

PALLIATIVE SEDATION AT THE END OF LIFE

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PRACTICE
GUIDELINES

Société québécoise
des médecins
de soins palliatifs


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Collège des médecins du Québec
Office 3500
1250, René-Lévesque Boulevard West
Montreal (Quebec) H3B 0G2
Telephone: 514 933-4441
or 1 888 MÉDECIN
Fax: 514 933-3112
Website: www.cmq.org
Email: info@cmq.org

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Odette Lord

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Barbara Pattison, C.Tr.

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Note: In this publication, the masculine gender is used without prejudice and solely to facilitate reading.

— Authors and collaborators

Société québécoise des médecins de soins palliatifs

DR. SAMIR AZZARIA, Maison Michel-Sarrazin, Quebec City

DR. ANDRÉANNE CÔTÉ, Hôpital Notre-Dame du CHUM, Montreal

DR. MICHELLE DALLAIRE, Maison Victor-Gadbois, Saint-Mathieu-de-Belœil

DR. GENEVIÈVE DECHÊNE, GMF du Sud-Ouest, Verdun

DR. FRANCE GAUVIN, CHU Sainte-Justine

DR. LOUISE LA FONTAINE, Maison Desjardins de soins palliatifs du KRTB

DR. BERNARD J. LAPOINTE, Sir Mortimer B. Davis Jewish General Hospital

DR. CHRISTIANE MARTEL, Maison Victor-Gadbois, Saint-Mathieu-de-Belœil

DR. PATRICK VINAY, President, Société québécoise des médecins de soins palliatifs

Collège des médecins du Québec

DR. SAMIR AZZARIA, Maison Michel-Sarrazin, Quebec City

DR. JUSTINE FARLEY-DESCHAMPS, St. Mary's Hospital Centre

DR. ROGER LADOUCEUR, Collège des médecins du Québec

DR. MICHÈLE MARCHAND, Collège des médecins du Québec

MS. ISABELLE MONDOU, Collège des médecins du Québec

DR. YVES ROBERT, Collège des médecins du Québec

— Organizations and people consulted

BARREAU DU QUÉBEC

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ET DES THÉRAPEUTES CONJUGAUX
ET FAMILIAUX DU QUÉBEC

QUÉBEC COLLEGE OF FAMILY
PHYSICIANS

QUÉBEC MEDICAL ASSOCIATION

RÉSEAU DES SOINS PALLIATIFS
DU QUÉBEC

DR. MARCEL ARCAND, Health and Social
Services Centre - University Institute of
Geriatrics of Sherbrooke

DR. YVETTE LAJEUNESSE, Institut
universitaire de gériatrie de Montréal

LEGAL ADVISORS FROM THE COLLÈGE
DES MÉDECINS DU QUÉBEC

PHYSICIANS FROM THE COLLÈGE
DES MÉDECINS DU QUÉBEC

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PREFACE

During debates about end-of-life care, it was felt that there was a need to provide a better framework for the use of palliative sedation for people at the end of life in Quebec. These guidelines are the result of a collaboration between the Société québécoise des médecins de soins palliatifs (SQMSP) and the Collège des médecins du Québec (CMQ). They are based on two documents recently produced by the SQMSP that reflect current best practices and consensus, *Recommandations québécoises pour la pratique de la sédation palliative, Principes et pratique* [Quebec recommendations for palliative sedation therapy, principles and practice] and its abridged version, *Outil pratique* [Practical tool], as well as on the reflection undertaken at the CMQ, which focused on controversial issues. In addition, many people and organizations concerned by the subject contributed their input. The guidelines also take into account relevant provisions of the *Act Respecting End-of-Life Care*, which came into force on December 10, 2015.

INTRODUCTION

While they are primarily intended for physicians, the purpose of these guidelines is to improve the entire Quebec population's understanding of this last-resort treatment and ensure it is used as judiciously as possible. The main considerations are presented, including the indications, the process behind the decision to administer palliative sedation, the medication used, monitoring and other care as well as the information that must be entered in the record or reported to the relevant authorities. Despite the complexity of certain issues, the document is short; the references have therefore been grouped under headings at the end of the guidelines instead of being included in the text. They may be consulted for further information. Practical tools are also provided in the appendices, including a decision tree and the required forms.

Chapter 1/ Definition, history and distinctions

“Palliative sedation” is defined as the use of sedative medications to relieve refractory symptoms by a reduction in consciousness. Depending on the level of consciousness, three levels of sedation may be distinguished: mild, intermediate and deep. Depending on the duration, sedation is often described as intermittent or continuous.

While the deliberate lowering of level of consciousness is an intervention that has been used in medical practice for many years, its use for symptom relief is more recent. In Quebec as elsewhere, this practice has developed gradually in palliative care settings over the last two decades.

Indeed, the primary goal of palliative care is to alleviate patient suffering, regardless of its nature. Yet, it is clear that at the end of life, although rarely, clinical situations of extreme suffering or distress arise that are difficult to relieve despite quality palliative care. Some symptoms may be impossible to control, despite the extensive therapeutic resources used. These symptoms, which are termed “refractory” and can be either physical or psychological, often have an intolerable effect on the patient’s well-being in the final stages of life. They can worsen as death approaches, compromising the possibility of a peaceful death and adding to the distress of family members. Symptoms may be so severe that communication becomes impossible, with the patient overcome by suffering. Sometimes, symptoms cannot be treated adequately without altering the patient’s level of consciousness. In these circumstances, medically induced sedation may be the most appropriate intervention. In other words, sometimes the only way to ensure comfort is to put the patient to sleep using pharmacological means. Palliative sedation is then considered a legitimate medical practice, indicated in exceptional cases for patients in the very terminal stage of their illness. Since the patient’s situation is deteriorating rapidly and cannot be controlled otherwise, palliative sedation is continuous in most cases, that is, it is maintained until the patient’s natural death.

Medically induced sedation must not be confused with the decreased level of consciousness associated with the natural progression of the illness or the use of medications that result in sedation as a side effect.

Palliative sedation must also be distinguished from respite sedation. Respite sedation involves administering a combination of medications to sedate the patient in order to reduce his distress and allow him to recover, if at all possible, from this complication. This type of sedation lasts around four hours if it is not repeated.¹

But what probably causes the greatest confusion and is the most widely debated issue stems from the fact that palliative sedation is often associated with euthanasia or medical aid in dying (MedAID). Palliative sedation and MedAID are both interventions intended to free the patient from his intolerable situation, but with MedAID the means used to do so is to end his life. It is true that continuous palliative sedation may shorten a patient's life if it is administered to a patient who has a long prognosis of survival (several weeks) and who is still able to eat and drink. This is why continuous palliative sedation is usually proposed and administered to a terminal patient whose death is imminent, that is, whose prognosis of survival is very short, often less than two weeks. Various publications show that continuous palliative sedation that is correctly administered to patients with a very short prognosis does not hasten death. Mean survival after the initiation of continuous palliative sedation is reported to be one to six days. Moreover, the term "terminal sedation" is falling into disuse, for the word "terminal" refers to the patient's clinical condition and not to sedation.

At present, palliative sedation is widely considered to be an essential practice to provide appropriate end-of-life care. Wherever it has been studied, a marked increase has been found in the use of palliative sedation and there is fairly broad consensus concerning the indications, the decision-making process and consent, the medication used, monitoring, record keeping and quality control. In short, on what currently constitutes "good medical practice" in palliative sedation for people at the end of life. There is also broad consensus on the need for fairly strict regulation of continuous palliative sedation. This last-resort intervention, which is increasingly used, and in increasingly diverse settings, raises particular issues that will be addressed throughout the document.

¹ For further information about sedation as a side effect of medications and respite sedation, please refer to the practice guidelines *Medical care in the last days of life*, 2016, pp. 23 and 26.

Chapter 2/ Indications

There is very broad consensus on the main symptoms for which palliative sedation is indicated at the end of life. They are listed in Table 1.

Table 1
Main symptoms

Hyperactive delirium with uncontrollable psychomotor agitation
Major and recurrent respiratory distress
Progressive and intractable dyspnea
Refractory seizures
Intolerable and untreatable pain
Copious and refractory bronchial secretions
Hemorrhagic distress
Intractable nausea and vomiting
Refractory psychological or existential distress that severely compromises comfort
Other refractory condition

Existential distress is still a subject of debate owing to the difficulty in assessing this type of suffering objectively. The consensus is that caution should be exercised in assessing its refractory nature. To be considered refractory, existential distress must resist a well-managed multidimensional therapeutic approach (listening, spiritual and religious support, psychotherapy, drug therapy, etc.) that involves several care providers.

2.1 REFRACTORINESS OF SYMPTOMS

The refractoriness of symptoms is universally considered to be a prerequisite for considering palliative sedation. Palliative sedation is used in exceptional cases if the treatments that are normally recommended fail to provide adequate relief. Symptoms then cause intolerable suffering, which may be physical, psychological, existential or spiritual. The decision to use palliative sedation is based on the presence of refractory and intolerable symptoms and the inability of standard therapies to provide adequate relief within an acceptable timeframe.

If there is any doubt as to either of these elements, health care teams are encouraged to seek the opinion of a palliative care team. The latter can carry out a thorough review of the approaches used for the patient thus far and ensure that other therapeutic options are no longer available or desirable in the situation. They may also give their opinion on the terminal nature of the patient's medical condition. That said, the person himself is still the best judge of whether or not his suffering is intolerable.

2.2 IMMINENCE OF DEATH

The terminal nature of the medical condition is the other prerequisite for considering the use of palliative sedation. By the terminal nature of the medical condition, we are obviously referring to "the terminal stage of the disease", when death appears to be both inevitable and imminent. However, it must be acknowledged that even this technical term leaves much room for interpretation. The same is true of the term "end of life". Many of the debates surrounding palliative sedation concern the issue of whether or not it should be used only in the final days of life, when death is very imminent.

2.2.1 IMPORTANCE AND LIMITATIONS OF THE PROGNOSIS OF SURVIVAL

To determine whether or not the patient's condition is terminal, we usually refer to the prognosis of survival.

This prognostic assessment is, among other things, based on:

- › the extent of the disease;
- › its rate of progression;
- › the rapidity of functional decline;
- › target organ involvement;
- › the presence of symptoms such as:
 - › anorexia-cachexia,
 - › dysphagia,
 - › low performance status,
 - › edema,
 - › dyspnea,
 - › delirium.

At the very end of life, the following will be observed:

- › spontaneous discontinuation of nutrition and hydration;
- › dysphagia;
- › ineffective cough;
- › rales;
- › generalized weakness and significant loss of mobility;
- › loss of interest in people;
- › increasingly predominant drowsiness to the point of unconsciousness; and
- › altered vital signs (decreased blood pressure, weak pulse, irregular breathing, desaturation, cold or mottled extremities, etc.).

Validated assessment tools have been developed to provide a better estimation of the prognosis. Nonetheless, this assessment is still difficult and inaccurate.

This is especially true, since, with the ageing of the population, the number of people in the final stages of life is constantly growing, by far exceeding the number of patients treated to date in palliative care hospices and palliative care units in hospitals, most of whom are cancer patients. Yet, the “end-of-life trajectories” of patients with heart or lung failure are very different. Punctuated by episodes of acute deterioration, they are less linear than a cancer patient’s trajectory. The trajectory of people with dementia is characterized by a much longer period of decline (Appendix I). So much so that we may question whether the prognosis of survival is still sufficiently reliable to be a determining factor in the decision.

The prognosis is nonetheless an extremely important factor. Despite its limitations, the prognosis of survival is still essential information at the end of life. Without it, it is difficult for patients or their families, as well as for caregivers, to make a decision that is not only informed, but that they will be able to accept in the longer term. In situations where symptoms prove to be refractory, all the stakeholders in the clinical situation are faced with a real dilemma. If sedation is initiated too late, the patient's refractory symptoms may not be relieved. If it is initiated too early, it may result in extremely difficult situations for those accompanying the patient: prolonged agony, in particular, or a foreshortened life, even if this was not the intention. It is not always easy to strike a balance.

2.2.2 INTERMITTENT OR CONTINUOUS SEDATION

Nevertheless, the very large majority of guidelines issued to date suggest considering the use of continuous palliative sedation only when the patient's death is expected within hours or days, possibly up to two weeks. Based on experience in palliative care in Quebec, few patients need continuous palliative sedation for more than one week before their death. For patients whose prognosis is longer than two weeks, intermittent sedation is recommended, to be administered for several hours or a few days, at which time the situation should be reassessed. Since the physiological context is very different here, special considerations regarding nutrition and hydration should be discussed and the treatment plan adjusted accordingly. However, the recent literature includes articles that address the possibility of using continuous sedation at an earlier stage in some very exceptional situations.

After careful consideration, and given the limited extent of current knowledge, consensus was reached on the practice that would be proposed to Quebec physicians in these guidelines:

Continuous sedation should be reserved for patients with refractory symptoms and a prognosis of survival of two weeks or less. For patients whose prognosis is uncertain or estimated to be more than two weeks, sedation may be initiated and will be intermittent or continuous depending on how the patient's condition evolves.

Thus, if a person at the end of life has refractory and intolerable symptoms, the option of palliative sedation should not be ruled out owing to prognostic uncertainty regarding the two-week timeframe. Sedation may be initiated. Depending on whether or not the patient's already precarious condition improves or deteriorates, sedation will be discontinued or extended, possibly until death. Clinical experience tends to show that the prognosis of survival often becomes clearer when certain symptoms are more adequately relieved. This guideline is intended to allow some leeway, but caution must still be exercised with respect to the premature use of continuous sedation.

Chapter 3/ Decision-making process and consent

The decision to reduce a person's level of consciousness is always sensitive. Also, this decision must be the culmination of a thorough process to ensure that the risks and benefits of all the relevant considerations have been weighed and all the stakeholders in the situation are respected, starting with the dying person. This process is illustrated in the form of a decision tree in Appendix II.

3.1 WRITTEN CONSENT IN THE EVENT OF CONTINUOUS SEDATION

Remember that a physician must always, except in an emergency, obtain consent from the patient or his representative before undertaking care of any nature (*Code of Ethics of Physicians*, section 28). If care involves lowering a person's level of consciousness, this obligation is clearly particularly important. Also, the physician must obtain free and informed consent from the patient or his representative before initiating any form of palliative sedation, irrespective of its expected depth or duration.

This obligation is also stipulated in the *Civil Code of Québec* (section 11).² To be valid, consent must be given by a person who is capable of giving his consent to care or, if the person concerned is incapable of giving his consent, by a person authorized by law to do so in his place (section 11). To be free, consent must not be given under pressure. For consent to be informed, the patient or authorized person must be advised of:

- › the diagnosis of the disease;
- › the nature and goal of treatment;
- › its benefits and risks;
- › other possible options; and of
- › the consequences of a refusal.

² Excerpt from the *Civil Code of Québec*: Section 11 – No one may be made to undergo care of any nature, whether for examination, specimen taking, removal of tissue, treatment or any other act, except with his consent. Except as otherwise provided by law, the consent is subject to no other formal requirement and may be withdrawn at any time, even verbally.
If the person concerned is incapable of giving or refusing his consent to care and has not drawn up advance medical directives under the Act respecting end-of-life care (chapter S-32.0001) by which he expresses such consent or refusal, a person authorized by law or by a protection mandate may do so in his place.

The *Act Respecting End-of-Life Care* provides for special requirements for consent to continuous palliative sedation.

- › It “must be given in writing on the form prescribed by the Minister and be filed in the patient’s record” (section 24, paragraph 3) (Appendix IV). The *Act Respecting End-of-Life Care* states that if the patient cannot date and sign the form referred to in section 24 because he cannot write or is physically incapable of doing so, a third person may do so in the patient’s presence. The third person may not be a member of the team responsible for caring for the patient, a minor or a person of full age incapable of giving consent (section 25). Indeed, it is recognized that the written consent requirement, while it is by no means a guarantee that this will be the case, can promote information sharing and discussion between stakeholders.
- › The person who gives consent to continuous palliative sedation “must among other things be informed of the prognosis for the illness, the irreversible nature of the sedation and the anticipated duration of the sedation” (section 24, paragraph 1). From a clinical standpoint, it is understood that indeed:
 - › The diagnosis of the disease alone is not sufficient and, despite its uncertain nature, the prognosis is a determining factor in the decision.
 - › It is also important to be able to estimate the duration of sedation as accurately as possible.
 - › Even if sedation is interrupted, the return of consciousness is not guaranteed, since it depends primarily on the underlying disease.
 - › Information about the procedure, including the eventual discontinuation of nutrition and hydration, and about monitoring and other care is also important.
- › The physician “must make sure that the request is being made freely, in particular by ascertaining that it is not being made as a result of external pressure” (section 24, paragraph 2), be it financial, psychosocial or relational.
- › The patient or his representative must be informed of his right to refuse the procedure or to postpone his decision and of the consequences of both.

3.1.1 CONSENT BY A COMPETENT PERSON

In an ideal situation, consent to palliative sedation would always be given by the patient when he is still competent. Also, it is suggested that discussions to obtain consent be started at an early stage, for example, as soon as a patient's medical condition points to the possible use of sedation. The information provided should be tailored to the clinical context and the patient's desire to hear it. At the same time, instructions regarding resuscitation and levels of medical intervention (LMI) must be updated. Throughout this process, the patient is assured that all comfort care will be continued during sedation.

When consent is obtained from the patient himself, the family's participation in the decision-making process is still eminently desirable. However, the decision is up to the patient himself and his family can only participate in the decision-making process with his agreement. Irrespective of whether they were involved in the decision regarding sedation, family members must understand the relevant explanations that the health care team gave them before starting sedation. Family meetings should be planned for this purpose and psychosocial support might be relevant. However, it is up to the patient to decide what information will be given to his family.

3.1.2 ADVANCE MEDICAL DIRECTIVES

It is important to hold these discussions when the person is still competent, all the more so since the *Act Respecting End-of-Life Care* has amended the *Civil Code of Québec* to give more weight to advance medical directives (AMDs). Therefore, if the person prepared AMDs when he was still competent, as provided for in the *Act Respecting End-of-Life Care*, they must be respected. These provisions could potentially be applied to continuous sedation (sections 51 to 62). However, the current form restricts the application of AMDs to two clinical situations and five specific types of care, which do not include palliative sedation. Whether or not palliative sedation is being considered, it is nonetheless essential that caregivers and the family of the person who is no longer competent know of any wishes he might have expressed regarding the clinical conditions and types of care set out in this form and comply with them.

3.1.3 PROXY CONSENT

If the person is incapable of giving their consent to care and in the absence of AMDs, proxy consent must be obtained. It must be given by a person who is authorized to do so under the provisions of the *Civil Code of Québec*.³ The decision must be made in the patient's best interest and take into account, as far as possible, any wishes he may have expressed before he became incompetent. Although a single representative is officially designated to give proxy consent, family consensus is desirable in this situation to avoid conflicts and violations prejudicial to the patient. Note that the representative will determine what information can be given to third parties.

Under the *Civil Code of Québec*, the authorization of the court is necessary:

- › in the event of persistent disagreements between the person authorized to give consent on behalf of the incompetent patient and the physician or the health care team;
- › where a person of full age who is incapable of giving consent categorically refuses to receive care to which his representative gave consent.

In the event of disagreement among family members, it is not up to the physician or the health care institution to apply to the court. The physician and his team receive their instructions only from the person who is authorized to give consent.

The *Civil Code of Québec* also states that consent is not required in case of emergency if it cannot be obtained in due time (section 13).⁴ In the context of palliative sedation, there is no obstacle to initiating palliative sedation in an emergency. However, once the emergency is under control, the usual consent procedure comes into effect again and proxy consent must be obtained if the health care team wishes to continue the procedure.

³ Excerpt from the *Civil Code of Québec*: Section 15 – *Where it is ascertained that a person of full age is incapable of giving consent to care required by his or her state of health and in the absence of advance medical directives, consent is given by his or her mandatary, tutor or curator. If the person of full age is not so represented, consent is given by his or her married, civil union or de facto spouse or, if the person has no spouse or his or her spouse is prevented from giving consent, it is given by a close relative or a person who shows a special interest in the person of full age.*

⁴ Excerpt from the *Civil Code of Québec*: Section 13 – *Consent to medical care is not required in case of emergency if the life of the person is in danger or his integrity is threatened and his consent cannot be obtained in due time. It is required, however, where the care is unusual or has become useless or where its consequences could be intolerable for the person.*

3.2 TEAMWORK

This intervention is impossible without the participation of all health care staff members, each contributing their own expertise. As far as possible, care providers who participate in providing care also participate in the decision-making process. The physician must ensure that the entire health care team clearly understands the procedure, its indication and its impact on family members and that it is willing to cooperate.

Of course, palliative sedation sometimes means that the decision-making process takes place in several stages, as illustrated in Appendix II.

3.3 MEDICAL DECISION

Even if all the stakeholders in the clinical situation participate in the decision-making process, the physician himself is responsible for deciding whether or not to use palliative sedation. Irrespective of the health care setting, he is the person who prescribes and initiates palliative sedation in collaboration with the nurse. Therefore, a member of the medical team must be present to initiate sedation.

Palliative sedation must be supported by detailed and accurate medical prescriptions. In addition, the patient must be closely monitored so that the medication and overall care provided can be tailored to each person's medical condition and response. Irrespective of the health care setting, the health care team must ensure that it is able to administer the treatment and provide care safely, which includes being adequately trained by the professionals concerned.

The medication prescribed to induce palliative sedation does not normally have a lethal effect at the doses recommended. Nonetheless, it is important that the indications, type of medication, dosage and method of administration comply with safety and efficacy standards and scientific evidence.

Chapter 4/ Medication used

To induce palliative sedation, the dosage of medications frequently administered at lower doses, either to reduce anxiety or to control mild delirium, can be increased to intentionally lower level of consciousness. Other agents can be added to produce deeper sedation if first-line agents are insufficient. The use of opioids for palliative sedation is not in keeping with good practices. The desired depth of sedation varies between individuals, since it depends on the severity of the symptom and the relief obtained. Thus, the depth of sedation varies depending on the patient's clinical response.

Commonly used agents include benzodiazepines, anticholinergics, neuroleptics (antipsychotics), barbiturates and propofol. Opioids, whose primary goal is to relieve physical pain or dyspnea, are administered concomitantly. Since opioids are not, strictly speaking, sedative agents, their use is not indicated if pain or dyspnea are not among the symptoms to be managed.

GENERAL PRINCIPLES:

- › Use an agent with several properties if there are several symptoms (a benzodiazepine for a patient who presents with seizures, recent alcoholism, severe anxiety, or a neuroleptic in the presence of agitation, nausea and vomiting).
- › Depending on what has been agreed, initiate treatment at the minimum dose or other dose, and increase based on the clinical response until the objective is achieved.
- › Limit the number of agents; there is no rationale for combining two benzodiazepines or two neuroleptics.
- › React promptly: if the first benzodiazepine used is ineffective or insufficient at an adjusted dose, it must be replaced or used in combination with a sedative medication from another drug class.
- › Check the compatibility of the drug combinations in the same infusion with the pharmacist.
- › Observe the patient to ensure that he does not have a paradoxical reaction to the medication and that an aspect of delirium aggravated by benzodiazepines does not develop.

- › Be vigilant when intermittent sedation is administered, for it can increase anxiety.
- › It is preferable to administer medications subcutaneously. If response is partial or absent, the effectiveness of this route of administration can be questioned and the intravenous route considered.
- › It is preferable to administer medications intravenously in the presence of anasarca or severe thrombocytopenia.
- › Keep intravenous access devices patent (Port-a-Cath, central line).
- › Remember that most sedative agents do not have an analgesic effect.

BENZODIAZEPINES

In addition to their hypnotic and anxiolytic properties, benzodiazepines have anticonvulsant, amnesic and relaxant properties. Their safety margin is large and the risk of respiratory depression is lower, which is why they are considered a first-line agent. They have a rapid onset of action and can be accurately titrated and adjusted to the patient's response. They are administered intravenously or subcutaneously. Midazolam is preferred over lorazepam, especially if it can be administered subcutaneously (pump).

The possible side effects are: tolerance and tachyphylaxia (at a dose of more than 20 mg of midazolam per 24 h, the addition of a second-line agent must be considered), paradoxical reaction (agitation, behaviour disorder, aggression), possible accumulation after administration for more than 24 to 48 hours.

ANTIPSYCHOTICS

Neuroleptics or antipsychotics are often used in combination with benzodiazepines. They are especially useful for treating patients with delirium accompanied by preterminal confusion or agitation. Methotrimeprazine and, occasionally, chlorpromazine are preferred over haloperidol due to their more potent sedative effect. They are less appropriate for patients with a history of seizures.

The adverse effects of these medications are: extrapyramidal effect, anticholinergic effect (urinary retention, confusion, exacerbation of delirium), lowering of the seizure threshold and skin irritation at the injection site.

ANTICHOLINERGICS

Anticholinergics that cross the blood-brain barrier (scopolamine) and are used to control terminal rales have pronounced sedative effects. They are sometimes used with an associated sedative intention to manage refractory delirium. This often induces coma which will become irreversible as the disease progresses. However, it is not a standard medication due to the risk of anticholinergic syndrome accompanied by secondary agitation.

PHENOBARBITAL

Phenobarbital, a barbiturate used for its anticonvulsant, sedative and hypnotic properties, is especially useful when tolerance to first-line agents or the presence of paradoxical effects is suspected. It may become the first choice for a patient on oral anticonvulsant therapy at a stable dose. It can be administered subcutaneously (or intravenously) every 4 to 6 h or every 8 h.

The disadvantages associated with its administration are: possible paradoxical excitation, drug interaction if it is expected to be used for more than a few days (potent enzyme inducer), skin irritation at the injection site (alkaline pH), risk of seizures if discontinued abruptly and hepatotoxicity.

ANESTHETICS

General anesthetics are reserved for cases refractory to the above-mentioned agents. Propofol can only be administered intravenously. Its rapid onset of action means that it can be adjusted accurately according to response and provides comfort within a very short timeframe. The use of propofol for palliative sedation is growing. The doses recommended still vary widely between references.

The possible side effects of propofol are: respiratory depression, negative inotropic effect (with a risk of bradycardia and hypotension), local irritation at the injection site, risk of infection and pancreatitis, propofol infusion syndrome (elevated triglycerides, metabolic acidosis, hepatomegaly, rhabdomyolysis, hypotension and bradycardia that may lead to asystole causing death).

The medication to be used is presented in Table 2.

Table 2
Medication to be used

MAIN AGENTS RECOMMENDED FOR PALLIATIVE SEDATION				
Agents	Route of administration	Starting dose	Mean effective dose	Reported range
Lorazepam	SC - IV - SL - TM	0.5 to 1 mg/h	6 to 12 mg/24 h	2 to 4 mg/h
Midazolam	SC - IV	0.5 to 1 mg/h	20 to 70 mg/24 h	3 to 450 (up to 1200) mg/24 h
Methotrimeprazine	SC - IV	12.5 to 25 mg/24 h	30 to 75 mg/24 h	25 to 300 mg/24 h
Chlorpromazine	SC - IV	25 to 50 mg/24 h	30 to 75 mg/24 h	25 to 900 mg/24 h
Phenobarbital	SC - IV	2 to 3 mg/kg (bolus)	600 to 1600 mg/24 h	200 to 2500 mg/24 h
Propofol	IV	1 to 3 mg/kg/h	1 to 5 mg/kg/h	1 to 9 mg/kg/h
Scopolamine	SC - IV	0.4 mg q 4 h	0.4 mg q 4 h	50 to 200 mcg/h
<p>Midazolam, methotrimeprazine and phenobarbital can be administered as a continuous infusion or in divided doses. Propofol must be administered as a continuous infusion and requires special monitoring.</p> <p>Route of administration: SC = subcutaneous; IV = intravenous; SL = sublingual; TM = transmucosal.</p>				

In most cases, medication is administered subcutaneously by regular injections (usually every 4 hours) or continuous subcutaneous infusion. Depending on the health care setting, a continuous subcutaneous infusion can be administered using a portable pump, a syringe driver or an infusion of 100 mL of NaCl 0.9% containing the medication planned for 24 hours, administered at a flow rate of 4 mL/h.

Chapter 5/ Nutrition and hydration

The discontinuation of artificial nutrition and hydration at the end of life raises many questions among the general public and in the health care community. It may make family members uncomfortable. Combined with the use of palliative sedation, it raises more questions of an ethical nature. They are influenced by intercultural and spiritual diversity in dietary practices and the value and meaning they are given. Having a clear understanding of and being able to clearly explain natural changes in nutrition and hydration needs at the end of life to family members greatly allay these concerns. Note that, legally, natural nutrition and hydration are also considered to be treatments to which the patient can consent or refuse.

The natural progression of a serious disease is generally accompanied in the final days by a deterioration in the patient's overall condition along with weakness, increasing confinement to bed, loss of appetite, weight loss, dysphagia and dyspnea. The patient often refuses to eat. Drinking is difficult. Appropriate mouth care prevents discomfort from dry mouth. At this point, while systematic reviews of the literature have not conclusively shown that nutrition and hydration are harmful for a person at the end of life, clinical experience tends to show that they can cause the patient additional discomfort. The tendency to retain water that develops naturally in the agony stage can have negative repercussions on the patient's comfort if he is hydrated beyond his level of thirst, irrespective of the route used.

This can lead to:

- › increased peritumoral edema and, consequently, secondary pain;
- › increased edema, effusion, ascites;
- › increased salivary, bronchial and gastrointestinal secretions, thus increasing the incidence of terminal rales, nausea and vomiting.

In fact, continuous palliative sedation rarely involves withholding nutrition or hydration, for they are usually discontinued spontaneously by the patient.

Chapter 6/ Monitoring the sedated patient

The goal of continuous palliative sedation is to free the patient, effectively and quickly, from symptoms that are causing intolerable and refractory suffering. The pharmacological agents used to provide relief are administered safely and the doses are adjusted proportionate to the patient's needs. The depth of sedation produced is determined based on the symptom to be relieved and the suffering it is causing. It is determined on a case-by-case basis and can vary over time depending on the patient's response.

Palliative sedation therefore requires close physician-nurse collaboration to ensure ongoing monitoring and medication adjustment, the ultimate goal being to achieve the desired depth of sedation and comfort. Monitoring the sedated patient will be added to the nursing care provided at the end of life and to family support when it is initiated as well as during sedation, agony and death.

Monitoring has three components:

- › monitoring the depth of sedation;
- › monitoring relief and comfort;
- › monitoring for side effects.

The table in Appendix III can be used as a basic framework both for organizing and documenting monitoring. It includes the three types of monitoring tools presented below.

6.1 MONITORING THE DEPTH OF SEDATION

The Richmond Agitation-Sedation Scale (RASS) is a smart choice because it is simple to use, accurate and appropriate for palliative care. It provides a complete description of the agitated patient, which is very useful, since agitation is a relatively common indication for the administration of sedation.

6.2 MONITORING THE LEVEL OF RELIEF AND COMFORT

RESPONSE ASSOCIATED WITH ANTALGIC TREATMENT

The goal of sedation is to put the patient to sleep in order to free him from his unbearable situation. In addition to the sedative, the administration of medications to maintain his overall comfort must be continued. Since sedative agents do not have a direct effect on pain control, opioids may be necessary. Opioids are not used to produce sedation: they are prescribed in combination with sedatives to relieve pain and dyspnea in some cases. Pain must therefore be systematically assessed during palliative sedation, even in an unconscious patient. The Nociception Coma Scale, adapted by Vinay et al., 2012, can be used to assess comfort in a comatose patient receiving palliative sedation.

RESPONSE ASSOCIATED WITH THE MAIN SYMPTOM FOR WHICH SEDATION IS BEING ADMINISTERED

Given the sedated person's altered level of consciousness, it is up to caregivers, that is, health care staff and/or carers, to evaluate the severity of the refractory symptom in order to assess the level of relief. Observing non-verbal behaviour will be the cornerstone of this assessment. Certain scales and parameters may be useful depending on the symptom targeted by sedation. In addition to the Richmond Agitation-Sedation Scale and the pain assessment scale, the Respiratory Distress Observation Scale (RDOS) can be used. Moreover, it is agreed that dyspnea must be assessed regularly in all sedated patients, even if respiratory difficulties are not the primary indication for the administration of sedation.

By administering sedation, we hope to see a rapid decrease in the severity of the symptom assessed. If using the RDOS scale, this means obtaining a total score of 4 or less. If this does not happen, despite the planned dose adjustments, the physician should be informed.

Since there is no objective assessment scale for many of the possible refractory symptoms (seizures, hemorrhagic distress, psychological or existential distress, intractable nausea and vomiting, etc.), it is agreed that the most accurate description possible must be given in the nurse's monitoring notes of the observations made concerning the targeted symptom. For example, based on the main indication for the initiation of palliative sedation, the number of seizures observed as well as their duration and severity, or the number of episodes of vomiting, the type and amount, or the presence or absence of bleeding, etc. will be documented. The effectiveness of sedation in controlling these symptoms has been clearly demonstrated.

6.3 MONITORING FOR SIDE EFFECTS

Since the overriding goal of continuous palliative sedation in a patient nearing death is his comfort, the parameters observed are mainly comfort oriented. Measurement of blood pressure, temperature or saturation, which does not contribute directly to the patient's comfort, should be suspended. Observing respiratory rate is helpful to ensure the absence of tachypnea that could lead to respiratory distress. In addition, sudden-onset respiratory depression attributable to palliative sedation should be monitored, for this side effect is not desirable. Thus the sudden onset of loud snoring and respiratory pauses when sedation is initiated or doses are increased may require a dose adjustment. This is why the physician should be informed. However, if the latter believes that decreasing sedation might cause a return of distress and thus compromise the patient's comfort, keeping the same prescription may be warranted.

Myoclonus or miotic pupils are signs potentially associated with intoxication or overdose from opioids, which are often administered concurrently with palliative sedation. While they do not require urgent intervention, these signs should be reported on the monitoring form (Appendix III, Legend 3).

6.4 FREQUENCY OF MONITORING

It is recommended that monitoring be performed just before sedation is initiated, then every 15 minutes until adequate relief is achieved. Remember that since this level of comfort varies depending on the patient and the symptom, a member of the medical team must be present when sedation is initiated. Subsequently, the physician could be reached quickly by telephone. He can then determine the therapeutic goal based on his overall assessment of the patient's suffering. For deep sedation, the goal is generally a score of -3 or -4 on the Richmond Agitation-Sedation Scale. For pain control as documented by the pain assessment scale for comatose patients or patients receiving palliative sedation, the target score is 8 or less. For the management of respiratory symptoms, the goal is a score of 4 or less on the Respiratory Distress Observation Scale (RDOS).

When the patient seems to be adequately relieved, he must be monitored at least every 8 hours. The frequency may be increased if there is a change in the patient's condition.

Chapter 7/ Patient care, family and caregiver support

Care that is respectful towards the sedated person, maintaining a “person-to-person” approach and sensitivity in all matters are essential during sedation for both the patient and his family who are witnesses. For caregivers, these attitudes and the respect they show confirm that the sedated patient still has full status as a person and that his dignity is upheld. This will also prevent caregivers from oversimplifying the care provided to a person who is still alive and whose presence is intact despite the loss of consciousness. During palliative sedation, other patient care is maintained and contributes to the patient’s comfort (patient mobilization, monitoring and rotation of subcutaneous or intravenous sites, monitoring for pressure ulcers, wound dressing, mouth care, verification of bladder emptying and intestinal transit, monitoring of infusion bags and tubing, monitoring for rales or signs of discomfort, etc.). But it goes without saying that care that is no longer necessary must be discontinued. Caregivers and family members are encouraged to talk to the patient, to explain the nature of the care provided and to touch him gently and in a caring manner. The patient must be carefully reassessed on a regular basis, for he is no longer able to complain about his discomforts.

7.1 FAMILY SUPPORT

The presence and support provided to family members are important during palliative sedation. It can be extremely beneficial for them, not only to help them in supporting their loved one at the end of life but also to help them cope with their impending bereavement. Once sedation has been initiated, family members may feel that their support is less meaningful, especially when there is no longer any communication with the now unconscious patient or when the end of life extends beyond the usual duration of agony. It is already, in a manner of speaking, a social death. This is why family members must be given appropriate and ongoing support by health care staff.

The care environment should also be conducive to intimacy between the patient and his family to allow a sense of emotional closeness to develop. In general, family members want to be involved in care and be informed of changes in their loved one's health.

7.2 CAREGIVER SUPPORT AND SPECIAL TRAINING

Caregivers can also experience discomfort in some situations where sedation is administered. This is why it is important to be attentive to their questions and concerns and have them participate as much as possible throughout the decision-making process.

Special training to ensure a proper understanding of all the aspects (ethical, medical, familial, social and spiritual) of palliative sedation must be given to both caregivers and volunteers.

A feedback session with health care team members can be very helpful after the patient's death to address any lack of understanding, ease any residual tensions and regain a certain sense of peace. This activity also allows health care providers to learn, as a team, from an experience and to deal with the next one more confidently, avoiding certain mistakes or blunders.

Chapter 8/ Record keeping

The following information should be entered in the record of a patient who is receiving palliative sedation:

- › The detailed assessment of the patient's condition and a list of the treatments received prior to sedation.
- › The key elements of the discussions and opinions of the members of the interdisciplinary team who participated in the decision to initiate palliative sedation.
- › The key information exchanged with the patient and/or his family members, including their declaration of their understanding of the situation and the effects of palliative sedation, in order to obtain their consent and a signed consent form in cases of continuous palliative sedation.
- › A copy of the prescriptions to be used for palliative sedation, the recommended medications and concentrations, routes of administration and doses to be administered.
- › Any change in doses and any addition of new medications must be noted in the medical record along with the rationale for doing so, specifying the exact times these prescriptions are effective.
- › All clinical monitoring by nurses and other members of the health care team (nursing assistants, family members of a patient who is being cared for at home in collaboration with nurses) must be done in close collaboration with the physician. This is vital to ensure the patient is followed safely throughout the administration of sedation. Thus, the physician will be able to consult the monitoring notes for the sedated patient before adjusting treatment. If it is agreed in advance that a monitoring table similar to the table in Appendix III will be used, it must be entered in the record.

The consent form (a link to the form is provided in Appendix IV) and report form (see Appendix V) must also be entered in the record.

Chapter 9/ Report and periodic assessment

Under the *Act Respecting End-of-Life Care*, palliative sedation may be provided in institutions, in palliative care hospices or at home. Institutions and palliative care hospices must adopt a policy and a code of ethics with respect to end-of-life care and the executive director must report annually to the board of directors on the carrying out of the policy. The report must include the number of times continuous palliative sedation was administered at the patient's home or in the premises of a palliative care hospice or in an institution by physicians practicing in a centre operated by the institution (section 8). The council of physicians, dentists and pharmacists (CPDP) must, in collaboration with the council of nurses of the institution, adopt clinical protocols for continuous palliative sedation that comply with the clinical standards developed by the professional orders concerned (section 33). The CPDP or its competent committee must also periodically assess the quality of the care provided, particularly with regard to applicable clinical protocols (section 34, paragraph 2). If no CPDP is established for the institution, the head of medical services or the physician responsible for medical care in the institution assumes these functions (section 35). For physicians practicing in a private health facility that provides sedation at home or in a palliative care hospice, the Act assigns responsibility for these functions to the Collège des médecins du Québec (CMQ) (section 36).

The various documents entered in the record are obviously essential for assessing the quality of the care provided.

A physician who administers continuous palliative sedation must therefore, within 10 days of its administration, inform the CPDP or its equivalent if he practices in an institution (section 34, paragraph 1) or inform the CMQ if he practices in a private health facility (section 36, paragraph 1).

The Commission sur les soins de fin de vie may require of the physicians and authorities concerned the information it needs for the performance of its functions, provided it is not possible to link that information to any specific patient having received care or to any specific professional having provided the care (section 45). This information could be useful for profiling end-of-life practices in Quebec, tracking developments in practices and contributing to research in these areas.

CONCLUSION

Palliative sedation is a very valuable, even essential, intervention to ensure that people receive the most appropriate care at the end of life, be it in hospital, a hospice, a long-term care centre or at home. The refractory symptoms some people may experience must be relieved.

Palliative sedation for people at the end of life is, nonetheless, a last-resort intervention that must be carefully regulated. Altering a person's level of consciousness, even temporarily, is sometimes necessary to provide relief, but is never trivial. Particular caution and sensitivity must be exercised when using continuous palliative sedation, since the distress that warrants depriving a person of consciousness until his death is a clear sign that death is inevitable and quite imminent.

— Practical tools

The appendices contain a number of tools developed to illustrate these various recommendations as well as the forms that must be completed in cases of continuous palliative sedation.

Appendix I shows the difference between various end-of-life trajectories. Appendix II presents, in the form a decision tree, the steps to follow when making the decision to initiate palliative sedation and continue it if necessary. Appendix III contains a monitoring table.

Appendix IV provides a link to the consent form that must be signed if continuous palliative sedation is being considered, while Appendix V provides the report form that the physician must complete and send to the designated authorities within 10 days of administration of continuous palliative sedation in order to ensure better control of the quality of care provided.

— Key points to remember

After reviewing clinician experience, the guidelines already issued by various organizations, the latest literature as well as the legal provisions that apply in Quebec, it was agreed that palliative sedation is a recommended end-of-life intervention provided the following conditions are met:

1. The decision to use palliative sedation is based on an informed analysis of the situation by a trained, experienced physician, supported by an interdisciplinary team.
2. The indications are limited to situations of physical, psychological or existential distress that is refractory to standard treatments, where the uncontrolled symptoms have an intolerable effect on the well-being of the patient, who cannot be adequately treated without lowering his level of consciousness.
3. The person is in the final stages of life. The patient's prognosis of survival is usually short, a few days to two weeks. If not, intermittent palliative sedation may be initiated and the situation reassessed later to determine whether sedation should be continued or not, possibly until death.
4. The person concerned must be capable of giving his consent to palliative sedation. If the person is unable to give consent to care, consent is given by an authorized person in accordance with the provisions of the *Civil Code of Québec*. The family's agreement is sought as far as possible. Consent is free and informed. If sedation is expected to be continuous, consent must be given in writing using the form prescribed by the Minister and kept in the person's record.
5. All other necessary comfort care continues to be provided to the patient.
6. Family members are given explanations and support throughout the decision-making process and administration of sedation.
7. Palliative sedation is administered in accordance with applicable medical and pharmacological guidelines, which include close monitoring.

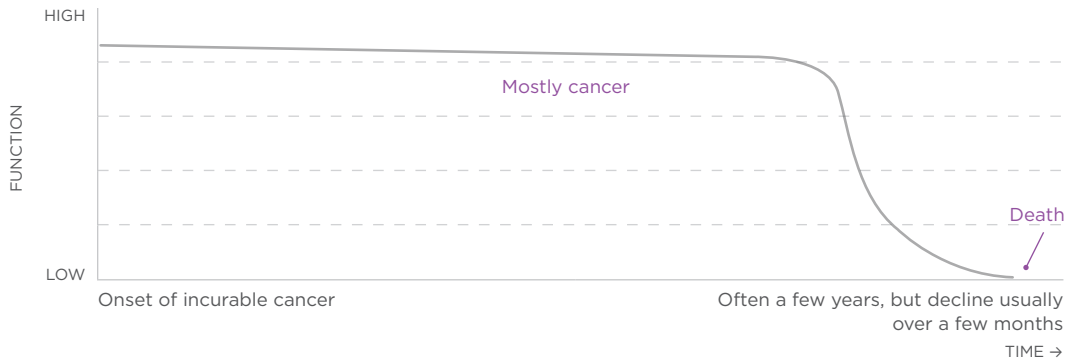
— Key points to remember

8. All activities associated with palliative sedation, including monitoring and other types of care, are clearly documented in the record.
9. A physician who administers continuous palliative sedation informs the authorities designated by law, within 10 days, to allow the quality of the care provided to be continuously assessed.

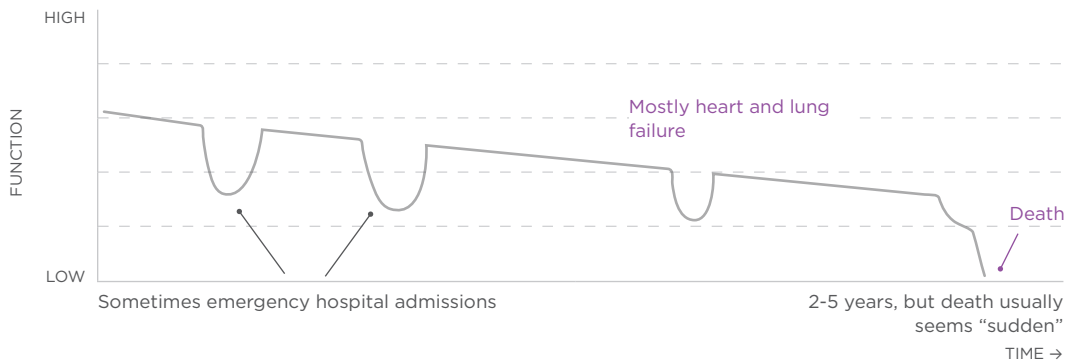
— Appendices

APPENDIX I - TYPES OF END-OF-LIFE TRAJECTORIES

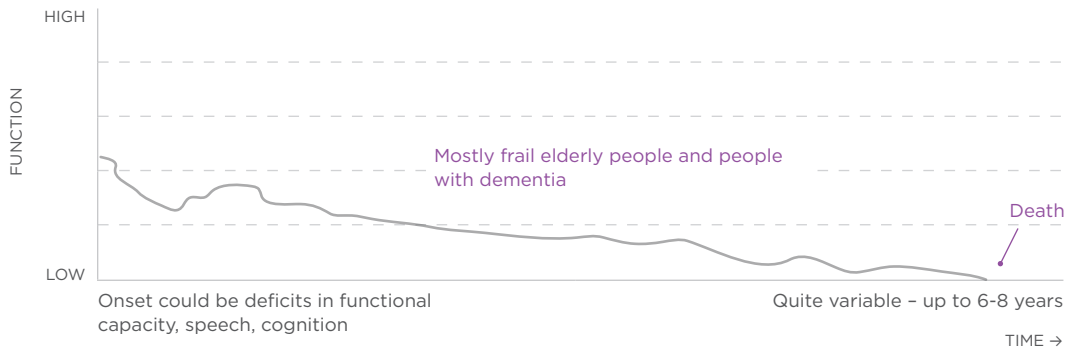
SHORT PERIOD OF EVIDENT DECLINE



LONG-TERM LIMITATIONS WITH INTERMITTENT SERIOUS EPISODES



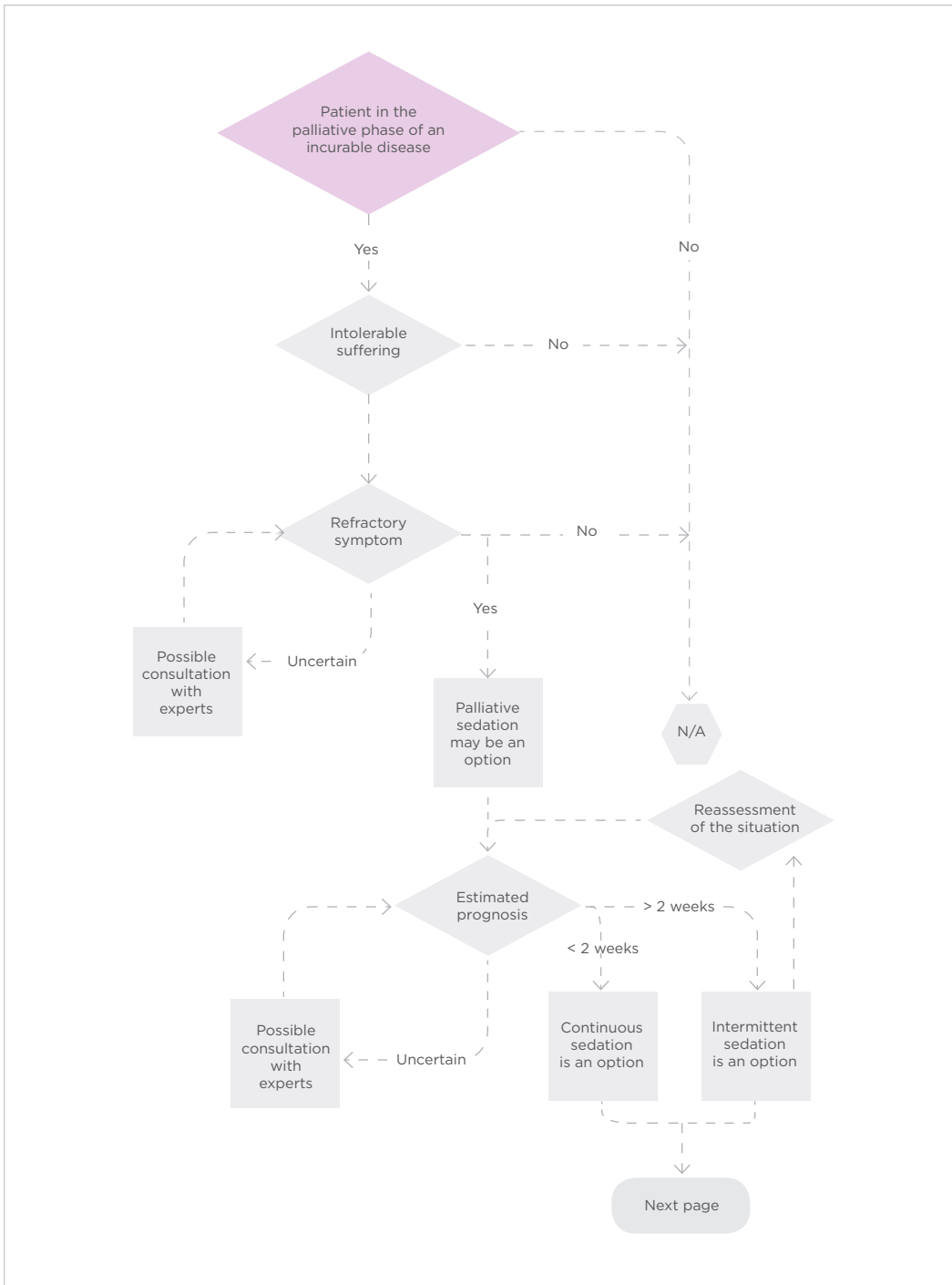
PROLONGED DWINDLING



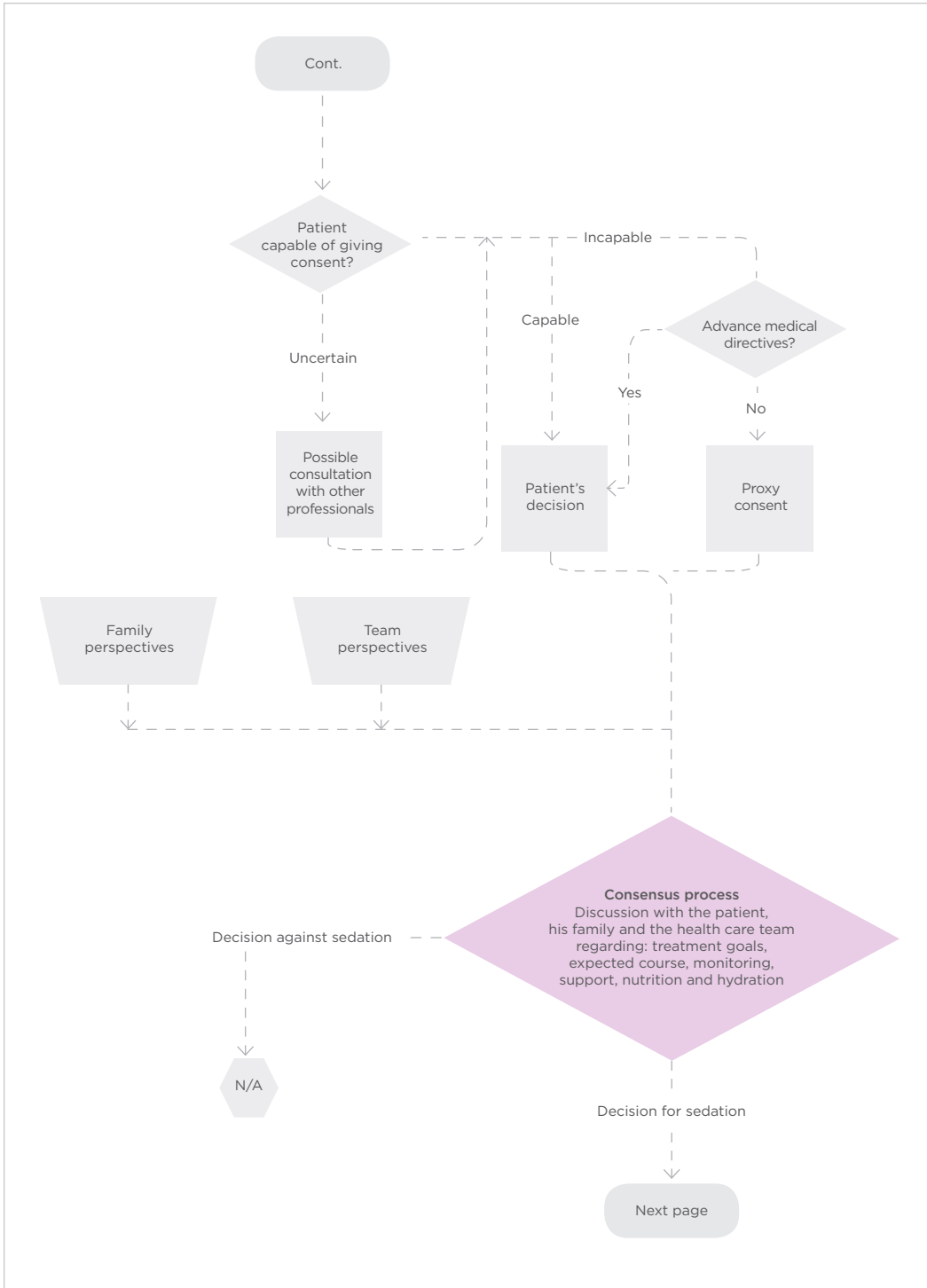
Source: INSPQ, 2006, adapted from Murray, 2005.

— Appendices

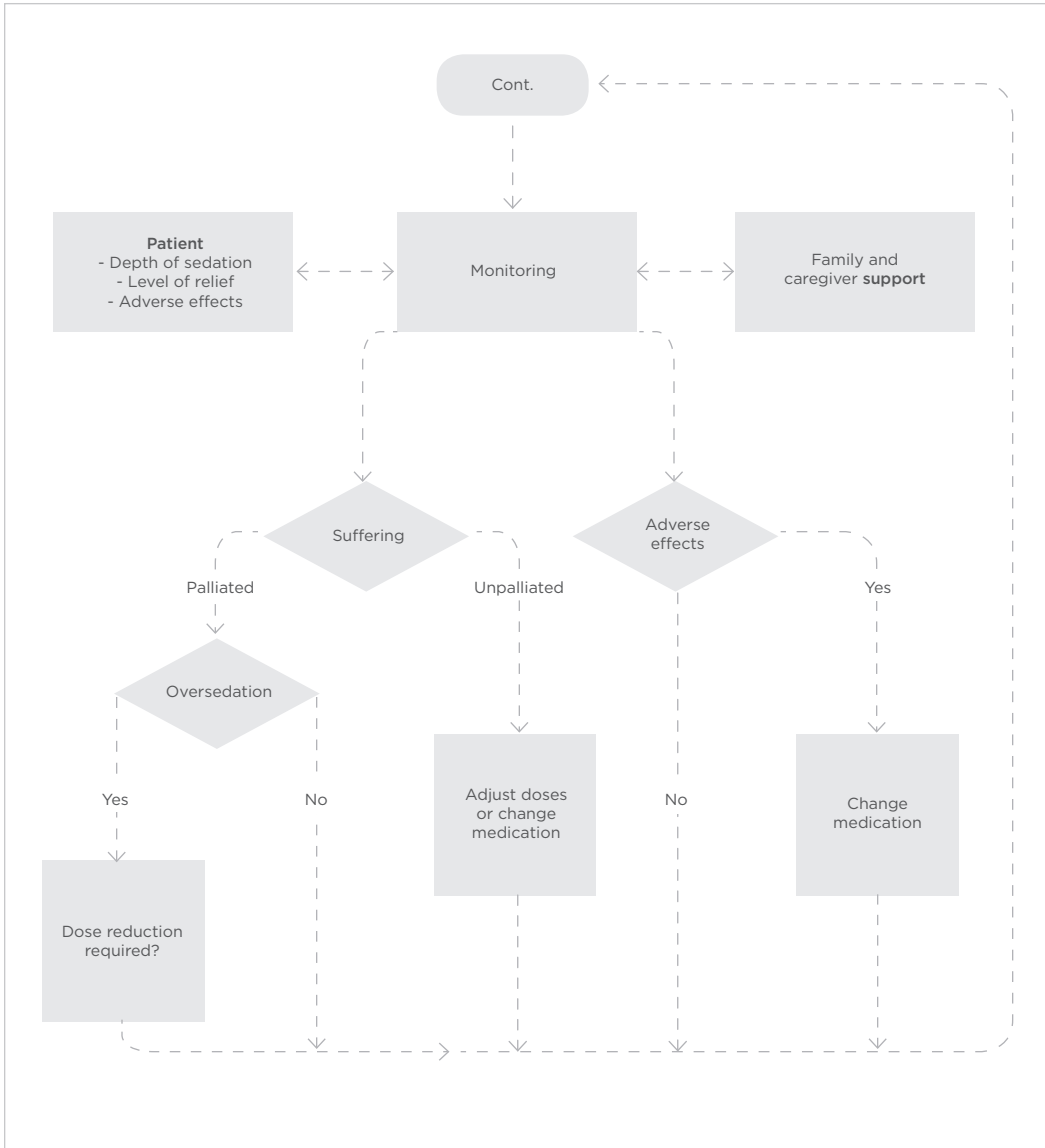
APPENDIX II - DECISION TREE



APPENDIX II - DECISION TREE (CONT.)



APPENDIX II - DECISION TREE (CONT.)



APPENDIX III - PATIENT MONITORING DURING PALLIATIVE SEDATION (CONT.)

Legend 1 - Richmond Agitation-Sedation Scale (RASS) (Sessler, 2002; Chanques, 2006; Thuong, 2008)		
Level	Description	Definition
+4	Combative	Combative, violent, immediate danger to the team
+3	Very agitated	Pulls to remove tubes and catheters and/or aggressive toward the team
+2	Agitated	Frequent nonpurposeful movements and/or fights the ventilator
+1	Restless	Anxious or apprehensive, but movements purposeful, infrequent, non-vigorous, non-aggressive
0	Alert and calm	
-1	Drowsy	Not fully alert but sustained awakening to voice (eye opening and contact > 10 s)
-2	Light sedation	Briefly awakens to voice (eye opening and contact < 10 s)
-3	Moderate sedation	Movement or eye opening to voice (no eye contact)
-4	Deep sedation	No response to voice, but movement or eye opening to physical stimulation (by shaking shoulder or rubbing sternum)
-5	Unarousable	No response to voice or physical stimulation (by shaking shoulder or rubbing sternum)

Legend 2 - Respiratory Distress Observation Scale (RDOS) (Campbell, 2008, 2010)			
	0 point	1 point	2 points
Heart rate (/min)	< 90	90-109	≥ 110
Respiratory rate (/min)	< 19	19-29	≥ 30
Restlessness: nonpurposeful movements	no	occasional	frequent
Paradoxical breathing pattern: abdomen moves in on inspiration	no		yes
Accessory muscle use: rise in clavicle during inspiration	no	slight rise	pronounced rise
Grunting at end-expiration: guttural sound	no		yes
Nasal flaring: involuntary movement of nares	no		yes
Look of fear: eyes wide open facial muscles tense brow furrowed mouth open teeth together	no		yes

Legend 3 - Other possible observations	
D	Respiratory distress (RR < 8/min.)
A	Respiratory pauses, apnea
S	Loud snoring
M	Myoclonus
P	Miotic pupils

— Appendices

APPENDIX IV - CONTINUOUS PALLIATIVE SEDATION CONSENT FORM

The consent form prescribed by the Minister in accordance with section 24 of the *Act Respecting End-of-Life Care* is available on the [MSSS Website](#).

— Appendices

APPENDIX V - CONTINUOUS PALLIATIVE SEDATION REPORT FORM

Patient

Last name

Health insurance number

First name

Record no.

Age

Sex

F

M

1. Institution

Name of the institution (CISSS, CIUSSS, CHU, etc.)

Care setting (check)

Home

Hospice - name

CHSLD¹ - name

CHSGS² - name

2. Main diagnosis and clinical condition

¹ CHSLD: Residential and long-term care centre

² CHSGS: General and specialized hospital centre

**APPENDIX V – CONTINUOUS PALLIATIVE SEDATION
REPORT FORM (CONT.)****3. Symptoms that warrant considering the use of continuous palliative sedation (check)**

Hyperactive delirium with uncontrollable psychomotor agitation

Major and recurrent respiratory distress

Progressive and intractable dyspnea

Refractory seizures

Intolerable and untreatable pain

Copious and refractory bronchial secretions

Hemorrhagic distress

Intractable nausea and vomiting

Refractory psychological or existential distress that severely compromises comfort

Other refractory condition – specify

4. Previous therapies tried

Pharmacological

including intermittent sedation

Yes

No

Non-pharmacological

5. Estimated prognosis of survival

Expected duration of continuous sedation (number of days)

**APPENDIX V - CONTINUOUS PALLIATIVE SEDATION
REPORT FORM (CONT.)**

6. Administration of continuous palliative sedation

Yes - date and start time

Year Month Day Hour

No - specify

Second opinion requested Yes No

7. Written consent obtained

Yes - attach a copy of the consent form (AH-880A-DT-9235)

No - specify

8. Medication prescribed

Medication	Route of administration	Starting dose*	Final dose*
Lorazepam			
Midazolam			
Methotrimeprazine			
Chlorpromazine			
Phenobarbital			
Propofol			
Scopolamine			
Other			

* Quantity of medication per unit of time (e.g., 1 mg/h, 450 mg/24h, 0.4 mg q 4h)

**APPENDIX V - CONTINUOUS PALLIATIVE SEDATION
REPORT FORM (CONT.)**

9. Hydration

Natural

discontinued spontaneously by the patient on (date)

Year Month Day

discontinued by the physician on (date)

Year Month Day

Artificial

discontinued on (date)

Year Month Day

10. Nutrition

Natural

discontinued spontaneously by the patient on (date)

Year Month Day

discontinued by the physician on (date)

Year Month Day

Artificial

discontinued on (date)

Year Month Day

**APPENDIX V - CONTINUOUS PALLIATIVE SEDATION
REPORT FORM (CONT.)**

11. Course until death

Peaceful death

Incomplete relief - specify

Complications - specify

Confirmation of death on (date)

Year

Month

Day

12. Attitude of family / health care team throughout the process

	Meeting (date)	Disagreement	Approval	Collaboration
Family				
Health care team				

13. Comments

**APPENDIX V – CONTINUOUS PALLIATIVE SEDATION
REPORT FORM (CONT.)****14. Report continuous palliative sedation form**

Completed on (date)

Year Month Day

And sent on (date)

Year Month Day

to the council of physicians, dentists and pharmacists³to the Collège des médecins du Québec⁴**15. Physician responsible**

Last name

First name

Licence no.

Professional contact information

Correspondence address

Telephone no.

Signature

³ If the physician practices his profession in a centre operated by an institution.

⁴ If the physician practices in a private health facility.

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