress (126,129).

HOW CAN WE IMPROVE OUR ABILITIES AND OUR CONSISITENCY IN ASSESSING AND TREATING PAIN AND SUFFERING?

Open discussions involving all members of the health care team and family, consulting and sharing when faced with difficult cases, improvements in education and research are needed. The development of a process to review our performance in palliative care within each ICU and national consensus guidelines will also improve our skill in assessing pain and suffering and improve our abilities to relieve it at the end-of-life.

Median Likert Score: Intensivist = 7 (range 5 to 7); Coroner = 6 (range 5 to 7)

Validation panel = 6 (range 5 to 7).

The process of withdrawal of life support should be well delineated with the agreement of the patient (when able), all health care workers and family members. Intensivists should be able to consult other Intensivists about difficult cases. Opportunities for re-assessment and discussion of the process must be established. Difficult cases should be shared (23,50,104,119,122).

An appropriate environment (both physical and interprofessional) and a process need to be developed in all ICUs to encourage and facilitate communication with family members and with the health care team (40,50,104,109).

Regular education in the palliation of pain and suffering should be provided to all Intensivists, nurses and other members of the ICU team. Furthermore, education of families, in terms of what to expect during the dying process and the means at our disposal to palliate patients, is needed (23,115,116).

Fostering research into this area of Intensive Care and applying relevant research from other fields such as Palliative Care Medicine will also help improve care in the ICU at the end-of-life (23,40,101,115,116).

National consensus guidelines involving nurses, administrators and coroners/medical examiners, by delineating good palliation practices, may eliminate any misunderstandings and fears the health care providers may have of prosecution for assisted suicide/euthanasia (5,23,113).

The assessment and treatment of pain and suffering should become part of the quality control in the ICU within every hospital (5, 40,113,114).

SUPPORT FOR THE INTENSIVE CARE UNIT STAFF.

The importance of psychological and emotional support for the ICU staff involved in palliating a dying patient is frequently overlooked. Developing a supportive working group, open communication and regular debriefings among members of the ICU team is crucial. The ICU social worker, pastoral care representative and, within the hospital, the departments of psychiatry and psychology may also be very helpful in enabling the ICU staff to continue to provide good palliative care.

Median Likert Score: Intensivist = 7 (range 5 to 7); Coroner = 7 (range 5 to 7)

Validation panel = 6 (range 5 to 7)

Psychological and emotional support for all those involved, including the Intensivist (who is too often neglected in these withholding/withdrawal situations) must be available. The value of a supportive working group is evident (115).

Before speaking with the patient's family, open communication within the health care team must occur in order to ensure that there is consensus about the level of the patient's pain and suffering and how this can be minimized. Efforts to be approachable, and to ensure the ICU staff feels comfortable raising concerns, should be made. All members of the Intensive Care Unit team should be invited to participate in discussions with the patient and family. Once the family has been involved, this dialogue must continue through rounds, progress notes and family meetings (109,115,122).

The Intensive Care Unit social worker and pastoral care representatives also play invaluable roles in providing the patient, family and ICU staff with emotional and psychological support during the dying process. Within the hospital, the departments of psychiatry and psychology may also be supportive. Regular debriefing for the ICU staff may be considered. After the patient's death, social workers and pastoral care could provide follow up support for the family and health care team (debriefing and bereavement support) (23,115,116).

PALLIATIVE CARE MEDICINE CONSULTATION.

Currently a formal Palliative Care consult is rarely requested during the withholding and withdrawal of life support. If the expertise exists within the ICU, such a consult is not required. A Palliative Care Medicine consultation could be useful to: 1) treat symptoms that are difficult to control, 2) treat difficult pain syndromes, 3) provide guidance on the use of adjuncts that we, as Intensivists, use infrequently in the dying process, 4) provide guidance when using analgesics/sedatives infrequently administered, 5) help when significant psychological issues within the family or health care team are evident, 6) provide guidance in ICUs where the practices of withholding/withdrawal of life support is infrequent, 7) help ease the patient's transfer to the ward if he/she survives the withholding/withdrawal process, and 8) provide ongoing help in relieving pain and suffering when death is protracted.

Median Likert Score: Intensivist = 7 (range 2 to 7); Coroner = 7 (range 5 to 7)

Validation panel = 5.5[5] (range 3 to 7)

Consulting Palliative Care Medicine to assist in the withholding/withdrawal of life support is currently rarely performed. If the expertise exists within the ICU, a Palliative Care Medicine consultation is not required. However, in the absence of such expertise, a

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[5] Some validation panelists rated their agreement as fractions on the Likert scale.

Palliative Care Medicine consult can be helpful. Furthermore, if the patient may survive the process of withdrawal of life support and can be transferred from the ICU to the ward, palliative care consultation may ensure quality end-of-life care especially if the dying process is prolonged and the physicians are uncomfortable with dying patients and their families (23).

Palliative Care Medicine consultation could also be useful to:

1) Treat symptoms that are difficult to control i.e. nausea;
2) Treat difficult pain syndromes i.e. neurogenic;
3) Provide guidance on the use of adjuncts (to provide relief) that we as Intensivists use infrequently in the dying process e.g. Nozinan;
4) Provide guidance when using analgesics/sedatives infrequently used;
5) Help when significant psychological issues within the family or health care team are evident;
6) Provide guidance in ICUs where the practices of withholding/withdrawal of care is Infrequent; and
7) Provide ongoing help in palliating pain and suffering when death is protracted.

TERMINAL SEDATION.

Terminal sedation, defined in the literature as sedation with continuous IV narcotics and/or sedatives until the patient becomes unconscious and death ensues from the underlying illness, is palliative care, not euthanasia. Since terminal sedation may arguably make the detection of euthanasia/assisted suicide more difficult, the intent of the Intensivist is crucial.

Median Likert Score: Intensivist = 7 (range 4 to 7); Coroner = 7 (range 4 to 7)

Validation panel = 6 (range 5 to 7)

Terminal sedation, defined in the literature (14,67-69,145) as sedation with continuous IV narcotics and/or sedatives until the patient becomes unconscious and death ensues from the underlying illness, is palliative care, not euthanasia.

While terminal sedation is well defined in the literature, some Intensivists in this panel do not like the inherent implication in the term "terminal sedation"(14,23,67,68,119,145). They feel it falsely implies an intent to terminate life. They suggest "end-of-life sedation" may be a more appropriate description of this type of palliative care. Perhaps this component of palliative care should be renamed; however, in order to avoid confusion with the current literature, this paper will use the term "terminal sedation".

Terminal sedation, similar to intermittent administration of narcotics/sedatives, requires balancing the beneficial pharmacological effects of the drugs and their side effects. These side effects may foreseeably hasten death. In many cases, it is impossible to separate the benefits of these drugs from their side effects (51,69,134). Decreasing sedation levels to avoid side effects may result in the provision of inadequate relief to the dying patient, and failure to control their pain and suffering is unethical. Frequent re-evaluation of the dying patient is essential to ensure that both under and over-treatment is avoided.

Since terminal sedation may arguably make the detection of euthanasia/assisted suicide more difficult, the intent of the Intensivist is crucial.

INTENT.

The intention of the Intensivist administering narcotics/sedatives to palliate dying patients can be assessed by careful documentation in the chart of: 1) the patient's medical condition and reasons leading to the initiation of palliative care, 2) the goal which is to relieve pain and suffering, 3) the way pain and suffering will be evaluated, and 4) the way in which drugs will be incremented and why. Intensive care units should develop guidelines governing the process of withholding and withdrawal of life support and Intensivists should justify and document any need to deviate from the policy and the anticipated modifications. The administration of drugs without any palliative benefit, e.g. lethal doses of potassium chloride or neuromuscular blockers, suggests an intent to euthanize/assist in the suicide of an individual patient.

Median Likert Score: Intensivist = 7 (range 4 to 7); Coroner = 7 (range 6 to 7)

Validation panel = 6 (range 3 to 7)

The intention of the Intensivist administering narcotics/sedatives to palliate dying patients can be assessed by careful documentation in the chart of:

1) the patient's medical condition and reasons leading to the initiation of palliative care*: relates to appropriateness of withholding/withdrawal in the given situation;

2) the goal is to relieve pain and suffering;

3) the way pain and suffering will be evaluated; and

4) the way in which drugs will be incremented and why.

*Should also include documentation of discussion with the patient and family and patient's wishes if known.

Documentation as described above is crucial. In its absence, it may be more difficult to distinguish palliative care from assisted death. Other means to distinguish the two include an evaluation of the drug administration process. This calls for an evaluation of the order sheets on the patient's chart to determine how the drugs were initiated, and how they were incremented. High initial amounts and rapid increments (large drug doses given too frequently for the effects of previous doses to be seen and evaluated) out of proportion to the pain and suffering of the dying patient may be suspicious for euthanasia. If a patient is already heavily sedated and is clearly comfortable or unconscious, further large doses of narcotics and/or sedatives may also be suspicious. The administration of drugs without any palliative benefit, i.e. potassium chloride, suggests an intent to euthanize/assist in the suicide of an individual patient.

Intensive Care Units and hospitals should have policies governing the process of withholding and withdrawal of life support. Intensivists should respect these policies. These policies need to be developed with the help of nurses, pastoral care and other care-givers since they are the ones constantly at the patient's bedside during the withdrawal process. If the policy is followed, then any deviations from the policy can be identified and reviewed. If the Intensivist needs to deviate from the policy in order to palliate a given patient, the reasons therefore and the anticipated modifications need to be clearly documented.

The measurement of serum drug levels of narcotics and sedatives in order to titrate these drugs is useless. Correlation between drug levels and effect is not documented and likely does not exist (26,69,121). Furthermore the development of tolerance renders drug levels meaningless. Even if correlation did exist, serum levels take time to perform and waiting for levels may result the undertreatement of pain and suffering and prolonged patient discomfort. The correlation between pre-mortem, postmortem drug levels and clinical control of pain is not known; therefore, measurements of drug levels are not valuable in assessing the intent of health care provider administering the drugs.

PRINCIPLE OF DOUBLE EFFECT.

If the amount of narcotics/sedatives required to relieve pain and suffering at the end-of-life may foreseeably cause hastening of death, although the physician's intent is solely to relieve suffering, this should be considered palliative care.

Median Likert Score: Intensivist = 7 (range 6 to 7); Coroner = 7

Validation panel = 7 (range 5 to 7).

DISTINCTION BETWEEN PALLIATIVE CARE AND EUTHANASIA.

The intent of the physician administering narcotics and sedatives to the dying patient is the most crucial distinction between palliative care and assisted death (euthanasia/assisted suicide). In order to avoid any misinterpretations, Intensivists must clearly document, in the patient's chart, their intentions and justify their actions during the withholding/withdrawal process.

Median Likert Score: Intensivist = 7 (range 4 to 7); Coroner = 7

Validation panel = 6 (range 4 to 7)

The most important way to distinguish palliative care from euthanasia/assisted suicide is by the intent of the physician administering the narcotics/sedatives. In an appropriate situation, once the decision has been made to withhold/withdraw life support, the intent of the Intensivist, and the contemplated process, needs to be well documented as discussed in the section on intent.

Patients in the ICU are most often already receiving large doses of narcotics and sedatives prior to any withholding or withdrawal of treatment. Palliative Care in the ICU is different than palliative care elsewhere since the withholding/withdrawal of life support systems which are already palliating patients' symptoms often necessitates higher drug doses than seen in other settings.

If a situation arises in which the amount of narcotics/sedatives given seems excessive (e.g., high doses given without a clear reason and/or rapidly incremented out of proportion to the known pharmacology of the chosen drugs) and it is not clear from the chart why this was the case, it may still not be a case of assisted death (euthanasia/assisted suicide). The physician or nurse in question may simply lack knowledge and skill and be unclear on the drug dosages required to palliate. While this lack of knowledge suggests the need for re-training in palliative care, there is no intent to euthanize/assist in the suicide of the patient. If, on the other hand, the physician or nurse is aware of drug doses and is clearly not treating signs of pain and suffering, his/her intent is much more suspect.

DISCUSSION

Our consensus guidelines detail the appropriate use of analgesics and sedatives in dying ICU patients. These guidelines are the first to consider the unique challenges encountered in palliating dying patients and encourage the provision of therapy clearly directed at the relief of pain and suffering even if the provision of such relief entails high doses of narcotics and sedatives. The goal of this project is not to contribute to the debate over whether euthanasia/assisted suicide could ever be considered ethically and morally acceptable. Rather, our guidelines represent a first step in developing a standard of care for dying patients in the ICU. By increasing the comfort of health care providers in distinguishing palliative care from euthanasia, our guidelines encourage them to provide good palliative care while practicing within the context of the current legal system banning euthanasia/assisted suicide.

The following discussion will explore our guidelines' contributions to the existing literature, discuss the difficulties and complexities we discovered in attempting to reach consensus and, finally discuss the implications of our consensus guidelines for practice and future research.

Contributions to Existing Literature.

Until recently, palliative care and Intensive care have been considered opposite ends of the care spectrum. Some studies have shown a frightening lack of pain control in surviving ICU patients (28,29,34). The large multicentre SUPPORT study reported 49.9% seriously ill patients complained of pain, 33% of whom had extremely severe pain (29). Whipple et al. examined pain control in 17 trauma patients during their initial ICU course: 27% of patients rated their pain as moderate and 47% as severe (29). In contrast 95% of housestaff and 81% of nurses felt these patients had received good pain control (29). Puntillo examined the pain experiences in 24 surgical ICU patients after their transfer from the ICU and found 63% rated their pain as moderate to severe (28).

The Ontario Chief Coroner's office has issued a memo defining palliative care as care: 1) intended solely to relieve suffering, 2) administered in response to symptoms or signs of suffering and commensurate with the suffering, and 3) that is not a deliberate infliction of death (17). Unfortunately, these guidelines are not specific to the ICU and no guidelines on how to determine whether the drugs administered are commensurate with suffering are provided. By detailing how analgesics and sedatives should be administered and titrated, our consensus guidelines clarify the Chief Coroner's definition of "palliative care", at least within the ICU context.

While the SCCM has published practice parameters (16) on analgesia and sedation in the ICU, our consensus guidelines are the first guidelines on the use of analgesia and sedation in *dying* ICU patients. The SCCM guidelines are not designed to resolve the unique problem physicians face when administering analgesia and sedation to dying patients: achieving balance between inadequate palliative care and euthanasia. No studies have explored how dying patients can best be palliated. Therefore our guidelines differ from the SCCM's since we used recognized consensus methods to explore the knowledge of expert Intensivists and coroners. By defining how analgesics and sedatives *should* be administered to provide good palliative care, our consensus guidelines will hopefully diminish the undertreatment of pain at the end-of-life.

Specific Insights.

During the development of these guidelines, several questions and topics were source of debate and/or contention among our panel members. I am certain our readers will raise some of these same concerns. Therefore, in this section, I will focus on topics in which we struggled to obtain consensus, whether between our panels or among our individual panel members, with the goal of increasing our understanding of why these areas were so troublesome.

Death as dramatic: The first consensus statement describes death in the ICU as dramatic. The use of this adjective was questioned by some members of the initial Intensivist panel as well as some on the validation panel. While their disagreement with the description of death as dramatic was insufficient to change the consensus statement, it is clear that it requires some explanation. The ICU staff is quite familiar with death in the Unit, and may no longer appreciate how death in the ICU is different from death in other parts of the hospital or at home. In the ICU, the dying patient is surrounded by tubes and technology. There is little privacy. The course of critical illness has caused the patient's emotions, as well as that of their family and caregivers, to swing from hope to despair. While the technology, the uncertainty and the force of these emotions are familiar to the ICU staff, they may bewilder and distress patients, families and loved ones. Even if the patient's pain and physical discomfort are controlled, their sense of grief, bewilderment and loss of control gives rise to suffering. Such suffering may deepen as chances of survival diminish. Every death is an emotional event in life. However, the intensity of emotion, the unique ICU environment and technology in addition to the lack of time to prepare for death, has lead us, for want of a better word, to call death in the ICU dramatic.

Drug doses: Throughout the development of this document, one Intensivist panel member consistently felt that any discussion of drug dosages was unnecessary and, moreover, would only lead to confusion and potential legal complications. While it is true that Intensivists, just as any other physicians caring for dying patients, should know the pharmacology of the drugs used to palliate, research has shown repeatedly that this is not true in practice (3,5,40,118,144). A lack of knowledge, fears of side effects and addiction as well as fears of hastening death continue to prevent us from appropriately using narcotics and sedatives to alleviate pain and suffering (3,5,40). This paper is not meant to be a substitute for such knowledge.

Confusion over the distinction between palliative care and assisted death arises precisely because neither the intent of the physician, nor the way in which the analgesics and sedatives will be titrated, is always evident. Until now, this confusion has only increased in situations when large doses of drugs are needed to palliate (35,17). Discussion of drug doses, how and when they should be administered and incremented (17), is crucial to clarify the borders of good palliative care, dispel fears of prosecution for assisted death and, thus, enable the provision of good end-of-life care.

Drug Levels: In contrast to the initial Intensivist panel, some of the coroners felt that serum drug levels would be the only definitive way to distinguish between palliative care and euthanasia. Due to the variable development of tolerance, serum drug levels do not correlate with the relief of symptoms (26,69). Serum drug levels should never be used in the care of dying patients. The time needed to obtain serum levels would exacerbate the undertreatment of their pain and distress. The use of postmortem serum drug levels is also not helpful. Furthermore, the subjectivity of intent determines culpability for murder under section 229 (a) of our current criminal code (55) and moral permissibility under the principle of double effect. In euthanasia or "mercy killing", a person is criminally responsible for intending death as a means to relieve suffering. Under the principle of double effect, a person intends to relieve suffering and only foresees the hastening of death (i.e. death as a side effect). Hence in providing sedation, the physician produces two effects: relief of suffering (which he/she intends) and hastening death (which he/she does not intend but only foresees). While the physician is morally responsible both for what he intends **and for what** he foresees, he might be more responsible for the ends he primarily intends when compared to the ends he merely accepts (foresees) (146). Therefore, the principle of double effect permits Intensivists to provide sufficient analgesia and sedation with the intent to relieve suffering, and, hastening death, while not intended, is accepted.

Thus, what the particular accused (physician), in the situation in question, intended is crucial, not what a reasonable person could be inferred to have intended under the same or relevantly similar circumstances (objective standard of intent). Even if drug levels could be used to decide whether a patient was killed by an overdose of narcotics/sedatives, in order to establish murder under section 229 (a), the prosecution would have to prove that the patient's death was the intent of the particular physician involved. Drug levels alone would not provide conclusive evidence of criminal intent.

Research into serum drug levels should be encouraged, not because of fears of prosecution for assisted death, but because, in these times of limited funding, research would be better directed at ways to improve the quality of end-of-life care.

Intent: The principle of double effect is currently used by most medical associations to permit their members to administer narcotics and sedatives, with the sole purpose to alleviate pain, even though their administration may hasten death (8,9,50,51). The principle of double effect relies on the intent of the physician administering these drugs to determine moral culpability (8,9). During the development of these guidelines, our panelists affirmed the importance of the intent of the Intensivist administering the analgesics and/or sedatives to the dying patient in distinguishing palliative care from euthanasia. However, we and some of our panel Intensivists (on both the initial and validation panels), fully acknowledge a note of caution is needed.

While sometimes a person's intent can be inferred from their actions, this is not always the case (8,9,55). In any event, in criminal law the inference must be drawn beyond a reasonable doubt. There is no way to empirically test for intent and our guidelines do not claim to do so. Intentions are unique to individuals (8). Many complex psychological motives may be involved in the formation of an intent (8,9). Someone's intent may therefore never be completely understood by another person or, for that matter, even by the person him/herself (8,9,147). In euthanasia ("mercy killing"), the agent intends to kill the patient in order to relieve intractable suffering. In criminal law, the agent would have the mens rea of murder because he/she intended to kill (55). The motive, in this example, to relieve suffering, is sometimes referred to as "ulterior intent" (55). In criminal law, direct intents (in our example, to kill) determine guilt while motives (or "ulterior intents") go to sentencing (55). To the extent that our intent cannot be fully known by others (147), the border between palliative care and euthanasia may never be crystal clear. We want to affirm the need for cautious evaluation on a case by case basis should any concerns arise over the intent of physicians' administering narcotics and sedatives to dying patients.

Since its role is so crucial in deciding moral and legal culpability, can we ever consistently and confidently determine the intent of another? One solution or approach may reside in virtue and care-based ethics (58-60,62,65). A virtuous physician has certain character traits that predispose him/her to habitually act for the patient's good (60,62,65). The ethics of care emphasizes the importance of situational context and of our relationships with others in moral reasoning (58,59). Concern, empathy, compassion and, consideration of the nature of our interpersonal relationships determines what is morally relevant and why (58,59). The ethics of care and virtue can allow the physician's intent to be more clearly interpreted and such interpretations trusted: if a physician is virtuous and will always act for the patient's good with care and compassion, the physician's motives and intents will always be moral or ethical. In terms of criminal law, the actus reus (killing) would not be accompanied by a culpable state of mind (mens rea) (55).

Medical schools and residency programs therefore need to focus more attention on the formation of the character of physicians, and broaden the scope of their ethical education to include more than just knowledge of Beauchamp's and Childress' (140) ethical principles (beneficence, non-maleficence, autonomy and justice). Perhaps renewal of interest and incorporation of virtue and care-based ethics in medical school curriculums will increase society's trust in the medical profession and increase our confidence in knowing the intentions of physicians.

Neuromuscular Blockers: Similar to comments in the current literature (119,141,142), most Intensivists on our original panel felt that withdrawing ventilatory support on a medically paralyzed patient did not permit adequate assessment of his/her pain and suffering. Since a paralyzed patient is unable to breathe, these Intensivists feel that withdrawing the ventilator and extubating these patients is, in fact, euthanasia. However, some Intensivists (1 on the original panel and 1 on the validation panel) disagree. They argue that we need not wait for the effects of paralyzing agents to wear off since the intent of the Intensivist is not to kill but rather to avoid any prolongation of suffering in cases where death is clearly inevitable. However a paralyzed patient cannot initiate any breaths and is completely dependent on the ventilator to live. Removing the ventilator will not just foreseeably hasten death, but will, arguably, directly cause it. While, in the majority of situations, the intent of the Intensivist is undoubtably not to kill the patient, potential for abuse (euthanasia) remains (141,119). All our Intensivists did agree that neuromuscular blockers should not be initiated after a decision has been made to withdraw the ventilator.

A further problem arises since, on occasion, the half-life of neuromuscular blockers is quite prolonged (119,141). Intensivists may rightly raise the question of how long ought we to wait for the drugs to wear off? Or, in the case of a severe critical illness neuropathy, how long ought we to wait for it to improve? While there is no denying that ensuring relief of pain and suffering can be more challenging in a paralyzed patient, Intensivists can use physiological signs of distress (tachycardia, hypertension, tachypnea) and can err on the side of administering more narcotics/sedatives if concerns arise that the patient is inadequately sedated (119,141,142).

When death is inevitable and the decision has been made to withdraw mechanical ventilation, the prolonged time interval (sometimes up to three weeks (119,141)) which may be required for neuromuscular blockers need to wear off or for a critical illness neuropathy to resolve, can result in significant emotional and psychological distress among family members and the ICU staff. Some propose setting an arbitrary time limit of 2-3 hours for neuromuscular blockers to wear off (119). If their effects haven't disappeared at the end of this interval, they suggest using heavy sedation/analgesia and proceeding with withdrawal of the ventilator (119). Another option would be to decrease the concentration of oxygen administered (FiO2) without decreasing the ventilator rate: the patient would still be given mechanical breaths but would breathe room air. This situation more closely resembles withdrawing the ventilator from a non-paralyzed patient.

Persistent Vegetative States: Controversy exists over whether patients in a persistent vegetative state are able to feel pain. Studies show that 90% of family members (137) and 30% of physicians (139) feel these patients have some awareness of pain. While cerebral metabolic studies suggest persistent vegetative patients have metabolic rates comparable to patients under a general anesthetic, the use of cerebral metabolic studies to assess awareness of pain are controversial (135, 138). Repeated physical examinations may help determine if an individual persistent vegetative patient is indeed able to feel pain (135). While physicians must treat the patient with narcotics and sedatives and not the family, families may be more adept at perceiving signs of pain than the healthcare provider since they frequently spend the most time with their persistently vegetative loved one (137). If there is any perception that a given persistent vegetative patient is feeling pain, the Intensivist should administer analgesics as in any other dying patient (135).

The differential diagnosis of persistent vegetative states include locked in syndromes and akinetic mutism (135,136). In contrast to PVS patients, these patients are able to feel pain and to suffer (135). If any doubt about the diagnosis exists, Intensivists should also err on the side of assuming the patient can experience pain and suffering and administer analgesics and/or sedatives as required.

Palliative Care Consultations: Many Intensivists on our original and our validation panels felt that palliation of pain and suffering at the end-of-life is a skill that every Intensivist should possess. Far from disputing the claim that palliative care medicine should be core ICU knowledge, we dispute the claim that it is (28,29,33,34). There is no proof in the current literature that Intensivists are better at relieving their dying patients' distress than other physicians. Research has revealed problems in alleviating pain even in hospice patients (1-4,40). While death in the ICU is different from death on palliative care ward, these differences do not mean Palliative Care Medicine has nothing to offer and/or teach the ICU staff or vice versa. Accepting the impossibility of excelling in all aspects of care, respecting our different abilities in different fields and learning from each other are crucial to improve our skills in caring for dying patients. Research into how the two fields can work together to improve palliative care in the ICU setting is needed.

Doctor-patient relationship: A few Intensivists on our validation panel commented on the role of the patient's intent in distinguishing palliative care from euthanasia. For example, a patient could request massive doses of narcotics and sedatives in an effort to commit suicide or be euthanized. We did not discuss this possibility in our consensus guidelines beyond commenting that patients or their surrogates cannot demand that physicians break the law or violate their professional code of ethics (106,107). In the ICU, critically ill patients are very vulnerable and the balance of power clearly resides with the physician, perhaps more than in any other field of medicine. Furthermore, for a variety of reasons (among them critical illness itself, decreased level of consciousness due to multisystem organ failure, and/or drugs), critically ill patients are rarely able to make requests for such high doses of narcotics and sedatives. Since the intent of the ICU physician plays a larger role in distinguishing palliative care from euthanasia, our guidelines focussed on the physician's role. Certainly, it is not inconceivable (although unlikely) that, in some situations, a patient could demand more drugs than he/she needs with a goal of deliberately hastening or causing death. However, the final responsibility for euthanizing or assisting in suicide will always rest with the physician.

Adult vs. Pediatric Guidelines: We started this Delphi process with a panel of adult and pediatric Intensivists. While similarities in their responses exist, differences in caring for dying pediatric and adult patients quickly became apparent necessitating different consensus statements. That the two panels diverged should not, in retrospect be surprising. Despite important similarities, the care of pediatric patients involves important different medical, legal and ethical considerations than seen in adults.

Implications for Research and Practice.

Our consensus guidelines could be used by all ICU physicians to improve the palliation of dying patients. However, consensus guidelines are only of benefit if they are disseminated and implemented. Several ways of increasing the likelihood of achieving these two goals exist:

i) The Canadian Critical Care Society and the Society of Critical Care Medicine (SCCM) should review and consider adopting these guidelines in their efforts to improve the quality of end-of-life care within the ICU.

Currently, great efforts are underway to improve the care provided to dying patients within the ICU and elsewhere. This interest in meeting the needs of dying patients and their families is evident in such educational programs such as EPEC (Education of Physicians on End-of-Life Care) and, in the recognition of the importance of palliative care and the need to increase its accessibility (70). These guidelines are a reflection of the current interest in end-of-life care within the ICU and an acknowledgment of the need for even greater efforts to improve the quality of end-of-life care in this setting.

ii) Critical Care Fellowship programs should consider incorporating these guidelines into their training programs to increase young Intensivists' awareness and understanding of the difficulties in caring for dying patients.

Currently, even formally trained ICU staff feel they lack sufficient knowledge to effectively manage pain and suffering (33,143,144). Despite the common perception of palliative care and Intensive care as representing opposite ends of a continuum of care (23), Intensivists on our panel viewed the provision of palliative care as a core ICU task. Thus, the causes of the ICU staff's discomfort with knowledge in palliative care

(33) (as seen by our panelists as well as in the literature), and the reasons for our failure to alleviate pain and suffering, are unclear (28,29,34). Perhaps it is because training programs currently emphasize technology, fail to recognize the importance of pain and suffering or assume discomfort associated with critical illness must be endured. The reasons our current training programs fail to provide sufficient knowledge to enable the ICU staff to alleviate pain and suffering would be an interesting topic for future research. In the meantime, our consensus guidelines call for ongoing education of the ICU staff in order to overcome this barrier to the provision of palliation in the ICU.

iii) Future efforts to improve these initial consensus guidelines requires input from other members of the ICU team.

The Association of Critical Care Nurses, respiratory therapists and pastoral care organizations, among others, should review these guidelines and suggest ways of improving them. Increasing participation in the development of consensus guidelines will not only serve to further focus attention on the care of dying ICU patients but has also been shown to increase the likelihood of their successful implementation.

In some Canadian cases of euthanasia (71-77), there is a suggestion of panic on the part of healthcare providers confronted with unrelieved pain and suffering (*R. v. Mattaya, R. v. De la Rocha, Dr. Morrison*). Our consensus guidelines recognize that the withholding and withdrawal of life-sustaining therapies can be emotionally and psychologically difficult for the ICU staff. Providing support to the ICU staff may prevent this panic and improve their ability to provide quality end-of-life care. Currently no studies to confirm this hypothesis exist. Institutions should explore how their staff's needs can best be met, ensure staff awareness and encourage them to use any programs subsequently developed. Future research can then explore the impact of such support on the ICU staff's comfort in caring for dying patients, and their abilities to provide quality of the end-of-life care.

iv) Coroners could use these guidelines to help distinguish between palliative care and euthanasia in the ICU setting.

As discussed, confusion between palliative care and euthanasia/assisted suicide can arise in the ICU context. In such cases, where concern has arisen over the amount of narcotics and sedatives administered to dying patients, our guidelines, by detailing how palliation should be administered to dying patients, could be used by coroners to help distinguish palliative care from euthanasia/assisted death. However, our guidelines are not meant to be an empiric test of intent; such a test is non-existent.

While increasing documentation may also help clarify intent if any future doubts arise, documentation is not a test of intent. More importantly, our consensus guidelines call for improved documentation of each dying patient's health care plan in order to facilitate communication among the health care team. If large doses of narcotics and/or sedatives are needed to palliate dying patients, Intensivists should not fear prosecution for assisted death (euthanasia/assisted suicide) if they fail to document their plan to care for these patients; rather, they should be concerned over failing to meet an acceptable standard of care.

Limitations

This study has four 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 it is possible that other Intensivists may not have arrived at the same consensus statements, panel members in this study had remarkably similar responses in each Delphi round. Although, we attempted to validate our consensus statements by using an independent panel of Intensivists, all of the panels were small. Questions regarding the generalizability to other Intensivists therefore remain.

Second, our consensus guidelines are physician based. Input from Palliative Care physicians and other health care professionals, such as nurses, social workers and pastoral care, etc. will also be important in our ongoing efforts to improve the quality of care we provide to dying patients in the ICU.

Third, patients have a different perspective on quality end-of-life care than health care providers (15). One of the important limitations of our consensus guidelines is their development 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. Research to explore how palliative care can be improved in the ICU from the patient's (if possible) and family's perspective is needed.

Fourth, while clinical practice guidelines are important in improving the quality of care, they are frequently not implemented in practice (5). Our consensus guidelines will be used by Intensivists to improve the care of dying patients and by coroners to distinguish palliative care from euthanasia. By using Intensivists and coroners to develop our consensus guidelines and recommending means of improving quality of care, we hope to " encourage buy-in" (5) and ensure implementation

These consensus guidelines are not meant to add to the debate whether euthanasia/assisted suicide should be legalized, nor are they meant to be a moral statement on whether euthanasia/assisted suicide should be permissible practices. Our goal is to help define palliative care in order to permit Intensivists to feel comfortable that they are practicing within the boundaries of our current legal system.

Conclusions.

These consensus guidelines on analgesia and sedation in dying ICU patients will help improve the quality of end-of-life care in the ICU and help distinguish palliative care from euthanasia/assisted suicide. More research and ongoing education in palliative care are certainly needed to provide ICU patients with a good death, at the very least, one free of pain and suffering

APPENDIX I

INITIAL DELPHI QUESTIONNAIRE— INTENSIVISTS.

1. How should patients' pain and suffering be controlled at the end-of-life? (which drugs?, when?, how much?) Please justify your answer.

2. What indications of the patient experiencing suffering and/or pain should be used to judge whether an appropriate amount of narcotic or sedative has been used?

3. Is there a maximal dose of narcotic or sedative that you would recommend not be exceeded? Please justify your answer.

4. During withdrawal of care, would you recommend that narcotics and/or sedatives be given in incremental doses once suffering is evident or before it begins?

5. Is euthanasia (as defined in section 2.3) acceptable or unacceptable?

6.a) Is terminal sedation (sedation to relieve pain until death occurs from the disease itself) euthanasia or acceptable practice?
  b) In terminal sedation, how should the drugs used to induce unconsciousness be incremented to palliate without causing death?

7. How can the intentions of the physicians administering sedatives/narcotics at the end of-life be assessed (eg. to palliate vs. to euthanize or to assist suicide)?

8. If the amount of narcotics and/or sedatives required to relieve pain and suffering at the end-of-life may forseeably cause hastening of death although the physician intends only to relieve pain and suffering, should this be considered assisted suicide or euthanasia?

9. How can palliative care be distinguished from euthanasia/assisted suicide in the ICU setting?

APPENDIX II

INITIAL DELPHI QUESTIONNAIRE--- CORONERS.

1. What indications of the patient experiencing suffering and/or pain should be used to judge whether an appropriate amount of narcotic or sedative has been used?

2. Is there a maximal dose of narcotic or sedative that you would recommend not be exceeded? Please justify your answer.

3. During withdrawal of care, would you recommend that narcotics and/or sedatives be given in incremental doses once suffering is evident or before it begins?

4. Is euthanasia (as defined in section 2.3) acceptable or unacceptable?

5. a) Is terminal sedation (sedation to relieve pain until death occurs from the disease itself) euthanasia or acceptable practice?
   b) In terminal sedation, how should the drugs used to induce unconsciousness be incremented to palliate without causing death?

6. How can the intentions of the physicians administering sedatives/narcotics at the end of-life be assessed (eg. to palliate vs. to euthanize or to assist suicide)?

7. If the amount of narcotics and/or sedatives required to relieve pain and suffering at the end-of-life may forseeably cause hastening of death although the physician intends only to relieve pain and suffering, should this be considered assisted suicide or euthanasia?

8. How can palliative care be distinguished from euthanasia/assisted suicide in the ICU setting?

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