

Framework for Continuous Palliative Sedation Therapy in Canada

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Preamble

Sedation is a commonly used procedure in many medical disciplines including palliative care. It is indicated for a variety of reasons and the type of sedation varies considerably. For example, intentional temporary sedation is sometimes used for procedures (chest-tube insertion, endoscopy, etc.) or insomnia whereas at other times sedation is unintentional (sometimes called secondary or consequential sedation) such as when sedation occurs as a side-effect of a drug being used to control a symptom. Thus the topic of sedation in palliative care practice is vast and complex.

To develop this framework the authors reviewed the international literature and palliative sedation policies and protocols from within and without Canada. Recommendations from the first draft were presented at two workshops to full-time and part-time palliative care physicians and to family physicians and a subsequent draft based on feedback from the workshops was then sent to selected inter-professional reviewers across Canada. Their feedback was incorporated into the next draft and this was sent to members of the Canadian Society of Palliative Care Physicians (CSPCP) who were then surveyed for their level of agreement with the recommendations. There was a 29.3% response with over 70% agreement with all but three of the recommendations. This final document addresses planned sedation for management of intolerable and refractory symptoms. It does not address emergency sedation e.g. for an acutely agitated and delirious patient.

Introduction and Background

The role of continuous palliative sedation therapy (CPST) still generates controversy. From the early 1990s, when CPST was first described^{1,2}, until the present day reports have raised concern about its potential for misuse, or abuse as a form of covert euthanasia^{3,4,5,6,7,8}. Correctly practiced it is an ethically and medically acceptable form of therapy⁹.

The expression “terminal sedation” first appeared in the literature in the 1990’s in Enck’s review of two articles concerning symptom control at the end of life². These papers suggested that up to 52% of patients near death had symptoms so resistant to available palliative treatments that only sedation was sufficient to control them. CPST appeared in

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the literature as an already existing practice and very little is known about its development prior to this appearance.

Assessment of CPST practice in Canada revealed a lack of coherent practices and policy and, where they exist, a wide variety in institutional and/or regional guidelines^{10,11,12,13,14}. The Board of the CSPCP agreed that it was time to follow the example of some other countries^{15,16,17} and associations¹⁸ and develop a consensus-based CPST framework for Canada on which local and/or regional policies and/or guidelines for CPST can be built. The choice of developing a framework versus a clinical guideline or protocol was intentional, as it was felt that a definitive direction on pharmaceutical needs, routes of administration, etc. will vary according to local availability, cost, and experience.

Many definitions have been put forward for sedation use in palliative practice, but at the core they share the ideas that CPST is:

- 1) The use of (a) pharmacological agent(s) to reduce consciousness
- 2) Reserved for treatment of intolerable and refractory symptoms
- 3) Only considered in a patient who has been diagnosed with an advanced progressive illness
- 4) Usually considered only in patients in whom death is expected within two weeks or less.

Sedation policies and/or guidelines should address the following areas:

- Definitions and Terms Used
- Indications
- Aims
- Ethical Considerations
- Nutrition and Hydration
- Cultural Aspects
- Decision-making and Informed Consent
- Drugs and Their Administration
- Monitoring and Outcomes

We considered grading the levels of evidence and strength of recommendations. However, the literature pertaining to CPST contains so little substantial evidence that we agreed it was pointless to do so. This framework is based on literature reviews, published research, case reports, expert opinion and evolving clinical practice.

Definitions and Terms Used

1). To avoid confusion local, regional and provincial/territorial CPST policies and guidelines in Canada should use the same definitions and terms.

Much of the difficulty in understanding not only what CPST is but also its indications, aims and practice lies in the fact that the existing literature has either not defined the terms used, or has used differing definitions^{19,20}. Although most of the definitions used here are generally accepted there has always been, and likely always will be, controversy over the term to use for the actual sedating procedure. This was discussed extensively before agreeing that CPST was if not the most acceptable then the least objectionable [definition](#). For consistency between policies and guidelines from different institutions, regions and provinces or territories the following definitions should be used:

Palliative Care (also in Canada “Hospice Palliative Care”) is “whole-person health care that aims to relieve suffering and improve the quality of living and dying”²¹

Continuous Palliative Sedation Therapy (CPST) is the intentional lowering of a patient’s level of consciousness in the last one to two weeks of life. It involves the proportional (titrated) and monitored use of specific sedative medications to relieve refractory symptoms and intolerable suffering. Sedation as a consequence of medications used to relieve a specific symptom is not regarded as CPST.

Refractory Symptoms are present “if all other possible treatments have failed, or it is estimated by team consensus, based on repeated and careful assessment by skilled experts, that no methods are available for alleviation within the time frame and risk/benefit ratio that the patient can tolerate”²².

Suffering is a state of severe distress associated with events that threaten the intactness of the person at one or more of the following domains: physical, psychosocial, and existential or spiritual²³. Although pain, dyspnea, delirium and nausea and vomiting are frequent causes of suffering at the end of life, hopelessness, remorse, anxiety, loneliness, and loss of meaning also cause suffering. Suffering involves the whole person in physical, psychological, and spiritual ways and can also affect family, friends, and caregivers²⁴. Family members frequently feel psychological distress when they see or perceive that their loved one is suffering²⁵.

Intolerable Suffering is “a sense of helplessness or loss in the face of a seemingly relentless and unendurable threat to quality of life or integrity of self”²⁶.

Existential Suffering^{24,27}, describes the experience of patients with advanced progressive illness who may or may not have physical symptoms but report suffering that is unrelated

to a psychiatric disorder or social isolation. It can be related to one or more of: meaninglessness in present life; sense of hopelessness; perceiving oneself as a burden on others; feeling emotionally irrelevant; being dependant; feeling isolated; grieving; loss of dignity and purpose; (fear of) death of self; or fear of the unknown.

Family²⁸ describes those who are closest to the patient in knowledge, care and affection, which may include:

- the biological family
- the family related by marriage/contract e.g. spouse, life-partner or significant other
- the family of choice and friends (including pets).

The patient decides who will be involved in his/her care and/or present at the bedside²⁸.

Euthanasia²⁹ means knowingly performing an act that is explicitly intended to end another person's life and that includes the following elements: the subject has a terminal illness; the agent knows about the person's condition and commits the act with the primary intention of ending the life of that person; and the act is undertaken with intention to kill although the motive is mercy.

Physician Assisted Suicide²⁹ means that a physician counsels, aids and/or abets a person to commit suicide through one or more of: use of lethal doses of drugs; prescribing lethal doses of such drugs; or supplying such drugs.

Indications

- 1) *CPST is indicated only for refractory and intolerable suffering, usually in the last two weeks of life.*
- 2) *The care team should have adequate experience and expertise to determine that the symptom is refractory and should reach consensus.*
- 3) *If the healthcare team does not have the necessary expertise and experience to make these assessments they should seek consultation with a clinician more experienced in CPST.*
- 4) *CPST for purely existential symptoms should only be initiated in rare cases of severe existential distress and after skilled multidimensional management directed at the physical, psychological and existential dimensions has been attempted, preferably in consultation with relevant experts (e.g. chaplain, ethicist, palliative care physician, etc.) in this area.*

The indication for CPST is refractory *and* intolerable suffering, usually from one or more physical symptoms, when death is expected within one to two weeks. Estimation of time remaining before death is difficult and there will be exceptions to this time frame. However, the longer the anticipated time before death the greater the ethical challenges and the more controversial the procedure, especially regarding decisions around nutrition and hydration during sedation. As always, each case must be considered individually.

An international paper that included a review of 22 case series found that in 55% of cases the refractory symptom for which sedation was indicated was delirium and/or terminal restlessness not responding to adequate treatment with haloperidol or other drugs¹⁹. Other refractory symptoms included dyspnea (27%), pain (18%) and nausea and vomiting (4%).

It is important to distinguish a refractory symptom from one that is difficult to treat²². The setting of care and the relative availability of interventions may be a factor in the determination of refractoriness³⁰. CPST in a patient who cannot communicate his/her wishes requires extra consideration to determine intolerability of a symptom. In this circumstance discussion with the patient's substitute decision maker (SDM) is mandatory.

Determining refractoriness and intolerability requires:

- 1) a rigorous assessment by a multidisciplinary team defining physical, psychological, social, emotional and existential/spiritual dimensions of the symptom(s)^{31,32}
- 2) ensuring that all available symptom-targeted medications, procedures or interventions attempted have been ineffective or produced unacceptable side effects, or if considered were ruled out as being too risky or burdensome for the patient, or were reasonably refused by the patient²² or by the SDM acting in accordance with the patient's previously expressed values and/or wishes.
- 3) consideration of additional factors influencing assessment of a refractory symptom. E.g. there is evidence in the literature that physician fatigue and burnout can lead to an increased use of CPST^{33,34}.

If the healthcare team does not have the necessary expertise and experience to make these assessments they should seek consultation with a clinician more experienced in CPST. If such expertise is not available locally e.g. in remote areas with little or no experience of CPST, the team should consider consultation via video-conference or telephone. A verbal discussion is preferable, so email is not recommended unless there is no alternative.

CPST for existential suffering is controversial^{35,36,37,38,39,40}, and healthcare professionals are uncertain about the role of CPST for management of existential suffering⁴¹. Existential suffering can exacerbate suffering from refractory physical symptoms⁴², or be significant in its own right. The ability of existential causes to produce suffering equal to or greater than that of physical symptoms should not be disregarded. However, CPST for purely existential symptoms should only be initiated in rare cases of severe existential distress and after skilled multidimensional management directed at the physical, psychological and existential dimensions has been attempted, preferably in consultation with relevant experts in this area (e.g. chaplain, ethicist, palliative care physician, etc.)¹⁹.

Aim

- 1) *The aim of CPST is to adequately relieve refractory and intolerable suffering of the patient.*
- 2) *Sedation should be carefully titrated to relief of suffering*
- 3) *The aim is not sedation but relief of suffering*

The aim or intention of CPST is the relief of suffering due to refractory and intolerable symptoms^{43,44,45} and not the sedation itself. There should be no intention to shorten life and no intention to bring about complete loss of consciousness although this latter may sometimes be necessary. The level of consciousness is lowered only as far as is

necessary to relieve the suffering. Thus, the intention of CPST can be assessed by the proportionality of the procedure⁴⁶ i.e. the combination and amount of drug used to reduce the level of consciousness should be just sufficient to alleviate distress. Viewing the actual sedation as the desired outcome is inappropriate.

Ethical Considerations

1. *CPST correctly practiced is not a form of euthanasia but a viable therapeutic option for the management of intolerable and refractory symptoms in the last 1 to 2 weeks of life.*
2. *Individual policies on the use of CPST should take into consideration the principles and considerations put forward by this consensus-based national framework.*
3. *Attention to the process of decision-making and to obtaining appropriate consent for CPST should be the central focus of any medical guidelines put into practice. The utilization of CPST needs involvement of all stakeholders on the team.*
4. *Any institution implementing a policy on CPST should consider having a separate policy and/or practice guidelines addressing medical decision-making regarding life-supporting modalities such as assisted ventilation and Nutrition and Hydration in the provision of End-of-Life Care.*
5. *To guard against abuse guidelines and policies must include safeguards ensuring care is delivered to accepted medical standards*

CPST has been a much debated and controversial issue within the field of palliative care⁴⁷. Many of the recurrent ethical questions related to CPST have stemmed from disagreement and a lack of conceptual clarity pertaining to intention, justification, application, consequences, and use of this therapy. It is toward these concerns that the development of a consensus-based framework is directed. Traditionally, the ethical authority for the use of CPST came from the moral imperative of medicine: to relieve human suffering^{19,48}. However, given that the “means and ends” of relieving human suffering remain contentious, and to sufficiently address this complex topic a more nuanced understanding of the ethical issues is required. The very broad concern of whether CPST is ethically justified contains within it narrower concerns. Table 1 outlines some of these narrower ethical concerns.

Table 1
Ethical Issues Central to the Use of CPST

1) Is PST a form of euthanasia?
2) Can a patient's free and informed consent ever be obtained in the context of intolerable suffering?
3) Is a treatment that relies on the decrease/absence of consciousness a means to remove suffering by removing the sufferer?
4) In what stage of the illness is it appropriate to use CPST?
5) In what circumstances is the withholding or withdrawing of treatments such as nutrition and hydration in CPST ethical?
6) Can policy related to CPST incorporate sufficient safeguards to prevent abuse?

1) **Is PST a form of euthanasia?** The data published to date indicates that the appropriate use of CPST does not shorten life^{49,50,51}. Clinicians continue to dispute the relationship between CPST and the hastening of death, but most often this concerns cases in which sedation is given outside the scope recommended in this framework, e.g. sedation given well beyond levels needed to palliate suffering and sedation given before death is imminent^{5,52}.

2) **Can a patient's free and informed consent ever be obtained in the context of intolerable suffering?** Given that CPST is by definition indicated in cases of intolerable suffering, one can ask whether some persons suffering in this way might be incapable of giving truly voluntary or fully capable consent. The concern is that such a patient might feel pressed by his or her suffering to accept offered palliation without adequate consideration. This framework accepts that to some degree such concerns cannot be eliminated. However three considerations justify CPST in spite of these concerns. First, by insisting before initiating CPST that all other reasonable alternatives have failed or were reasonably rejected, the framework precludes the opportunity to choose CPST "prematurely" or under duress of suffering. As a result the patient will be left to choose between ongoing suffering or CPST, with no other choices remaining. Second, by encouraging teams to follow accepted consent procedures (*see* "Decision-making and Informed Consent"), the framework supports the kind of voluntary and capable decision-making that these procedures seek to promote. Third, by encouraging teams to consider, discuss and revisit the question of CPST frequently and diligently, the framework goes

beyond typical consent procedures in order to maximize the voluntariness and capacity of these decisions.

3) Is a treatment that relies on the decrease/absence of consciousness a means to remove suffering by removing the sufferer?

Sentience is a powerful and shared human value that informs much of our philosophical and theological understanding of personhood. The implication of a decision to use CPST is that symptom relief could not be obtained without intentionally clouding consciousness. To assist in understanding the appropriate and ethical use of CPST, proportionality, intentionality, and titration play a key role. There should be consensus that the harm of suffering warrants the harm of reduced consciousness; it should be clear that the intention is to palliate; and both these features should be apparent in the titration of sedation to relief of suffering. This calls for prudence and transparency to be demonstrated throughout the decision-making process⁵³, with agreement on a clear treatment goal i.e. relief of suffering by the proportional use of sedative medication to adequately relieve suffering without overshooting that goal (*see* Appendix p3 of the decision algorithm).

4) In what stage of the illness is it appropriate to use CPST? When death is imminent sedation, even when deep and continuous, has not been shown to hasten death, provided this sedation is titrated to suffering. Thus, offering CPST in the last weeks of life has not traditionally been identified as a distinct ethical problem^{54,55}. Understanding that precise prognostic certainty is rarely possible, in this context a condition of “imminence” can be recognized and acceptably defined clinically as “dying” or “being in the last stages of life”. This is typically taken as meaning hours or days, or at most less than two weeks, to live⁵⁵.

5) In what circumstances is the withholding or withdrawing of treatments, such as nutrition and hydration, in CPST ethical? The linkage of CPST with presumed life-shortening effects, such as the withholding of hydration and nutrition (N&H)⁵⁶ continues to cause concern. Decision-making regarding the use of N&H needs to be made independently of a decision for CPST and clear reasons for the use or not of N&H documented to justify this decision^{57,58} (*see* “Nutrition and Hydration” and p2 of the decision algorithm, Appendix). An institution involved in the provision of end-of-life care should consider having policies and/or practice guidelines to assist decision-making involving the withholding and/or removal of life supportive therapies (e.g. ventilatory support, N&H) and these guidelines should be kept in mind whenever considering the use of CPST.

6) Can policy related to CPST incorporate sufficient safeguards to prevent abuse?

Ultimately, agreeing to use the ethical requirement of a favorable risk-benefit ratio involves accepting risks that are commensurate with the gravity of the clinical indication⁵⁹. In doing so we need to acknowledge that the potential for abuse does exist in CPST, and so build within guidelines and policies safeguards that ensure that care is

delivered within accepted medical guidelines⁶⁰. All policies created for the initiation of CPST must require: shared decision-making processes; clear documentation of the refractory nature of the symptoms experienced; adherence to an informed consent process; and that the administration of medications is titrated to the relief of the symptoms being treated (*see* Decision Algorithm in Appendix)

Nutrition & Hydration

- 1) *The ethical aspects of PST are distinct from the ethical aspects of nutrition and hydration, and so each should be considered separately on its own merits.*
- 2) *Any discussion of CPST should address the role of nutrition and hydration during sedation.*

The ethical and clinical aspects of nutrition and hydration in the dying patient are separate and distinct from the ethical and clinical aspects of CPST^{36,46}. The withdrawal or withholding of hydration is not an essential element of CPST for refractory symptoms at end of life¹⁹. Unfortunately, although there is an extensive, albeit inconclusive, literature concerning nutrition and hydration for the patient dying of cancer none of this literature relates to sedated imminently dying patients. A thorough review of the relevant literature concluded that there was insufficient evidence about either the beneficial or harmful effects of fluid administration to terminally ill patients to permit recommendations⁶¹. Thus, it is not surprising to find that opinions and practices vary^{62,63,64}. The psychological, ethical, cultural, religious and/or legal implications of nutrition and hydration management in palliative patients also need consideration⁶⁵.

In cases where a permanently sedated patient is expected to survive for more than a few days some would argue that dehydration would hasten death, whereas others would be of the opinion that giving fluids would neither prevent death nor make it more comfortable, but prolong the dying process. There is no evidence for either view.

An international group concluded that neither nutrition nor hydration is physiologically relevant in the sedated patient if death is imminent¹⁹, but went on to comment that account should be taken of cultural preferences and styles of decision-making. Even medically futile provision of nutrition and hydration may have cultural, religious and psychological benefits.

Cultural Aspects

- 1) *Staff providing palliative care and/or initiating CPST should receive appropriate training in cultural competency.*
- 2) *CPST-related decision-making should incorporate specific cultural and religious/spiritual values and practices into the plan of care for patients and families.*
- 3) *The use of culturally trained language interpreters, if available within an appropriate time, when dealing with patients and family members who do not speak the primary language is advisable. The health care team should not rely solely on family members to act as interpreters when discussing treatment options, including CPST.*

Health care decisions for families and patients involve more than just consideration of the medical facts. Family history, culture (personal, familial, societal and institutional), philosophies, spiritual/religious constructs and attending beliefs all play a major role in determining how decisions will be made. Consequently, health care is a place for the collision of cultural differences and potential conflict⁶⁶.

Culture can be broadly understood as a set of learned and shared beliefs and values that are applied to all our interactions, and ultimately to the interpretation given to one's experience. It is the lens through which we view the world, resulting in ways of naming and understanding reality, and as such plays a significant role in health care decision-making¹⁹. Healthcare professionals (HCPs) should be aware that health care has its own culture, which when unchecked plays out as the "dominant" culture and can lead to the perception by staff that the medical way of doing things is always the preferred way (ethnocentrism)⁶⁷.

Health, illness and disease and the fundamental expectations about how those who are ill and suffering should behave are concepts replete with assumptions and values that reflect culturally different views. For example, the indications for CPST may be present for one culture (HCPs) but not for another (patient)⁶⁸. This emphasizes the importance of communication and the consensus process described in the section of this framework on decision-making (*see also* decision algorithm, Appendix). However, consensus is not always possible, and in some cultures there may instead be a recognized decision-maker. When assessing patient and family perceptions it is wise to consider the use of professional cultural and linguistic translators, if available, since one can never assume that a culture is shared, even within a family. HCPs must also be aware that although a

patient may share a set of cultural values/beliefs he/she may choose not to adhere to them.

Table 2 outlines some of the significant cultural aspects pertaining specifically to CPST⁶⁹. Training and proficiency in cultural competency can help facilitate the health care team in the important role of determining their own and the patient's and family's attitude towards and underlying beliefs about CPST⁷⁰. An HCP can refuse to provide treatment that, although meeting professional standards and ethical requirements, for them is unethical or morally unacceptable, but they must transfer care to someone who will provide it.

Table 2
Cultural Considerations for the use of Palliative Sedation Therapy⁶⁹

Value and meaning given to pain and suffering
Importance of consciousness in the dying process
How decisions are made by the patient and family
Value and meaning placed on food and hydration
Death rituals/spiritual beliefs and practices
Communication pattern and systems (truth telling, disclosure, and hope system)
Meaning of death and dying
Perception by the patient/family of the role of the health care practitioners
Cultural understanding of Illness versus disease, and health care practices used for treatment (traditional and medical models)

Informed Decision-Making

- 1) *Decisions regarding CPST should conform to the accepted national, provincial and institutional policies for decision-making and informed consent in law and medical ethics.*
- 2) *Discussions of CPST should address specific decision-making considerations as outlined in table #4-3 and be documented in the patient's chart.*
- 3) *CPST does not need "special consent", but does require thorough documentation of the process of obtaining consent.*
- 4) *Decisions regarding CPST should involve all relevant members of a healthcare team, one of whom should, preferably, be a clinician experienced in CPST.*
- 5) *Health care providers should monitor for and address disagreement and/or distress among the patient's family, among the healthcare workers, or between family and healthcare workers, which may arise from discussions of CPST.*

As with any medical decision, decisions about CPST should be made in a manner that is clinically, ethically and legally appropriate (*see* decision algorithm, appendix). This requires attention to the process of arriving at decisions and to the substance of what is to be decided upon. It also requires the surpassing of purely clinical issues and the minimum standards of the law by considering details of the patient's personal context, including their culture, and concerns of family and friends.

In Canada, common law precedence and statutory law provide a framework to direct and evaluate medical decision-making⁷¹. For decisions to be legally valid the patient must be capable of making the decision and must make his/her choices voluntarily. Furthermore, these choices must be informed, and specific to the procedure proposed, and not obtained through fraud or misrepresentation.

The process ensuring these conditions in the case of CPST is the same as for other procedures. Where there is concern about a patient's capacity to make a decision capacity must be assessed using a recognize approach⁷² and/or in consultation with appropriate professionals may be necessary. If the patient is not capable the SDM must be sought. As in all cases of medical decision-making, the patient or SDM should understand the

patient's condition, the treatments available, and the potential harms and benefits of these treatments and also of no treatment. The SDM should be aware of the patient's values, goals, preferences and wishes, and make any decisions based on these, especially if expressed in an advance directive. Discussions regarding medical treatment should be clearly documented in the patient's records.

As CPST is part of the continuum of symptom management the form of consent is the same as for any non-invasive symptom management processes i.e. verbal consent from the patient or SDM. However, the discussions between the patient or SDM, family and healthcare team should be comprehensively documented.

Discussion of CPST should also address issues pertinent to CPST in particular (table 3). These issues concern the condition of the patient, the procedure and intention of CPST, and the consequences for the patient and family.

Table 3
Decision-Making Considerations Specific to CPST

That the patient's disease will result in the patient's death, and how imminent this might be.
That there should be consensus that the patient has refractory and intolerable suffering.
That the aim of CPST is to reduce suffering, not hasten death.
That the sedation will be titrated to the relief of suffering.
That the patient will have a reduced or non-existent ability to communicate after initiation of CPST.
That the patient will be monitored for relief of suffering and the adverse effects of sedation.
That if CPST is stopped, the patient's symptoms and suffering may recur.
That decisions about concurrent treatments need to be made (e.g. fluid and nutrition, medication review).

Decisions about CPST should involve as many persons as it is likely to impact. It is usually appropriate to include, beside the patient if able to participate, the family of the patient and the patient's healthcare team. Occasionally other relevant persons may be included. Notwithstanding this inclusiveness, the appropriate ethical and legal norms of confidentiality have to be respected. Decisions about CPST should be made with the aid of a health care team that includes an experienced palliative care clinician. Where this is unfeasible the attending physician should attempt to obtain a second opinion from a clinician experienced in CPST, if not in person then by video-conference or telephone.

Because decisions about CPST may affect so many persons there is potential for disagreement and uncertainty, and therefore discussions concerning CPST should begin early, take place repeatedly and be documented on each occasion. If disagreement does arise, others beyond the immediate care team may need to be consulted to help resolve the issues and to provide support (e.g. ethicist, chaplain. *See* algorithm appendix).

These discussions should take as much time, patience and understanding as is necessary, but be balanced against the urgency to relieve the patient's suffering. Professionals should recognize that patients, their family and friends, and the professionals involved, including themselves, might be distraught, stressed and overwhelmed. As far as possible, the healthcare professionals involved in the discussions should remain sensitive to the patient's culture, emotions and traditions; the institutional culture and policy; and the hopes on all sides (HCPs, patient and family) that will underlie these discussions. Disagreements and tensions should be addressed with all the experience and resources available, both within the institution wherein the discussions take place and beyond to those with extra expertise.

Drugs and Their Administration

- 1) *Benzodiazepines or sedating antipsychotics are recommended for palliative sedation.*
- 2) *Drugs used for CPST should be titrated to relieve suffering through sedation*
- 3) *Opioids and haloperidol should not be used for CPST, although when appropriate they may continue to be administered in a patient receiving CPST.*

Several reviews describe the medications that are presently used for CPST, and although no good evidence exists to recommend one medication over another, these reviews show that certain medications are preferred^{16,19,44,45,73,74,75}. The reviews discuss the following medications:

- Benzodiazepines are the most commonly used medication for CPST, and of these midazolam is most frequently used⁴⁴. Because it is administered parenterally midazolam can be used in all stages of sedation and because of its short half-life it can be more easily titrated than other benzodiazepines. It also possesses anxiolytic, anticonvulsant and muscle relaxant properties. In some patients benzodiazepines may have a paradoxical excitatory effect.

- Sedating antipsychotics are less commonly used for CPST, but of these chlorpromazine and methotrimeprazine are preferred. Both medications can be administered parenterally and have neuroleptic properties which may be helpful in cases where CPST is used for a patient with profound terminal delirium.
- Haloperidol is another antipsychotic medication that has been used for CPST, but it has weaker sedative properties than chlorpromazine and methotrimeprazine and is a poor choice.
- Barbiturates (e.g. phenobarbital) and drugs such as propofol are also occasionally used for CPST⁷⁶.
- Opioids are a poor choice for CPST because deep sedation will occur only when toxic doses are used, risking neuroexcitatory effects and respiratory depression leading to hastened death. However, it may be appropriate to continue to provide opioid therapy e.g. for pain management, in a sedated patient.

The actual choice of one sedative over another will depend on the clinical experience of practitioners and institutional policies.

The use of palliative sedation presents a conceptual challenge in the case of delirium. Pharmacological treatments directed at easing the delirium may also cause sedation as a side-effect (secondary or consequential sedation) but this differs from CPST when sedation is a directly intended treatment. For example, less sedating anti-psychotics such as haloperidol may be used to manage delirium, but haloperidol is not recommended as a first-line sedative drug. Other anti-psychotics that are sedating (e.g. methotrimeprazine) may in lower doses treat delirium with little sedation and in larger doses cause obvious sedation. Ultimately however, these conceptual nuances do not affect the principles outlined elsewhere in this framework. It remains the case that sedation should be titrated to relieve suffering and therefore that deep and continuous sedation for (terminal) delirium is a last resort, used when suffering remains intolerable and refractory despite other treatments.

Monitoring and Outcomes

1. A patient receiving CPST should be monitored for:

- a. Relief of suffering*
- b. Level of consciousness (depth of sedation)*
- c. Potential adverse effects of sedation*

2. Family and HCPs should be monitored for:

- a. Psychological distress*
- b. Spiritual distress*

Because the aim of palliative sedation therapy is to bring relief to suffering and to provide comfort staff need to ensure that these aims are achieved. But, because the sedated patients are not as aware, or are unaware if deeply sedated, of body discomforts they are at risk of skin breakdown, joint injury, etc. Staff also need to ensure that there are no adverse pharmacodynamic effects from the sedative drugs.

All patients receiving CPST should have documented monitoring of:

- relief of suffering as assessed by verbal comments of the patient or the caregiver(s), facial expressions, and/or body movements or posture;
- level of consciousness (depth of sedation) as assessed by responses to verbal or non-painful physical (mechanical) stimuli.
- adverse effects related to sedation. Depending on the depth of sedation, this might include susceptibility to limb/joint injury, skin breakdown, respiratory depression, etc.
- potential treatment options for symptom palliation other than sedation

Many papers addressing CPST do not consider monitoring, but when this is addressed the advice has been to monitor the patient every 20 minutes until adequate sedation has been achieved and then a minimum of three times day^{16,18}. In practice, it is likely that frequency of monitoring will vary based on the location of care e.g. home or institution. Certainly, patients should be assessed frequently until adequate sedation has been achieved and then at least once a day.

Monitoring should include patient comfort so any scale devised for this patient population should have this orientation. Monitoring scales exist to assess communication⁷⁷, level of sedation^{78,79}, motor activity⁸⁰, and agitation^{77,79} of sedated patients but their usefulness in CPST patients has not been proven. Scales assessing level of consciousness due to trauma or disease⁸¹ do not seem appropriate, and scales involving administration of painful stimuli are not acceptable within the palliative care context. Those scales oriented towards agitation may not be appropriate for monitoring a patient sedated for reasons other than agitation e.g. pain, dyspnea. A scale for use in CPST has been proposed, but addresses only the level of sedation, not comfort, relief of suffering or adverse effects, and at one level requires a moderately painful stimulus (pinching of the trapezius muscle)⁸².

Patients receiving continuous sedation during the last few days of life do not require measurements of “vital signs” as they do not contribute to goals of care^{18,19}, unless such monitoring would contribute to the comfort of the patient and/or family. Dose reduction should be considered if adverse effects attributable to the sedation occur, especially if apnea or a significant decrease in respiratory rate occurs. But caregivers need to be aware that changes in the breathing pattern, and other signs such as tachycardia, sweating, etc., are often part of the disease or dying process. If there is any doubt, a palliative care clinician can advise.

The experience of having a patient sedated is usually stressful for family and caregivers. It is important to provide psychosocial and spiritual support for the patient's family, and care teams should address and support each other with respect to the emotional burdens of the HCPs involved. Inter-professional debriefing conferences should be held if necessary.

As part of the monitoring process staff should continue to record the indication for CPST, the aim and whether or not it has been achieved i.e. relief of suffering. Sedating drug dosages should be meticulously recorded, especially any additional doses administered and any change in dosage.

Building Policy

- 1) *Institutions and programs providing end-of-life care should have written policies that safely guide the process of CPST to protect patient, family and health care providers*
- 2) *Consultation with regulatory and legal authorities to review policies should be considered*
- 3) *Ensure wide consultation within the agency or institution during development of a policy*
- 4) *Develop patient and family educational material that support policies and inform patients and families of the procedure(s) and their rights.*

Institutions and programs offering CPST should have written policies that guide the process of CPST and protect the rights of patient, family and health care providers. The policy (or policies) should be widely reviewed within the agency or institution, including regulatory and legal input if necessary. Written information for families and patients is useful. A healthcare personnel education program to inform family and patients of the policies and protocols and of their rights to refuse to participate in the procedure will be necessary. A team of administrators, front-line staff, bioethicist and palliative care health care providers should develop policy, which should cover the following:

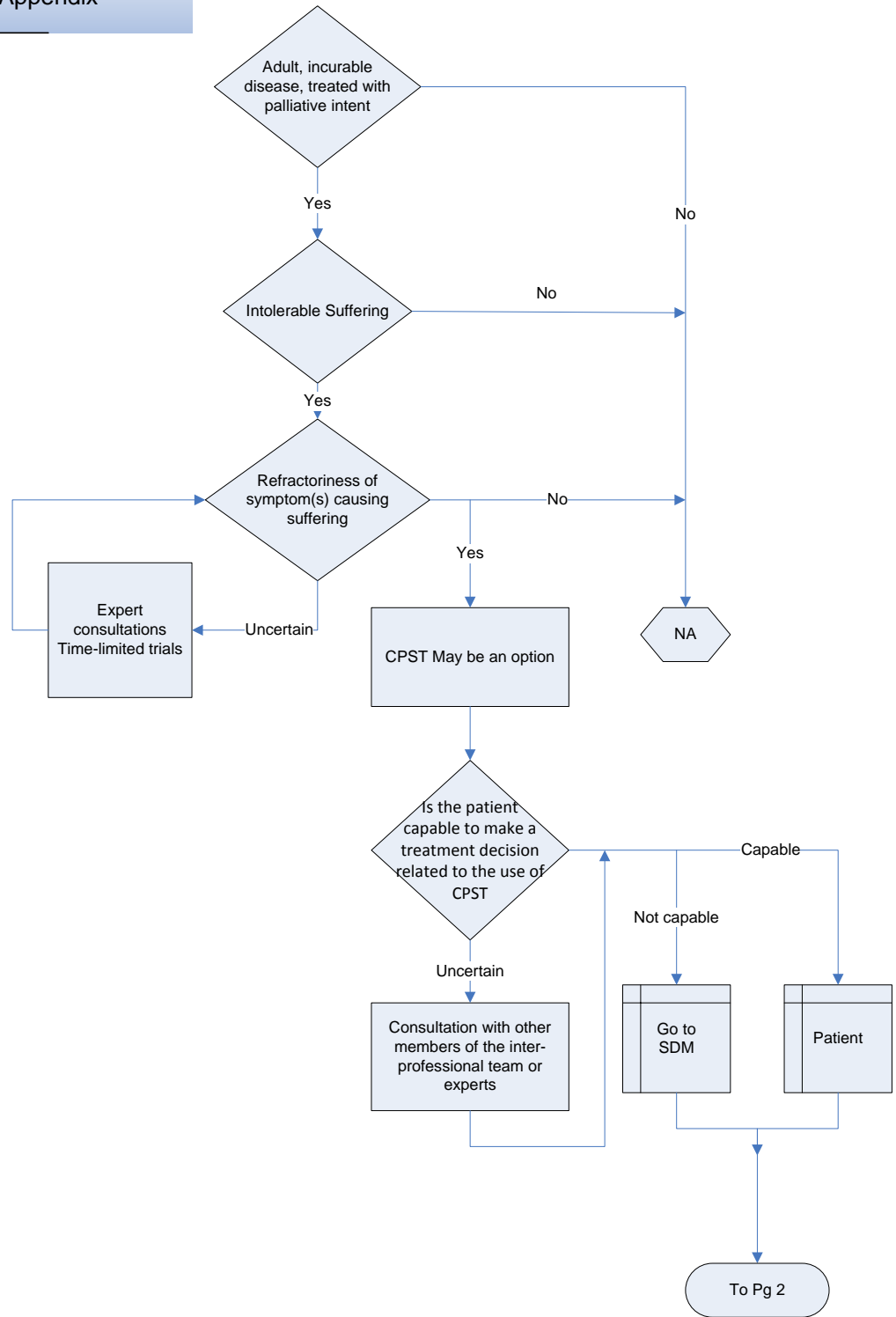
- acceptance of the national framework
- specific processes for the institution or program for decision-making, consent, implementation and monitoring
- data collection from cases requiring CPST
- quality improvement reviews

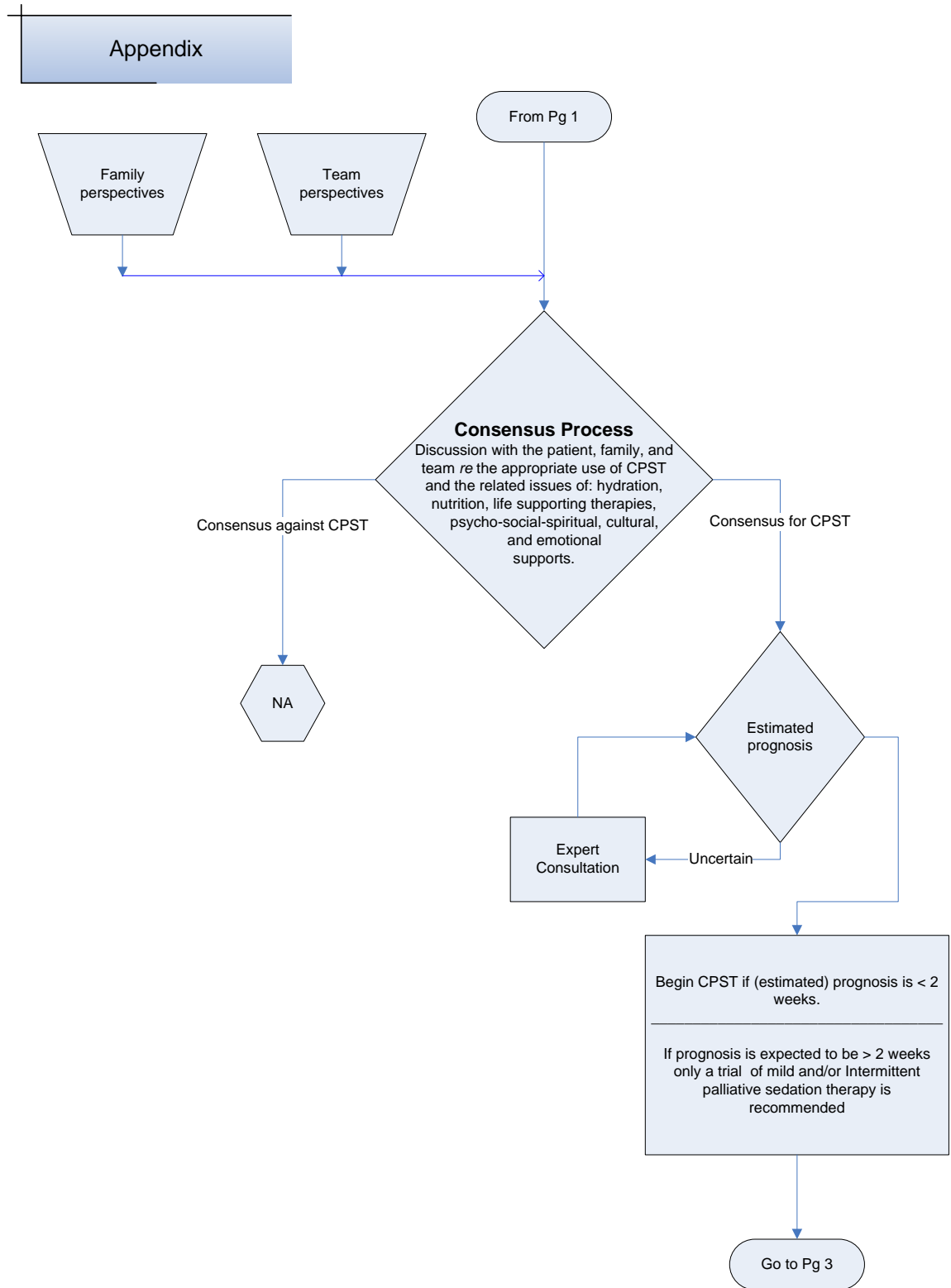
- patient/family perspectives

Summary

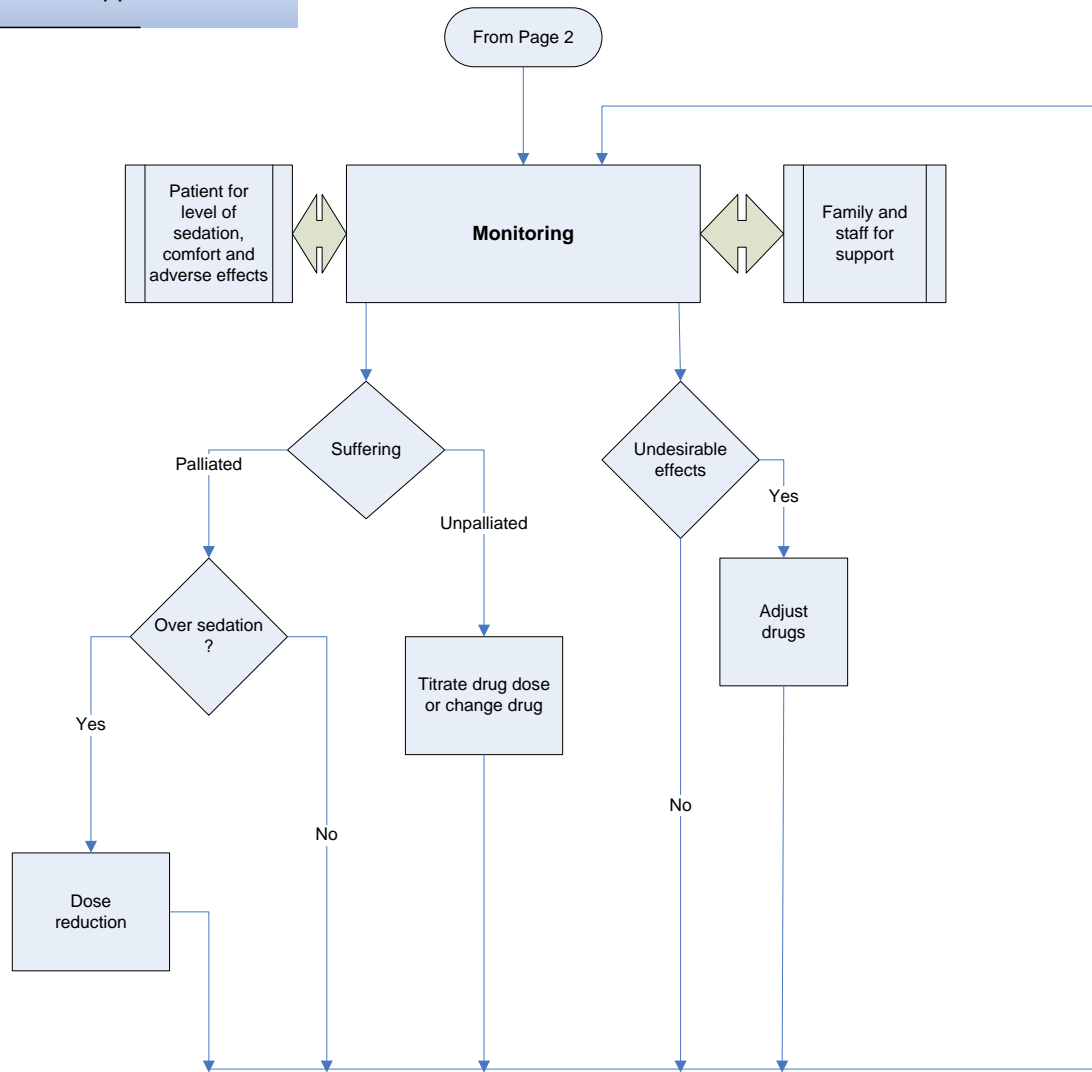
This consensus framework for continuous palliative sedation therapy has been developed to standardize an approach that will be medically acceptable, ethically sound and protect the rights of patients, families and health care providers in Canada. Correctly applied, CPST is an effective way of managing refractory symptoms and intolerable suffering.

Appendix





Appendix



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