GOVERNMENT OF DUBAI

DUBAI HEALTH AUTHORITY

Platelet Rich Plasma (PRP)

Guidelines

Version 1

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Health Policies and Standards Department

Health Regulation Sector (2014)

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I. Scope

These guidelines apply to any facility of Dubai Healthcare Sector, subject to licensure under Dubai Health Authority (DHA) establishment law and who want to provide Platelet Rich Plasma (PRP) treatment in the Emirate of Dubai.

This document shall be implemented in accordance to the Policy On Practising New Clinical Procedures.

DHA has the right to amend this document stipulated herein without prior notice; the latest version of the guidelines shall be published on the DHA website www.dha.gov.ae.

II. Purpose

DHA is the sole responsible entity for ensuring that all health facilities and healthcare professionals in the Emirate of Dubai provide the highest level of safety and quality patient care at all times. These guidelines outline the basic mandatory requirements for a facility and healthcare professionals to be able to provide PRP treatment.

III. Definitions

Dubai Healthcare Sector: All health facilities that fall under governmental, semi-governmental, private and facilities operating in free zone areas excluding Dubai Healthcare Authority (DHCA).

Healthcare professional :healthcare personal working in healthcare facilities and required to be licensed as per the applicable laws in United Arab Emirates.

Patient: individual who receives medical attention, care or treatment by any healthcare professional or admitted in a health facility.

Platelet Rich Plasma: a therapy using blood with high levels of Platelets containing growth factors for acceleration in healing and regeneration.

Licensure: issuing a license to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

IV. Acronyms

CT	**:**	Computed Tomography
DHA	:	Dubai Health Authority
DHCA	:	Dubai Healthcare Authority
FDA	**:**	Food and Drug Administration
HRD	:	Health Regulation Department
LLC	**:**	Limited Liability Company
MRI	**:**	Magnetic Resonance Imaging
NSAIDs	**:**	Nonsteroidal Anti-Inflammatory Drugs
PRP	:	Platelet Rich Plasma
UAE	:	United Arab Emirates
SME	:	Subject Matter Experts

1. Introduction

DHA has developed these guidelines to assist health facilities and healthcare professionals in performing safe procedures, promote patient education and define the scope and anticipated effects of Platelet Rich Plasma (PRP) treatment.

2. PRP practicing Physician Requirements

Any physician willing to practice PRP must be:

2.1 DHA licensed.

2.2 Provide evidence of training

2.3 Shall be specialized in one of the following fields:

- 2.3.1 Orthopedics
- 2.3.2 Sports Medicine
- 2.3.3 Dermatology
- 2.3.4 Plastic Surgery
- 2.3.5 Oral and Maxillofacial Surgery

Note: Any other specialty who applies for this medical procedure will be reviewed case by case and will be asked for evidence of training and experience.

3. Training Requirements

3.1 The physician must have:

- 3.1.1 Appropriate knowledge about diagnosis, standard treatments, benefits, risks, methods of preparation and applying to the appropriate patient in the appropriate situation.
- 3.1.2 Training and understanding of appropriate graft selection and preparation of such a graft with or without additive supports (calcium, thrombin, etc.).
- 3.1.3 Training and expertise for the use of guidance technology (i.e. CT, fluoroscopic, ultrasound, etc.) either through residency, fellowship, sufficient post-graduate training program.

3.1.4 Training by the manufacturer of the equipment and maintain evidence of the same.

3.1.5 Ability to determine the appropriate indication and contraindications for PRP use.

3.1.6 Training in the recognition and management of any complications.

3.1.7 Training with use of proper pain management strategies for post-procedure pain control.

3.1.8 Competency to optimize patient outcome by use of adjunctive bracing, physical therapy, medications and other strategies.

3.2 The assistant shall undergo certified training and maintain its evidence.

4. Application Procedure

4.1 The procedure requires the physician and an assistant to aid in preparation of a PRP graft, maintenance of aseptic technique and saving images on ultrasound (if applicable).

4.2 Pre-procedure considerations:

4.2.1 Specific indication correlated with physical exam and confirmed with imaging studies such as x-ray, ultrasound, MRI, or CT scan prior to treatment.

4.2.2 Appropriate patient education and discussion with an informed consent signed prior to the initiation of the procedure.

4.2.3 Contraindications to the procedure are reviewed prior to initiation, discussed and approved by the patient.

4.2.4 Analgesics (no NSAIDs) or anxiolytics have to be administered, if applicable.

4.3 The physician must explain clearly the risks, benefits, expected course, follow-up and acceptable activities to the patient.

5. Procedure Requirements

5.1 PRP machines used in facilities must be from approved vendors.

5.2 PRP procedure shall be practiced using standardised and approved equipment or kits.

5.3 PRP should be obtained using a separating device designed for autologous blood.

5.4 Special attention should be paid to the sterility of the product, sterility of technique and specialized sterile kits should be used.

5.5 A closed system that prevents exposure of the blood and cellular components to the open air in the room and allows for minimal manipulation of the tissue shall be used.

5.6 Informed Consent form must be made available to the patient before the procedure . The consent form must contain all the fields identified in the sample Consent Form (please refer to *Appendix 1).*

5.7 Each patients sample should be labelled with name and patient's file number.

5.8 The PRP procedure including; blood drawing, centrifugation and administering the final product must be done in the same room where the patient is present.

5.9 All patients have to fill a "Patient Feedback Form" to give us heir opinion on the PRP treatment provided.

6. Infection Control

6.1 Hygiene is of prime importance to avoid and protect both client and operator from disease transmission. The infection control procedures shall abide by those mentioned in the "Hospital Regulation" or "Outpatient Care Facility Regulation" that can be accessed via www.dha.gov.ae in addition to the special precautions related to the PRP procedure.

6.2 Special infection control measures may include but not limited to:

6.2.1 Sterile single use needles and syringes should be used with appropriate handling and disposal.

6.2.2 Aseptic conditions in the area that the procedure is conducted.

6.2.3 Disposable gloves must be worn at all times during the treatment and the cleaning process.

6.2.4 All disposable items used during the treatment must be discarded in a specialized medical waste bag.

6.2.5 Hands must be scrubbed between treatments.

7. General Considerations

7.1 The patient must be aware of all other alternatives treatment procedure. This shall be documented in the patient's health record in the health facility.

7.2 The health facility shall:

7.2.1 Maintain effective Preventive Maintenance (PM) for each medical equipment used for PRP treatment as per the manufacturer recommendations.

7.2.2 Contract with a specialized and quality approved company to regularly collect, transport and destroy medical waste materials according to the conditions issued by Public Health Department in Dubai Municipality.

7.2.3 Provide information required by DHA for auditing purpose.

7.3 Promotions and advertisements for the PRP treatment shall be approved by the Ministry of Health (MOH).

Appendix 1. Consent Form (sample)

Informed Consent Form For Patients Undergoing Platelet Rich Plasma (PRP) Treatment

(Name of Healthcare Professional) _____
(Name of Health Facility) _____
(Name of Patient) _____
This Informed Consent Form has two parts:

- **Information Sheet (to share information about the treatment with you)**
- **Certificate of Consent (for signatures if you agree to go ahead with the treatment)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction:

I, Dr. _____ with license No:_____ shall be performing the PRP treatment on Miss/Mrs./Mr. _____ aged _____ years, on date _____.

Description of the Process

Describe to the patient or customer, what will happen on a step-by-step basis. The patient shall be informed that procedure is newly introduced and the amount of supporting research and study available.

Side Effects

Potential patients should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it.

Complications

Inform and explain any possible complications like (but not limited to) infection, tendon rupture, tissue damage, nerve injuries that could be caused as a result of the PRP treatment.

Discomforts

Explain and describe the type and source of any anticipated discomforts that are in addition to the side effects and risks discussed above.

Benefits

Mention only those activities that will be actual benefits of the PRP treatment.

Confidentiality

Explain how the clinical team will maintain the confidentiality of data, especially with respect to the information about the patient .

Right to Refuse treatment/procedure

This is a reconfirmation that the patient has the right to refuse the treatment.

Alternatives to clinical procedure or treatment

It is important to explain and describe the established standard treatment or procedure for the patient's condition.

PART II: Certificate of Consent

This section can be written in the first person. It should include a few brief statements about the treatment and be followed by a statement similar to the one in bold below. The healthcare professional performing the PRP treatment and the person going over the informed consent must sign the consent.

Example:

Patient Consent statement

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to try this new treatment and understand that I have the right to withdraw from the procedure or treatment at any time without in any way affecting my medical care.

Name of Patient: _____ _____

Signature of Patient: _____ _____

Date: _____

Witness statement

I have accurately read or witnessed the accurate reading of the consent form to the potential patient, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____

Signature of witness: _____

Date: _____

Healthcare Professional Declaration:

I have adequately explained to the patient about the procedure along with risks, adverse effects and the standard alternatives that are available for the procedure. I have permitted time and opportunity for the patient to ask questions and all questions have been answered to my knowledge

Name of healthcare professional: _____

Signature of healthcare professional : _____

Date: _____

8. References

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