College of Physicians and Surgeons of British Columbia

# Position Statement

## Use of Ketamine in the Treatment of Mood Disorders

### DETAILS

**Department/program:** Non-Hospital Medical and Surgical Facilities Accreditation Program

**Date:** July 30, 2020

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### PURPOSE

Position statements from the College provide background information and express or clarify the College's intent on a particular matter. They are intended as guidance for stakeholders in areas where events are evolving or changing rapidly, the implementation of processes and procedures may be premature, the implementation of a guideline or standard may not be necessary, another credible body (i.e. professional association) has already established guidelines or standards, or it is timely to communicate the College's broad intent before or as policies and procedures are developed.

This document addresses the use of Ketamine in the treatment of mood disorders.

### BACKGROUND

Ketamine is a dissociative anesthetic agent capable of producing amnesia, analgesia and all degrees of sedation, including general anesthesia. Ketamine is sometimes used to treat neuropathic pain or other painful conditions in patients where standard conventional pain therapies have been unsuccessful. Ketamine is also an emerging off-label treatment for mood disorders although its efficacy and safety, for this indication, have not been evaluated in large-scale clinical trials.

### POSITION

The Non-Hospital Medical and Surgical Facilities Accreditation Program (NHMSFAP) Committee is responsible for determining the medical, surgical, dental and anesthesia procedures that in the community-setting may only be performed in accredited non-hospital facilities.

In addition, the NHMSFAP Committee is responsible for establishing accreditation standards, policies, rules, procedures and guidelines to ensure the delivery of high-quality and safe services in non-hospital facilities.

#### Introduction

Patients have a right to make decisions about their health care including choosing investigational, complementary or alternative therapies in place of, or as an adjunct to, conventional medicine.

Physicians who choose investigational, complementary or alternative therapies alone or in combination with conventional medicine must practise in a manner that is informed by medical evidence and science and is in keeping with their professional, ethical and legal obligations. Physicians must always act within the scope of their practice based on their qualifications, skill and knowledge, and level of competence.

**Appropriate setting**

- Ketamine administration by any route, including oral, intranasal, intramuscular (IM), subcutaneous (SC) and intravenous (IV) **must** be performed in an accredited non-hospital facility.

**Governance and leadership**

- Ketamine for the treatment of mood disorders **must** only be administered by an anesthesiologist in an accredited facility.
- Ketamine for the treatment of mood disorders **must** only be prescribed by a psychiatrist for a patient under their care.
- Anesthesiologists administering ketamine for the treatment of mood disorders **must** have the requisite credentials for privileges as outlined in the provincial privileging dictionaries: http://bcmqi.ca/credentialing-privileging/dictionaries/view-dictionaries.
- Anesthesiologists administering ketamine for the treatment of mood disorders **must** have applied for and been granted privileges by the medical director of the non-hospital facility.
- Physicians prescribing or administering ketamine for the treatment of mood disorders **must** do so in accordance with the College *Complementary and Alternative Therapies* practice standard.
- Human resources management shall be in accordance with the NHMSFAP *Human Resources* standard with the following modifications:
    - Nursing staff in the pre-admission, admission and treatment room areas shall possess the education and qualifications of nursing staff in the post-anesthesia care area, and
    - Nursing staff shall hold current advanced cardiac life support (ACLS) certification.

**Ketamine dosing**

- Ketamine intravenous infusion dosing is restricted to a weight-based dose limit of 0.5 mg/kg IV over 40 minutes.
- Ketamine intramuscular dosing is restricted to a weight-based dose limit of 0.1-0.4 mg/kg IM.
- Ketamine subcutaneous dosing is restricted to a weight-based dose limit of 0.1-0.5 mg/kg SC.

**Informed consent**

- The consent process must include a consent discussion with the patient, documentation of the consent discussion in the patient's medical record and completion of a consent form.

  *Guidance: Both the psychiatrist requesting the treatment and the anesthesiologist planning to administer the treatment should document their consent discussions in the patient's medical record. A consent form should be completed in the psychiatrist's office and sent to the non-hospital booking office prior to the patient's admission to the non-hospital facility. As the*

*administration of ketamine is not for anesthesia associated with surgery/procedures, a consent form should also be completed by the anesthesiologist.*

- The consent discussion must include the rationale for providing an investigational, complementary, or alternative therapy as explained to the patient.
- A "rolling" consent may be suitable for the same treatment performed consecutively. Confirmation that the consent remains valid should be documented at each patient visit.

**Pre-admission evaluation and selection**

- Patient evaluation must be performed in advance of the day of the procedure (e.g. several days to weeks) to allow for optimal patient preparation and pre-treatment work-up including the necessary testing and consultation(s).
- Pre-admission evaluation and selection shall be in accordance with the NHMSFAP *Pre-admission Evaluation and Selection* standard.
- Pre-admission evaluation must include a comprehensive psychiatric assessment and management plan.
- Pre-admission assessment must include obstructive sleep apnea (OSA) screening using a validated tool (e.g. STOP-Bang) and should be performed in advance of the day of the treatment.
- Patients **must** be aged 19 years or older.
- Ketamine **must** only be considered by the patient's interdisciplinary care team when standard conventional pharmacological treatment(s) and psychotherapy (e.g. cognitive behavioral therapy, interpersonal therapy) have been unsuccessful.

**Psychiatric assessment**

- The comprehensive psychiatric assessment and management plan **must** be completed by the referring psychiatrist and include at a minimum:
    - Psychiatric history including past and current psychiatric diagnoses, psychotic or aggressive ideas and behaviors, suicidal ideas, intentional self-injury, hospitalization and emergency department visits for psychiatric issues, psychiatric treatments (type, duration, and where applicable doses) and response to psychiatric treatments.

      *Guidance: The baseline assessment should include symptom severity to allow for comparative evaluation of clinical change with treatment. The treatment history should confirm previous adequate trials of antidepressant treatments.*
    - Medical history including relevant past or current medical illnesses, hospitalizations and treatments.
    - Allergies or drug sensitivities.
    - Medication history including both prescribed and non-prescribed medications, herbal and nutritional supplements, and vitamins and the side effects of these medications.
    - Substance use history including use of tobacco, alcohol, and other substances (e.g. marijuana, cocaine, heroin, hallucinogens) and any misuse of prescribed or over-the-counter medications or supplements.

*Guidance: JAMA Psychiatry's consensus statement on the use of ketamine in the treatment of mood disorders strongly recommends baseline urine toxicology screening to ensure the accuracy of the reported substance use and medication record.*

- Physical exam including mental status examination and review of systems including height, weight and body mass index (BMI), vital signs, skin including any signs of trauma, self-injury or drug use, cardiopulmonary status, past or current endocrinological disease, past or current infectious disease (e.g. STIs, HIV, tuberculosis), past or current neurological or neurocognitive disorders or symptoms, past or current symptoms or conditions associated with significant pain and discomfort.

  *Guidance: This can be performed by the psychiatrist or can be performed by another physician (e.g. general practitioner). Assessment may occur directly or by review of the results of a recent assessment by another clinician. Review of systems should include general/systemic, skin, HEENT, respiratory, cardiovascular, gastrointestinal, genitourinary, musculoskeletal, neurological, hematological, endocrine. The review of systems should also evaluate potential risk factors associated with ketamine treatment.*

- Relevant laboratory and other diagnostic testing.

  *Guidance: This includes but is not limited to laboratory testing, ECG. Testing should made according to established guidelines such as "Choosing Wisely" and should be based upon the patient's clinical characteristics.*

- Impression and plan including the rationale for treatment selection.

**Admission**

- Admission and pre-procedure care shall be in accordance with the NHMSFAP *Admission and Pre-procedure Care* standard with the following exceptions:
  - Surgical site marking does not apply, and
  - Pre-operative checklist does not apply.
- Known or suspected latex sensitivity or allergy shall be managed in accordance with the NHMSFAP *Latex Allergy* standard.
- IV access shall be established for all patients.

  *Guidance: A tested saline lock or running IV is initiated and maintained until the patient meets established discharge criteria (i.e. objective discharge scoring system and other patient specific discharge criteria).*

**Treatment unit/area/room**

- Each treatment chair/bed/stretcher space shall be equipped with:
  - Cardiac monitor
  - Pulse oximeter
  - End-tidal carbon dioxide concentration monitor
  - Automatic blood pressure monitor

  - Suction equipment including suction canisters and liners, tubing, suction tips and catheters
  - Oxygen equipment including oxygen supply and regulator, nasal cannulas, masks and oral airways
  - Bag-valve-mask device
  - Artificial airways in various types and sizes
- The unit/area/room shall be equipped with
  - Temperature monitoring equipment
  - Clinical support supplies such as stethoscope, intravenous (IV) catheters and solutions, medications, ophthalmoscope

**Treatment unit/area/room staffing**

- Two registered nurses both competent in critical care or post-anesthesia care shall be present in the unit/area/room at all times when the patient is receiving treatment.

  **OR**

- One registered nurse (RN) competent in critical care or post-anesthesia care **and** one anesthesiologist shall be present in the unit/area/room at all times when the patient is receiving treatment.
- An anesthesiologist shall be in continuous attendance at the facility until the patient meets discharge criteria and is immediately available (i.e. can attend to the treatment room without undue delay) throughout the treatment.
- When the treatment unit/area/room is staffed with one RN and one anesthesiologist, there shall be a third regulated health professional immediately available to assist in the event of an emergency.
- The psychiatrist or anesthesiologist shall be in attendance at the facility throughout treatment in the event that the patient experiences prominent transient dissociative or psychotomimetic effects.
- The psychiatrist or anesthesiologist shall assess the patient just prior to discharge to evaluate the patient for potential behavioural risks including suicidal ideation.
- If the psychiatrist is not in attendance at the facility, they shall be immediately available by telephone throughout treatment until the patient is discharged.
- One-to-one nurse to patient ratios shall be observed.

**Patient monitoring**

- The following monitoring shall be in continuous use throughout the treatment:
  - Electrocardiography

    *Guidance: The cardiac rhythm should be interpreted at baseline prior to start of the treatment and a rhythm strip secured into the patient's medical record. In addition, the cardiac rhythm should be interpreted if there is any change from baseline (e.g.*

*bradycardia, tachycardia, life-threatening rhythm) and another rhythm strip secured into the patient's medical record.*

- Pulse oximetry

  *Guidance: At a minimum, oxygen saturation (as displayed by pulse oximeter) should be recorded at baseline, then q5min x 3, then q15min x 3.*

- Capnography when patients exhibit a sedation scale of greater than or equal to 2

  *Guidance: Sedation is a continuum and it is not always possible to predict how an individual patient will respond. Capnography (continuous monitoring of end-tidal CO) is considered best practice and is **highly recommended** for all patients under any level of sedation.*

- Level of consciousness and depth of sedation shall be frequently assessed.

  *Guidance: At a minimum, the patient's level of consciousness and level of sedation should be documented at baseline, then q5min x 3, then q15min x 3.*

- Blood pressure and respiratory rate shall be frequently assessed.

  *Guidance: At a minimum, the patient's blood pressure and respiratory rate should be documented at baseline, then q5min x 3, then q15min x 3.*

- The patient shall remain in the treatment room/area/unit for an appropriate length of time.

  *Guidance: Minimum length of stay is 30 minutes after the IV infusion is discontinued. Minimum length of stay after IM or SC injection is 30 minutes.*

- Intravenous access is maintained until the patient meets discharge criteria.

**Discharge**

- Patients shall be appropriately prepared for discharge in accordance with the NHMSFAP *Discharge* standard.

**Medication management**

- Ketamine infusions shall be prepared **only** by a pharmacy (i.e. commercially packaged or pharmacy-prepared pre-mixed solutions of ketamine). Whenever possible a single standard concentration should be used.
- Ketamine infusions shall be administered:
  - Using a dedicated line
  - **Only** using an infusion control device/syringe pump with a locked control panel
  - By continuous infusion **only** (i.e. not by patient-controlled devices or bolus dosing)
- Prior to administering ketamine, there shall be an independent double-check to ensure the right patient, the right medication, the right dose, the right route and the right infusion pump settings (e.g. medication strength/concentration, dosing formula (e.g. mcg/kg/min, units/hr) weight). The independent double-check should be documented.

*Guidance: An independent double-check involves two regulated health professionals (e.g. 2 RNs or 1 RN and 1 anesthesiologist) separately checking (alone and apart from each other, then comparing results) the infusion settings in accordance with the physician's order.*

- Medication inventory, preparation, administration, storage and wastage shall be in accordance with the NHMSFAP *Medication Management* standard.

**Infusion control device/syringe pump safety**

- The makes/models of the infusion/syringe pumps available within the facility shall be limited. Having only one or two makes/models of pump is recommended.
- The infusion/syringe pump shall be equipped with a free-flow protection mechanism.
- There shall be instructions and/or a user guide for each type of infusion/syringe pump in use at the facility. The instructions and/or user guide should be clear and readily available to staff.
- Staff shall receive training on the safe use of each make/model of infusion/syringe pump in use at the facility and training records should be maintained.
- Staff competence in the safe use of each make/model of infusion/syringe pump shall be evaluated and documented at least every two years.

**Infrastructure**

- Each treatment chair/bed stretcher space shall be at minimum 7.5 $m^2$ (80 $ft^2$).
- Each treatment chair/bed/stretcher shall have the following minimum clearances:
    - Each side of the bed 1200 mm (4ft)
    - Between beds 1800 mm (6ft)
    - Foot of the bed 1500 mm (5ft)
- Equipment shall be managed in accordance with the NHMSFAP *Equipment Management* standard.
- Electrical systems and electrical safety shall be in accordance with the NHMSFAP *Electrical Systems and Safety* standard.
- Medical gas systems shall be in accordance with the NHMSFAP *Medical Gas – Free-standing Tank System* standard and/or the NHSMFAP *Medical Gas – Pipeline System* standard.
- Occupational health and safety shall be managed in accordance with the NHMSFAP *Occupational Health and Safety* standard.
- HVAC parameters in the treatment unit/area/room are at least 6 total air-changes and 2 outside air-changes.

  *Guidance: All new and/or renovated facilities are required to meet the HVAC requirements as specified in the CSA Z317.2 Special requirements for heating, ventilation and air-conditioning (HVAC) systems in health care facilities for an examination, treatment and consulting room: minimum total air-changes six; minimum outside air-changes two. Existing facilities that have been granted a variance by the NHMSFAP Committee are not required to meet the HVAC requirements until the variance term specified by the committee has expired. Air-change rates*

*should be assessed annually by an HVAC technician and documented in the HVAC service records on file at the facility.*

**Emergency preparedness**

- The facility and staff shall be prepared for emergencies in accordance with the NHMSFAP *Emergency Preparedness* standard.
- Emergency cart medication and equipment shall be in accordance with the NHMSFAP *Class 1 General Anesthesia Facility Emergency Cart* standard with the following exceptions:
    - Succinylcholine is not required

      **Note:** If the anesthesiologist chooses to stock succinylcholine, even for emergency purposes then the facility **must** also have a malignant hyperthermia kit in accordance with the NHMSFAP *Malignant Hyperthermia* standard.

**Infection prevention and control**

- A clean environment shall be provided in accordance with the NHMSFAP *Environmental Cleaning* standard.
- Routine practices and additional precautions shall be in accordance with the NHMSFAP *Routine Practices and Additional Precautions* standard.
- Quality control and infection control measures for point-of-care laboratory testing (e.g. blood glucose) shall be in accordance with the NHMSFAP *Point-of-Care Testing* standard.
- Injection practices, single-use devices practices and multi-dose vial practices shall be in accordance with the NHMSFAP *Single-use Devices and Multi-dose Vials* standard.
- The hand hygiene program and hand hygiene practices shall be in accordance with the BC Ministry of Health's *Best Practices for Hand Hygiene in All Healthcare Settings and Programs*.
- Cleaning, disinfection and sterilization of critical and semi-critical medical devices shall be in accordance with the BC Ministry of Health's *Best Practice Guidelines For Cleaning, Disinfection and Sterilization of Critical and Semi-critical Medical Devices*.
- Waste shall be safely and appropriately segregated, contained, handled, stored and disposed of in accordance with the NHMSFAP *Waste Management* standard.

**Medical records and documentation**

- Patient information, medical records, medical record systems and documentation shall be in accordance with the NHMSFAP *Medical Records and Documentation* standard.
- Patient monitoring by an anesthesiologist shall be documented using an anesthetic record.
- Patient monitoring by a registered nurse shall be documented using a sedation record.

**Policy and procedures**

- There shall be policy and procedures for the role and responsibilities of the psychiatrist prescribing the use of ketamine for mood disorders.

*Guidance: The policy and procedures should clarify their role and responsibilities including pre-admission evaluation, informed consent, immediate post-treatment evaluation and continuity of care.*

- There shall be policy and procedures for the role and responsibilities of the anesthesiologist administering ketamine for mood disorders.

  *Guidance: The policy and procedures should clarify their role and responsibilities including pre-admission evaluation, informed consent, immediate post-treatment evaluation and continuity of care.*

- There shall be policy and procedures pertaining to the use of ketamine for mood disorders.

  *Guidance: Policy and procedures should outline staff qualifications, staffing levels, patient selection and preparation, patient monitoring and post treatment care and discharge*.

**Quality improvement**

- Facilities accredited to administer ketamine for mood disorders should have a quality performance program in place to monitor, evaluate and improve the quality of services.
- Immediate post-treatment follow-up and continuity of care should be established for all patients.

## REFERENCES

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