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COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Stem Cell Regenerative Therapy Standards

Version January 2018 – v1

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1.0 Preamble

This document addresses privileges and standards for Stem Cell Regenerative Therapy and is intended to supplement the CPSA's standards for *Non-Hospital Surgical Facilities (NHSF).*

Physicians may only provide services that involve Adipose-Derived Stem/Stromal Cells (ADSC) and/or Bone Marrow Aspirate Concentrate (BMAC) in a non-hospital facility in Alberta that is accredited by College of Physicians & Surgeons of Alberta (CPSA).

These CPSA Stem Cell Regenerative Therapy Standards are requirements which are in addition to those stipulated in Government of Canada regulations for cell therapy products in humans.

Alberta physicians and NHSFs shall comply with these CPSA Standards. Further, if analysis of the stem cell aspirate or fluoroscopic guidance is necessary, then separate CPSA accreditation will be required by the respective CPSA programs of Diagnostic Laboratory Medicine and/or Diagnostic Imaging.

Physicians who perform Regenerative Therapy in an NHSF are encouraged to participate in active collaborations to identify outcome measures and aggregate outcomes data in addition to making their methods and results available for peer review.

The CPSA's accreditation does not imply the endorsement of stem cell regenerative therapy by the CPSA. Rather, the regulating body's oversight that health services occurring within the non-hospital surgical facility comply with accreditation standards.

2.0 Physicians Providing Stem Cell Services: Qualifications

2.1 Physicians who perform Regenerative Therapy in an NHSF shall:

a. Be a physician licensed to practice medicine in Alberta;

-and -

b. Be certified as a specialist in the appropriate field with evidence of recognized training in Regenerative Therapy;

-or-

c. Have evidence of appropriate and sufficient training with experience that is suitable to the Registrar.

2.2 A satisfactory postgraduate training program acceptable to the Registrar for sufficient training and experience shall include clear demonstration and evidence of:

a. Peer training preceptors with credentials acceptable to the Registrar;

b. Both didactic and hands-on training;

c. A clear description of the amount and the nature of the hands-on training, including:

i. The selection of procedures;
ii. The preparation of patients;
iii. Maintenance of asepsis in non-hospital settings;
iv. Intra-operative patient monitoring;
v. Post-operative care and follow-up;
vi. Quality improvement in surgical services;
vii. Hands-on training in the surgical technique of bone marrow aspiration and/or liposuction;
viii. Processing and delivery of the aspirate.

2.3 The Registrar may require a preliminary assessment prior to approving procedure privileges when there is insufficient information about the physician's training, experience or performance to satisfy the CPSA.

2.4 The physician shall maintain competence through continuing education in the procedures performed.

2.5 Adipose derived stem cell aspiration is considered by the CPSA as a form of the liposuction surgical procedure:

a. Eligibility for privileges in adipose tissue aspiration shall include a minimum of one year of a residency training program resulting in demonstrated competency with the procedure;

-or-

b. Completion of postgraduate training in adipose tissue aspiration commensurate with the background of surgical training and experience of the applicant which is acceptable to the Registrar.

2.6 Conditions may be attached to privileges in adipose stem cell harvesting, restricting physicians to one or more of the following:

a. Specified anatomical sites;
b. Volume of the aspirate to a maximum of 240 mL;
c. Type of anesthesia;
d. Procedural Technique (collection, isolation and administration).

2.7 Bone marrow derived stem cell aspiration is considered by the CPSA as a form of the bone biopsy surgical procedure:

a. Eligibility for privileges in bone marrow aspiration shall include a minimum of one year of a residency training program resulting in demonstrated competency with the procedure;

-or-

b. Completion of postgraduate training in bone marrow biopsy commensurate with the background of surgical training and experience of the applicant which is acceptable to the Registrar.

2.8 Conditions may be attached to privileges in bone marrow stem cell harvesting, restricting physicians to one or more of the following:

a. Specified anatomical sites;
b. Maximum volume of aspirate;
c. Bone Marrow derived stem cell aspirate to a maximum of 120 mL;
d. Type of anesthesia;
e. Procedural Technique (Collection, Isolation and administration).

2.9 All physicians who administer patient-managed gas inhalation anesthesia shall maintain current certification in health care provider cardiopulmonary resuscitation/AED and ACLS and meet all requirements listed in these accreditation standards *under section 6.0 Intra-Operative Management: Anesthesia.*

3.0 Intraoperative Image Guidance

3.1 Ultrasound guidance

a. Point of care ultrasound does not require specific physician approval from the CPSA as stated in the *Bylaws of the CPSA subsection 36 (6) (a)*.

3.2 Fluoroscopic Guidance

a. Fluoroscopy aided services shall require separate accreditation by the CPSA Diagnostic Imaging Accreditation Program.

i. All physicians who perform guided fluoroscopy shall be recognized as a specialist in radiology with CPSA modality approval;

–or-

ii. Obtain modality approval as a non-radiologist with restricted fluoroscopy applicable to that modality as specified within the *CPSA Diagnostic Imaging Accreditation "Physician Approvals" training requirement standards*.

b. All facilities which provide fluoroscopy shall comply with CPSA Diagnostic Imaging Accreditation Standards specific to that modality.

4.0 Assisting Personnel: Qualifications

4.1 At least one assistant who is continuously in attendance of the patient shall have documented training and experience with:

a. Procedural Technique (Collection, Isolation and administration);
b. Monitoring and documentation of vital signs;
c. Maintaining aseptic fields and instruments;
d. Assisting in emergency procedures including the use of a bag-valve-mask device and current certification in cardiopulmonary resuscitation/AED use;
e. Infection Prevention and Control, including medical device reprocessing; and
f. Assembly, calibration, programming and/or operation of equipment.

5.0 Procedures

5.1 There shall be written procedures for all surgical procedures in the facility involving adipose tissue aspiration and/or bone marrow aspiration.

5.2 There shall be written procedures for all non-surgical procedures in the facility involved in the process of the stem cell regenerative therapy.

6.0 Preoperative Evaluation

6.1 The pre-operative evaluation by the surgeon shall also include the following determinations:

a. Absence of contraindications;

b. A pre-anesthetic assessment for patient-administered nitrous oxide not exceeding 50% of concentration inhalation which includes:

i. A review of the patient's clinical record;
ii. A medical interview with the patient;
iii. A physical examination relative to anesthetic aspects of care;
iv. A review and ordering of tests as indicated;
v. A review or request for medical consultations as necessary for patient assessment and planning of peri-operative care;
vi. Orders for pre-operative preparation such as fasting, medication, or other instructions as indicated; and,
vii. A signed consent for the procedure/anesthetic that is part of the patient's clinical record.

7.0 Intra-Operative Management: Anesthesia

7.1 The CPSA recognizes patient-administered gas inhalation as a form of anesthesia due to its sedating properties which may obtund awareness and protective reflexes.

7.2 The gas inhalation provision shall be from the appropriate nitrous oxide compressed medical gas provider as Entonox, the homogeneous gas containing a mix of 50% oxygen and 50% nitrous oxide compressed into a cylinder. This includes the Demand Valve/Regulator/Mask/Hose for use with Entonox cylinders. Substitution shall not occur.

7.3 Patient-administered gas inhalation shall only occur with:

a. Documentation of prescreening for:

i. Inability to follow verbal instructions;
ii. Intoxication with alcohol or drugs;
iii. Altered mental status;
iv. Medication allergy or sensitivity.

b. Documentation of successful patient teaching/ instruction with return demonstration of competency to self-administer.

c. Monitoring and documentation of patient tolerance.

7.4 Patients undergoing patient-administered gas inhalation shall receive adequate instruction by qualified facility staff prior to use with documentation in the patient record.

7.5 Continual patient monitoring with vital signs documented at a minimum of every 5 minutes during the administration of gas inhalation shall occur via a second individual. This second individual shall be trained on gas inhalation equipment, set up, administration, patient monitoring and vital sign documentation and shall not be assisting in the surgical procedure.

7.6 No additional sedating medications shall be administered prior to or during patient-administered gas inhalation.

7.7 Patients undergoing patient-administered gas inhalation shall be continuously evaluated with at least the following:

a. Visualization of patient's use (technique, frequency, pallor and respiratory effort) under appropriate lighting;

b. Pulse oximeter with audible signal recognition;

c. Apparatus to measure blood pressure with an appropriately sized cuff; and

d. Vital signs documented at a minimum of every 5 minutes.

8.0 Medical Records

8.1 The peri-operative record shall contain a designated section and be completed for:

a. Unique identifier and expiry date of stem cell collection/separation/administration device(s);

b. The anatomical site(s) prepped and number of times accessed for collection;

c. The volumes and time of aspirate;

d. The volumes and time of stem cells isolated;

e. The anatomical sites prepped, treated, time and the volume of stem cells injected per site;

f. The use of guided techniques, if any;

g. Surgical technique complications, if any;

h. Amounts of aspirate and stem cell isolate discarded in appropriate medical waste container(s) for human tissue;

i. Documentation of vital signs at a minimum of every 5 minutes during the procedure.

9.0 Harvesting Systems

9.1 Due to their inability to filter or sterilize the end product, all harvesting systems shall demonstrate the ability to avoid contaminants of debris and ambient air particulates at all stages of the stem cell process.

9.2 Commercial harvest kits, centrifuges and other specialized medical equipment shall be approved for use by Health Canada.

9.3 Design specifications shall comply with the manufacturer's instructions.

9.4 If facilities augment the specialized medical equipment and centrifuges with the preparation of their own in-house harvesting kit, the following criteria shall be met:

a. The kits are comprised of only commercially prepared sterile medical supplies (i.e. syringes, 3-way stopcock, etcetera);
b. There is unique identifier and expiry date labeling on the in-house harvest equipment for tracking;
c. Processing of the specimen outside of the sterile field shall meet all requirements listed within the *Section 11.0 Stem Cell Collection & Separation Equipment.*

10.0 Stem Cell Collection & Separation Equipment

10.1 The intraoperative procedure shall be restricted to simple processing steps of anticoagulants containing antimicrobial properties, enzymatic digestion and centrifugation.

10.2 The stem cells concentrate shall not be compounded or administered with other substances.

11.0 Stem Cell Collection & Separation

11.1 Stem cell collection and separation done outside of the sterile field shall adhere to current good tissue practices as per Health Canada's Guidance Document for Cell, Tissue and Organ Establishments – Safety of Human Cells, Tissues and Organs for Transplantation.

11.2 The collection and separation of the specimen/stem cell product shall be performed by a physician approved by the Registrar to perform stem cell procedures or by an appropriately trained a regulated health care professional designated to those responsibilities by the Medical Director.

11.3 Stem cells collected and separated in the facility shall be restricted to minimally manipulated autologous cells of the patient.

11.4 Stringent aseptic procedures and technique shall be followed during the collection and separation of the specimen/stem cell product.

11.5 Collection, separation and administration containers shall be clearly labeled with the patient's name, second identifier in addition to date and time of collection.

11.6 The stem cell separation process from collection to administration shall only occur in the operating room with the patient present and attended by the CPSA approved physician an appropriately trained a regulated health care professional designated to those responsibilities by the Medical Director.

11.7 Separated blood, bone marrow and adipose tissue products shall be used within the time frame specified by the equipment manufacturer and shall not exceed three (3) hours post-collection.

12.0 Discharging the Patient

12.1 The physician approved for patient-administered gas inhalation service shall remain on the premises of the NHSF until the patient meets documented pre-determined recovery criteria using a validated grading system (e.g. Analgesia and Anesthesia…, Current Researches, Volume 49(6): 924-934, Nov-Dec 1970. "A Postanesthetic Recovery Score" by J.A. Aldrete and D. Kroulik.).

12.2 Instructions not to drive or operate hazardous equipment for 24 hours after receiving patient-administered gas inhalation shall be given to the patient and accompanying adult.

13.0 Resources

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