

Team Name: Regional Palliative Care Team	Reference Number: CLI.5910.SG.03
Team Lead: Regional Director, Seniors/Palliative Care	Program Area: Palliative Care
Approved by: Executive Director - West	Policy Section: General
Issue Date: October 16, 2017	Subject: Sedation for Palliative Purposes
Review Date:	
Revision Date:	

## STANDARD GUIDELINE SUBJECT:

Sedation for Palliative Purposes

#### PURPOSE OF GUIDELINE

The purpose of this guideline is to provide recommendations:

- 1. Regarding indications for the use of **Sedation for Palliative Purposes (SPP)\***.
- 2. To support the decision-making process involved in considering the implementation of SPP.
- 3. Regarding medication use in administering SPP.
- 4. Regarding the monitoring of patients who are receiving SPP.
- 5. Regarding documentation for the use of SPP.

#### BACKGROUND

Symptom control in the dying patient has advanced considerably in the past decades, yet there are instances in endof-life care, despite the efforts of all involved, when symptoms remain uncontrolled and intolerable to the patient.

The intervention being described in this document is consciously and intentionally referred to as **"Sedation for Palliative Purposes (SPP)**" as this term is a more specific description of the goal of the proposed intervention.

SPP is valuable therapeutic intervention that, in certain cases, can and should be initiated to facilitate a more comfortable death. It is the planned and **proportionate**\* use of sedation to reduce consciousness in an **imminently dying** patient with the goal to relieve suffering that is intolerable to the patient and **refractory** to interventions that are acceptable to the patient.

The term "palliative sedation" is more commonly found in the literature, but is interpreted in various ways by different **healthcare professionals**\*.

\*Words in **bold** can be found in the Glossary

## WHAT SEDATION FOR PALLIATIVE PURPOSES IS NOT

Sedation for Palliative Purposes is NOT:

- 1. Temporary sedation of a patient to manage symptoms in circumstances in which the patient has an underlying reversible pathophysiology and efforts are being made to reverse the concerning symptoms.
- 2. Respite sedation.
- 3. An unintended adverse effect of treatment (e.g. opioid-related sedation).
- 4. Sedation with the temporary use of antipsychotics and/ or sedatives to treat delirium.
- 5. Procedure-related sedation.
- 6. Sedation intended to hasten or cause death.
- 7. The sedation of patients whose life expectancy is more than 2 weeks.

### SEDATION FOR PALLIATIVE PURPOSES VS. EUTHANASIA/PHYSICIAN-ASSISTED SUICIDE (MEDICAL ASSIST IN DYING – MAID)

Not uncommonly, sedation for palliative purposes is erroneously considered to be part of the spectrum of **euthanasia**/assisted suicide (e.g. MAID). While the overall goal for both sedation for palliative purposes and euthanasia/assisted suicide is to relieve suffering, the nature and intended immediate outcome of their interventions differ significantly.

The intervention in euthanasia/assisted suicide is intended to end the life of the patient, and the relief of suffering is achieved through the intended death of the patient. In sedation for palliative purposes, if accepted guidelines are followed regarding proportionate dosing, monitoring for adverse effects, and prognosis of the underlying terminal condition, neither the medication nor the duration of sedation compromise the patient; relief of suffering is achieved through reduced alertness and awareness and death occurs as the natural course of the underlying illness unfolds.

There are many published definitions of euthanasia, **physician-assisted suicide**, and **physician-assisted death**. The definition of physician-assisted death can be particularly confusing, as some reputable references define it as synonymous with physician-assisted suicide (e.g. Canadian Medical Association Policy Update 2014: *Euthanasia and Assisted Death*), while others consider it to encompass both euthanasia and assisted suicide.

The recent decision by the Supreme Court of Canada regarding physician-assisted death (Carter v. Canada (Attorney General), 2015 SCC 5) affirmed the decision by the BC Supreme Court (Carter v. Canada (Attorney General), 2012 BCSC 886), which contained the following definitions. In view of their anticipated influence on health care regulation and related legislation in Canada, these definitions will be used for this document:

**Euthanasia**: the intentional termination of the life of a person, by another person, in order to relieve the first person's suffering (CMA, 2014, Carter v. Canada, 2012, Carter v. Canada, 2015).

Medical Assistance in Dying (MAID): encompasses both euthanasia and physician-assisted suicide. It is defined in Bill C-14 as:

(a) the administering by a medical practitioner or nurse practitioner of a substance to a person, at their request, that causes their death; or

(b) the prescribing or providing by a medical practitioner or nurse practitioner of a substance to a person, at their request, so that they may self-administer the substance and in doing so cause their own death.

**Physician-Assisted Suicide:** the act of intentionally killing oneself with the assistance of a medical practitioner, or person acting under the direction of a medical practitioner, who provides the knowledge, means, or both (CMA, 2014, Carter v. Canada, 2012, Carter v. Canada, 2015).

This guideline was developed by the Palliative Care Program of the Winnipeg Regional Health Authority, is used with permission, and has been updated to reflect local resources available in Southern Health-Santé Sud.

### <u>SCOPE</u>

This guideline provides recommendations for adult and pediatric clinical practice when SPP is being considered as an intervention. This guideline is intended for healthcare professionals working in the following settings:

- 1. Acute care facilities
- 2. Personal Care Homes
- 3. Home

## LEVELS OF EVIDENCE

Randomized controlled trials (RCTs) are challenging in palliative care, and even more challenging in the area of SPP. The majority of references used in this document are consistent with level IV evidence, unless otherwise noted.

### Grading of evidence

- la: systematic review or meta-analysis of RCTs.
- Ib: at least one RCT.
- Ila: at least one well-designed controlled study without randomization.
- IIb: at least one well-designed quasi-experimental study, such as a cohort study.
- III: well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case-control studies and case series.
- IV: expert committee reports, opinions and/or clinical experience of respected authorities

http://www.patient.co.uk/doctor/different-levels-of-evidence

## INDICATIONS FOR SEDATION FOR PALLIATIVE PURPOSES

Sedation for Palliative Purposes is indicated to relieve suffering in a patient who is expected to die in the next 2 weeks as the result of an underlying condition. The suffering must be intolerable to the patient <u>and</u> refractory to interventions deemed acceptable to the patient.

### Why 2 Weeks?

An expected natural death within 1-2 weeks from an underlying life-limiting condition is a common criterion in palliative sedation guidelines (Schildmann & Schildmann, 2014). In circumstances of an abrupt cessation of fluid intake (e.g. withdrawing tube feeds in persistent vegetative state or acute massive stroke where a comfort-only approach is followed), death typically occurs within 1-2 weeks related to the effects of dehydration (Cranford, 1991). Palliative sedation without hydration results in an abrupt cessation of fluid intake, which is unlikely to cause death in the context of an underlying life-limiting condition with a prognosis of less than 2 weeks. Death will result from the natural progression of the underlying condition.

Recommendations:

- 1. The patient's goals of care should be consistent with Advanced Care Plan (ACP) level 'C'.
- 2. The **healthcare team** should possess or seek **expertise** to determine that the physical/ emotional/**existential suffering** is refractory.

- 3. The healthcare team should possess expertise in determining if all available symptom management options have been considered or consult other available Resources for Decision Making (CLI.5910.SG.03.SD.01).
- 4. The healthcare team should possess expertise in prognostication or consult with available experts in this determination.
- 5. The decision to consider SPP is a **collaborative** and interprofessional process. A team approach is required.
- 6. If the healthcare team involved lacks expertise in SPP, they must consult the Southern Health-Santé Sud Palliative Care Program.

The sedation needs of patients in the intensive care unit (ICU) who are undergoing withdrawal of life sustaining therapies (WLST) are often different than those described in this document, but many of the major principles remain the same. In this special patient population, death is often imminent and sedation may already be in use as a part of the symptom-control strategy.

## **PROGNOSTICATION**

Prognostication is an essential component of assessing whether an individual meets the criteria for SPP. There is a point in a patient's clinical trajectory, along with his/her presenting symptoms, at which a momentum of decline might suggest that the patient is more imminently dying.

Recommendations:

- 1. SPP is indicated only in patients who are imminently dying (i.e. within the next 2 weeks)
- 2. If there is uncertainty about prognostication, the Southern Health-Santé Sud Palliative Care Team is available for consultation.

## **DECISION-MAKING**

Discussions about SPP may be raised by the patient, family or members of the healthcare team. Decisions regarding SPP should involve the **patient** or **substitute decision-makers** (SDM), the **family**, as well as involved members of the **healthcare team**.

Recommendations:

- 1. It is understood that the patient with **decision-making capacity** is the primary decision maker in his or her own care.
- 2. If the patient is unable to communicate by any available means, or deemed to lack decision-making capacity, discussions with the SDM and/or family are required.
- 3. If uncertainty exists about the patient's decision-making capacity, further consultation with other Resources for Decision Making (CLI.5910.SG.03.SD.01) is recommended.
- 4. Decisions regarding SPP should be congruent with the patient's previously expressed wishes or preferences (e.g. instructions provided in a **healthcare directive** or communicated to a proxy or SDM). Where the patient's specific preferences have not been communicated, decisions should follow the patient's known values or beliefs. If these are not known, decisions should reflect the decision-maker's understanding of the patient's best interests (e.g. What is needed now, in this specific circumstance, to secure the patient's overall comfort and well-being).
- 5. If there is ongoing disagreement between those deciding on behalf of the patient (SDM/family), or within the healthcare team, or between the SDM/family and healthcare team, consultation with other Resources for Decision Making (CLI.5910.SG.03.SD.01) is recommended.
- 6. If the decision to implement SPP is made, documentation should include:

- a. The refractory nature of the symptoms being addressed;
- b. The intolerability of the suffering;
- c. Patient prognosis;
- d. Patient goals of care;
- e. The target level of sedation (e.g. Richmond Agitation-Sedation Scale: Palliative Care [RASS- PAL] CLI.5910.SG.03.SD.02); and
- f. Details of the discussions with the patient, SDM and/or family and the healthcare team. This should include how any expressed concerns were addressed.
- 7. Re-evaluate the patient periodically to ensure that SPP remains consistent and effective to meet the patient's goals of care.

## **CONSIDERATIONS REGARDING HYDRATION AND NUTRITION**

Patients who receive SPP are neither likely to be able to independently eat or drink, nor have the desire to do so. Current literature indicates that as death nears the medical provision of nutrition or encouragement of intake beyond the patient's desire does not extend life or improve comfort or quality of life. Diminished food and fluid intake in the final phase of a progressive life-limiting condition is a natural part of the dying process and tends not to be associated with thirst or hunger (Dev, Dalal & Bruera, 2012; Bruera et al., 2013).

Recommendations:

- 1. The initiation or continuation of hydration or nutrition by parenteral or enteral routes is not recommended in the context of SPP, as it is not consistent with an approach that allows an expected death to unfold naturally and does not address comfort issues.
- 2. In situations where intravenous fluids will continue for the delivery of specific medications, the approach should be conservative.
- 3. If there is ongoing disagreement regarding the use of hydration and nutrition, consultation with other Resources for Decision Making (CLI.5910.SG.03.SD.01) is recommended.

# **REVIEW OF CONCURRENT MEDICATIONS**

In the context of SPP, the goal of care is comfort. Medications and routes may need to be modified based on the clinical situation.

Recommendations:

- 1. All concurrent medications should be reviewed and evaluated regarding the goals related to their use and their role in contributing to the patient's comfort.
- 2. In situations where opioids are already part of the medication regime to support the patient's comfort, they should be continued.
- 3. As the oral route will be lost, alternate routes for medication administration should be evaluated (e.g. sublingual, buccal, subcutaneous, intranasal, intravenous, and rectal).

## MEDICATIONS USED IN SEDATION FOR PALLIATIVE PURPOSES

There is very little evidence guiding the choice of specific medications for sedation for palliative purposes. Some common themes exist in published approaches, reflecting general knowledge about the pharmacotherapeutics of sedation and analgesia, as well as expert opinion.

The care setting will have an impact on available medications, routes of administration, and staff resources and experience.

Recommendations:

- 1. Opioids should not be used as primary or sole sedating agents. Deep sedation with opioids generally occurs at doses that also cause respiratory depression. Sustained opioid administration particularly in the context of diminished fluid intake risks the development of opioid-induced neurotoxicity, with worsening hyperalgesia, agitation, and myoclonus.
- 2. Opioids should be continued in patients currently receiving opioids for known existing pain or dyspnea; a source of pain or dyspnea prior to sedation would be expected to remain once sedation has been initiated.
- 3. Opioids are reasonable as supplements to primary sedating agents when there is uncertainty about underlying pain or dyspnea. The assessment of distress in non-communicative patients is challenging, and typically involves a degree of instinct/intuition on the part of family and health care providers. It is reasonable to provide a regularly scheduled baseline opioid regimen within safe parameters with regards to adverse effects as a foundational reassurance that potential pain and air hunger are being addressed.
- 4. Benzodiazepines used alone may result in delirium, with paradoxical agitation and restlessness. When used in sedation for palliative purposes, they are generally used in combination with a sedating antipsychotic and/ or sedative such as methotrimeprazine.

### Routes of Administration

Routes of medication administration should be considered when initiating SPP, and are dependent on the care setting in which SPP is being considered.

Recommendations:

- 1. A non-oral route of administration should be chosen, as the ability to safely swallow will be lost. Small volumes (up to approximately 1 mL) administered by the buccal/sublingual and intranasal routes are minimally invasive; medications are either absorbed transmucosally or swallowed reflexively with saliva.
- 2. The subcutaneous route is effective for many medications, and supported in a variety of care settings.
- 3. The intravenous route is reliable and effective, if supported in the care setting.
- 4. Occasionally, a preexisting feeding tube is left in place to administer medications, even when medical administration of food and fluids has been discontinued.

### Specific Medications

Most commonly, an antipsychotic and/ or sedative such as a benzodiazepine is used in sedation for palliative purposes. Some medications recommended to consider when initiating SPP include:

- 1. Antipsychotics
  - a. Methotrimeprazine (Nozinan®) is the most commonly prescribed antipsychotic in sedation for palliative purposes. This is a sedating phenothiazine, which can be administered intravenously or subcutaneously (off-label). The parenteral preparation may also be administered buccally (also off-label), where it is likely absorbed following reflexive swallowing of the small administered volumes.
  - b. Haloperidol is generally not very sedating and is therefore not a preferred antipsychotic in SPP.

### 2. Benzodiazepines:

- a. Lorazepam is usually administered sublingually, although in some settings intravenous administration is supported.
- b. Midazolam is a potent benzodiazepine, available for intravenous administration in some care settings. Other routes of administration described in the literature include subcutaneous, intranasal, and buccal; these routes are off-label, however. The dose for transmucosal and subcutaneous midazolam is significantly higher than for intravenous administration due to pharmacokinetic considerations such a bioavailability

and peak serum levels. This introduces the risk of excessive dosing if the prescribed intravenous dose is the same as other routes.

- 4. Other less commonly used medications, generally indicated only when adequate sedation is not achieved with methotrimeprazine and a benzodiazepine, include:
  - a. Phenobarbital: In palliative care settings this is generally prescribed for intermittent subcutaneous administration without a loading dose, typically on a q6h or q8h schedule. The dose is empirically titrated to effect, with ongoing vigilance for potential adverse effects (notably respiratory depression).
  - b. Propofol: the use of propofol for palliative sedation has been described in the literature for both adults and children. However, this is limited to approved care settings such as Critical Care, where there is policy and procedure support for its use, as well as the presence of clinician expertise (McWilliams et al., 2010; Anghelescu et al., 2012).

## Why Are Dose Recommendations/Ranges Not Included?

It is very challenging to provide specific recommendations regarding medications and doses that safely and effectively address both pediatric and adult patients, under a broad range of clinical circumstances. Highly variable parameters such as such as symptom severity, patient weight, comorbid conditions, concomitant medications, and baseline tolerance to sedatives and opioids will influence the response to a medication dose.

If the prescribing clinician is uncertain about medication doses for sedation for palliative purposes, consultation with Pharmacy, an experienced colleague, or with the Southern Health-Santé Sud Palliative Care Team is recommended.

## MONITORING AND DOCUMENTATION

Monitoring and assessment should include the ongoing need for SPP, its effectiveness in relation to the targeted level of sedation, and adverse effects. Modifications to the medications and care plan should be made based on the patient's responses and previously stated goals of care.

Recommendations:

- 1. A patient receiving SPP shall have ongoing assessment for:
  - a. Appearance of comfort
  - b. Depth of sedation
    - i. A tool to measure the patient's level of sedation should be used.
    - ii. The Richmond Agitation Sedation Scale- Palliative (RASS- PAL) is a <u>possible</u> tool to consider (CLI.5910.SG.03.SD.02). Healthcare teams may choose to use a sedation tool common to their care setting.
  - c. Respiratory rate and pattern

## Notes:

- A progressive slowing of the respiratory rate, along with a <u>regular</u> respiratory pattern is suggestive of excessive dosing of benzodiazepines and/or opioids and requires intervention.
- The respiratory pattern in the natural dying process is typically one of regular, rapid, shallow breathing, which in the final minutes or hours develops increasing apneic episodes, typically interspersed with clusters of rapid breathing. This is not a pattern typical of medication overdose.

- Patients who do not have a urinary catheter are at risk for urinary retention. This should be considered as a potential source of agitation.
- 2. Assessments of the patient's clinical status should be completed and documented at baseline and before each subsequent dose of medication which has been prescribed for SPP.
  - a. Documentation should occur at a minimum of every 4 hours.
  - b. In the home setting, teaching must be done with the care providers regarding assessing the respiratory rate and pattern, and when to contact the Southern Health-Santé Sud Palliative Care Team.
- 3. Assessments of the patient's clinical status should be documented if there is a change in the dosing of medications prescribed for SPP, including if a medication is held.
- 4. Aside from respiratory rate and pattern, the monitoring of other vital signs is not required.

When administering SPP, exploration and documentation of the family member's and the healthcare team's emotional response during the process is an important element of care.

## **GLOSSARY**

**Collaborative process:** When the Health Care Team engages in joint planning for the care of the Patient with shared responsibility and decision making that includes the Patient and family / Substitute Decision Maker (see Advance Care Planning – Goals of Care CLI.5910.PL.008).

# Decision-Making capacity includes:

- a) Ability to understand the Information and to make a decision about the proposed course of action;
- b) Ability to understand the nature and the anticipated effect(s) of the proposed Procedure(s), Treatment(s), or Investigation(s); and
- c) Ability to understand the alternatives and risks, including the consequence(s) of not proceeding with the proposed course of action.

**Existential suffering**: present when circumstances lead to emotional suffering, with or without physical symptoms. It can be related to the perception of meaninglessness, a sense of hopelessness, a perception of being a burden to others, feeling emotionally irrelevant, feeling isolated, the loss of dignity, and /or a fear of death or the unknown (Dean et al, 2012; Fraser Health CPG, 2011).

**Expertise:** is exhibited by an individual who has knowledge and experience with a particular set of skills or behaviors (Norman, 2002).

**Family:** "is defined by the patient or, in the case of minors or those without decision-making capacity, by those identified as surrogates for the patient. In this context, family members may be related or unrelated to the patient; they are individuals who provide support and with whom the patient has a significant relationship." (National Consensus Project on Quality Palliative Care Guidelines, 2009).

**Goals of Care:** the intended purposes of health care interventions and support as recognized by both a Patient or Substitute Decision Maker and the Health Care Team (see Advance Care Planning – Goals of Care CLI.5910.PL.008).

**Health Care Directive (HCD)**: A self-initiated document that allows individuals to make health care preferences known in the event that they are unable to express them. In Manitoba, a Health Care Directive may indicate the type and degree of health care interventions the person prefers and/or may indicate the name(s) of a person(s) who has

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been delegated to make decisions (i.e. a "Proxy"). In the absence of evidence to the contrary, a person who is 16 years of age or older is presumed to have the capacity to make a Health Care Directive. Generally speaking, a Health Care Directive is binding on health care professionals, unless the request for interventions is illegal or inconsistent with accepted standards of practice.

**Healthcare professionals:**- an individual who is registered with a regulated health profession; individuals who assess and advise patients and colleagues to provide preventive, curative, rehabilitative and supportive health services which are informed by evidence and anecdotal practice.

Healthcare team: Consists of members of the patient care team who are working collaboratively.

**Imminently dying**: as the result of an underlying disease process, death is expected within the next 2 weeks (Dean, Champlain CPG; Fraser Health CPG).

**Patient:** refers to any individual who is the recipient of assessment, intervention and/or support from health care professionals in any care setting. A person who is registered for or receiving medical treatment. May also be referred to as clients or residents.

**Physician-Assisted Death** and **Physician-Assisted Dying**: terms that encompass physician-assisted suicide and voluntary euthanasia that is performed by a medical practitioner or a person acting under the direction of a medical practitioner (CMA, 2014, Carter v. Canada, 2012, Carter v. Canada, 2015).

**Procedure-related sedation (conscious sedation)**: the use of medications to temporarily induce a decreased level of consciousness for the duration of the procedure.

**Proportionate**: the intervention and medication administered is titrated to achieve the desired outcome (de Graeff & Dean, 2007; Dean, 2012).

**Refractory:** A 'refractory' symptom is defined as "a symptom for which there is no appropriate treatment available within the given time frame that the patient can tolerate or for which the risk-benefit ratio is not acceptable to the patient." (de Graeff & Dean, 2007, p. 69)

**Respite sedation**: a time limited trial in an attempt to break a cycle of physical or psychological suffering (Salacz & Weissman, 2004).

**Sedation for palliative purposes:** is the planned and proportionate use of sedation to reduce consciousness in an imminently dying patient with the goal to relieve suffering that is intolerable to the patient and refractory to interventions that are acceptable to the patient.

**Substitute Decision Makers:** refers to a third party identified to participate in decision –making on behalf of a person who lacks decision- making capacity concerning disclosure. The task of substitute decision- maker is to faithfully represent the known preferences and/or the interests if the incapable person (see Advance Care Planning – Goals of Care CLI.5910.PL.008).

**Suffering**: "a sense of helplessness or loss in the face of a seemingly relentless and unendurable threat to quality of life or integrity of self (Cassel, 1999). "Although pain, dyspnea, delirium, nausea and vomiting are frequent causes of suffering at the end-of-life, hopelessness, remorse, anxiety, loneliness, and loss of meaning also a cause suffering. Suffering involves the whole person in physical, psychological, and spiritual ways." (Fraser Health CPG, 2011).

### **SUPPORTING DOCUMENTS:**

CLI.5910.SG.003.SD.01 CLI.5910.SG.03.SD.02 Resources for Decision Making Richmond Agitation-Sedation Scale: Palliative Version (RASS-PAL)

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