

# Topical Medications: Ensuring Quality & Safety for Individualized Clinical Outcomes

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# Objectives

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Following this presentation, attendees should be able to:

1. Review aspects of demand for personalized medications to treat individual athletes or sports-related injuries
2. Discuss growing partnerships between sports medicine physicians and compounding pharmacists to optimize clinical outcomes
3. Identify best-practices in training and accreditation for compounding pharmacies and products
4. Discuss opportunities to grow clinical services through interprofessional practice settings

# Personalized Medication

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- The movement toward personalized medicine is not limited to genetic testing and traditional medications
- Compounding medications in the realm of sports medicine is an area where physicians and pharmacists can work together to individualize treatment based on specific injuries or needs relative to various athletic demands<sup>1</sup>
  - Combine several medications, supplements or vitamins into single dose capsules
  - Incorporate medications and supplements into powders for reconstitution (non-sterile)
  - Combine medications in several classes into creams, gels, or other topical applications to improve function and healing
  - Formulations can be standardized and/or individualized from a common base ingredient/recipe
  - Standardized formulations may be covered through insurance
  - Systemic side effects can be reduced through the use of topical medications and increase treatment options for some athletes or patients

# Pharmacists' Roles in Sports Medicine

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- The Olympics has facilitated growth in the pharmacy profession in specialized areas such as sports pharmacy<sup>2</sup>
- **Sports Pharmacy** involves the use of medications in athletes whether for therapeutic treatment of injury or performance enhancement<sup>1-3</sup>
  - Increasing capacities as members of interprofessional teams → explore and treat sports-related injuries & address the special needs of the athlete (especially in the management of neuropathic & musculoskeletal pain)
  - Increased the development of safe, individualized options for treatment
  - Customized preparations can be tailored to improve clinical outcomes allowing physicians to adjust medications they prescribe to meet specific purposes or standards
  - Not limited to treatment & prevention of injury or exacerbation, but also to specialized drug education, monitoring, and therapeutic selection

# Scope of Sports Pharmacy<sup>3</sup>

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Professional Standards	
Awareness	Awareness of drugs in sports for performance, prevention and treatment of disease
Therapy	Knowledge of therapeutic uses to support sports-related illness or injury
Prevention	Use of pharmacotherapy to prevent illness and maintain well-being
Optimization	Safe and rational use of nutrition and supplementation to optimize health and performance
Abuse	Knowledge of drugs for competitive advantage
Detection	Drugs of abuse, misuse (intended or unintended), adverse events

# One Shoe Doesn't Fit All

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- Different athletes may require different doses of medication for the same injury
- Different sized bodies, variations in metabolism, comorbidities & concurrent medications → increase the need for individualized formulations or preparations which may not be commercially available
- FDA approval process is intended for mass-produced and distributed medications, but has approved for the use of compounded medications for individuals under the care of a physician to address specific health needs<sup>1,4</sup>
  - Some commercially available products are limited in strengths and dosage formulas
  - Compounding is a means of calibrating an exact dose to a specific patient, which results in increased accuracy in treatment
  - Quality & Safety are paramount to ensure the practice of good medicine

# Topical Medications

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- Inhaled preparations
  - Gels
  - Solutions
  - Creams/lotions
  - Sprays
  - Suppositories
  - Powders
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- Adjuvants to increase penetration: heat, friction, iontophoresis, phonophoresis, etc.
  - Delivery devices: pumps, jars, tubes, capsules (to be broken or pierced), applicators (i.e. stick, click dispensing), dialing doses, etc.

# Opportunities for Incorporating Topical Medications in Sports Medicine Practice<sup>1,3,5</sup>

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- Topical Medications offer leverage with treatment options
  - Increased concentrations at the site of injury compared to systemic concentrations
  - Dosing according to length of 'strip' or pump
  - Use of Iontophoresis & Phonophoresis to facilitate delivery of the medication beneath the skin (gels)
- Management of Pain & Inflammation
  - Decrease pathways of tolerance and addiction
  - Reduce drowsiness, cognitive delay and performance limitations
- Antifungal, Antibacterial & Skin Preparations
  - Blisters, ulcers, tears, rash, eruptions, sun exposure/protection, etc.
- Hemorrhoids or other rectal application of medications
  - Simultaneous internal and external application

# Partnerships between Sports Medicine Physicians & Pharmacists

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- Advanced Pharmacy Practice Experience in Sports Pharmacy<sup>2</sup>
  - UCSF 2006 (NCAA sports focus relative to doping, banned substances, testing, counseling, drug information, etc.)
- Residency Training with exposure to Athletics, High-Performance Athletes, Sports Medicine Practices (growing opportunities for training and collaborations)<sup>3</sup>
- Sports Medicine Clinics with contracted compounding services or in-house compounding services
  - Injury specific topical medications
  - Work specifically to address billing and insurance issues
- Variations in clinical practice settings (community-based to orthopedics) requires access to pharmacists that understand sports and exercise sciences, injury and care of the athlete as a unique patient population

# Unique Opportunities for Treatment & Collaboration in Care<sup>1,3,5</sup>

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- Altering delivery systems to improve clinical outcomes for athletes → increased need for specialized compounding pharmacists with knowledge of sports medicine specialty
- Many classes of medications when taken orally may increase GI upset, require special dosing for hepatotoxic or renal issues, have unintended side effects that limit dosing or duration, or create adverse effects for athletes and patients
  - Bypass the gut (first pass) bypass the problems
- Topical medications provide a unique delivery route that potentially minimize side effects or eliminate drug interactions by decreasing systemic exposure
  - Treating at the site of the injury may lead to improved recovery or response times, facilitate healing with direct application, and reduce the length of time needed for treatment

# Topical Medications & Compounding... So What?

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- As in many professions, there is a belief that practicing is ‘an art and science’
- With pharmacy compounding, pharmacists can work with physicians to customize preparations for patients to enhance healing, optimize care, and individualize/personalize treatments
- In pharmacy, compounding can be practiced at two levels:
  - General knowledge for simple compounded prescriptions
    - Training associated with Doctor of Pharmacy curriculum
  - Advanced training and certification through national & international compounding pharmacy organizations
    - Pharmacy Compounding Centers of America (PCCA)
    - International Academy of Compounding Pharmacists (IACP)
    - Pharmacy Compounding Accreditation Board (PCAB)

# Specialized Training & Education of Compounding Pharmacies / Pharmacists

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- Professional Compounding Centers of America (PCCA)<sup>1</sup>
  - Education and training of compounding pharmacists
  - Quality control and assurance of chemicals and formulations
  - Standardized preparation recipes (quality and safety measures)
  - Registered and inspected by FDA & DEA
  - Consulting, R&D, technical support



- International Academy of Compounding Pharmacists (IACP)<sup>6</sup>
  - Advocacy, legislation, specialty practice
  - Ensuring rights of physician to prescribe, pharmacists to prepare, and patient to access personalized medications



# Accreditation of Compounding Pharmacies

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- Pharmacy Compounding Accreditation Board (PCAB)<sup>7</sup>
  - Accreditation for sterile and non-sterile pharmacy compounding
  - Quality and safety assurance
  - Uniform standards for sound practices
  - Collaboration of 8 leading pharmacy organizations to move voluntary accreditation to standardized accreditation for compounding services
  - Promotion of specialization to physicians
  - Educating patients on compounding services



# A Little Bit of Education...

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- Compounding pharmacists and pharmacies that partner with sports medicine physicians and practices not only serve to provide specialized products & treatment options, but they also provide additional clinical support:
  - Provide additional education on compounded formulations
  - Monitor for banned or restricted substances
  - Serve as resources to observe outcomes (injury improvement, monitor for side effects, ensure safe use)
  - Provide additional sources of literature and information to patients and physicians
  - Work to specialize formulations for your practice setting or patient population
  - Work with insurance companies to increase billable services and products
  - Reduce over-the-counter products that may prevent proper healing, prolong healing, or interfere with treatment outcomes

# Audience Q&A

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- What have your experiences been with compounding pharmacies or pharmacists?
- What have your experiences been with pharmacists who specialize or practice in areas such as sports pharmacy or specialty compounding for sports medicine patients?
- How have you determined the criteria to select your compounding services?

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