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SPECIAL CONTRIBUTION

PM&R

Curriculum for training in orthobiologics

Michael Auriemma MD[1] | Haylee Borgstrom MD[2] | David Itskevich DO[3] | Ryan Kruse MD[4] | Erek Latzka MD[5] | Josh Martin MD[6] | Brittany Moore MD[7] | Marc Gruner DO, MBA[8] | Marko Bodor MD[9] | John Cianca MD[10] | Prathap Jayaram MD[11] | Karen Knight MD[12] | Walter I Sussman DO[5,13] | Christine Townsend MD[14] | Joanne Borg-Stein MD[15]

[1]Regenerative Orthopedics and Sports Medicine, North Bethesda, Maryland, USA

[2]Spaulding Rehabilitation Hospital/Harvard Medical School, Charlestown, Massachusetts, USA

[3]Regenerative Orthopedics & Sports Medicine, North Bethesda, Maryland, USA

[4]University of Iowa, Iowa City, Iowa, USA

[5]Boston Sports & Biologics, Wellesley, Massachusetts, USA

[6]Metro Orthopedics & Sports Therapy, Potomac, Maryland, USA

[7]Apex Orthopedics and Sports Medicine, Overland Park, Kansas, USA

[8]OrthoBethesda, McLean, Virginia, USA

[9]Bodor Clinic, Napa, California, USA

[10]Human Performance Center, Bellaire, Texas, USA

[11]Emory University School of Medicine, Atlanta, Georgia, USA

[12]Panorama Orthopedics and Spine Center, Golden, Colorado, USA

[13]Tufts University, Department Orthopedics and Rehabilitation, Boston, Massachusetts, USA

[14]Montefiore Med Ctr/Albert Einstein COM Yeshiva Univ Sports Medicine Fellowship, New York, New York, USA

[15]Spaulding Rehabilitation Hospital, Charlestown, Massachusetts, USA

Correspondence
Michael Auriemma, Regenerative Orthopedics and Sports Medicine, North Bethesda, Maryland 20852, USA.
Email: mikeauriemma@gmail.com

INTRODUCTION

There are currently a number of educational offerings in orthobiologics, but there is no comprehensive, standardized approach to education and training in the field. This curriculum (available online curricula.aapmr.org) provides a framework to identify the necessary knowledge, skills, and attitudes pertaining to orthobiologic treatments of orthopedic and musculoskeletal conditions. It can be used as a guide for institutions and residency programs to develop training or for individual practitioners looking to assess and augment their own knowledge and skills pertaining to orthobiologic treatments.

AUDIENCE

The primary target audience of this document is physiatrists, with core competencies aligning with physical medicine and rehabilitation (PM&R) postgraduate year-2 through year-4 training, and specialized competencies aligning with fellowship and more advanced training. This template, however, can be easily modified to fit the

This curriculum has received an Affirmation of Value from the American Medical Society for Sports Medicine (AMSSM), the Biologics Association (BA), the Interventional Orthobiologics Foundation (IOF), and the American Academy/Association of Orthopedic Medicine (AAOM).

training needs of physicians from other specialties who are considering practicing in orthobiologics.

SCOPE

This curriculum is not intended to be a comprehensive overview of all nonsurgical treatments for orthopedic and musculoskeletal conditions. Instead, it focuses on treatments that meet the definition of an orthobiologic, with greater emphasis placed on such treatments that align with current U.S. Food and Drug Administration guidelines. As the regulatory landscape evolves over time, it is anticipated that this curriculum will require updating.

It should also be noted that this document does not advocate for any specific treatment modality. Rather, the goal is to outline important knowledge, skills, and attitudes that physicians practicing orthobiologics should be familiar with. Not all physicians practicing in orthobiologics will perform all the listed procedures; nevertheless, to provide the most accurate information and effective care to patients, those practicing in orthobiologics need to be familiar with the existence of and evidence base (or lack thereof) for all relevant orthobiologic treatments.

The Curriculum Workgroup recognizes that other interventions, such as percutaneous tenotomy and shockwave technologies, contain mechanisms of action that overlap with orthobiologics and are potential alternative treatment options. However, because these treatments do not meet the definition of an orthobiologic, they are considered beyond the scope of this document. Similarly, surgical applications of orthobiologics are beyond the scope of this curriculum.

STRUCTURE

This document was developed in accordance with the American Academy of Physical Medicine and Rehabilitation's (AAPM&R) process for curricula in specialized topics. These curricula are designed to define the full spectrum of training needs in a specific clinical area from residency through practice. AAPM&R's approach is to develop curricula from an aspirational and educational perspective, not a regulatory one. For that reason, it is not prescriptive in how it is applied; rather, this document provides a broad and comprehensive framework from which any program or practitioner can identify gaps in training and adapt the curriculum to their diverse needs.

This curriculum includes competencies in two primary groups:

- Core competencies: What every physiatrist should know regarding orthobiologics at the completion of residency training (levels 1–3), and
- Specialized competencies: What physicians should know to practice in orthobiologics (levels 4–6).

Core and specialized competencies are further stratified into basic, intermediate, and advanced categories, as well as by knowledge, skill, and/or attitude. This taxonomy serves as a guideline for identifying educational needs and designing programs and resources to meet those needs.

METHODS

The *Curriculum for Training in Orthobiologics* was written by the AAPM&R Orthobiologics Curriculum Workgroup, overseen by the AAPM&R Orthobiologics Workgroup and Medical Education Committee.

The Curriculum Workgroup consisted of eight subject matter experts and followed an established peer-review process, including virtual and in-person meetings over 6 months, to accomplish the following:

- Review the process that AAPM&R uses for developing curricula, including the structure, terms, and template;
- Define the parameters and assumptions for the curriculum including the target audience, which treatments would be included or not included, and the organization of content;
- Develop the knowledge, skills, and attitudes to define the competencies that (1) all physiatrists should have achieved at the completion of residency, and (2) all specialists practicing in orthobiologics should have;
- Discuss and vet the competencies and their level of difficulty through an in-person peer-review process;
- Finalize the content and submit for review by the AAPM&R Orthobiologics Workgroup, the AAPM&R Medical Education Committee and external organizations, with final approval by the AAPM&R Board of Governors.

CONTENT AREAS

The curriculum is broken down into seven content areas:

- Background and basic science
- Prerequisite knowledge and skills
- Regulations and ethics
- Platelet-rich plasma
- Bone marrow aspirate concentrate
- Microfragmented adipose transfer
- Emerging technologies

As the field of orthobiologics continues to grow, it is important to ensure that practitioners are equipped with the tools needed to be successful. This curriculum outlines the current competencies that are essential to ensure that residents, those in fellowship training, and practicing physicians have the foundation required to effectively optimize patient care. Because the field continues to evolve, this curriculum is expected to be a living document and will be updated accordingly.

DISCLOSURE

Dr Cianca is a member of the AAPM&R Board of Governors. Dr Gruner reports consulting fees from PACES, State of Maryland, Rubicon Founders, Apex Medical; Board and founder with equity of Limber. Dr Sussman reports the following Trice Medical, Medical Advisory Board; Lipogems LLC, Consultant. Apex Biologics, Consultant Interventional Orthobiologic Foundation, Board Member.

You can access this curriculum and the other curricula in this series at curricula.aapmr.org.

ORCID

Michael Auriemma https://orcid.org/0000-0003-0249-7324
Ryan Kruse https://orcid.org/0000-0002-6736-8577
Marc Gruner https://orcid.org/0000-0001-7722-8757
Prathap Jayaram https://orcid.org/0000-0001-6209-5410

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Curriculum for Training in Orthobiologics

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BACKGROUND COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
Define orthobiologics.	X				X				
Summarize the most common orthobiologic substances: platelet rich plasma (PRP), bone marrow aspirate concentrate (BMAC), microfragmented adipose tissue (MFAT).	X				X				
Identify emerging orthobiologic substances (including exosomes, alpha-2-macroglobulin [A2M], interleukin receptor antagonist protein [IRAP], culture-expanded stem cells, platelet poor plasma [PPP], etc.).	X						X		
Classify FDA compliant and non-compliant orthobiologic substances.	X					X			
Describe the natural healing model for soft tissue injuries (inflammation, proliferation, remodeling).	X				X				
Compare the various growth factors believed to play a role in the natural healing model for soft tissue injuries.	X					X			
Explain the pathophysiology of acute musculoskeletal (MSK)/orthopedic injuries, including ligament, muscle, tendon, fibrocartilage, nerve, bone and cartilage (American Academy of Physical Medicine and Rehabilitation [AAPM&R] MSK curriculum, pg. 1-2).	X				X				
Explain the pathophysiology of chronic degenerative MSK/orthopedic conditions, including ligament, muscle, tendon, fibrocartilage, nerve, bone and cartilage (AAPM&R MSK curriculum, pg. 1-2).	X				X				
Describe typical non-operative and operative treatment options for acute MSK/orthopedic injuries (AAPM&R MSK curriculum, pg. 5, 7-8, 11-32).					X				
Describe typical non-operative and operative treatment options for chronic degenerative MSK/orthopedic conditions (AAPM&R MSK curriculum, pg. 5, 7-8, 11-32).					X				
Analyze the limitations of typical non-operative and operative treatments of acute MSK injuries (AAPM&R MSK curriculum, pg. 5, 7-8, 11-32).	X					X			
Analyze the limitations of typical non-operative and operative treatments of chronic degenerative MSK conditions (AAPM&R MSK curriculum, pg. 5, 7-8, 11-32).	X					X			
Define the "treatment gap" as it pertains to osteoarthritis (OA).	X					X			
Non-orthobiologic injection treatments									
Identify typical non-orthobiologic injection treatments for intra vs extraarticular conditions, including: - Hyaluronic acid (HA) - Steroids - Non-steroidal anti-inflammatory drugs (NSAIDs) - Dextrose 5% in Water (D5W) - Saline - Prolotherapy	X				X	X			
Explain the mechanisms of action/theory behind the above non-orthobiologic injection treatments for intra vs extraarticular conditions.	X				X	X			
Recognize that insurance coverage for the above therapies can vary significantly.	X					X			
Summarize the historical role prolotherapy plays in establishing a basis for orthobiologic treatments.	X						X		
Early orthobiologic treatments - autologous blood injection (ABI)/whole blood									
Recall the constituents of whole blood; whole blood includes red blood cells (RBCs), which contain heme free radicals and may contribute to oxidative damage.	X						X		
Identify the limited indications for use of whole blood (no longer in use with the advent of better alternatives).	X						X		

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PRE-REQUISITE SKILLS AND KNOWLEDGE COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
HISTORY AND EXAMINATION (MSK/SPORTS MEDICINE)									
Discuss the presentation of a broad spectrum of musculoskeletal conditions as detailed in the AAPM&R MSK curriculum (2022)1.	X				X				
Correlate the onset of symptoms with underlying tissue pathophysiology.	X				X				
Assess for medical comorbidities that may affect orthobiologic candidacy.	X					X			
Inquire about medications that may affect orthobiologic candidacy.	X					X			
Evaluate patient's prior treatments.	X				X				
Assess patient's knowledge of and/or attitudes regarding biologic treatment options.			X			X			
Evaluate patient-centered treatment goals including pain management, function and timeline.	X		X			X			
Perform a comprehensive musculoskeletal examination of the relevant body region: shoulder, elbow, wrist/hand, hip, knee, ankle/foot, spine, trunk (AAPM&R MSK curriculum, pg. 33-36).	X	X				X			
IMAGING/DIAGNOSTIC STUDIES									
Summarize the utility of various imaging modalities related to assessment of tissue pathology: joint, bone, muscle, tendon, ligament, nerve, spine.	X				X				
Interpret basic and advanced imaging and diagnostic studies (x-ray, magnetic resonance imaging [MRI], computed tomography [CT], ultrasound, electromyography [EMG]/nerve conduction study [NCS]).	X	X				X	X		
Describe how imaging features of OA influence biologic treatment options.	X						X		
Review how imaging features of tendinopathy influence biologic treatment options.	X						X		
Explain how imaging features of muscle injury influence biologic treatment options.	X						X		
Outline how imaging features of ligament injury influence biologic treatment options.	X						X		
Identify imaging findings that would limit orthobiologics as an effective treatment option.	X						X		
Perform and interpret point-of-care MSK ultrasound findings to guide interventional approach.	X	X						X	
IMAGE GUIDANCE FOR PROCEDURES (ULTRASOUND AND/OR FLUOROSCOPY)									
Evaluate the utility of image guidance for procedures targeting various tissue pathology: joint, bone, muscle, tendon, ligament, meniscus, labrum, fascia, nerve, disc.	X				X				
State the indications for and limitations of ultrasound vs fluoroscopic guidance.	X					X			
Perform interventional procedures with ultrasound and/or fluoroscopic guidance.	X	X					X		
Compare various percutaneous procedure techniques targeting tendon pathology, including needle tenotomy, intratendinous injection, peritendinous injection, and needle scraping.	X						X		
Describe various approaches to targeting a site of tissue pathology.	X						X		
REFERENCES									
1AAPM&R MSK curriculum, 2022.									

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REGULATORY GUIDELINES AND ETHICS COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
REGULATORY GUIDELINES									
Identify the Food and Drug Administration (FDA) as the primary agency which regulates the use of orthobiologics in the United States.	X			X					
Compare and contrast the various agencies that enforcce orthobiologic regulations, including which aspects each is responsible for enforcing, including: - FDA, specifically the Center for Biologics Evaluation and Research (CBER): products and devices - Federal Trade Commission: marketing - Individual state licensing boards: practice of medicine	X						X		
List the professional and international organizations that offer guidelines and position statements on orthobiologic use, including: - AAPM&R - American Medical Society for Sports Medicine (AMSSM) - Intrnational Society for Stem Cell Research (ISSCR) - Federation of State Medical Boards (FSMB) - American Society of Interventional Pain Physicians (ASIPP) - American Academy of Orthopaedic Surgeons (AAOS)	X						X		
FDA CLASSIFICATION FOR REGULATORY OVERSIGHT OF ORTHOBIOLOGICS									
Define, accoording to the FDA, "human cells, tissues, and cellular based products" (HCT/Ps), which are regulated by Title 21 Code of the Federal Regulations Part 1271.	X						X		
Identifty which commonly used orthobiologics are classified as HCT/Ps (MFAT, BMAC).	X						X		
Recognize which orthobiologic products do not require regulation as HCT/Ps (PRP, PPP).	X						X		
Describe the FDA's tier risk for classification of orthobiologics: Tier 1) Lowest risk: Only regulation is to follow current good tissue practices (CGTP), for infection/ contamination safety Tier 2) Low risk: CGTP, registration with FDA/CBER, and annual reporting (including adverse events) Tier 3) Higher risk: Require, in order, preclinical trials, pharmacology/toxiciy studies, Investigational New Drug (IND) approval for human clinical trials, and biologics license application (BLA) prior to marketing	X						X		
Identify where orthobiologic agents fall within these tiers/sections: Tier 1) PRP, PPP. These are blood product products, and NOT regulated like 361 products Tier 2) Section 361.""Human cells, tissues, and cellular based products"" (HCT/Ps) fall into this tier. Cellular products that fit Title 21 Code of the Federal Regulations Part 1271, including MFAT and BMAC that fit Tier 3) Section 351. Amniotic products, cultured mesenchymal cells, cell products that do not meet criteria to fit in tier 3	X						X		

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REGULATORY GUIDELINES AND ETHICS COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
Describe the four criteria that must be met for an HCT/P to qualify as a 361 product, and the significance of that qualification. 1) The HCT/P is minimally manipulated 2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent 3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P, and 4) Either: i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function, or ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and: a) Is for autologous use b) Is for allogeneic use in a first-degree or second-degree blood relative, or c) Is for reproductive use	X						X		
Define the same surgical procedure exception (1271.15b) and its three criteria (""same day same procedure""), namely: 1. Tissue must be removed from and implanted in same patient within the same procedure 2. With HCT/P remaining in original form 3. With minimal manipulation (ie, nothing beyond rinsing, cleaning, labeling and temporary storage)	X						X		
Recognize that the same surgical procedure exception supercedes the four criteria for an HCT/P to qualify as a 361 product.	X						X		
Explain the 510K pathway (devices/ kit approval, not the product) and when it is required.	X						X		
Recognize that since 2021 the FDA has increased regulation of birth products, enforcing them as 351 products and limiting their use to IND.	X						X		
Relate the possible penalties and repercussions of breaking FDA regulations.	X						X		
Recognize guidance is subject to changes, and providers must stay up to date with current events. (ie, ruling in August 2022, USA vs California Stem Cell Treatment Center, conclusion differed from prior cases).	X						X		
PRODUCT-SPECIFIC REGULATIONS/DEBATES									
Identify commonly advertised products that are not currently legal (amniotic/ birth tissues, culture expanded stell cells, exosomes).	X						X		
Differentiate between FDA-cleared and FDA approved, and how this pertains to orthobiologics.	X						X		
Define the term "off-label use" and how it pertains to orthobiologics.	X						X		
Clarify that the term "off-label use" does not indicate a lack of evidence based research.	X						X		
Discuss various interpretations of MFAT and stromal vascular fraction (SVF), as either 361 products (used via the same surgical procedure exception) or 351 products, and how these various interpretations affected the regulation of SVF, MFAT.	X						X		
Describe limitations in advertising orthobiologics per the Federal Trade Commission (FTC), such as avoiding advertising "stem cells" and specific "off-label" uses of orthobiologics.	X						X		

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REGULATORY GUIDELINES AND ETHICS COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
ETHICS									
Explain the concept of transparency as it pertains to research.	X			X					
Identify common misnomers in orthobiologics.	X				X				
Demonstrate how to timely address misleading public representations of research.		X			X				
Define the principle of patient/subject autonomy and how it pertains to informed consent.	X			X					
Discuss the necessary components of informed consent.	X			X					
Recognize that there are no devices or orthobiologic products that have been FDA-approved for treatment of OA or tendinopathy.	X						X		
Recognize the social inequity within orthobiologic use.	X		X	X					
Discuss potentional conflicts of interest for physicians using orthobiologics.	X			X					
List resources for patients to obtain reliable information on the use of orthobiologics, including: - Tissue Reference Group - CBER - Office of Communication, Outreach and Develpoment (OCOD) - ISSCR's website for patient resources - Stem Cell Basics from the NIH	X						X		
Identify common unethical tactics used to sell orthobiologic therapies, referred to in the literature as ""co-opted tokens of scientific legitimacy"", including but not limited to: - Registering clinical trials but not reporting results - Publishing in journals without adequate research methods or peer review - Offering discounts or financial incenives for cash procedures - Providing expert opinion or celebrity endorsement - Overemphasizing benefit/exaggerating effects - Misleading nomencalture (not stem cells or mesenchymal cells) - Forming organizations to self regulate - Joining established academic or professional societies to suggest legitimacy by association	X						X		

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PLATELET-RICH PLASMA (PRP) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
DEFINITION/BASIC SCIENCE									
Define Platelet-rich plasma (PRP).	X				X				
Compare leukocyte rich vs leukocyte poor PRP.	X				X				
Describe the leukocyte profile (neutrophils, monocytes, lymphocytes) as it pertains to leukocyte rich PRP.	X						X		
Distinguish the relative action of the various leukocytes (neutrophils, monocytes, lymphocytes).	X							X	
Report the history of PRP use and how it relates to use in MSK/sports medicine (including autologous conditioned plasma [ACP]).	X						X		
Explain why PRP is not considered a cell based orthobiologic.	X						X		
Identify commonly used activator agents for PRP.	X							X	
Differentiate between in vitro vs in vivo activation.	X							X	
Discuss ways to classify PRP (platelet, leucocyte, red blood cells (RBCs), and activation [PLRA], platelet, activation, white blood cells [PAW], Mishra).	X						X		
Demonstrate how to calculate the total dose/total deliverable platelets within PRP.		X					X		
List and discuss important elements within PRP, including growth factors (VEGF, TGFb, IGF1, PDGF, bGFG) and bioactive proteins (stromal derived factor 1a, TNF, IL-6, IL-8).	X								X
Describe the therapeutic mechanism of action of PRP, including how it influences the typical healing cascade.	X					X	X		
Summarize ways PRP may influence cartilage disorders like OA.	X					X	X		
Outline ways PRP may influence tendon and soft tissue pathology.	X					X	X		
Discuss ways PRP may influence nerve pathology.	X					X	X		
Identify ways PRP may influence spondylosis.	X					X	X		
Compare the mechanism of action of corticosteroids to that of PRP.	X					X	X		
CLINICAL CONDITIONS WITH EVIDENCE SUPPORTING USE									
Discuss levels of evidence for PRP in various acute injuries and chronic degenerative conditions.	X						X		
Identify and discuss the areas that have the highest levels of evidence (ie, Level I).	X					X			
Propose how clinical evidence in one condition may have applicability to other conditions.	X						X		
Recognize the importance of platelet dose as it pertains to clincial efficacy.	X					X			
JOINTS									
Define goals of PRP with OA.	X					X			
Discuss PRP outcomes in high quality studies for knee OA (Level I Evidence).	X					X			
Explain how patient factors may influence PRP outcomes in setting of OA, including disease severity and comorbidities.	X						X		

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PLATELET-RICH PLASMA (PRP) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
Summarize how the following PRP procedural factors may influence PRP outcomes in setting of OA: leukocyte concentration, platelet dose/volume, concomittant use of viscosupplementation, concomittant use of cell based orthobiologic.	X						X		
TENDONS AND FASCIA									
Define goals of PRP in tendinopathies.	X					X			
Discuss PRP outcomes in high quality studies for common extensor tendinopathy (Level I Evidence).	X						X		
Describe PRP outcomes in high quality studies for gluteus medius tendinopathy (Level I Evidence).	X						X		
Discuss PRP outcomes in high quality studies for plantar fasciopathy (Level I Evidence).	X						X		
Explain how patient factors may influence PRP outcomes in setting of tendinopathy/fasciopathy including disease severity, presence/degrees of tears, and comorbidities.	X						X		
Summarize how the following PRP procedural factors may influence PRP outcomes in setting of tendinopathy/ fasciopathy: leukocyte concentration, platelet dose/volume, concomittant needle tenotomy, concomittant use of viscosupplementation, concomittant use of cell based orthobiologic.	X						X		
LIGAMENT									
Define goals of PRP in ligament injuries.	X					X			
Discuss PRP outcomes in studies for elbow ulnar collateral ligament (UCL) tears (Level I Evidence).	X						X		
Explain how patient factors may influence PRP outcomes in setting of ligament injury including disease severity, presence/degrees/locations of tears and comorbidities.	X						X		
Summarize how the following PRP procedural factors may influence PRP outcomes in setting of ligament injuries: leukocyte concentration, platelet dose/volume.	X						X		
NERVE									
Define goals of PRP in nerve pathologies.	X					X			
Discuss PRP outcomes in studies for carpal tunnel syndrome (Level I Evidence).	X						X		
Explain how patient factors may influence PRP outcomes in setting of nerve pathologies including disease severity, location of pathology and comorbidities.	X						X		
Summarize how the following PRP procedural factors may influence PRP outcomes in setting of nerve pathologies: leukocyte concentration, platelet dose/volume, hydrodissection.	X						X		
CONTRAINDICATIONS									
List absolute contraindications to PRP injection/procedures.	X				X				
Recall relative contraindications to PRP injection/procedures.	X					X			
Analyze elements in a person's hematologic/oncologic history that could influence candidacy for PRP.	X						X		

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PLATELET-RICH PLASMA (PRP) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
PRE-PROCEDURE PREPARATION									
Compare pros and cons of corticosteroid injection to PRP injection in a patient with (1) OA (2) tendinopathy without high grade tear (3) tendinopathy with high grade tear.	X						X		
List medications that may interfere with PRP efficacy pre procedure (including timing considerations).	X					X			
Describe how the following medications could affect PRP procedure efficacy: antiplatelet medications, non-steroidal anti-inflammatory drugs (NSAIDs), anticoagulants, corticosteroids, immunosuppressants, statins.	X						X		
Outline ways to optimize PRP injections/procedures.	X					X			
Perform informed consent (indication/benefits/risks/alternatives/costs/FDA status) of procedure and discuss what to expect during the procedure.		X			X				
PRODUCT PREPARATION/PROCEDURE									
Describe how PRP is created.	X					X			
Compare and contrast different PRP preparations (eg, plasma based vs buffy coat preparations, number of spins, manual vs automated).	X						X		
Identify the elements that make a PRP injection a heterogenous treatment.	X						X		
Recognize CGTP and their applicability to PRP.	X						X		
Explain how local anesthetic may interfere with PRP efficacy.	X						X		
List ways to reduce local anesthetic at/within intended target tissue for PRP procedure.	X						X		
Demonstrate how to perform an ultrasound-guided blood draw.		X					X		
Evaluate pros and cons of nonguided vs image guided PRP procedure.	X			X					
Discuss proper placement of PRP for joint, tendon, muscle, ligament, nerve and spine pathology.	X				X	X			
Design a PRP procedure (procedural set up, use of anticoagulant, needle gauge, anethetic use, PRP Volume, ancillary injectates, structures to avoid).		X					X		
Perform an ultrasound-guided PRP procedure for joint pathologies.		X				X			
Perform an ultrasound-guided PRP procedure for bone pathologies.		X						X	
Perform an ultrasound-guided PRP procedure (with and without tenotomy) for tendon pathologies.		X					X		
Perform an ultrasound-guided PRP procedure for ligament pathologies.		X					X		
Perform an ultrasound-guided PRP procedure for muscle pathologies.		X					X		
Perform an ultrasound-guided PRP procedure for (with and without hydrodissection) for nerve pathologies.		X					X		
Perform an image-guided PRP procedure for spine pathologies.		X						X	
Anticipate and manage common pitfalls that may occur during the procedure and processing.		X					X		
POST-PROCEDURE CARE									
List medications that may interfere with PRP efficacy post-procedure (including timing considerations).	X					X			
Describe how the following medications could affect PRP procedure efficacy: antiplatelet medications, NSAIDs, anticoagulants, corticosteroids, immunosuppressants, statins.	X						X		

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PLATELET-RICH PLASMA (PRP) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
Discuss anticipated post-procedure course over days, weeks, months and years (including post-procedure pain and anticipated improvement).	X					X			
Manage post-procedure pain.	X	X				X			
Manage possible side effects of PRP injection/procedures.	X	X				X			
Identify reasons to consider off-loading procedural area targetted after a PRP procedure.	X						X		
Compare post PRP rehabilitiation protocols for soft tissue vs joint pathology.	X						X		
Explain how the phases of healing (inflammatory, proliferative, remodeling) for soft tissue pathologies can be incorporated into rehab protocols.	X						X		
Design a post PRP return to activity/rehabilitation protocol after joint, tendon/fascia (with and without tenotomy/fasciotomy), ligament, muscle, nerve and spine procedures.		X					X		
Discuss reasons to consider repeat PRP procedures and timing.	X						X		
Propose next steps if PRP procedure doesn't achieve the patient's goals for care.	X						X		

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BONE MARROW ASPIRATE CONCENTRATE (BMAC) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
DEFINITION/BASIC SCIENCE									
Define and contrast Bone marrow aspirate concentrate (BMAC) vs bone marrow aspirate (BMA).	X					X			
Discuss the role of concentrating BMA via centrifugation process and how it affects composition.	X						X		
Differentiate the following terms: BMAC, medicinal signaling cells (MSC), mesenchymal stem/stromal cells, bone marrow derived stem cells, culture expanded stem cells.	X					X			
List the cellular and acellular components of BMAC.	X						X		
Review the therapeutic mechanism of action, trophic and immunomodulatory effects of MSC in BMAC.	X						X		
Identify method(s) for quantifying dose and determining quality of BMAC (total nucleated cell count, colony-forming unit-fibroblast [CFU-F] assay, flow cytometry with specific cluster of differentiation [CD] markers for MSC).	X							X	
Discuss ways BMAC may influence cartilage disorders like OA.	X						X		
Relate ways BMAC may influence tendon and soft tissue pathology.	X						X		
Describe ways BMAC may influence spondylosis.	X						X		
CLINICAL CONDITIONS WITH EVIDENCE SUPPORTING USE									
Outline levels of evidence for BMAC procedures in various acute injuries and chronic degenerative conditions.	X						X		
Identify and discuss the areas that have higher levels of evidence.	X						X		
Propose how clinical evidence in one condition may have applicability to other conditions.	X						X		
Recognize the importance of MSC dose as it pertains to clincial efficacy.	X							X	
Define goals of BMAC procedures in various acute injuries and chronic degenerative conditions.	X						X		
Explain how patient factors may influence BMAC outcomes including age, disease severity, and comorbidities.	X						X		
Discuss ways BMAC may affect joint pathologies (knee OA level II evidence, femoral head avascular necrosis [AVN] level III, osteochondral lesions of the knee and ankle level III evidence).	X						X		
Describe ways BMAC may affect soft tissue pathologies (patellar tendinopathy, anterior cruciate ligament [ACL] tears, rotator cuff tears level IV or V evidence).	X						X		
Explain ways BMAC may affect spine pathologies (intervertebral disc degeneneration level III evidence).	X						X		
CONTRAINDICATIONS									
List absolute contraindications to BMAC injection/procedures.	X						X		
Recall relative contraindications to BMAC injection/procedures.	X						X		
Analyze patient factors that could influence candidacy for BMAC such as osteoporosis or hematologic/oncologic history.	X							X	

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BONE MARROW ASPIRATE CONCENTRATE (BMAC) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
PRE-PROCEDURE PREPARATION									
Compare the advantages and disadvantages of performing BMAC procedures compared to other orthobiologic treatment options.	X						X		
List medications that may interfere with BMAC efficacy pre procedure (including timing considerations).	X						X		
Perform informed consent (indication/benefits/risks/alternatives/costs/FDA status) of procedure and discuss what to expect during the procedure related to harvesting.		X						X	
Locate and identify bony landmarks and target sites for harvest, using ultrasound if needed.		X						X	
Recognize benefits of posterior iliac crest as a site for BMA harvest.	X		X					X	
Demonstrate familiarity with contents of bone marrow aspiration harvesting instruments/kit.	X							X	
Formulate plan for amount of BMA necessary for procedure and predict final volume of BMAC per harvested volume of BMA.		X						X	
Discuss limitations in maximum recommended volume of BMA based on body habitus, age, etc.	X							X	
PRODUCT PREPARATION/PROCEDURE									
Prepare for harvest procedure using sterile technique (gown and gloves, skin preparation and draping).		X					X		
Assemble instruments requiring priming with recommended anticoagulant.		X						X	
Demonstrate local anesthesia technique for harvesting and injection procedure.		X						X	
Consider other means of anesthesia/analgesia beyond local (conscious sedation, inhaled nitrous oxide, epidural anesthesia, etc).		X							X
Demonstrate image-assisted access of posterior iliac crest bone marrow manually and potentially power instrument-assisted (drill).		X						X	
Recognize the importance of smaller harvesting syringes to increase negative pressure and improve cellular composition of BMAC product.		X	X					X	
Compare and contrast various harvesting needle designs and effects on BMAC product.		X						X	
Evaluate the pros and cons of single vs multi-site harvesting techniques.		X						X	
Perform single and/or multi-site harvesting techniques.		X						X	
Anticipate and manage common pitfalls that may occur during the procedure and processing.		X						x	
Identify reasons to stop the procedure, including dry tap.	X							X	
Discuss pros and cons of nonguided vs image guided BMAC procedures in different sites.	X							X	
Perform image-guided BMAC procedure for joint pathologies.		X						X	
Perform image-guided BMAC procedure for bone pathologies.		X							X
Perform image-guided BMAC procedure (with and without tenotomy) for tendon pathologies.		X						X	
Perform image-guided BMAC procedure for ligament pathologies.		X						X	
Perform image-guided BMAC procedure for spine pathologies.		X							X

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BONE MARROW ASPIRATE CONCENTRATE (BMAC) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
POST-PROCEDURE CARE									
Provide wound/skin care recommendations of harvest and injection sites.	X						X		
List medications that may interfere with BMAC efficacy post-procedure (including timing considerations).	X							X	
Describe how the following medications could affect BMAC procedure efficacy: antiplatelet medications, NSAIDs, anticoagulants, corticosteroids, immunosuppressants, statins.	X						X		
Discuss anticipated post-procedure course over days, weeks, months and years (including post-procedure pain and anticipated improvement).	X						X		
Manage post-procedure pain.	X	X					X		
Manage possible side effects of BMAC injection/procedures.	X	X						X	
Identify reasons to consider off-loading procedural area targeted after a BMAC procedure.	X							X	
Compare post BMAC rehabilitiation protocols for soft tissue vs joint pathology.	X							X	
Explain how the phases of healing (inflammatory, proliferative, remodeling) for soft tissue pathologies can be incorporated into rehab protocols.	X							X	
Design a post BMAC return to activity/rehabilitation protocol after joint, bone, tendon/fascia (with and without tenotomy/fasciotomy), ligament, and spine procedures.		X						X	
Discuss reasons to consider repeat BMAC procedures and timing.	X							X	
Consider referal to hematology/oncology in the case of a dry tap.	X							X	
Propose next steps if BMAC procedure doesn't achieve the patient's goals for care.	X							X	

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MICROFRAGMENTED ADIPOSE TRANSFER (MFAT) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
DEFINITION/BASIC SCIENCE									
Define and differentiate the following terms: lipoaspirate, MFAT, SVF, adipose derived stem cells, medicinal signaling cells (MSC), culture expanded stem cells.	X					X			
Describe the structural architecture of adipose tissue.	X					X			
List the cellular and acellular components of MFAT.	X						X		
Outline the physiologic action of perivascular pericytes, incuding their effects on local cells.	X						X		
Review the therapeutic mechanism of action of MFAT.	X						X		
Identify ways MFAT may influence cartilage disorders like OA.	X						X		
Discuss ways MFAT may influence tendon and soft tissue pathology.	X						X		
CLINICAL CONDITIONS WITH EVIDENCE SUPPORTING USE									
Discuss levels of evidence for MFAT procedures in various acute injuries and chronic degenerative conditions.	X						X		
Identify and discuss the areas that have higher levels of evidence.	X						X		
Propose how clinical evidence in one condition may have applicability to other conditions.	X						X		
Define goals of MFAT procedures in various acute injuries and chronic degenerative conditions.	X						X		
Explain how patient factors may influence MFAT outcomes including disease severity, body habitus and comorbidities.	X						X		
Discuss ways MFAT may affect joint pathologies (knee OA level I evidence, shoulder OA level I evidence).	X						X		
Describe ways MFAT may affect soft tissue pathologies.	X						X		
CONTRAINDICATIONS									
List absolute contraindications to MFAT injection/procedures.	X						X		
Recall relative contraindications to MFAT injection/procedures.	X						X		
Analyze patient factors that could influence candidacy for MFAT such as hematologic/oncologic history.	X							X	
PRE-PROCEDURE PREPARATION									
Compare the advantages and disadvantages of performing MFAT procedures compared to other orthobiologic treatment options.	X						X		
List medications that may interfere with MFAT efficacy pre procedure (including timing considerations).	X						X		
Perform informed consent (indication/benefits/risks/alternatives/costs/FDA status) of procedure and discuss what to expect during the procedure related to harvesting.		X						X	
Describe the pros and cons of the most common target sites for harvest.		X						X	
Locate the most appropriate target sites for harvest, using ultrasound if needed.		X						X	
Demonstrate familiarity with contents of lipoaspirate harvesting instruments/kit.	X							X	
Formulate plan for amount of lipoaspirate necessary for procedure and predict final volume of MFAT per harvested volume of lipoaspirate.		X						X	

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MICROFRAGMENTED ADIPOSE TRANSFER (MFAT) COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
PRODUCT PREPARATION/PROCEDURE									
Describe the composition of tumescent fluid and the role of each individual component.	X							X	
Discuss the appropriate steps involved in a successful tissue harvest.		X						X	
Outline the ideal technique used during tissue harvest.		X						X	
Demonstrate the ideal technique used during tissue harvest.		X						X	
Identify commonly used techniques for the processing of lipoaspirate (including microfilter and mechanical resizing).		X						X	
Anticipate and manage common pitfalls that may occur during the procedure and processing.		X						X	
Recall appropriate injectate volumes for various pathologies.	X							X	
Identify needle and syringe sizes required to successully inject MFAT.	X							X	
Discuss pros and cons of nonguided vs image guided MFAT procedures in different sites.	X							X	
Perform ultrasound-guided MFAT procedure for joint pathologies.		X						X	
Perform ultrasound-guided MFAT procedure for tendon pathologies.		X						X	
Perform ultrasound-guided MFAT procedure for ligament pathologies.		X						X	
POST-PROCEDURE CARE									
Provide wound/skin care recommendations of harvest and injection sites including post-procedure harvest site compression.	X						X		
List medications that may interfere with MFAT efficacy post-procedure (including timing considerations).	X							X	
Describe how the following medications could affect MFAT procedure efficacy: NSAIDs, corticosteroids, immunosuppressants, statins.	X						X		
Discuss anticipated post-procedure course over days, weeks, months and years (including post-procedure pain and anticipated improvement).	X						X		
Manage post-procedure pain.	X	X					X		
Manage possible side effects of MFAT injection/procedures, including seroma formation and contour deformity.	X	X						X	
Identify reasons to consider off-loading procedural area targeted after a MFAT procedure.	X							X	
Compare post MFAT rehabilitiation protocols for soft tissue vs joint pathology.	X							X	
Explain how the phases of healing (inflammatory, proliferative, remodeling) for soft tissue pathologies can be incorporated into rehab protocols.	X							X	
Design a post MFAT return to activity/rehabilitation protocol after joint, tendon/fascia, fat pad and ligament procedures.		X						X	
Evaluate reasons to consider repeat MFAT procedures and timing.	X							X	
Propose next steps if MFAT procedure doesn't achieve the patient's goals for care.	X							X	

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EMERGING TECHNOLOGIES COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
EMERGING ORTHOBIOLOGIC INJECTIONS									
Describe the fundamentals of additional orthobiologic injections providers may encounter, including the elements below.									
OTHER AUTOLOGOUS BLOOD-BASED PRODUCTS									
Platelet-poor plasma (PPP)									
Assess indications for use: preferentially muscle pathology.	X								X
Describe current level of evidence for PPP.	X								X
Summarize constituents: fibrinogen and fibronectin, PDGF and IGF-1 for myogenic effect, A2M.	X								X
Explain mechanism of action: fibroblast proliferation and angiogenesis, myogenic effect (PDGF, IGF-1).	X								X
Review FDA guidance: blood product similar to PRP (ie, not regulated).	X					X			
Autologous blood injection (ABI)/whole blood									
Identify indication for limited use in tendinopathy.	X								X
Describe level of evidence for ABI/whole blood for tendinopathy.	X								X
Summarize constituents: same constiuents as PRP with addition of RBCs and additional unwanted cells (eg, neutrophils).	X								X
Recognize limited applicability in joints due to increased RBC content which contain heme free radicals and may contribute to oxidative damage.	X								X
Review FDA guidance: blood product similar to PRP (ie, not regulated).	X					X			
Alpha-2-macroglobulin (A2M)									
Assess indications for use: OA, newer technology mostly in animal models.	X								X
Describe level of evidence for A2M including for OA.	X								X
Summarize constituents: plasma protein, produced in the liver, locally by macrophages and fibroblasts.	X								X
Explain mechanism of action: blocks degradative enzymes including matrix metalloproteases (MMPs), such as collagenase and trypsin.	X								X
Review FDA guidance: blood product similar to PRP (ie, not regulated).	X					X			
Interleukin receptor antagonist protein (IRAP)/autologous conditioned serum (ACS)									
Assess limited indications for use: OA, used in veterinary medicine for horses and in Europe.	X								X
Summarize constituents: IL-1RA protein.	X								X
Explain mechanism of action: IL-1RA protein is a natural inhibitor of the pro-inflammatory effect of IL1β.	X								X
Review status of FDA guidance.	X					X			

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EMERGING TECHNOLOGIES COMPETENCY				CORE			SPECIALIZED		
				1	2	3	4	5	6
	Knowledge	Skill	Attitude	Basic	Intermediate	Advanced	Basic	Intermediate	Advanced
NON-AUTOLOGOUS PRODUCTS									
Amniotic products									
Describe limit in indications: none, no orthopedic injectables are FDA compliant.	X								X
Identify variety of types that may be encountered: dehydrated non-viable amnionic products (live cells not encountered).	X								X
Summarize dehydrated tissue constituents: washed and cryopreserved cord and placental tissues (no live cells).	X								X
Understand and comply with FDA guidance: banned, nothing is FDA compliant. Additionally, products from amnion fluid or membranes were all withdrawn in 2021.	X					X			
Exosomes									
Describe limit in indications: none at this time, poorly understood.	X								X
Summarize constituents: membrane-bound extracellular vesicles, contains protein, lipids, mRNA and microRNA.	X								X
Explain mechanism of action: poorly understood, cell-cell communication and of transmission of macromolecules between cells.	X								X
Recall FDA guidance: avoid, no reasonable FDA compliant method exists to obtain desirable exosomes.	X					X			
NON-FDA COMPLIANT ADVANCED CELLULAR THERAPIES									
SVF (Stromal vascular fraction)									
Describe limit in indications: not currently approved, but same indications as MFAT.	X								X
Identify current level of evidence for SVF (knee OA, rotator cuff tears).	X								X
Summarize constituents: much higher concentrations of MSCs compared to traditional MFAT.	X								X
Outline preparation: may include enzymatic digestion of support cells to release MSCs in very high concentrations.	X								X
Review FDA guidance: more than minimally manipulated so noncompliant, but FDA-approved human studies ongoing.	X					X			
Culture expanded cells									
Describe limit in indications: not currently approved, but same as MFAT and BMAC.	X								X
Identify current level of evidence for culture expanded cells.	X								X
Summarize constituents: much higher concentrations of MSCs compared to traditional MFAT and BMAC.	X								X
Outline preparation: expand colony-forming units (CFU) on cell culture, may take weeks to grow cells.	X								X
Review FDA guidance: more than minimally manipulated so noncompliant, not same day use.	X					X			