cpsa
COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

Performance of Autologous Platelet Rich Plasma Therapy in Unaccredited Settings

A Guideline for Physician Office/Clinic Setting

VERSION AUGUST 2017
Last updated: October 2024

Approval Date:	June 27, 2018
Originating Committee:	Advisory Committee on Non-Hospital Surgical Facilities
Prepared by:	Medical Facility Accreditation Committee College of Physicians & Surgeons of Alberta

Introduction

This guideline was prepared for Alberta licensed physicians who offer and perform platelet rich plasma services.

Platelet rich plasma (PRP) therapy is based on the theory that the use of a patient's own blood factors may improve tissue repair and healing. The validity of any potential beneficial effects of PRP therapy continue to undergo further definition and evaluation. This also includes the variability with: technique, number of injections, spacing of injections, number/concentration/exogenous activation of platelets, with/without leukocytes and a definition of the appropriate candidate.

The PRP procedure involves multiple steps that require the handling of blood products. Special attention should be paid to maintaining the sterility of technique and product to ensure patient safety. The risk of contamination reflects the number of steps within the PRP procedure. Contamination can easily occur during venipuncture, selection/handling of collection devices, separation containers, multiple centrifugation runs to isolate the PRP layer and the injection of the concentrated aliquot. The ability to perform all steps of the PRP procedures without contamination is critical due to the inability to filter-sterilize the end product prior to injection.

Although the processing and administration of autologous blood products is perceived as low risk activity for patients, extra diligence is required to ensure mislabeling or misidentification of the blood product does not occur.

Physicians who currently are or are considering the provision of PRP therapy may also benefit in reviewing the *Stem Cell Regenerative Therapy Standards* available on the CPSA web site.

Alberta licensed physicians choosing to offer and perform platelet rich plasma services are advised to comply with the following guidelines:

1. Physicians interested in providing PRP therapy should ask:

- Is the purpose of the PRP Therapy for a recognized application?
- Are there any relative contraindications to the PRP therapy?
- What are the available methods and commercial kits for collection and processing of PRP? What are the advantages and disadvantages of each?
- What validation of the method or commercial kit has been done? What on-site validation should be done?
- Who will be performing the procedure?
- How much training is required and how will they be trained?

2. Prior to use of a PRP method or commercial kit, the following need to occur:

- Commercial kits, centrifuges and other specialized medical equipment must be approved by Health Canada,
- Method validation to ensure it is performing as intended, including platelet counts and collection volumes,
- Equipment calibration and use of equipment as directed by manufacturer's instructions
- Commercial kit verification to ensure they are performing as intended,
- Inspection and validation of incoming materials and new lot numbers, and
- Special attention must be paid to the maintenance of the sterility of technique and product to ensure patient safety and product quality.

3. Procedures should be written which address the following:

- Informed consent from the patient,
- Purpose of the procedure,
- Blood sample collection, identification and handling,
- Stepwise instructions for equipment set up/preparation,
- Stepwise instructions for the procedure,
- If using a commercial kit, following of the manufacturer's instructions, including immediate disposal of single-use supplies (e.g. needles, syringes, etc.),
- Establishment of an acceptable volume of sample collection and end product PRP aliquot(s),
- Medical record documentation,
- Limitations of the procedure,
- Adverse event protocols related to all phases of the procedure including remedial actions to be taken when complications and/or errors occur, and
- Procedures and patient selection processes should be updated at intervals to conform to emerging evidence in the literature.

4. Training and on-going competency assessment of personnel should be performed and documented:

- All health care providers involved in or performing PRP therapy must successfully complete a comprehensive training program that describes all aspects of the procedure to ensure they can perform their role accurately with consistency.
- All health care providers involved in or performing PRP therapy must be assessed for competence prior to being allowed to perform the procedure or their assigned tasks for PRP therapy service and on an on-going basis at defined intervals (training does not equate to competency).
- Training and competency assessment programs should be updated when any changes occur to the PRP therapy services.

5. Safety issues to be considered include:

- Staff personal protective equipment (e.g. gloves, gowns, protective eye wear, masks) and hand hygiene. Refer to "Blood & Body Fluid Precautions" located on myhealth.alberta.ca.
- Evaluation and follow-up of workers after accidental exposure to blood and body fluids. Refer to "Blood & Body Fluid Precautions" located on myhealth.alberta.ca.
- A safety training program for employees who routinely work with blood or other infectious materials.
- Special waste disposal considerations.
- Infection prevention and control procedures.
- Cleaning requirements for contaminated surfaces and supplies.
- Management of patient adverse events/reactions during and after the procedure.

6. Blood sample collection and processing must be strictly controlled to ensure the safety and quality of the PRP.

Issues to consider include:

- Collection:
  - Patient identification
  - Infection prevention and control procedures
  - Sample labelling with the patient/client name and patient/client unique identification number
  - Volume collected
- Processing:
  - Hand hygiene and aseptic technique
  - Maintenance of sample identification and traceability
  - Maintenance of sample integrity and sterility
  - Centrifuge spin speed and time
- Administration:
  - Sample identification
  - Infection prevention and control procedures

- **Quality Control:**

  - Periodic checks of:
    - volume collected
    - Centrifuge calibration
    - Platelet counts and recovery
  - If using a commercial kit, quality control and/or calibration must be performed as specified by the manufacturer.

- **Post-procedure considerations:**

  - Safe disposal of samples and collection devices.
  - Cleaning and disinfection of blood sample equipment, environment and procedural room as per the CPSA Infection Prevention and Control (IPAC) standards and recommended best practice resources.
  - Review the blood sample/end product results within patient's medical record (individually and group for accuracy and trends).
  - There must be arrangements/processes in place to respond to and act upon any adverse event and document the decision and the rationale in the patient record.
    - Discuss the decision and the rationale for the decision with the patient as appropriate.
    - Include reference to any communication about the decision with other members of the patient's health care team.
  - Current literature indicates responses to PRP are variable, depending on a number of PRP factors, the application plus the host.

9. Procedure Documentation:

Key steps of the PRP procedure must be consistently documented in the patient's medical record.

10. PRP Therapy Challenges:

- Healthcare providers performing PRP therapy should be aware of the following challenges:
  - Health Canada regards point of care autologous PRP therapy as the practice of medicine via authorized health professionals through their provincial regulatory bodies' oversight.
  - Quality assurance of the procedure.
  - Procedure limitations and accuracy of the concentration of PRP components in the end product.
  - Infection prevention and control.

11. Business Practices:

- Business/financial interests are not to direct the delivery of PRP therapy services.

Acknowledgement

The CPSA Medical Facility Accreditation Committee gratefully acknowledges the Diagnostic Laboratory Program for sharing the framework and information in the development of these guidelines.

References

1. Aesthetic Surgery Journal. Current Evidence for Clinical Efficacy of Platelet Rich Plasma in Aesthetic Surgery: A Systematic Review. Frautschi B. et al; CA, USA; 2016.
2. Canadian Blood Services. Background Paper for the Tissue Expert Committee: How can the Canadian tissue donation and transplantation system best ensure consistent safety and quality; Canadian Blood Services Organ and Tissues Donation and Transplantation Steering Committee; Ottawa 2011.
3. Cell Stem Cell. Oversight for Clinical Uses of Autologous Adult Stem Cells: Lessons from International
Regulations; Lysaght T.et al: Cambridge, MA; 2013.
4. Cell Stem Cell. New Japanese Initiative on Stem Cell Therapies; Konomi K.et al: Cambridge, MA**;** 2015.
5. Centers for Disease Control and Prevention. Summary of Infection Prevention Practices in Dental Settings. National Center for Chronic Disease Prevention and Health Promotion. GA, USA; 2016.
6. CLSI. Essential Tools for Implementation and Management of a Point-of-Care Testing Program. CLSI document POCT04, 3rd Ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2006.
7. CLSI. Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline. CLSI document POCT07-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.
8. CLSI. Selection Criteria for Point-of-Care Testing Devices; Approved Guideline. CLSI document POCT09-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.
9. CSA. Point-of-care testing (POCT) - Requirements for quality and competence. CAN/CSA Z22870-07:2006(E); Mississauga, ON; 2007.
10. CSA. Blood and blood components. CAN/CSA-Z902-10(R0215); Mississauga, ON; 2015.
11. CSA. Cells, Tissues, & Organs for Transplantation & Assisted Reproduction: General Requirements – CAN/CSA-Z900.1-03; Mississauga, ON; 2012.
12. CSTM. Standards for Hospital Transfusion Services, Version 4. Canadian Society of Transfusion Medicine; Markham ON; 2017.
13. Europeon Spine Journal. A new simplified technique for producing platelet-rich plasma: a short technical note. Marlovit S. et al: Switzerland; 2004.
14. GOC. Guidance Document for Cell, Tissue and Organ Establishments - Safety of Human Cells, Tissues and Organs for Transplantation, GOC, https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/regulatory-initiatives/cells-tissues-organs/guidance-document-safety-human-cells-tissues-organs-transplantation.html#a1; Confirmed access 2017.
15. GOD. Platelet Rich Plasma (PRP) Guidelines, Government of Dubai, Dubai Health Authority; Dubai, 2014.
16. Journal of Cutaneous and Aesthetic Surgery. Principles and Methods of Preparation of Platelet-Rich Plasma: A Review and Author's Perspective. Dhurat D. & Sukesh M.S.; India 2014.

17. NICE. Platelet-rich plasma injections for osteoarthritis of the knee; Interventional procedure guideline. London UK; 2014.
18. NICE. Autologous blood injection for tendinopathy; Interventional procedure guideline. London UK; 2013.
19. PIDAC. Infection and Control for Clinical Office Practice. Public Health Ontario; ON; 2015.
20. The International Cellular Medical Society Guidelines for the Use of Platelet Rich Plasma; International Cellular Medicine Society; NV, USA; 2011.
21. Revista Brasileira De Ortopedia. Platelet-rich plasma (PRP) applied during total knee arthroplasty; Guerreiro J. et al: Brazil; 2014.
22. WHO. WHO best practices for injections and related procedures toolkit. World Health Organization; Switzerland; 2010.
23. WHO. WHO guidelines on drawing blood: best practices in phlebotomy. World Health Organization; Switzerland; 2014.