

Autologous Blood/ Platelet-rich Plasma

Clinical Expert

Kimberly G. Harmon, MD

Professor

Department of Family Medicine

Department of Orthopaedics and Sports Medicine

University of Washington

Seattle, WA

WA - Health Technology Assessment

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of \$10,000.		✓
2.	Equity interests such as stocks, stock options or other ownership interests.		✓
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		✓

If yes to #7, provide name and funding Sources:

If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X 
 Signature _____ Date _____

Kimberly Harmon
 Print Name _____

So we may contact you regarding this information, please provide the following:

Email Address: 

Phone Number: 

UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE

Curriculum Vitae

Kimberly G. Harmon, M.D.

University of Washington Sport Medicine Center at Husky Stadium
3800 Montlake Boulevard
Seattle, WA 98195
206-598-3294
kharmon@uw.edu

- 1) **Personal Data:** Place of Birth: St. Louis, MO
Citizenship: U.S.A.
Date of Birth: November 6, 1966

- 2) **Education:**

B.S. in Pre-Professional Science, University of Notre Dame, May 1989
M.D., Indiana University School of Medicine, May 1993

- 3) **Postgraduate Training:**

Residency: Memorial Hospital Family Medicine
South Bend, IN
1993-1996

Fellowship: Ball Memorial Hospital Primary Care Sports Medicine
Muncie, IN
1996-1998

- 4) **Faculty Appointments:**

January 1998-June 2000 Clinical Instructor
Department of Family Medicine
Department of Orthopaedics
University of Washington
Seattle, WA

July 2000-June 2005 Clinical Assistant Professor
Department of Family Medicine
Department of Orthopaedics and Sports Medicine
University of Washington
Seattle, WA

July 2005- June 2010	Clinical Associate Professor Department of Family Medicine Department of Orthopaedics and Sports Medicine University of Washington Seattle, WA
July 2010 – March 2012	Clinical Professor Department of Family Medicine Department of Orthopaedics and Sports Medicine University of Washington Seattle, WA
March 2012 – present	Professor Department of Family Medicine Department of Orthopaedics and Sports Medicine University of Washington Seattle, WA

5) **Hospital Appointments:**

January 1998-present	Attending Physician University of Washington Medical Center Seattle, WA
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6) **Honors:**

- Notre Dame Scholar, 1985-86
- Notre Dame Athletic Trainer Scholarship, 1987-89
- Mead Johnson Award for Graduate Education in Family Practice, 1995
- Chief Resident, Memorial Family Practice, 1995-96
- Fellow, American College of Sports Medicine, 2003-present
- Board of Directors, American Medical Society for Sports Medicine, 2002-2006 (re-elected 2004)
- Chair, Membership Committee, American Medical Society for Sports Medicine, 2002-2006
- Best Poster Presentation, AMSSM 15th Annual Meeting, Miami, FL.
Rothmier J, Harmon KG, O’Kane JW. Exertional ataxia in a college football player (Abstract) Clin J Sports Med 2006.
- 2nd Vice President, American Medical Society for Sports Medicine, 2007-2008.
- Best Overall Research Award, Rendezvous II – An International Sports Medicine Meeting: “Adequacy and Effectiveness of Emergency Response Planning for Sudden Cardiac Arrest in High Schools with Automated External Defibrillators” by Drezner JA, Harmon KG, Heistand J, Cramer M, Rao A. Las Vegas, NV, March 2008
- Harry Galanty Young Investigator’s Award, Rendezvous II – An International Sports Medicine Meeting: “Details and Outcomes of Resuscitation Following Sudden

- Cardiac Arrest in High School Student Athletes from the United States” by Rao A, Drezner JA, Cramer M, Harmon KG. Las Vegas, NV, March 2008
- 1st Vice President, American Medical Society for Sports Medicine, 2008 – 2009.
 - Harry Galanty Young Investigator’s Award, American Medical Society for Sports Medicine 18th Annual Meeting. “Warning Symptoms and Family History in Children with Sudden Cardiac Arrest” by Fudge J, Drezner J, Harmon K, Berger S, Campbell R, Vetter V. Tampa, FL, April 2009.
 - NCAA Research Award, American Medical Society of Sports Medicine 18th Annual Meeting. “Sudden Cardiac Arrest at Collegiate Athletic Venues” by Rao A, Harmon K, Drezner J. Tampa, FL, April 2009.
 - President, American Medical Society for Sports Medicine, 2009-2010.
 - Best Overall Research Award, American Medical Society for Sports Medicine 19th Annual Meeting. “Incidence and Etiology of Sudden Death in National Collegiate Athletic Association (NCAA) Athletes” by Asif I, Harmon K, Drezner J, Klossner D. Cancun, Mexico, April 2010.
 - Immediate Past President, American medical Society for Sports Medicine, 2010-2011.
 - Harry Galanty Young Investigator’s Award, American Medical Society for Sports Medicine 20th Annual Meeting. “The Accuracy of ECG Interpretation in Competitive Athletes: A Comparison of Physicians Specialties” by Asif I, Drezner J, Fean R, Harmon K, Owens D, Prutkin J, Rao A, Salerno J, Stout K. Salt Lake City, UT April 2011.
 - Research Subspecialty Award, 2011 Western Regional Meeting. “Incidence, Etiology, and Survival Trends from Sudden Cardiac Arrest in Children and Young Adults Age 0-35 in King County, Washington: A 30-Year Review.” Meyer L, Drezner J, Fahrenbruch C, Stubbs B, Maeda C, Harmon K, and Eisenberg M. Carmel, CA, January 2011.
 - Board of Directors, American Medical Society for Sports Medicine Foundation 2011-2014.
 - Parker J. Palmer “Courage to Teach” Award for Program Director Excellence – finalist, 2011.
 - Hall Health Primary Care Center Professional Staff Award, 2011.
 - Society of Teacher’s of Family Medicine Best Research Award 2012 for “Incidence of Sudden Cardiac Death in National Collegiate Athletic Association Athletes” Harmon KG, Asif I, Klossner D, Drezner J. *Circulation*. 2011;123(15):1594-600.
 - 2012 Harry Galanty Young Investigator’s Award: “Cardiovascular Screening in Young Athletes: A Prospective Study Comparing the PPE Monograph 4th Edition to ECG” by Fudge J, Drezner J, **Harmon KG**, Owens D, Prutkin J, Salerno J, Rao A, Asif I, Pelto H, Haruta A. American Medical Society of Sports Medicine 21st Annual Meeting. Atlanta, GA, April 2012.
 - Parker J. Palmer “Courage to Teach” Award for Program Director Excellence – finalist, 2012
 - Key note address. Vancouver, British Columbia. September 2012. **Harmon KG**, Platelet Rich Plasma for Chronic Tendinopathy. The 2nd International Scientific Tendinopathy Symposium

- 2013 Harry Galanty Young Investigator's Award: "Incidence of Sudden Cardiac Arrest in High School Students and Student-Athletes." by Toresdahl B, Rao A, **Harmon KG**, Drezner J. American Medical Society for Sports Medicine 22nd Annual Meeting, San Diego, CA April, 2013.
- Delegate to White House Healthy Kids & Safe Sports Concussion Summit, May 29, 2014.
- Washington State Athletic Trainers' Association (WSATA) Physician's Award, July 2014
- Heroes for Young Hearts Award, Parent Heart Watch, January 2015.
- Member Pac-12 Conference Brain Trauma Task Force, March 2015 – present
- Pac-12 Student Athlete Health Board, July 2015 – present
- Medical Advisory Board of the National Basketball Players Association, August 2015 – present
- Strategic Advisory Board National Basketball Association, September 2015 - present

7) **Board Certification:**

American Board of Family Practice, 1996-2003, 2002-2009, 2009-2019
Certificate of Added Qualification in Primary Care Sports Medicine, 1997-2007, 2007 – 2017.

8) **Licensure:**

State of Washington: MD00035714

9) **Professional Memberships:**

American Board of Family Practice
American Academy of Family Physicians
American Medical Society for Sports Medicine
American College of Sports Medicine

10) **Teaching Responsibilities:**

Clinical Instruction:

School of Medicine:

- Instructor, HuBio 550: Introduction to Clinical Medicine. Musculoskeletal Examination, (1999-2000)
- Instructor, HuBio 553: Musculoskeletal Core Course. Musculoskeletal Examination, (2000)

Residency:

- Faculty Preceptor, Orthopedics & Sports Medicine, required rotations for PGYI and PGYII residents, University of Washington Family Medicine Residency. Supervise residents 1-2 half days per week in Sports Medicine clinics. (1998-present)
- Faculty Preceptor, Sports Medicine, elective rotation PGYII residents interested in applying to sports medicine fellowships, University of Washington Internal Medicine Residency (2005-present)
- Faculty Preceptor, Sports Medicine, elective rotation PGYII residents interested in applying to sports medicine fellowships, University of Washington Pediatrics Residency (2003-present)
- Faculty Preceptor, Sports Medicine, elective rotation for PGYII residents from outside programs applying to University of Washington Primary Care Sports Medicine Fellowship. Supervise visiting residents 2-3 half days per week for 2 week rotations, 1-5 visiting residents a year. (2000-present)
- Faculty Preceptor, Women's Health, elective rotation PGYII residents, University of Washington Pediatric Residency. (1999-2000)

Fellowship:

- Faculty Preceptor, University of Washington Primary Care Sports Medicine Fellowship. Responsibilities include sports medicine continuity clinic (1 session 6-12 months a year), training room clinic (1 session per week 12 months a year) and event supervision of sports medicine fellow. (1998-present)
- Faculty Preceptor, required rotation for Physical Medicine and Rehabilitation Sports Medicine Fellow. ½ day a week for 2 months. (2009 – present)

Educational Administration:

Undergraduate:

- Faculty Sponsor, research project (Nels Carroll), University of Washington, Project entitled, "Incidence and effects of fatigue in collegiate distance running student athletes" (2006-2007)
- Faculty Sponsor, GEN ST 350 (Yvonne Tyler), University of Washington, Project entitled, "Stingers, Brachial Plexopathy and Transient Quadriplegia in College Football." (2006)
- Faculty Sponsor, GEN ST 350 (Paul Homer), University of Washington, Project entitled, "Platelet Rich Plasma" (2009)

Residency:

- Faculty Sponsor, research project (William Callahan), University of Washington, Project entitled, "Ferritin Levels in Female Collegiate Distance Runners" (2006-2007)
- Liaison between UW Medical Center, the Department of Family Practice, and Hall Health Primary Care Center in assessing compliance with Medicare regulations and supervision requirements and establishing Hall Health as a non-hospital teaching site for the University of Washington Department of Family Medicine and Department of Pediatrics (2006-2013)

Fellowship:

- Director, Primary Care Sports Medicine Fellowship, University of Washington. (2004 – 2014) Responsibilities included:
 - Coordinate rotations, arrange preceptors, and adjust schedule as necessary.
 - Obtain, record, and discuss evaluations of the fellow by rotation preceptors.
 - Obtain, record, and discuss evaluations of the rotation and rotation preceptors by the fellow.
 - Ensure compliance with ACGME standards and policies
 - Ensure compliance with UWMC standards and policies
 - Ensure compliance with Medicare standards and policies
 - Negotiate and execute complex working agreements between Hall Health Primary Care Center, UWMC, and the Department of Family Practice
- Course Director, Sports Academic Conference, 2004 – 2008, four meetings monthly September through May including an imaging conference, journal club, and didactic presentations.
- Course Chair, Musculoskeletal Ultrasound Didactic Course, 2010, developed MSK US course in conjunction with PM&R and rheumatology in accordance with AMSSM curriculum for sports medicine, PM&R, rheumatology, and MSK radiology fellows and faculty.
- Co-Chair, MSK US Committee, 2010 – 2013, formed to ensure competence and collaboration among specialties performing MSK US

Didactic Presentations:

- University of Washington Physician's Assistants Class
 - 1998 Eating Disorders
- University of Washington Family Medicine Residency:
 - 1999 Stress Fractures
 - 1999 Knee Exam and Common Problems of the Knee
 - 2001 Mild Traumatic Brain Injury
 - 2001 Joint Injections: Indications and Technique
 - 2001 Exercise-Induced Amenorrhea
 - 2002 Joint Injections: Indications and Technique
 - 2003 GI/GU Problems in Athletes
 - 2003 Evaluation and Treatment of Neck Pain
 - 2003 Evaluation and Treatment of Back Pain
 - 2003 Foot and Ankle Problems
 - 2004 Anemia and Low Iron in Athletes: Effect on Performance and Optimal Treatment
 - 2004 Concussion in Sport
 - 2005 Tendinosis and Tendinopathy: Pathogenesis and Emerging Treatments
 - 2006 Special Concerns of the Female Athlete
 - 2009 Emerging Treatments in Tendinopathy
- University of Washington Family Medicine Residency Faculty
 - 2010 Joint Injections
 - 2010 Emerging Concepts and Treatments in Tendinopathy

- University of Washington School of Medicine, HuBio 553
 - 1999 Knee, Hip, and Ankle, 1999
- University of Washington Physical Medicine and Rehabilitation Residency
 - 1999 Stress Fractures
 - 2001 Knee Exam and Common Knee Problems
 - 2004 Knee Exam and Common Knee Problems
 - 2009 Tendinopathy: Pathogenesis and Emerging Treatments
 - 2013 Platelet Rich Plasma in Musculoskeletal Injuries
- University of Washington School of Medicine, Ortho 585, Sports Medicine:
 - 1999 Concussion
 - 2000 Concussion in Sport
 - 2001 Mild Traumatic Brain Injury in Sport
 - 2002 Mild Traumatic Brain Injury in Sport
 - 2003 Concussion: Diagnosis and Return to Play
 - 2004 Concussion
 - 2005 Concussion in Sport
 - 2006 Concussion in Sport
 - 2006 GI/GU Problems in the Athlete
 - 2006 Anemia and Low Iron in Athletes: Effect on Performance and Optimal Treatment
 - 2007 Concussion in Sport
 - 2007 Special Concerns of the Female Athlete: Iron Deficiency, Exercise Associated Menstrual Dysfunction, and Eating Disorders
 - 2008 Concussion in Sport
 - 2008 Special Concerns of the Female Athlete: Iron Deficiency, Exercise Associated Menstrual Dysfunction, and Eating Disorders
 - 2009 Special Concerns of the Female Athlete: Iron Deficiency, Exercise Associated Menstrual Dysfunction, and Eating Disorders
 - 2009 GI Problems in Athletes
 - 2010 Special Concerns of the Female Athlete: Iron Deficiency, Exercise Associated Menstrual Dysfunction, and Eating Disorders
 - 2010 GI Problems in Athletes
 - 2011 Platelet Rich Plasma
 - 2011 Concussion in Sport
 - 2012 Concerns and Controversies in Concussion
 - 2012 Platelet Rich Plasma
 - 2013 Concerns and Controversies in Concussion
 - 2013 Platelet Rich Plasma
 - 2014 Concerns and Controversies in Concussion
 - 2014 Platelet Rich Plasma
- University of Washington Orthopaedic Sports Medicine Conference
 - 2002 Update on Mild Traumatic Brain Injury
- University of Washington Nurse School of Nursing, Nurs 501
 - 2003 Evaluating Common Musculoskeletal Problems
 - 2005 Evaluating Common Musculoskeletal Problems
 - 2006 Evaluating Common Musculoskeletal Problems

- University of Washington Internal Medicine Residency
 - 2005 Knee Exam and Common Knee Problems
- University of Washington Nurse School of Nursing, Nurs 5CLIN 500
 - 2006 Musculoskeletal Assessment
 - 2008 Comprehensive Musculoskeletal Assessment
- University of Washington Nurse School of Nursing, Nurs 510
 - 2004 Musculoskeletal Complaints
 - 2005 Musculoskeletal Complaints
 - 2006 Musculoskeletal Complaints
 - 2007 Musculoskeletal Complaints
 - 2008 Upper Extremity Injuries
- University of Washington Primary Care Sports Medicine Fellowship, Sports Medicine Academic Conference Series:
 - 2005 Sports Hernia
 - 2005 Tendinopathy: Pathogenesis and Emerging Treatments
 - 2005 Changing Paradigms in Concussion Management
 - 2005 Muscle Injury and the Use of Corticosteroid in Sport
 - 2006 Medical Legal Aspects of Sports Medicine
 - 2007 Concussion: Update and Controversies
 - 2008 Emerging Treatments in Tendinopathy
 - 2009 Inflammation: Friend or Foe. From Corticosteroids to Platelet Rich Plasma
 - 2010 Tendinopathy and Platelet Rich Plasma
 - 2011 Update on Platelet Rich Plasma
 - 2012 Sickle Cell Trait and the Athlete
 - 2013 Update on Platelet Rich Plasma
- University of Washington Masters in Sports Leadership Program, EDLP 598
 - 2007 Ethical and Institutional Issues in Sports Medicine
 - 2007 Ethical and Institutional Issues in Sports Medicine II
 - 2008 Medical Care in Collegiate Athletes
- University of Washington Pain Seminar
 - 2013 Platelet Rich Plasma in Musculoskeletal Injuries
- University of Washington Rheumatology Grand Rounds
 - 2015 Platelet Rich Plasma in Musculoskeletal Medicine

Continuing Medical Education Attended:

- American Medical Society for Sports Medicine 9th Annual Meeting, San Diego, CA, 2000
- American Medical Society for Sports Medicine 10th Annual Meeting, San Antonio, TX, 2001
- University of Washington 29th Annual Advances in Family Practice, Seattle, WA 2001
- American Academy of Family Practice Sports Medicine: Strategies for Treating Athletes, St. Louis, MO, 2002

- American College of Sports Medicine 49th Annual Meeting, St. Louis, MO, 2002
- American Medical Society for Sports Medicine 11th Annual Meeting, Orlando, FL, 2002
- American Medical Society for Sports Medicine 12th Annual Meeting, San Diego, CA 2003
- American College of Sports Medicine 50th Annual Meeting, San Francisco, CA, 2003
- Providence Medical Center 10th Annual Sports Medicine Conference, Winthrop, WA, 2004
- American Medical Society for Sports Medicine 13th Annual Meeting, Vancouver, B.C. 2004
- American College of Sports Medicine 51st Annual Meeting, Indianapolis, IN 2004
- American Medical Society for Sports Medicine 14th Annual Meeting, Austin, TX, 2005.
- American Medical Society for Sports Medicine 15th Annual Meeting, Miami, FL, 2006.
- University of Washington Women's Healthcare Update, Seattle, WA 2007
- American Medical Society for Sports Medicine 16th Annual Meeting, Albuquerque, NM, 2007
- American Medical Society for Sports Medicine 17th Annual Meeting, Las Vegas, NV, 2008.
- Musculoskeletal Ultrasound, Mayo, MN 2008.
- American Medical Society for Sports Medicine 18th Annual Meeting, Tampa, FL, 2009.
- American College of Sports Medicine 56th Annual Meeting, Seattle, WA 2009
- American Academy of Family Practice Board Review Course, Seattle, WA 2009.
- American Medical Society for Sports Medicine 19th Annual Meeting, Cancun, Mexico, April 2010
- Advanced Musculoskeletal Ultrasound Work-Shop, at the American Medical Society for Sports Medicine 19th Annual Meeting, Cancun, Mexico, April 2010
- American College of Sports Medicine 57th Annual Meeting, Baltimore, MD 2010
- American Orthopedic Society for Sports Medicine Annual Meeting, Providence, RI 2010
- American Academy of Physical Medicine and Rehabilitation Annual Meeting, Seattle, WA 2010
- American Medical Society for Sports Medicine 20th Annual Meeting, Salt Lake City, UT 2011.
- Advanced Team Physician Course, Calvi, Corsica, France, 2011
- 3rd IOC World Congress on Injury and Illness Prevention, Monte Carlo, Monaco, 2011
- Swedish Society of Sports Medicine, Gotthenberg, Sweden, 2011
- American Medical Society for Sports Medicine 21st Annual Meeting, Atlanta, GA 2012
- 2nd International Scientific Tendinopathy Symposium, Vancouver, BC 2012
- American Medical Society for Sports Medicine 22nd Annual Meeting, San Diego, CA 2013

- 60th Annual American College of Sports Medicine Annual Meeting, Indianapolis, IN 2013.
- 55th American Society of Hematology Annual Meeting and Exposition, New Orleans, LA 2013.
- American Medical Society for Sports Medicine 23rd Annual Meeting, New Orleans, LA 2014.
- 4th IOC World Congress on Injury and Illness Prevention, Monte Carlo, Monaco, 2014
- The OrthoBiologic 5th Annual Conference on Regenerative Medicine, Las Vegas, NV, 2014.
- American Medical Society for Sports Medicine 24th Annual Meeting, Hollywood, FL, April 2014.
- 62nd American College of Sports Medicine Annual Meeting, San Diego, CA 2015.

11) **Editorial Responsibilities:**

- Co-Guest Editor, Clinics in Sports Medicine, The Athletic Woman, 1998-2000.
- Series Editor, The Physician and Sportsmedicine, AMSSM Case Study Series, 1997-2000.
- Editorial Board, The Physician and Sportsmedicine, 1998-2005.
- Series Editor, The Physician and Sportsmedicine, Practice Essentials, 2000-2005.
 - Developed series concept devoted to distilling essential diagnostic information into clinically applicable format with a focus on management and return to play issues.
 - Solicited, reviewed (also peer-reviewed) and edited articles for publication.
- Associate Editor, Current Reviews in Musculoskeletal Medicine, 2005 – 2008
 - Journal launched March 2008 published by Springer
<http://crmm.edmgr.com/>
 - Multi-disciplinary journal targeted to sports medicine professional from various backgrounds (family medicine, orthopedics, physical medicine and rehabilitation, pediatrics, internal medicine, physical therapy).
 - Appointed and managed five assistant editors.
 - Initial pre-launch quota of 35 submitted articles.
- Associate Editor, The British Journal of Sports Medicine 2008 – present
- Reviewer, Clinical Journal of Sports Medicine
- Reviewer, British Journal of Sports Medicine
- Reviewer, Medicine and Science in Sports and Exercise
- Reviewer, Annals of Internal Medicine
- Reviewer, Sports Health
- Reviewer, Circulation
- Reviewer, Pediatrics
- Reviewer, Scandinavian Journal of Sports and Exercise
- Reviewer, British Medical Journal

12) Special National Responsibilities:

- American Medical Society for Sports Medicine, Diversity Task Force 1996-1997.
- American Medical Society for Sports Medicine, Diversity Committee 1997-2000.
- American Medical Society for Sports Medicine, Public Relations Committee, 1997-2003.
- Chairperson, Membership Committee, American Medical Society for Sports Medicine, 2002-2006.
- Board of Directors, American Medical Society for Sports Medicine, 2002-2004.
- Board of Directors, American Medical Society for Sports Medicine, 2004-2006.
- American College of Sports Medicine Committee on Women, Sport, & Physical Activity, 2004-07.
- National Collegiate Athletic Association Committee on Competitive Safeguards and Medical Aspects of Sports, 2003-2007.
- American Medical Society for Sports Medicine, Program Committee 2004-2005, 2007-2010.
- Preparticipation Physical Evaluation (PPE) Monograph, 4th Edition – Writing group member representing the American Medical Society for Sports Medicine (2007-2009)
- American Medical Society for Sports Medicine, 2nd Vice President, 2007-2008
- American Medical Society for Sports Medicine, 1st Vice President, 2008 – 2009.
- National Collegiate Athletic Association, working group for Pregnancy Toolkit, a resource for institutions, coaches, athletic trainers, and athletes dealing with pregnancy. 2008.
- American Institute of Musculoskeletal Medicine Musculoskeletal Ultrasound Working Group, 2008.
- Course Chair, Musculoskeletal Ultrasound Pre-Conference, Tampa, FL, 2009.
- American Medical Society for Sports Medicine, President, 2009 – 2010.
- Course Director, Musculoskeletal Ultrasound Pre-Conference, Cancun, Mexico, 2010.
- American Medical Society for Sports Medicine, Immediate Past President 2010 – 2011.
- American Medical Society for Sports Medicine, Education Committee, 2010 – present.
- Chair, American Medical Society for Sports Medicine, Executive Director Search Committee, 2010.
- Chair, American Medical Society for Sports Medicine Concussion Position Statement writing group, 2011.
- American Medical Society for Sports Medicine Foundation, Board Member, 2011 – present
- American Medical Society for Sports Medicine, Program Committee, 2010 – 2011.
- Participant, ACSM and CHAMP Summit on SCT: Mitigating Risks for Warfighters and Athletes, Washington D.C., September 2011.
- AMSSM representative to Inter-association task force of preventing sudden death in collegiate conditioning sessions, Colorado Springs, CO, January 2012.

- Writing Group, Summit on ECG Interpretation in Athletes. Sponsored by the American Medical Society for Sports Medicine in partnership with the European Society of Cardiology Section of Sports Cardiology, Pediatric & Congenital Electrophysiology Society (PACES), the FIFA Medical Assessment and Research Center (F-MARC), and the British Journal of Sports Medicine, the goal is to develop consensus standards and a comprehensive online training module to educate physicians around the world in ECG interpretation in athletes. Seattle, WA. February 2012
- Co-chair , American College of Sports Medicine Task Force on Sickle Cell Trait and the Athlete. Indianapolis, IN March 2012.
- Consultant, Department of Defense. Sickle Cell Trait in the Athlete/Warrior, Washington, D.C., January 2013.
- American Medical Society for Sports Medicine, Program Committee, 2012 - present
- Chair, American Medical Society for Sports Medicine Task Force on Musculoskeletal Ultrasound Curriculum, 2013-2014.
- AMSSM representative to College Athletic Trainers Association/NCAA Safety in College Football Summit, Atlanta, GA, January 2014.
- American Medical Society for Sports Medicine Task Force on Sports Medicine Ultrasound, 2014-2015
- AMSSM delegate, White House Summit on Healthy Kids & Safe Sports Concussion Summit, May 29, 2014.
- Representative NCAA Task Force on Sudden Cardiac Death in Athletes, Sept 2014.
- Chair, AMSSM Academic Interest Group, July 2014 – present
- Cardiac Safety Research Consortium and the Federal Drug Administration Pediatric Think Tank Meeting, Bethesda, MD, February 2015.
- Course faculty, Advanced Sports Medicine Ultrasound Course, American Medical Society for Sports Medicine 24th Annual Meeting, Hollywood, FL, April 2015.
- Pac-12 Conference Brain Trauma Task force, 5/2015 – present.
- Pac-12 Student Athlete Health Board, 7/2015 – present
- Chair, Medical Advisory Board, National Basketball Association Players Association, 9/2015 – present
- National Basketball Association Strategic Advisory Board – 10/2015 - present

13) Special Local Responsibilities:

Department of Family Medicine

- Clinical Faculty, 1998 – 2012
- Faculty Primary Care Sports Medicine Fellowship 1998 – present
- Director Primary Care Sports Medicine Fellowship 2004 – 2014
- Advancement Committee, 2012 – present
- Regular Faculty, February 2012 - present
- Sports Medicine Section Chief , July 2012 – present
- Clinical Chairs Advisory Committee, July 2012 – present

- Industry Relations Committee, July 2015 – present

Hall Health Primary Care Center:

- Medical Director, Eating Concerns Program, Hall Health Primary Care Center, 1998-1999.
- Unit Head, Hall Health Physical Therapy Clinic, University of Washington, 2003-2010.
- Director, Primary Care Sports Medicine Fellowship, Hall Health Primary Care Center, University of Washington, 2004-present.
- Unit Head, Hall Health Intercollegiate Athletic Department Clinic, University of Washington, 2006 – present.
- Co-chair, Sports Medicine and Rheumatology Essentials for the Primary Care Provider, 2006, 2008
- Section Chief, Sports Medicine Section (PT, X-ray, ICA, Sports Medicine Clinic), 2007 – 2010.
- Musculoskeletal Services Director, 2010 – March 2013

Medical School:

Co-chair, Sports Medicine and Rheumatology Essentials for the Primary Care Provider, 2006, 2008

Chair, Musculoskeletal Ultrasound Privileging Working group – April – July 2015
 Appointments and Promotions Committee – July 2015 - present

University:

- Team Physician, St. Mary's College, South Bend, IN, 1993-1996
- Assistant Team Physician, University of Notre Dame, South Bend, IN, 1993-1996
- Team Physician, Ball State University, Muncie, IN, 1996-1997
- Team Physician, University of Washington, 1998-present
 - Responsible for medical care for cheerleading (1998-2006), volleyball (1998-2002), men's and women's cross country (1998-2010), men's and women's track (1998-2010), women's basketball (1998-2013), softball (1999-2000), men's and women's swimming (1999-2000), and football (1999-present). Includes two training room clinics per week and coverage of home and some away events (football). Also includes coverage of various local, regional, and national tournaments as well as bowl games (list available upon request)
- Associate Head Team Physician, University of Washington, 2004-present
- Committee Member, UWMC Seattle Marathon Medical Care and Coverage, 2006
- Event Physician and Medical Coordinator, Seattle Breast Cancer 3-Day Walk for the Cure, 2006 – 2009
- Head football physician, 2013 – present.

Local Community

- Event Physician, Muncie Endurathon (Ironman qualifier), 1992, 1996, 1997

- Team Physician, Washington High School, South Bend, IN, 1993-1996
- Volunteer Physician, National Youth Sports Program, South Bend, IN, 1993-1996, Pre-participation physicals
- Event Physician, Sunburst Triathlon, South Bend, IN, 1995
- Event physician for the 1995 NCAA Regional Men's Tennis Tournament
- Event Physician, Gus Macker 3 on 3 Basketball Tournament, Muncie, IN, 1996, 1997
- Team Physician, York Town High School, Muncie, IN 1996-1997
- Team Physician, Muncie Southside High School, Muncie, IN, 1997
- Event Physician, State of Indiana Golden Gloves Tournament, Indianapolis, IN, 1997
- Event Physician, National Christian Collegiate Athletic Association Men's National Basketball Tournament, 1997
- Event Physician, Big Ten Women's Basketball Championship, Indianapolis, IN, 1997
- Event Physician, National Collegiate Athletic Association National Swimming and Diving Championships, Indianapolis, IN, 1997
- Event Physician, Washington State High School State Basketball Championships, 1998-2000
- Event Physician, University of Washington Pac-8 Hockey Championship Tournament, 2004
- Event Physician, NCAA Regional Women's Basketball Tournament, 2004
- Event Physician, Seattle Breast Cancer 3-Day, 2006, 2007, 2008, 2009
- Event Physician, Seattle Marathon, 2007, 2008
- Cardiac screening, Blanchet High School, 2008
- Pre-participation exams, Blanchet High School, 2008
- Event Physician, NCAA Regional Women's Basketball Tournament, 2009
- Event Physician, NCAA Regional Women's Basketball Tournament, 2010
- Pre-participation exams, Blanchet High School, 2010
- Cardiac Screening, Auburn High School, 12/2010
- Cardiac Screening Jackson High School, 2/2011
- Cardiac Screening South Whidbey Island High School, 3/2011
- Pre-participation exams, Blanchet High School, 2011
- Cardiac Screening Garfield High School, 8/2011
- Cardiac Screening Redmond High School, 10/2011
- Cardiac Screening Nathan Hale High School, 11/2011
- Cardiac Screening Franklin High School, 2/2012
- Cardiac Screening Burien High School, 4/2012
- Cardiac Screening Roosevelt High School, 5/2012
- Pre-participation exams, Blanchet High School, 2012
- Cardiac Screening Lindbergh High School, 7/2012
- Cardiac Screening Snohomish High School, 11/2012
- Medical Advisory Board, Nick of Time Foundation, 2013 - present
- Cardiac Screening Holy Names High School, 1/2013
- Cardiac Screening Edmonds-Woodway High School, 2/2013
- Cardiac Screening Bishop Blanchet High School, 4/2013
- Cardiac Screening Cascade High School, 5/2013

- Cardiac Screening Issaquah High School, 6/2013
- Cardiac Screening Shoreline Community Center, 8/2013
- Cardiac Screening Enum Claw High School, 10/2013
- Cardiac Screening Juanita High School, 11/2013
- Cardiac Screening Mercer Island High School, 12/2013
- Cardiac Screening Meadowdale High School, 2/2014
- Cardiac Screening Monroe High School, 3/2014
- Cardiac Screening Inglemore High School, 5/2014
- Cardiac Screening Marysville Pilchuck, 8/2014
- Cardiac Screening Pacific Northwest Ballet, 9/2014
- Cardiac Screening Bellingham High Schools, 10/2014
- Cardiac Screening Lake Washington High School, 11/2014
- Cardiac Screening Ingraham High School, 12/2014
- Cardiac Screening Garfield High School, 3/2015
- Cardiac Screening Bellevue High School, 4/2015
- Cardiac Screening Mariner High School, 5/2015
- Cardiac Screening Mountlake Terrace High School, 6/2015
- Cardiac Screening Lake Stevens Mid-High School, 8/2015

14) **Research Funding:**

- Drezner JA, **Harmon KG**. “AED and ICD Use in Sports: Expansion and Development of National Registries.” National Operating Committee on Standards for Athletic Equipment (NOCSAE) – \$62,465. (2006-2007)
- Drezner JA, **Harmon KG**. “AED Use in Sports: Expansion of a National Registry.” National Operating Committee on Standards for Athletic Equipment (NOCSAE) – \$49,217. (2007-2008)
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- **Harmon KG**, Drezner JA. “Outcomes of Autologous Growth Factor Therapy in the Treatment of Sports-related Soft Tissue Injuries: A Prospective Study.” (Sonosite) for \$353,521. (2011-2013)
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c. Published Books:

None

d. Other Publications:

None

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22. Pelto H, Prutkin J, Owens D, Salerno J, **Harmon KG**, Drezner J. “Electrocardiographic Findings in Patients with Hypertrophic Cardiomyopathy: an Evaluation of the ‘Seattle Criteria’.” Clin J Sport Med. 2013 Mar;23(2):124

23. Asif I, Johnson S, Schmieg J, Toresdahl B, Pelto H, Smith T, Fairbrother J, Zakrajsek R, Fisher L, **Harmon KG**, Drezner J. "The Psychological Impact of Cardiovascular Screening: The Athlete's Perspective." *Clin J Sport Med.* 2013 Mar;23(2):126
24. **Harmon KG**, Drezner J, Lopez-Anderson M, Owens D, Maleszewski J, Ackerman M. "Etiology of Sudden Cardiac Death in NCAA Athletes." *Clin J Sport Med.* 2013 Mar;23(2):125
25. Toresdahl B, Rao A, **Harmon KG**, Drezner J. "Incidence of Sudden Cardiac Arrest in High School Students and Student-Athletes." *Clin J Sport Med.* 2013 Mar;23(2):125
26. Salerno J, Pelto H, Prutkin J, Owens D, **Harmon KG**, Drezner J. "Electrocardiographic Findings in Patients with Hypertrophic Cardiomyopathy: an Evaluation of the 'Seattle Criteria' *Clin J Sport Med.* 2013 Mar;23(2):125
27. **Harmon KG**, Drezner J, Rao A. Platelet Rich Plasma for Chronic Tedinopathy. *Brit J Sport Med.* 2013 June;47(9).
28. **Harmon KG**, Drezner J. Measuring Sudden Cardiac Arrest and Death Incidence in Minnesota High School Athletes: a Comparison of Methodology and Implications for Prevention Strategies. *Brit J Sports Med.* 2014 48(7):605.
29. **Harmon KG**, Asif I, Ellenbogen R, Drezner J. The Incidence of Sudden Cardiac Arrest and Death in United States High School Athletes. *Brit J Sports Med.* *Brit J Sports Med.* 2014 48(7):
30. Asif A, Price D, Fisher L, Zakrajsek R, Raabe J, Bejar M, Larsen L, Rao A, **Harmon KG**, Drezner J. Screening for Sudden Cardiac Death in Athletes: The Psychological Impact of Being Diagnosed with Potentially Lethal Disease. *Brit J Sports Med* *Brit J Sports Med.* 2014 48(7):562.
31. Asif I, Price D, Jenkins J, Lett A, Irwin M, Johnson S, Toresdahl B, Pelto H, Smith T, **Harmon KG**, Drezner J. Psychological Implications of Advanced Cardiac Screening: No Differences in Anxiety Levels Based on Reason for False Positive Result. *Brit J Sports Med.* 2014 48(7):563.
32. Asif I, Hadley D, **Harmon KG**, Drezner J. Cardiovascular Screening in NCAA Athletes: Findings from a Multicenter ECG-Inclusive Program. *Brit J Sports Med* *Brit J Sports Med.* 2014 48(7):602.
33. Toresdahl B, Pelto H, Fudge J, **Harmon KG**, Rao A, Asif I, Owens D, Prutkin J, Salerno J, Drezner J. Effectiveness of Cardiac Screening Inclusive of ECG in Young Athletes. *Brit J Sports Med.* 2014 48(7).
34. Lett A, Drezner JA, Price D, Jenkins J, Irwin M, Johnson S, Toresdahl B, Pelto H, Rao A, **Harmon KG**, Asif I. ECG Screening During the Pre-participation Examination Does Not Cause Undue Anxiety in Competitive Athletes. 2014: 24(2);164-165.
35. Toresdahl B, Pelto H, Fudge J, **Harmon KG**, Rao A, Asif I, Owens D, Prutkin J, Salerno J, Drezner J. "Effectiveness of Cardiac Screening Inclusive of ECG in Young Athletes" *Clin J Sports Med.* 2014: 24(2);164.
36. Rao AL, Asif IM, Drezner JA, Toresdahl B, **Harmon KG**. "Suicide in NCAA Athletes: A Nine-Year Analysis of the NCAA Resolutions Database" 2014: 24(2);168.

37. Mulgrew K, Toresdahl B, Pelto H, Owens D, Prutkin J, Salerno J, Rao A, Harmon KG, Drezner J. "Evaluation of Cardiac Murmurs in High School Student Athletes: Should Echocardiography Be Standard?" 2014: 24(2);165.

16) Other

a. Poster Presentations:

1. **Harmon KG**, Roush MB. Hip Pain in a Recreational Walker. Case presentation at Canadian Academy of Sports Medicine Annual Meeting, Silver Star, B.C., Canada, 1997.
2. Rothmier J, **Harmon KG**, O’Kane JW. Exertional ataxia in a college football player. American Medical Society for Sports Medicine 15th Annual Meeting, Miami Beach, 2006.
3. Drezner JA, **Harmon KG**, Heistand J, Cramer M, Rao A. Effectiveness of Emergency Response Planning for Sudden Cardiac Arrest in United States High Schools with Automated External Defibrillators. 2nd World Congress on Sports Injury Prevention. Tromso, Norway, 2008.
4. Drezner JA, Rao A, Cramer M, **Harmon KG**. Details and Outcomes of Resuscitation Following Sudden Cardiac Arrest in High School Student Athletes from the United States. 2nd World Congress on Sports Injury Prevention. Tromso, Norway, 2008.
5. Fudge J, Drezner J, **Harmon KG**, Berger S, Campbell R, Vetter V. Medical Evaluation of Syncope and Unexplained Seizure Activity in Children with Sudden Cardiac Arrest. American Medical Society for Sports Medicine 19th Annual Meeting, Cancun, Mexico, April 2010.
6. Fean R, Drezner J, **Harmon KG**. PRP Therapy in the Management of Chronic Patellar Tendinopathy. American Medical Society for Sports Medicine 19th Annual Meeting, Cancun, Mexico, April 2010.
7. Pelto H, Salerno J, **Harmon KG**, Drezner J. Near-Syncope in a High School Athlete: Requirements of the Diagnostic Evaluation. Case Poster Presentation. AMSSM 2012 Annual Conference.
8. Pelto H, Drezner J, Hadley D, **Harmon KG**, Owens D, Prutkin J, Salerno J. Electrocardiographic Findings in Patients with Cardiomyopathy. Works in Progress poster presentation. University of Washington Department Fair 2012
9. Pelto H, Drezner J, Hadley D, **Harmon KG**, Owens D, Prutkin J, Salerno J. Electrocardiographic Findings in Patients with Cardiomyopathy. Works in Progress poster presentaiton. Society of Teachers of Family Medicine Annual Conference 2012.
10. Homer P, Drezner J, Rao A, **Harmon KG**. Effectiveness of Platelet Rich Plasma on Human Tendons. American Medical Society for Sports Medicine 21st Annual Meeting, Atlanta, GA, 2012. Harmon KG, Drezner JD, Rao A.
11. Salerno J, Pelto H, Prutkin J, Owens D, Harmon K, **Drezner J**. Electrocardiographic Findings in Patients with Hypertrophic Cardiomyopathy: an Evaluation of the ‘Seattle Criteria’. Heart Rhythm Society 2013 Annual Meeting, Denver, CO, May 2013.
12. **Harmon KG**, Rao A, Drezner JA. The Effectiveness of Platelet Rich Plasma in Chronic Tendinosis. American Medical Society for Sports Medicine 22nd Annual Meeting, New Orleans, LA, 2014.

13. Asif IM, Price D, Fisher L, Zakrajsek R, Raabe J, Bejar M, Larsen L, Rao AL, **Harmon KG**, Drezner JA. Psychological Impact of Young Competitive Athletes Diagnosed with Serious or Potentially Lethal Cardiac Disease. American Medical Society for Sports Medicine 22nd Annual Meeting, New Orleans, LA 2014.
14. Prutkin JM, Toresdahl GB, Pelto H, Fudge J, **Harmon KG**, Rao AL, Asif IM, Owens DS, Salerno JC, Drezner JA. Effectiveness of Cardiac Screening Using ECG in High School Athletes. Heart Rhythm Society, San Francisco, CA, 2014.
15. Asif IM, **Harmon KG**, Maleszewski J, Owens D, Prutkin J, Salerno J, Zigman M, Ellenbogen R, Ackerman M, Drezner JA. Incidence and Etiology of Sudden Cardiac Death in NCAA Athletes: 10 – Year Data. American Heart Association Annual Meeting, Chicago IL, November 2014.
16. Asif IM, **Harmon KG**, Maleszewski J, Owens D, Prutkin J, Salerno J, Zigman M, Ellenbogen R, Ackerman M, Drezner JA. Incidence and Etiology of Sudden Cardiac Death and Arrest in US High School Athletes. American Heart Association Annual Meeting, Chicago IL, November 2014.
17. Zigman ML, Prutkin J, **Harmon KG**, O’Kane J, Pelto H, Rao AL, Hassebrock JD, Petek BJ, Teteak C, Timonen M, Owens DS, Drezner JD. Cardiovascular screening in college athletes: A 4-year Analysis from the University of Washington. University of Washington Department of Family Medicine Fair. April 2015.
18. Siebert DM, Kucera KL, Cox L, **Harmon KG**, Drezner JA. A prospective study on the incidence and outcomes of sudden cardiac arrest in competitive athletes: data from two national centers. University of Washington Department of Family Medicine Fair. April 2015.

b. Local and Regional Lectures by Invitation:

1. **Harmon KG**. Anterior Cruciate Ligament Rupture in Women. Grand Rounds Ball Memorial Hospital, Muncie, IN, 1997.
2. **Harmon KG**. Stress Fractures: Current Concepts. Grand Rounds Ball Memorial Hospital, Muncie, IN, 1997.
3. **Harmon KG**. Scoliosis: Basketball Player: A Case Report. Podium presentation at the American College of Sports Medicine Regional Meeting, South Bend, IN, 1997.
4. **Harmon KG**. As the Seasons Change. REI Lecture Series, Seattle, WA, 1998.
5. **Harmon KG**. Patellafemoral Pain. Roosevelt Women’s Clinic, Seattle, WA, 1999.
6. **Harmon, KG**. Musculoskeletal Exam. Madigan Hospital Internal Medicine Residency, Madigan, WA, 2000.
7. **Harmon, KG**. Common Knee Problems. Madigan Hospital Internal Medicine Residency, Madigan, WA, 2000.
8. **Harmon KG**. Common Knee Problems. Providence Medical Centers 6th Annual Sports Medicine Conference, Winthrop, WA, 2000.
9. **Harmon KG**. Concussion. Providence Medical Centers 6th Annual Sports Medicine Conference, Winthrop, WA, 2000.
10. **Harmon KG**. Controversies and Rationale for Use of Oral Corticosteroids in Sport. Sports Medicine Forum, Seattle, WA, 2000.
11. **Harmon, KG**. Anemia in the Athlete. Providence Medical Center 10th Annual Sports Medicine Conference, Winthrop, WA 2004.

12. **Harmon, KG.** Pre-Participation Exam. Providence Medical Center 10th Annual Sports Medicine Conference, Winthrop, WA 2004.
13. **Harmon, KG.** The Hip and Groin. Sports Medicine & Rheumatology Conference, University of Washington, Seattle, WA, January 2007
14. **Harmon, KG.** Concussion. Sports Medicine & Rheumatology Conference, University of Washington, Seattle, WA, January 2007
15. **Harmon, KG.** Low Back Pain. Workshop at Sports Medicine & Rheumatology Conference, University of Washington, Seattle, WA, January 2007
16. **Harmon, KG.** Neck and Back Pain. Hall Health Primary Care Center Continuing Medical Education Series. Seattle, WA, October, 2007.
17. **Harmon, KG.** Practical and Ethical Issues of Athletes Competing with Cardiac Issues. Washington State Athletic Trainers Association Annual Meeting. Bellevue, WA, March 2008.
18. **Harmon, KG.** Emerging Concepts and Treatments in Tendinopathy. Seattle Spine & Rehabilitation Bi-Monthly Seminar. Seattle, WA, September 2008.
19. **Harmon KG.** Concussion, Sports Medicine & Rheumatology Conference, University of Washington, Seattle, WA, December 2008.
20. **Harmon KG.** Emerging Concepts and Treatment in Tendinopathy. Sports Medicine & Rheumatology Conference, University of Washington, Seattle, WA, December 2008.
21. **Harmon KG.** Concussion: The Sports Medicine Perspective. University of Washington Neurology Grand Rounds, Seattle, WA April 2009.
22. **Harmon KG.** Platelet Rich Plasma. Washington State Athletic Trainers Annual Meeting, Tacoma, WA, June 2010.
23. **Harmon KG.** Hip: Clinical Applications of Musculoskeletal Ultrasound. Sonosite CME, Seahawks Training Facility, Renton, WA, July 2010.
24. **Harmon KG.** Knee: Clinical Applications of Musculoskeletal Ultrasound. Sonosite CME, Seahawks Training Facility, Renton, WA, July 2010.
25. **Harmon KG.** Implementing US Into Your Practice. Sonosite CME, Seahawks Training Facility, Renton, WA, July 2010.
26. **Harmon KG.** Musculoskeletal Ultrasound in Clinical Practice. Sonosite National Business Meeting, Seattle, WA April 2011.
27. **Harmon KG.** Platelet Rich Plasma. Therapeutic Associates Lecture Series, Seattle, WA September 2011.
28. **Harmon KG.** The Clinical Use of Platelet Rich Plasma in Musculoskeletal Injuries. Puget Sound Blood Center Research Seminar, Seattle, WA June 2012.
29. **Harmon KG.** The Treatment of Tendinopathy - Beyond RICE: The Use of Biologics. Family Medicine Grand Rounds. Seattle WA. November 2012.
30. **Harmon KG, Rao, A.** Dangers Facing Young Athletes: Coping with Doping, Concussion, and Sudden Cardiac Arrest. Mini-Med School. Seattle, WA March 2013.
31. **Harmon KG.** Concussion. Hall Health Continuing Medical Education Series. Seattle, WA, June 2013.
32. **Harmon KG.** Biologics and Regenerative Medicine at the University of Washington. Seattle ARCS Foundation. Seattle, WA, November 2013.

33. **Harmon KG.** Biologics and Regenerative Medicine in Musculoskeletal Injuries. Sunset Club. Seattle, WA, May 2014.
34. **Harmon KG.** Conservative Treatment of Proximal Hamstring Injuries. Orthopaedic Grand Rounds. Seattle, WA, July 2014.
35. **Harmon KG.** Platelet Rich Plasma and Ultrasound in Sports Medicine. Washington State Athletic Trainer's Annual Meeting. Seattle, WA. July 2014.
36. **Harmon KG.** Sickle Cell Trait and the Athlete. Osteopathic Medical Conference and Exposition. Seattle, WA. October 2014.
37. **Harmon KG.** Sudden Cardiac Death in Athletes. Osteopathic Medical Conference and Exposition. Seattle, WA. October 2014.
38. **Harmon KG.** Platelet Rich Plasma in Sports Injuries. Bellevue Tennis Club Men's Group. Bellevue, WA. November 2014.
39. **Harmon KG.** Regenerative Medicine in Sports. University of Arkansas Athletic Training Class. Via Skype. October 2015.

c. National Lectures by Invitation:

1. **Harmon KG, Roush MB.** Chest Pain in a Cross Country Athlete. Case presentation at American Medical Society for Sports Medicine Annual Meeting, Colorado Springs, CO, 1997.
2. **Harmon KG, Dick R.** The Relationship of Skill to ACL Rupture. Research presentation at American Medical Society for Sports Medicine Annual Meeting, Colorado Springs, CO 1997.
3. **Harmon KG, Roush MB.** Heel Pain in a Collegiate Diver. Case presentation at American College of Sports Medicine Annual Meeting, Denver, CO, 1997.
4. **Harmon KG.** Anti-inflammatory Use in Sports. Research presentation at American Medical Society for Sports Medicine Annual Meeting, Hilton Head, SC, 1999.
5. Drezner JA, **Harmon KG.** Low Back Pain in a Recreational Athlete: A Case Report. American Medical Society for Sports Medicine 9th Annual Meeting, San Diego, CA, 2000
6. **Harmon KG.** Pre-Participation Exam. UW 29th Annual Advances in Family Practice, Seattle, WA, 2001
7. **Harmon KG.** Foot and Ankle Problems. American Academy of Family Practice Sports Medicine: Strategies for Treating Athletes, St. Louis, MO, 2002.
8. **Harmon KG.** Chronic Fatigue, Fibromyalgia, RSD. American Academy of Family Practice Sports Medicine: Strategies for Treating Athletes, St. Louis, MO, 2002.
9. **Harmon KG.** Pelvis, Hip and Femur. Podium presentation at American Academy of Family Practice Sports Medicine: Strategies for Treating Athletes, St. Louis, MO, 2002.
10. **Harmon KG.** Gender Differences in ACL Injuries. Workshop presentation at AMSSM Annual Meeting in Buena Vista, FL, 2002
11. **Harmon, KG.** Upper Spinal Injuries. American Academy of Family Practice Sports Medicine: Strategies for Treating Athletes, Tucson, AZ, 2003.
12. **Harmon, KG.** Lower Spinal Injuries. American Academy of Family Practice Sports Medicine: Strategies for Treating Athletes, Tucson, AZ, 2003.

13. **Harmon, KG.** Anemia in the Athlete. American Academy of Family Practice Sports Medicine: Strategies for Treating Athletes, Tucson, AZ, 2003.
14. **Harmon, KG.** GI/GU Problems in the Athlete. American Academy of Family Practice Sports Medicine: Strategies for Treating Athletes, Tucson, AZ, 2003.
15. **Harmon, KG.** Pre-Participation Exam. University of Washington 31st Annual Advances in Family Practice, Seattle, WA 2003.
16. **Harmon, KG.** Pre-Participation Sports Advice. University of Washington 33rd Annual Advances in Family Practice, Seattle, WA 2005.
17. **Harmon, KG.** Exercise in Pregnancy. American College of Sports Medicine Team Physician's Course Part I, Orlando, FL 2006.
18. **Harmon KG.** Special Concerns of the Female Athlete. Podium presentation at American College of Sports Medicine Team Physician's Course Part I, Orlando, FL 2006.
19. **Harmon KG.** Medical Legal Aspects of Sports Medicine. American College of Sports Medicine Team Physician's Course Part I, Orlando, FL 2006.
20. **Harmon KG.** Getting Published. Workshop presentation at American Medical Society for Sports Medicine 15th Annual Meeting in Miami, FL, 2006.
21. Rothmier J, Drezner J, **Harmon K.** Automated External Defibrillators in Washington State High Schools. Research presentation at American Medical Society for Sports Medicine 15th Annual Meeting in Miami, FL, 2006.
22. Chun J, Drezner JA, **Harmon KG.** Exercise Related Sudden Death: A Prospective Observational Study in the United States. Research presentation at American Medical Society for Sports Medicine 16th Annual Meeting in Albuquerque, NM 2007.
23. **Harmon KG.** Pardon the Sports Medicine Interruption. American Medical Society for Sport Medicine 16th Annual Meeting in Albuquerque, NM 2007.
24. **Harmon KG.** Musculoskeletal Problems I – Common Overuse Injuries. American Academy of Family Practice Board Review Course. Seattle, WA 2007
25. **Harmon KG.** Musculoskeletal Problems II – Common Issues Related to Trauma and Fractures. Academy of Family Practice Board Review Course. Seattle, WA 2007
26. **Harmon KG.** Musculoskeletal Problems III – Common Pediatric Disorders. Academy of Family Practice Board Review Course. Seattle, WA 2007
27. **Harmon KG.** Selected Issues in Sports Medicine. Academy of Family Practice Board Review Course. Seattle, WA 2007
28. **Harmon KG.** Concussion. University of Washington 35th Annual Advance in Family Practice, Seattle, WA 2007.
29. **Harmon KG.** Musculoskeletal Problems I – Common Overuse Injuries. American Academy of Family Practice Board Review Course. Seattle, WA 2007
30. **Harmon KG.** Musculoskeletal Problems II – Common Issues Related to Trauma and Fractures. Academy of Family Practice Board Review Course. Seattle, WA 2008
31. **Harmon KG.** Musculoskeletal Problems III – Common Pediatric Disorders. Academy of Family Practice Board Review Course. Seattle, WA 2008
32. **Harmon KG.** Selected Issues in Sports Medicine. Academy of Family Practice Board Review Course. Seattle, WA 2008
33. **Harmon KG.** Presidential Address. American Medical Society for Sports Medicine 18th Annual Meeting. Tampa, FL, April 2009

34. **Harmon KG.** Musculoskeletal Problems I – Common Overuse Injuries. American Academy of Family Practice Board Review Course. Seattle, WA 2009
35. **Harmon KG.** Musculoskeletal Problems II – Common Issues Related to Trauma and Fractures. Academy of Family Practice Board Review Course. Seattle, WA 2009
36. **Harmon KG.** Musculoskeletal Problems III – Common Pediatric Disorders. Academy of Family Practice Board Review Course. Seattle, WA 2009
37. **Harmon KG.** Selected Issues in Sports Medicine. Academy of Family Practice Board Review Course. Seattle, WA 2009
38. Asif I, **Harmon KG**, Drezner J, Klossner D. Incidence and Etiology of Sudden Death in NCAA Athletes. American Medical Society for Sports Medicine 19th Annual Meeting, Cancun, Mexico, April 2010.
39. Toresdahl B, Drezner J, **Harmon KG.** Automated External Defibrillators in United States High Schools as a Marker of Emergency Preparedness for Sudden Cardiac Arrest. American Medical Society for Sports Medicine 19th Annual Meeting, Cancun, Mexico, April 2010.
40. **Harmon KG.** Sickle Cell Trait: Environmental Challenges. American Medical Society for Sports Medicine 19th Annual Meeting, Cancun, Mexico, April 2010.
41. **Harmon KG.** Presidential Address. American Medical Society for Sports Medicine 19th Annual Meeting, Cancun, Mexico, April 2010.
42. **Harmon KG.** Sickle Cell Trait and the Athlete. AMSSM Exchange Speaker at the American College of Sports Medicine, Baltimore, MD, May 2010.
43. **Harmon KG.** Biologic Treatment of Tendons. AMSSM Exchange Speaker at the American Orthopedic Society for Sports Medicine, Providence, RI, July 2010.
44. **Harmon KG.** Ultrasound and Platelet Rich Plasma in Sports Medicine. American Academy of Physical Medicine and Rehabilitation. Musculoskeletal Ultrasound Pre-Conference Course. Seattle, November 2010.
45. **Harmon, KG.** Basic and Clinical Science of Platelet Rich Plasma, American Academy of Physical Medicine and Rehabilitation Annual Meeting. Seattle, November 2010.
46. **Harmon, KG.** Musculoskeletal Ultrasound, NBA Team Physicians Meeting, Los Angeles 2011.
47. Drezner J, Fudge J, **Harmon K**, Berger S, Campbell R, Vetter V. Medical Evaluation of Syncope and Unexplained Seizure Activity in Children with Sudden Cardiac Arrest. North American Primary Care Research Group, Seattle, WA, November 2011.
48. Asif I, Drezner J, Fean J, **Harmon K**, Owens D, Prutkin J, Rao A, Salerno J, Stout K. Accuracy of ECG Interpretation in Competitive Athletes. American Medical Society for Sports Medicine 20th Annual Meeting, Salt Lake City, UT, April 2011.
49. Toresdahl B, Drezner J, Rao A, **Harmon K.** Outcomes of Sudden Cardiac Arrest in U.S. High Schools: A Prospective Study from the National Registry for AED Use in Sports. American Medical Society for Sports Medicine 20th Annual Meeting, Salt Lake City, UT, April 2011.
50. **Harmon KG.** Strategies for Managing the Collapsed Athlete. Consortium for Health and Military Performance/ Human Performance Research Center & American College of Sports Medicine Conference on Sickle Cell Trait: Mitigating Risk for Warfighters & Athletes. Bethesda, MD. September 2011.

51. **Harmon KG.** Future Research Agenda and Strategies. Consortium for Health and Military Performance/ Human Performance Research Center & American College of Sports Medicine Conference on Sickle Cell Trait: Mitigating Risk for Warfighters & Athletes. Bethesda, MD. September 2011.
52. **Harmon KG.** Epidemiology of Death Associated with Sickle Cell Trait in NCAA Athletes. Indianapolis, IN. March 2012.
53. **Harmon KG.** Epidemiology of Death Associated with Sickle Cell Trait in the Military. Indianapolis, IN. March 2012.
54. **Harmon KG.** Platelet Rich Plasma: Understanding the Variables. American Medical Society for Sports Medicine 21st Annual Meeting, Atlanta, GA, April 2012.
55. **Harmon KG.** The Incidence of Sudden Cardiac Death in NCAA Athletes. Society of Teachers of Family Medicine 45th Annual Meeting. Seattle, WA, April 2012.
56. **Harmon KG.** Emerging Treatments for Overuse Injuries. 40th Annual Advances in Family Practice and Primary Care. September 2012.
57. **Harmon KG.** Causes of Sudden Cardiac Death in Athletes: Do We Have It Right?. Prevention of Sudden Cardiac Death in the Young. Seattle, WA, January 2013.
58. **Harmon KG.** Improving the Customary Pre-Participation Exam. Prevention of Sudden Cardiac Death in the Young. Seattle, WA, January 2013.
59. **Harmon KG.** Keys to Improving the Sports Physical. Parent Heart Watch 8th Annual Meeting. Seattle, WA, January 2013.
60. Drezner J, Owens D, Prutkin J, Salerno J, Pelto H, Prosser S, Ackerman D, Baker R, Batten C, Bytowski J, Courson R, Paul S, Poddar S, Reifsteck F, Skaggs G, **Harmon KG**, Rao A, O’Kane J, Hadley D, and Froelicher V. “Electrocardiographic Screening in NCAA Athletes: A Multicenter Feasibility Trial in Division I Programs.” American Medical Society for Sports Medicine 22nd Annual Meeting, San Diego, CA April, 2013.
61. Pelto H, Prutkin J, Owens D, Salerno J, **Harmon KG**, Drezner J. “Electrocardiographic Findings in Patients with Hypertrophic Cardiomyopathy: an Evaluation of the ‘Seattle Criteria’.” American Medical Society for Sports Medicine 22nd Annual Meeting, San Diego, CA April, 2013.
62. Asif I, Johnson S, Schmieg J, Toresdahl B, Pelto H, Smith T, Fairbrother J, Zakrajsek R, Fisher L, **Harmon KG**, Drezner J. “The Psychological Impact of Cardiovascular Screening: The Athlete’s Perspective.” American Medical Society for Sports Medicine 22nd Annual Meeting, San Diego, CA April, 2013.
63. **Harmon KG**, Drezner J, Lopez-Anderson M, Owens D, Maleszewski J, Ackerman M. “Etiology of Sudden Cardiac Death in NCAA Athletes.” American Medical Society for Sports Medicine 22nd Annual Meeting, San Diego, CA April, 2013.
64. Toresdahl B, Rao A, **Harmon KG**, Drezner J. “Incidence of Sudden Cardiac Arrest in High School Students and Student-Athletes.” American Medical Society for Sports Medicine 22nd Annual Meeting, San Diego, CA April, 2013.
65. Salerno J, Pelto H, Prutkin J, Owens D, **Harmon KG**, Drezner J. “Electrocardiographic Findings in Patients with Hypertrophic Cardiomyopathy: an Evaluation of the ‘Seattle Criteria’ American Medical Society for Sports Medicine 22nd Annual Meeting, San Diego, CA April, 2013.
66. **Harmon KG.** Management of Concussion in Primary Care. 41th Annual Advances in Family Practice and Primary Care. September 2013.

67. **Harmon KG**, “The Use of Platelet Rich Plasma in Musculoskeletal Injuries.” International Association Dance Medicine and Science Annual Meeting, Seattle, WA, October 2013.
68. **Harmon KG**, “The Use of Platelet Rich Plasma in the Non-surgical Management of Sports Injuries; Hype or Hope?” American Society of Hematology Annual Meeting, New Orleans, LA December 2013.
69. **Harmon KG**. “The Incidence of Sudden Cardiac Arrest in the Young.” Parent Heart Watch 9th Annual Meeting, Cary, NC, January 2014.
70. **Harmon KG**. “Sickle Cell Policies and Controversies.” American Medical Society for Sports Medicine 23rd Annual Meeting, New Orleans, LA, April 2014.
71. **Harmon KG**. “Evidence Based Perspectives on Cardiac Care and Screening.” National Athletic Trainer’s Association. Indianapolis, IN, June 2014.
72. **Harmon KG**. “Keeping Your Patients Active: Treatment of Overuse Injuries”. 42th Annual Advances in Family Practice and Primary Care. Seattle, WA. September 2014.
73. **Harmon KG**. “The Incidence of Sudden Cardiac Arrest in NCAA Athletes.” NCAA Task Force on Sudden Cardiac Death in Athletes. Indianapolis, IN. September 2014.
74. **Harmon KG**. “History, Physical and ECG: What is the Evidence? What are we Finding?” Parent Heart Watch 10th Annual Meeting. Scottsdale, AZ. January 2015.
75. **Harmon KG**. “Can We Develop a Uniform Approach to Screening?” Cardiac Safety Research Consortium Pediatric Think Tank. Federal Drug Administration. Bethesda, MD. Feb. 2015.
76. **Harmon KG**. “The Preparticipation Exam in NCAA Athletes” American Medical Society for Sports Medicine 24th Annual Meeting, Hollywood, FL, April 2015.
77. **Harmon KG**. “The Incidence and Etiology of Sudden Cardiac Death: Do We Have it Right?” American Medical Society for Sports Medicine 24th Annual Meeting, Hollywood, FL, April 2015.
78. **Harmon KG**, Zigman, ML, Drezner JA. “The Effectiveness of Screening History, Physical Exam and ECG to Detect Potentially Lethal Cardiac Disorders in Athletes: A Systematic Review/Meta-Analysis” American Medical Society for Sports Medicine 24th Annual Meeting, Hollywood, FL, April 2015.
79. **Harmon KG**. “Cardiovascular Screening in Athletes: Issues and Evidence” Pac-12 Medical Meeting, Las Vegas, NV, May 2015.
80. **Harmon, KG**. “Acute Assessment and Initial Management of Concussion” American Academy of Neurology Sports Concussion Conference” Denver, CO, July 2015.
81. **Harmon, KG**. Keynote Address. “Sudden Cardiac Death in Athletes: Prevention Strategies and Current Controversies” Corvallis, OR, August 2015.

d. International Lectures by invitation

1. **Harmon, KG**. Working as a Team Physician: Pearls and Pitfalls, International Olympic Committee Advanced Team Physician Course. Calvi, Corsica. April 2011.

2. **Harmon, KG.** Anterior Tibial Cortex Stress Fractures, International Olympic Committee Advanced Team Physician Course. Calvi, Corsica. April 2011.
3. **Harmon, KG.** Return to Play With a Defibrillator or Pacemaker, International Olympic Committee Advanced Team Physician Course. Calvi, Corsica. April 2011.
4. **Harmon, KG.** A Female Athlete With Disordered Eating – How Do You Decide Return to Play. International Olympic Committee Advanced Team Physician Course. Calvi, Corsica. April 2011.
5. **Harmon, KG.** Strengths and Limitations of Using History and Physical Examination to Identify Athletes at Risk, International Olympic Committee World Conference on Prevention of Injury and Illness in Sport, Monte-Carlo, Monaco. April 2011.
6. **Harmon, KG.** The Team Physician Experience: US Perspective. Swedish Society for Sport Medicine. Gothenburg, Sweden. May 2011.
7. **Harmon, KG.** Platelet Rich Plasma. Swedish Society for Sports Medicine. Gothenburg, Sweden. May 2011.
8. **Harmon KG,** Platelet Rich Plasma for Chronic Tendinopathy. The 2nd International Scientific Tendinopathy Symposium – Keynote Address. Vancouver, British Columbia. September 2012.
9. **Harmon KG,** Measuring Sudden Cardiac Arrest and Death Incidence in Minnesota High School Athletes: a Comparison of Methodology and Implications for Prevention Strategies. Monte Carlo, Monaco, April 2014.
10. **Harmon KG,** Asif I, Ellenbogen R, Drezner J. The Incidence of Sudden Cardiac Arrest and Death in United States High School Athletes. Monte Carlo, Monaco, April 2014.

Washington State
Health Care Authority


Agency Medical Director Comments

Autologous Blood & Platelet-rich Plasma

May 20, 2016

Shana Johnson, MD
Physical Medicine & Rehabilitation
WA – Health Care Authority

Platelet-rich Plasma & Autologous Blood




- Promise as a regenerative therapy
- Local delivery of a high dose of growth factors and other bioactive proteins

2

Washington State
Health Care Authority

Autologous Blood & Platelet-rich Plasma

Indications for PRP or ABI



- Tendinopathies**
 - Lateral epicondylitis
 - Achilles tendinopathy
 - Patellar tendinopathy
 - Rotator cuff tendinopathy
- Plantar fasciitis**
- Acute musculoskeletal injuries**
- Osteoarthritis**

3

Washington State Health Care Authority

Autologous Blood & Platelet-rich Plasma

Current State Agency Policy

- Medicaid** – Non-covered
- PEBB** – Investigational/Experimental
- Labor & Industries** – Non-covered
- Dept of Corrections** – Prior Authorization

4

Washington State Health Care Authority

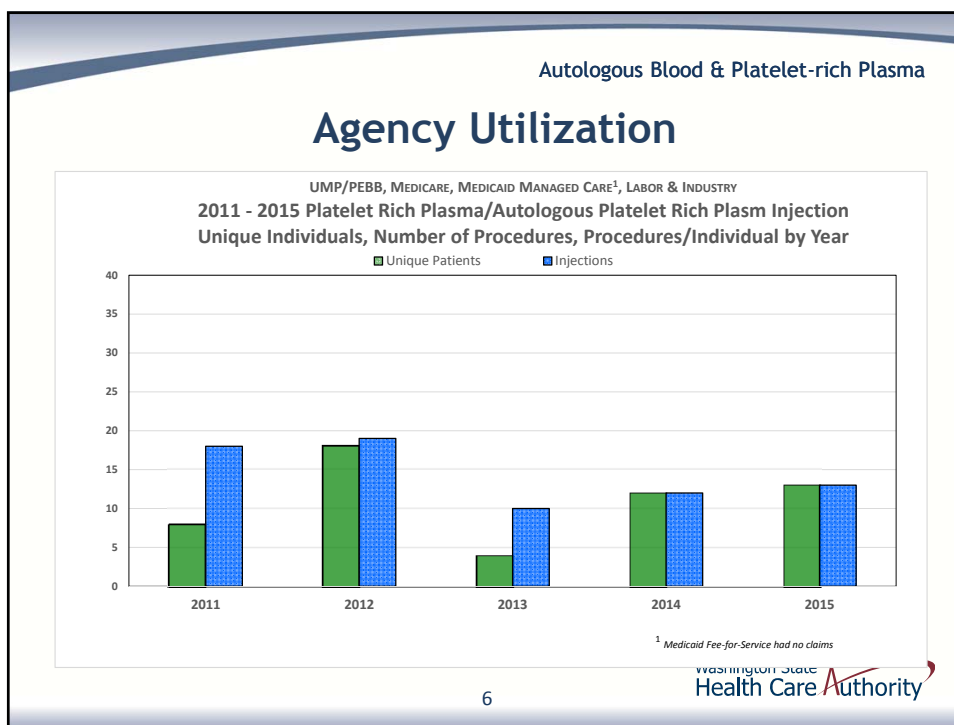
Autologous Blood & Platelet-rich Plasma

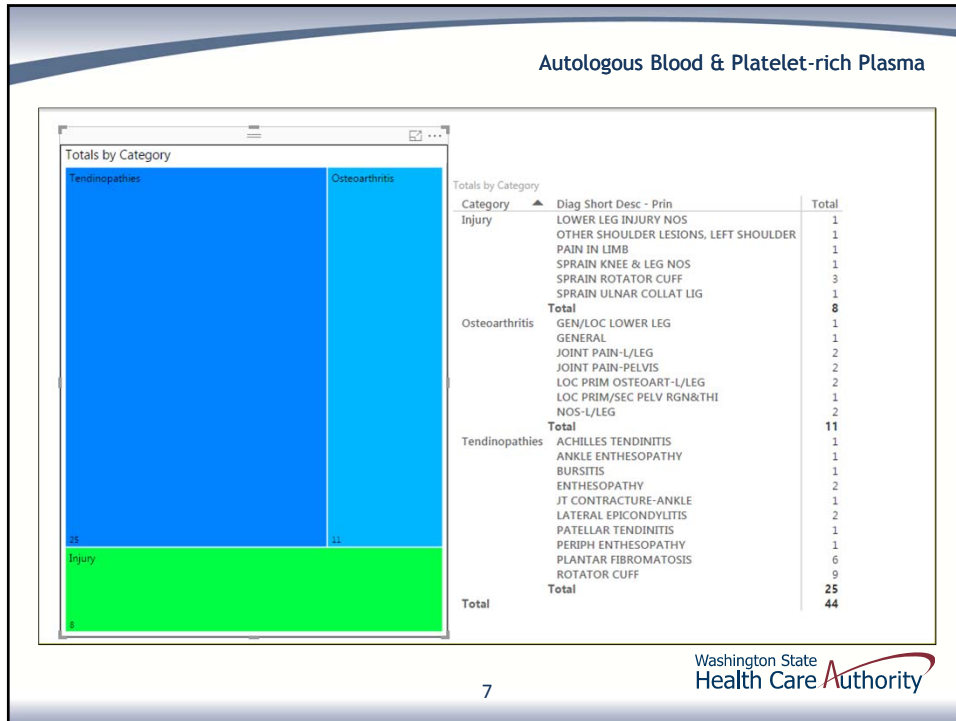
Agency Medical Director Concerns – Emerging Therapy

Safety = **Medium**
Efficacy = **Medium/ High**
Cost = **Medium**

Washington State Health Care Authority

5





Autologous Blood & Platelet-rich Plasma

Centers for Medicare and Medicaid Services (CMS)

PRP – An autologous blood-derived product – will be covered only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds.

8

Washington State Health Care Authority

Autologous Blood & Platelet-rich Plasma

Payers – Other

Aetna

- Considers autologous blood injection and platelet-rich plasma **experimental and investigational** for the treatment of tendinopathies (e.g., elbow, heel, knee, patella, and shoulder) and all other indications.

Cigna

- Does not cover the use of autologous platelet-derived growth factors (also known as PRP, platelet gel, platelet-rich concentrate, autogenous platelet gel, or platelet releasate) for ANY condition or indication because their use is considered **experimental, investigational, or unproven**

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Health Care Authority

Autologous Blood & Platelet-rich Plasma

Clinical Guidelines

Mixed recommendations. Some support use in lateral epicondylitis (4 guidelines). Other indications are not supported or not commented on.

- American College of Occupational and Environmental Medicine (2012) – Supports use for chronic lateral epicondylitis
- American Academy of Orthopaedic Surgeons (2013) – No recommendation regarding PRP use for knee OA

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Autologous Blood & Platelet-rich Plasma

Health Technology Assessments

HTAs have noted inadequate evidence of efficacy or low quality of evidence.

NICE (2013/2014)

- Evidence of efficacy inadequate for tendinopathies, plantar fasciitis, knee OA

HEALTHPACT (2013)

- Low quality evidence for knee OA

CADTH (2014)

- Insufficient evidence to guide recommendations

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Autologous Blood & Platelet-rich Plasma

Systematic Reviews

Systematic reviews have suggested benefit of PRP in knee OA

- Laudy (2014) knee OA--PRP injections more effective at improving function compared with HA and saline injections at 6 months
- Meheux (2015) knee OA--There is moderate evidence suggesting that PRP injections are more efficacious than HA and saline at improving function and pain up to 12 months post-injection (5/6 trials showed significant differences)
- Kanachanatwan (2015) Knee OA PRP was associated with better short-term (≤ 1 year) functional outcomes (WOMAC, IKDC, and EQ-VAS) than that of treatment with HA or placebo.

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Autologous Blood & Platelet-rich Plasma

Elbow Epicondylitis

Outcomes were the same or better with PRP or ABI versus control group

PRP vs Control (Anesthetic, Steroid)

- Short-term--Pain and function were similar between groups
- Intermediate term-- better with PRP (pain scores, pain success, function)
- Long-term—better with PRP (function scores, pain score, pain success)

ABI vs Control (steroid)

- Short-term—better with ABI (pain and function scores)
- Intermediate term—better with ABI (pain and function scores)

PRP vs ABI

- Short-term—better with PRP (pain and function)
- Intermediate term—better with PRP (function)

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Health Care Authority

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Autologous Blood & Platelet-rich Plasma

Knee Osteoarthritis

Only knee OA had evidence of benefit with PRP

PRP vs HA

- Short-term—no differences in pain or function
- Intermediate term—PRP better (function scores, pain success)
- Long-term—PRP better (pain and function success, function scores)

PRP vs Saline

- Short-term—better with PRP (pain and function scores)
- Intermediate-term—better with PRP (pain and function scores)
- Long-term—no data

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Autologous Blood & Platelet-rich Plasma

Agency Recommendation

PRP and ABI are Non-covered for the following conditions:

- Achilles tendinopathy
- Patellar tendinopathy
- Rotator cuff tendinosis and/or partial tear
- Plantar fasciitis
- Acute injuries
- TMJ OA
- Hip OA

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Autologous Blood & Platelet-rich Plasma

Agency Recommendation

PRP is a covered benefit under the following conditions:

1. Diagnosis of chronic lateral epicondylitis
 - a. After failure of conservative therapy
 - b. No more than one without clinically meaningful improvement in pain and function
 - c. Maximum of one in one year
2. Diagnosis knee osteoarthritis
 - a. After failure of conservative therapy
 - b. No more than three without clinically meaningful improvement in pain and function
 - c. Maximum of three in one year

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Autologous Blood & Platelet-rich Plasma

Questions?

More Information
www.hca.wa.gov/hta/Pages/Platelet-rich_Plasma.aspx

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Order of Scheduled Presentations:

Autologous Blood/ Platelet-rich Plasma Injections

Name	
1	
2	
3	

No requests to provide public comment on the technology review were received.

Autologous Blood or Platelet-Rich Plasma Injections

May 20, 2016

Prepared by:

Robin Hashimoto, PhD
Andrea C. Skelly, PhD, MPH
Erika Brodt, BS

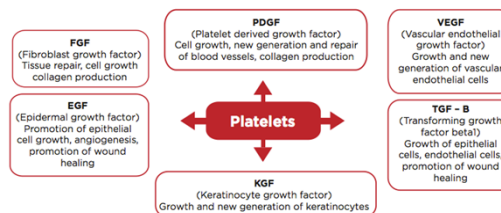


Image source: http://www.physiciansrehabilitation.com/platelet_rich_plasma.html

1

Background

- Platelet Rich Plasma (PRP) Injections & Autologous Blood Injections (ABI)
 - Both blood products are autologous
 - Both introduce growth factor-rich platelets to site of injury
 - PRP contains a supraphysiological concentration of platelets
 - Platelets contain over 30 growth factors that stimulate healing by recruiting stem cells and inducing cell proliferation, cell differentiation, and extracellular matrix formation





<http://cnmhealth.com/2015/11/11/collagen-induction-therapy/>

2

Indications for PRP and/or ABI (in included studies)

- Tendinopathies
 - Tennis elbow (lateral epicondylitis)
 - Achilles tendinopathy
 - Patellar tendinopathy
 - Rotator cuff tendinopathy
- Plantar fasciitis
- Traumatic musculoskeletal injuries
 - Acute local muscle injury
 - Ankle sprain
 - Osteochondral lesions to the talus
 - Achilles tendon rupture
 - Temporomandibular joint (TMJ) dislocation
- Osteoarthritis
 - Knee
 - Hip
 - TMJ
- Low back pain:
 - no studies met inclusion criteria





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Image source: <http://www.painmanagementworks.com/accelerate-your-bodys-natural-healing-with-platelet-rich-plasma-therapy-prp/>

3

PRP injection procedure

PROCESS OF PRP THERAPY

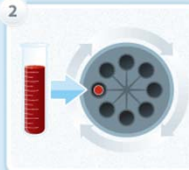
1



Collect blood

9-60ml of blood is drawn from the patient's arm.

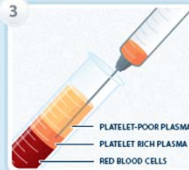
2



Separate the platelets

The blood is then placed in a centrifuge. The centrifuge spins and separates the platelets from the rest of the blood components.

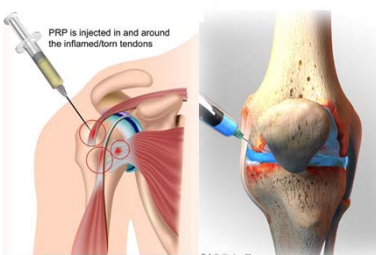
3




Extract platelet-rich plasma

Extract 3-6ml of platelet-rich plasma.

www.stemcellorthopedic.com





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4

Key Questions

1. What is the evidence of the short- and long-term **efficacy and effectiveness** of autologous PRP or whole blood injections compared with alternative treatment options or no treatment/placebo?
2. What is the evidence regarding short- and long-term **harms and complications** of autologous PRP or whole blood injections compared with alternative treatment options or no treatment/placebo?
3. Is there evidence of **differential efficacy, effectiveness, or safety** of autologous PRP or whole blood injections compared with alternative treatment options no treatment/placebo? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation?
4. What is the evidence of **cost-effectiveness** of autologous PRP or whole blood injections compared with alternative treatment options?



5

Inclusion Criteria

- Population:
 - Patients with musculoskeletal soft tissue injuries, tendinopathies, osteoarthritis, or low back pain.
 - (skin wounds, bone fractures, maxillofacial surgery, dental conditions were excluded)
- Intervention:
 - Autologous PRP or whole blood injections
 - (injections used in conjunction with other procedures such as surgery were excluded)
- Comparators:
 - Alternative treatment(s), placebo, or no treatment



6

Comparators in included studies

- Conservative
 - Dry needling/ peppering
 - Corticosteroid and/or anesthetic injection
 - Saline injection
 - Hyaluronic acid (HA) injection
 - Dextrose prolotherapy injections
 - Exercise
 - Extracorporeal shock wave therapy (ESWT)
 - Low level laser therapy
 - Transcutaneous electrical nerve stimulation (TENS)
- Surgery



7

Inclusion Criteria

- Outcomes:
 - Primary outcomes:
 - Function
 - functional success (% patients)
 - function outcome measure scores
 - Pain
 - pain success (% patients)
 - pain outcome measure scores
 - Harms or complications
 - Secondary outcomes:
 - Time to recovery, return to normal activities (sports, work, or activity level), quality of life, patient satisfaction, recurrence, medication use, secondary procedures (e.g., surgery)
 - (Non-clinical outcomes were excluded)
 - Follow-up definitions:
 - Short-term: ≤ 3 months
 - Intermediate-term: >3 to <12 months
 - ≥ 12 months



8

Inclusion Criteria

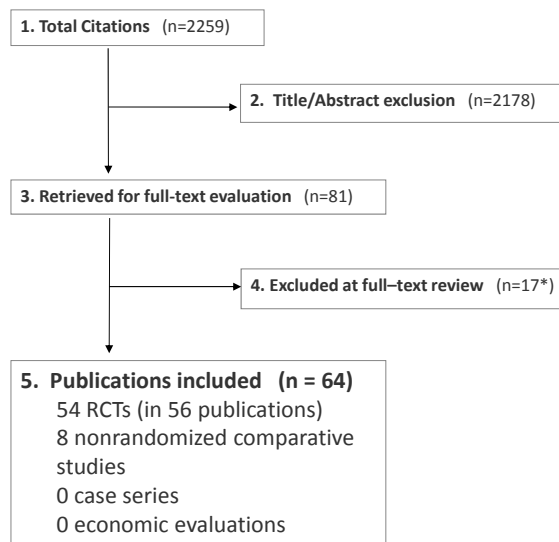
- Study design:

- **Focus was on studies with the least potential for bias.**
- **KQ1** (efficacy, effectiveness)
 - RCTs
 - Nonrandomized comparative (cohort) studies
- **KQ2** (safety)
 - RCTs
 - Nonrandomized comparative (cohort) studies
 - Case series specifically designed to evaluate harms with $N \geq 100$
- **KQ3** (differential efficacy and safety)
 - RCTs that stratified results for both treatment groups by patient characteristics of interest, e.g.:
- **KQ4** (cost)
 - Formal economic analyses:
 - Cost-effectiveness, cost-utility, cost-minimization, or cost-benefit studies

Pain success	PRP	Steroid
Male	75% (75/100)	60% (60/100)
Female	80% (80/100)	75% (75/100)



Literature Search



Search period: through November 23, 2015

Strength of Evidence (SoE)

- SoE for the overall body of evidence for primary outcomes was assessed based on the following domains:
 - **Risk of bias:** the extent to which the included studies have protection against bias
 - Appropriate randomization
 - Allocation concealment
 - Intention to treat analysis
 - Blind assessment of outcomes
 - Co-interventions applied equally
 - Adequate follow-up ($\geq 80\%$) and similar % follow-up between groups ($< 10\%$ difference)
 - Controlling for confounding
 - **Consistency:** the degree to which the included studies report results that are similar in terms of range and variability.
 - **Directness:** describes whether the evidence is directly related to patient health outcomes.
 - **Precision:** describes the level of certainty surrounding the effect estimates.
 - **Publication bias:** is considered when there is concern of selective publishing.



Overall Strength of Evidence (GRADE)

Quality rating	Interpretation
High	High confidence that the evidence reflects the true effect.
Moderate	Moderate confidence in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Insufficient	Very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of the effect.



KQ1: Efficacy and Effectiveness

Tendinopathies
Plantar Fasciitis
Acute Injuries
Osteoarthritis



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Tendinopathies


Tennis Elbow
Achilles Tendinopathy
Patellar Tendinopathy
Rotator Cuff Tendinosis and/or Partial Tears



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Tennis Elbow: PRP vs. ABI (1 of 4 slides)

- Evidence base: 4 RCTs
 - N=28-150 per trial
- Minimum symptom duration: 3-6 months
 - 3 months: 3 RCTs
 - 6 months: 1 RCT
- Number of injections: 1-2
 - Single injection: 3 RCTs
 - 2 injections: 1 RCT

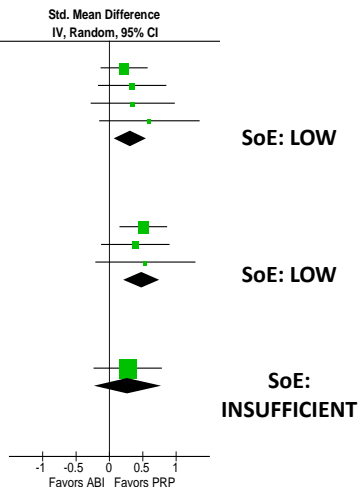



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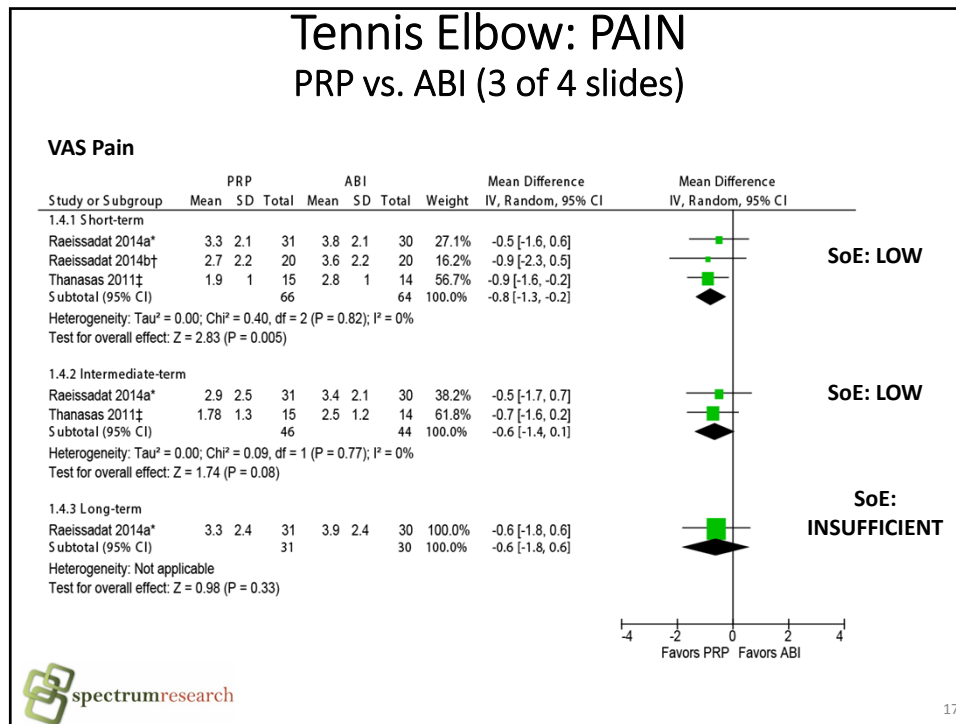
Tennis Elbow: FUNCTION PRP vs. ABI (2 of 4 slides)

Study or Subgroup	PRP			ABI			Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI	
	Mean	SD	Total	Mean	SD	Total				
1.3.1 Short-term										
Creaney 2011†§	-33	20.5	70	-37.7	21.9	60	50.3%	0.22 [-0.13, 0.57]		
Raeissadat 2014a*	79.5	12	31	75	14	30	23.5%	0.34 [-0.16, 0.85]		
Raeissadat 2014b†	82.4	12.3	20	77.2	16.5	20	15.4%	0.35 [-0.27, 0.98]		
Thanasas 2011‡	9.2	0.9	15	8.7	0.7	14	10.8%	0.60 [-0.15, 1.35]		
Subtotal (95% CI)			136			124	100.0%	0.31 [0.06, 0.56]		SoE: LOW
Heterogeneity: Tau ² = 0.00; Chi ² = 0.86, df = 3 (P = 0.83); I ² = 0%										
Test for overall effect: Z = 2.48 (P = 0.01)										
1.3.2 Intermediate-term										
Creaney 2011†§	-35.8	23.7	70	-46.8	18.6	60	58.8%	0.51 [0.16, 0.86]		
Raeissadat 2014a*	81.2	16	31	74.9	16	30	28.1%	0.39 [-0.12, 0.90]		
Thanasas 2011‡	9.3	0.5	15	8.9	0.9	14	13.1%	0.54 [-0.20, 1.28]		
Subtotal (95% CI)			116			104	100.0%	0.48 [0.21, 0.75]		SoE: LOW
Heterogeneity: Tau ² = 0.00; Chi ² = 0.17, df = 2 (P = 0.92); I ² = 0%										
Test for overall effect: Z = 3.49 (P = 0.0005)										
1.3.3 Long-term										
Raeissadat 2014a*	78.2	18	31	73.2	18	30	100.0%	0.27 [-0.23, 0.78]		
Subtotal (95% CI)			31			30	100.0%	0.27 [-0.23, 0.78]		SoE: INSUFFICIENT
Heterogeneity: Not applicable										
Test for overall effect: Z = 1.07 (P = 0.29)										

Outcome measures reported:
 -Creaney: Inverse of ΔPRTEE (thus PRTEE (0-100 (best)))
 -Raeissadat 2014a, 2014b: MMCPJE (0-100 (best))
 -Thanasas: Liverpool elbow score (0-10 (best))


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- ### Tennis Elbow: PRP vs. ABI (4 of 4 slides)
- Insufficient evidence:
 - Pain success: no difference between groups (short-, intermediate-, and long-term)
 - No evidence:
 - Function success
 - Secondary outcomes:
 - No difference between groups
 - Surgery (intermediate-term): 1 RCT
 - Composite of function success and no surgery (intermediate-term): 1 RCT
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Tennis Elbow: PRP vs. Control (1 of 10 slides)


- Evidence base: 8 RCTs + 2 cohort studies
 - N=25-240 per RCT
- Control group:
 - Steroid injections: 5 RCTs
 - Anesthetic injections: 2 RCTs
 - Dry needling: 1 RCT (compared PRP + DN vs. DN)
- Minimum symptom duration: 1.5-6 months
 - 1.5 months: 1 RCT
 - 3 months: 3 RCTs
 - 6 months: 3 RCTs
- Number of injections: 1-2
 - Single injection: 5 RCTs
 - 2 injections: 1 RCT



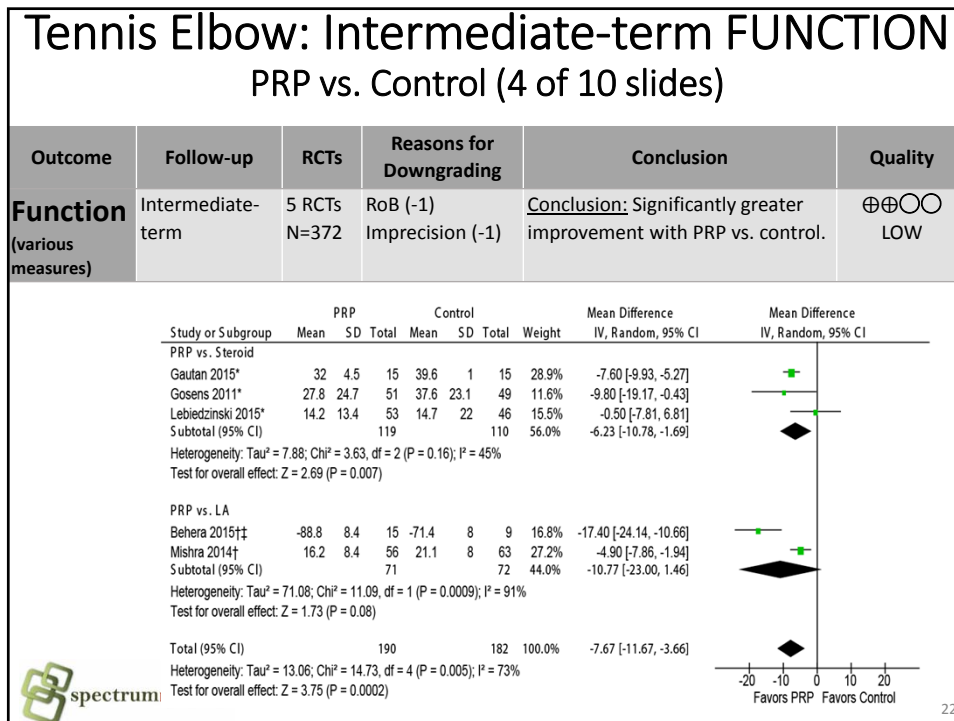
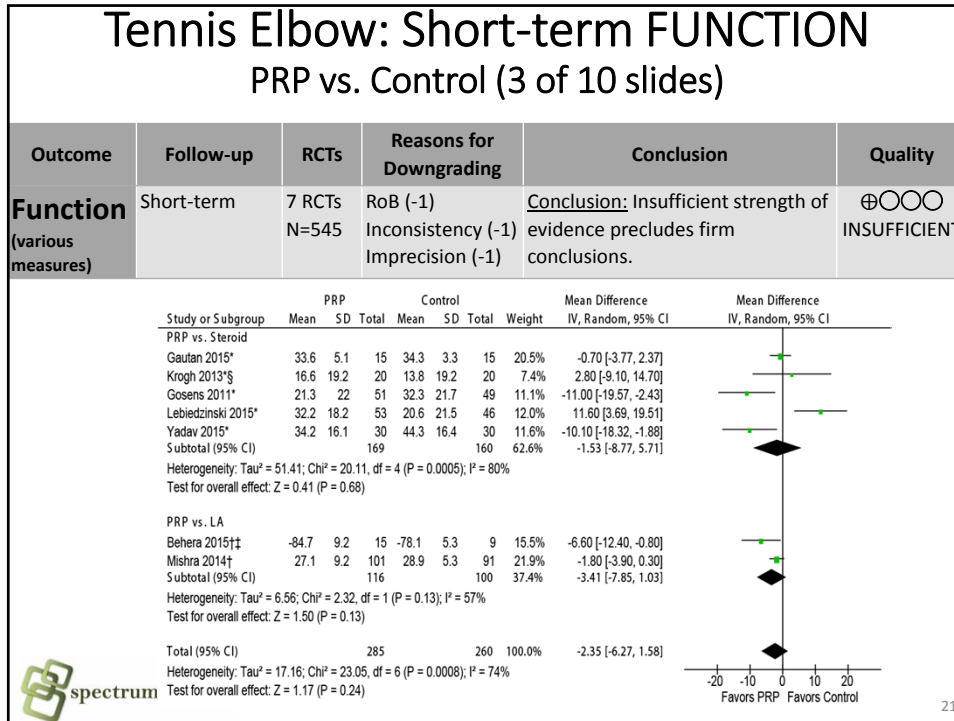
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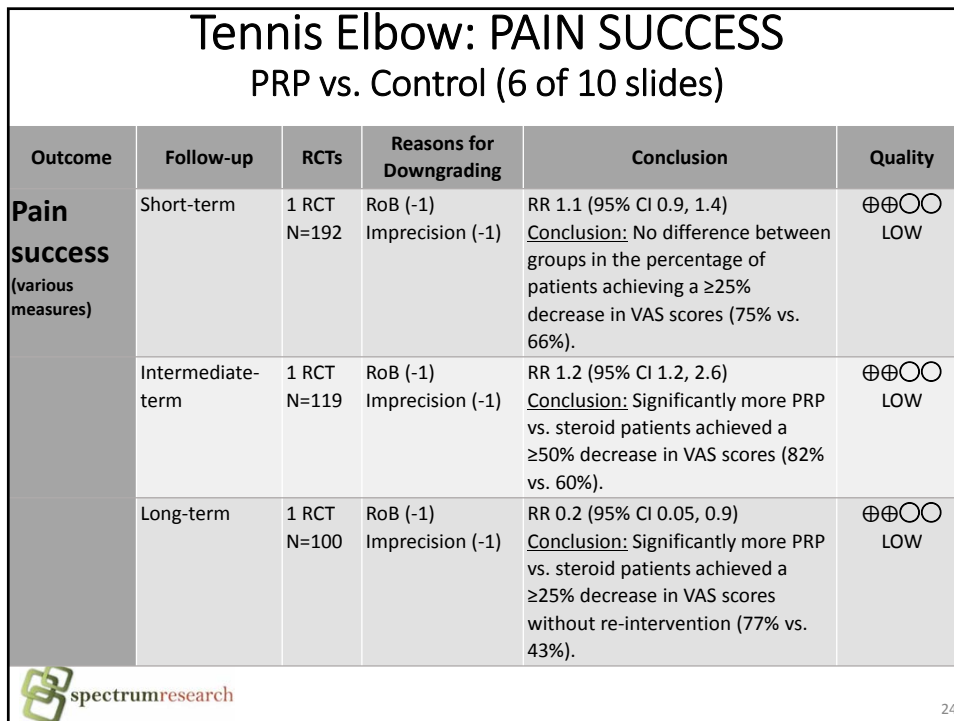
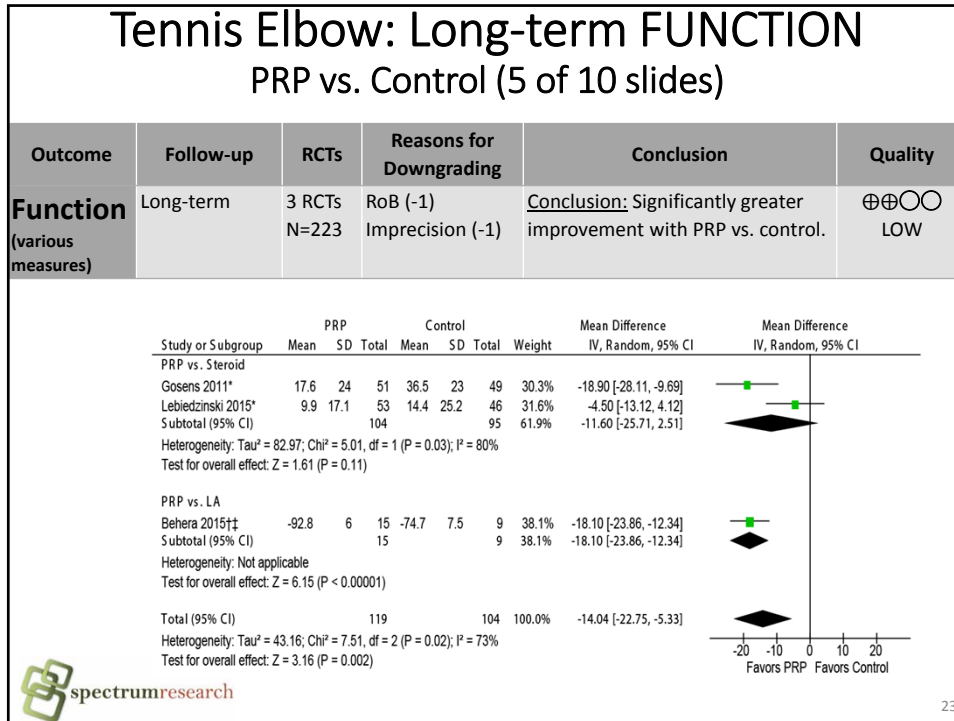
Tennis Elbow: FUNCTION SUCCESS PRP vs. Control (2 of 10 slides)

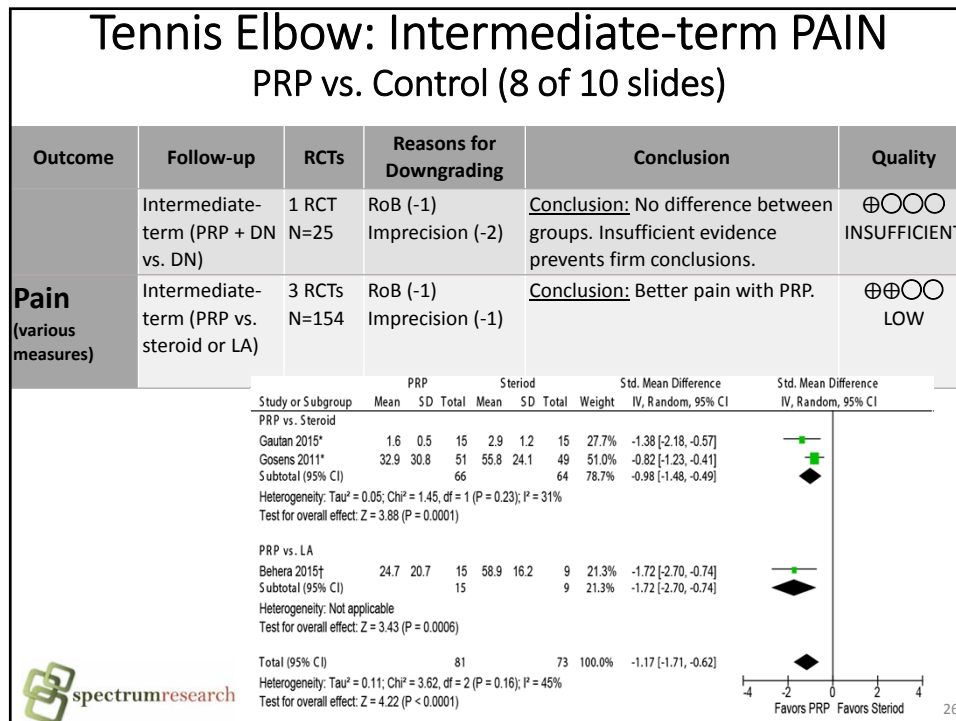
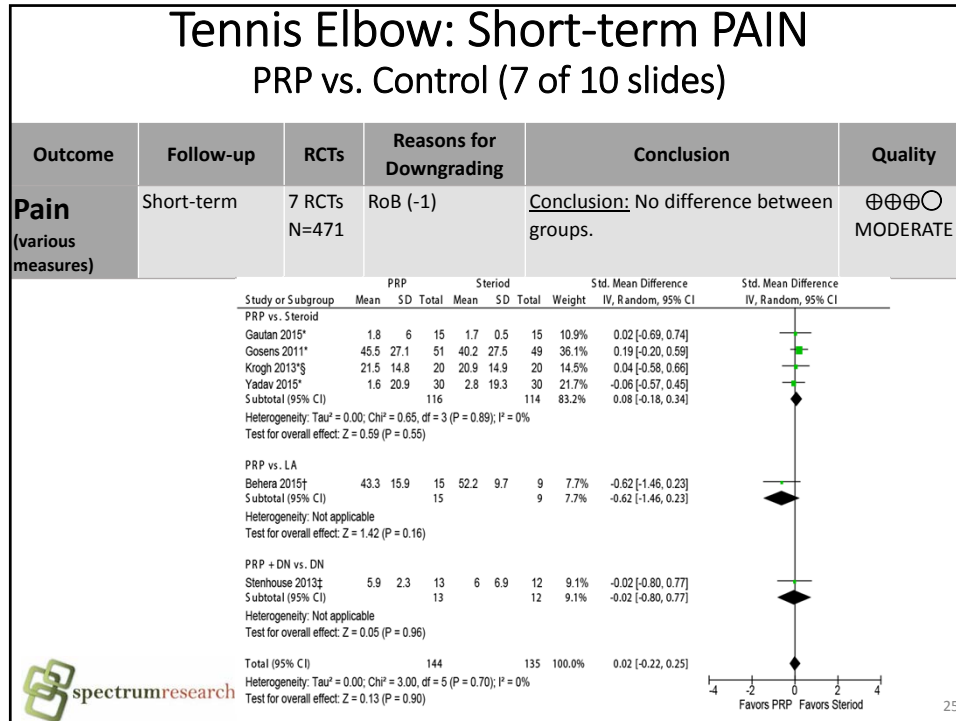
Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Function success (various measures)	Short-term	1 RCT N=99	RoB (-1) Imprecision (-1)	RR 1.0 (95% CI 0.7, 1.4) <u>Conclusion:</u> No difference between PRP and steroid groups.	⊕⊕○○ LOW
	Intermediate-term	1 RCT N=99	RoB (-1) Imprecision (-1)	RR 1.0 (95% CI 0.8, 1.3) <u>Conclusion:</u> No difference between PRP and steroid groups.	⊕⊕○○ LOW
	Long-term	2 RCTs N=199	RoB (-1) Inconsistency (-1) Imprecision (-1)	<u>Conclusion:</u> Insufficient results preclude firm conclusions.	⊕○○○ INSUFFICIENT

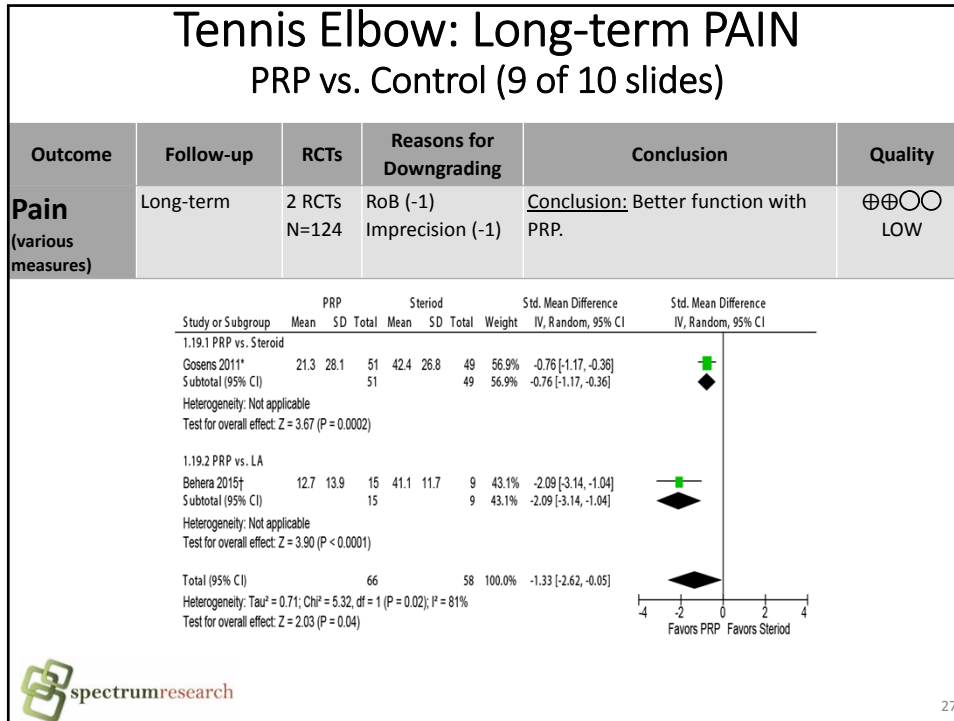


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- ### Tennis Elbow: Secondary Outcomes PRP vs. Control (10 of 10 slides)
- Secondary outcomes:
 - Full recovery/no symptoms
 - Short-, intermediate-, long-term: Worse outcome with PRP vs. steroid (1 RCT)
 - Additional procedures
 - Long-term: Better outcome with PRP vs. steroid (1 RCT)
-
- spectrumresearch 28

Tennis Elbow: ABI vs. Control (1 of 4 slides)

- Evidence base: 3 RCTs + 3 quasi-RCTs
 - N=50-80 per trial
- Control group:
 - Steroid injections: 6 trials
 - ESWT: 1 trial (trial had 2 control groups)
- Minimum symptom duration:
 - 6 months: 1 trial
 - (Mean symptom duration ranged from 1-10 months)
- Number of injections:
 - Single injection: 1 RCT



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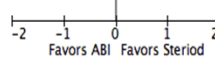
Tennis Elbow: FUNCTION ABI vs. Control (2 of 4 slides)

Study or Subgroup	ABI		Steroid		Total	Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI	
	Mean	SD	Mean	SD					
1.11.1 Short-term									
Arik 2014*	19.4	9.1	40	34.5	17.5	40	27.0%	-1.07 [-1.54, -0.60]	
Singh 2013*	14.86	3.48	30	20.2	9.88	30	25.7%	-0.71 [-1.23, -0.19]	
Kazemi 2010†	6.9	12.6	30	32.4	19.4	30	24.3%	-1.54 [-2.12, -0.96]	
Ozturan 2010‡	19.5	12	18	20.6	6.88	20	23.0%	-0.11 [-0.75, 0.53]	
Subtotal (95% CI)			118			120	100.0%	-0.87 [-1.41, -0.33]	
Heterogeneity: Tau ² = 0.22; Chi ² = 11.54, df = 3 (P = 0.009); I ² = 74%									
Test for overall effect: Z = 3.18 (P = 0.001)									
1.11.2 Intermediate-term									
Ozturan 2010‡	20.7	8.87	18	27.1	7.67	20	100.0%	-0.76 [-1.42, -0.10]	
Subtotal (95% CI)			18			20	100.0%	-0.76 [-1.42, -0.10]	
Heterogeneity: Not applicable									
Test for overall effect: Z = 2.25 (P = 0.02)									
1.11.3 Long-term									
Ozturan 2010‡	18.6	10.16	18	27.5	8.48	20	100.0%	-0.94 [-1.61, -0.26]	
Subtotal (95% CI)			18			20	100.0%	-0.94 [-1.61, -0.26]	
Heterogeneity: Not applicable									
Test for overall effect: Z = 2.72 (P = 0.007)									

*PRTEE (0-100 (worst))

†Quick DASH (0-100 (worst))

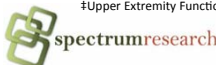
‡Upper Extremity Functional Scale (8-80 (worst))



SoE: LOW

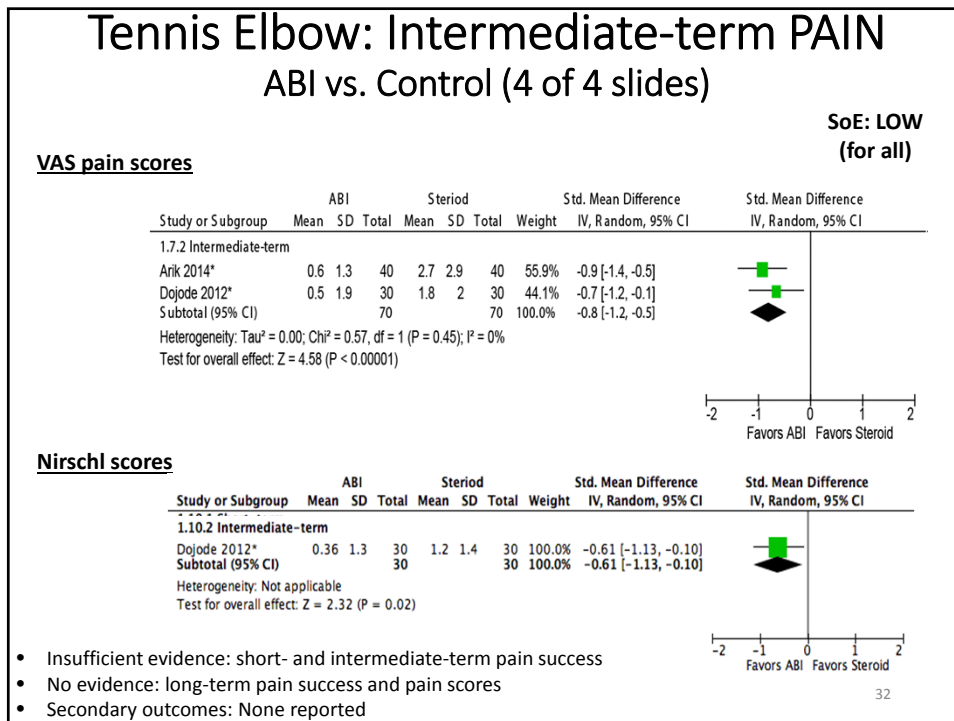
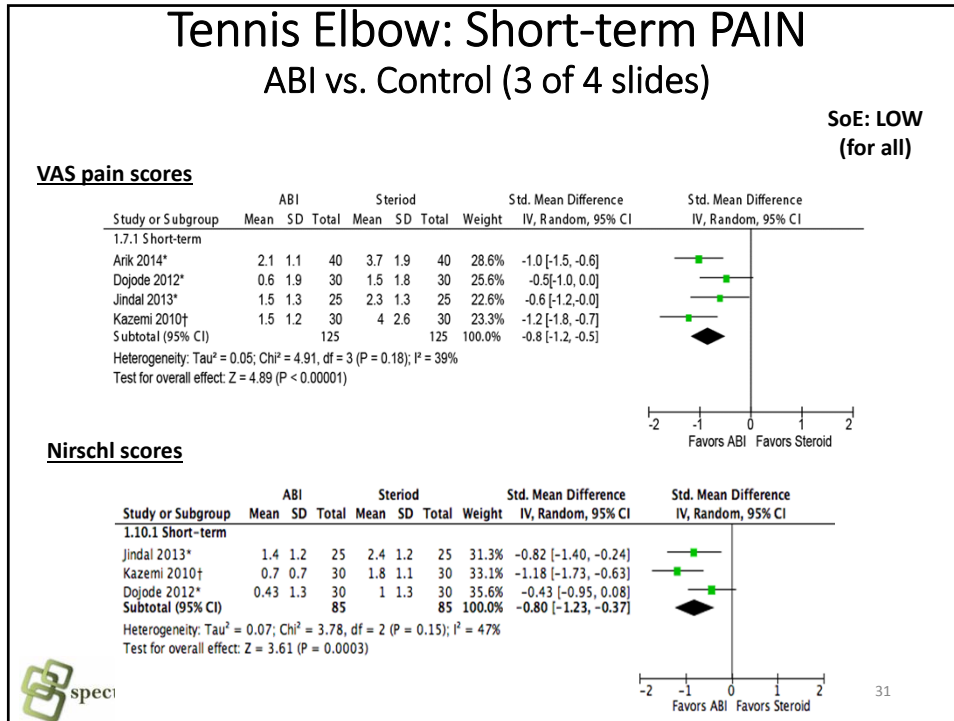
SoE: INSUFFICIENT

SoE: INSUFFICIENT



- No evidence: Function success

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Summary: Tennis Elbow

- In general, outcomes were the same or better with PRP or ABI versus control groups.
 - PRP vs. ABI: Short-term benefit with PRP for pain and function (Low SoE), and in intermediate-term function (but no difference in pain) (Low SoE for all).
 - PRP vs. Control: Although pain and function (scores and success) were similar between groups in the short-term (insufficient to moderate SoE), by the intermediate-term they were better with PRP (pain scores & success, function) (but no difference in function success) (Low SoE). Long-term function scores and pain scores & success was better with PRP (Low SoE).
 - ABI vs. Control: Better short-term results with ABI with respect to pain and function scores, and similar results were seen for pain scores in the intermediate-term (Low SoE for all).



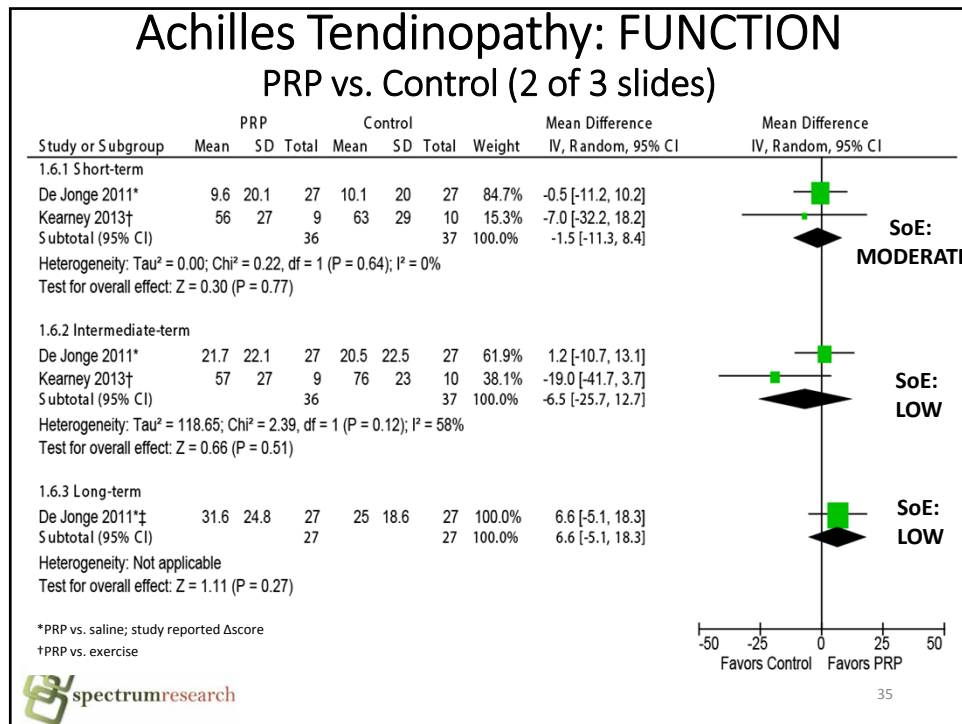
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Achilles Tendinopathy: PRP vs. Control (1 of 3 slides)

- Evidence base: 2 RCTs
 - N=20-54 per trial
- Control group:
 - Saline injection: 1 RCT
 - Exercise: 1 RCT
- Minimum symptom duration: 2-3 months
- Number of injections: not reported




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- ### Achilles Tendinopathy: PRP vs. Control (3 of 3 slides)
- No evidence:
 - Pain
 - Pain success
 - Function success
 - Secondary outcomes:
 - No difference between groups
 - HR-QoL (short-, intermediate-term): 1 RCT, PRP vs. exercise
 - Overall health state (short-, intermediate-term): 1 RCT, PRP vs. exercise
 - Return to sport (short-, intermediate-, long-term): 1 RCT, PRP vs. saline
 - Patient satisfaction (short-, intermediate-, long-term): 1 RCT, PRP vs. saline
 - Secondary procedures (intermediate-term): 1 RCT, PRP vs. saline
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Achilles Tendinopathy: ABI vs. Control (1 of 2 slides)

- Evidence base: 2 RCTs
 - N=40 tendons-53 patients per trial
- Control group:
 - Exercise: 1 RCT (compared ABI + exercise vs. exercise alone)
 - Dry needling: 1 RCT
- Minimum symptom duration: 3 months
- Number of injections: 1-2

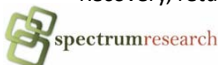


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Achilles Tendinopathy: ABI vs. Control (2 of 2 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Function (VISA-A (0-100 (best)))	Short-term (ABI vs. exercise)	1 RCT 28 tendons	RoB (-1), Imprecision (-2)	MD 9.3 (95% CI 2.1, 16.5) <u>Conclusion:</u> Greater improvement with ABI; insufficient strength of evidence prevents firm conclusion.	⊕○○○ INSUFFICIENT
	Short-term (ABI vs. DN)	1 RCT N=50	RoB (-1), Imprecision (-2)	MD 0.3 (95% CI -8.1, 8.7) <u>Conclusion:</u> No difference between groups; insufficient strength of evidence prevents firm conclusion.	⊕○○○ INSUFFICIENT
	Intermediate-term	1 RCT N=50	RoB (-1), Imprecision ^{3,4} (-2)	MD -1.2 (95% CI -10.2, 7.8) <u>Conclusion:</u> Insufficient strength of evidence prevents firm conclusion	⊕○○○ INSUFFICIENT

- No evidence: Function success, Pain success, Pain, long-term Function
- Secondary outcomes: no differences between groups in any outcome
 - Recovery, return to sport (intermediate-term): 1 RCT, ABI vs. DN




Comparators:
Bell: ABI vs. dry needling
Pearson: ABI + exercise vs. exercise

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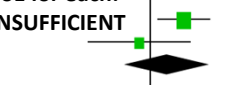
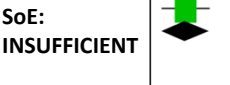
Patellar Tendinopathy: PRP vs. Control (1 of 4 slides)

- Evidence base: 2 RCTs
 - N=20-46 per trial
- Control group:
 - Extracorporeal shock wave therapy: 1 RCT Dry needling: 1 RCT (compared PRP + DN vs. DN alone)
- Minimum symptom duration: 1.5-6 months
- Number of injections: 1-2




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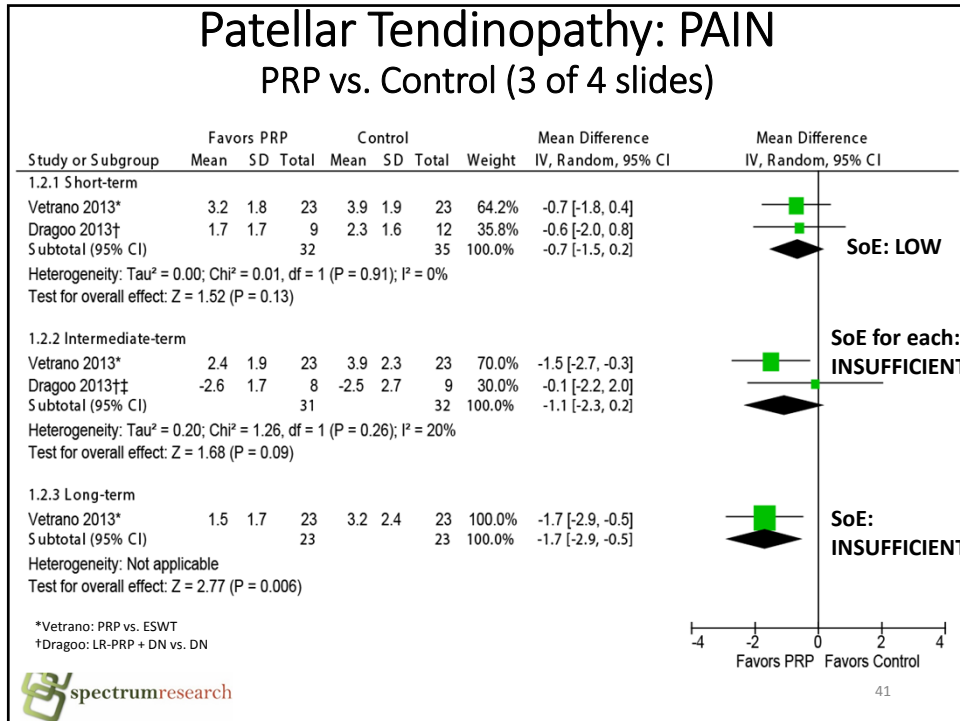
Patellar Tendinopathy: FUNCTION PRP vs. Control (2 of 4 slides)

Study or Subgroup	PRP			Control			Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
1.1.1 Short-term									
Vetrano 2013*	76.2	16.5	23	71.3	19.1	23	74.2%	4.9 [-5.4, 15.2]	 <p>SoE: LOW</p>
Dragoo 2013†	66.4	20.2	9	52	20.3	12	25.8%	14.4 [-3.1, 31.9]	
Subtotal (95% CI)			32			35	100.0%	7.4 [-1.5, 16.2]	
Heterogeneity: Tau ² = 0.00; Chi ² = 0.84, df = 1 (P = 0.36); I ² = 0%									
Test for overall effect: Z = 1.62 (P = 0.10)									
1.1.2 Intermediate-term									
Vetrano 2013*	86.7	14.2	23	73.7	19.9	23	62.6%	13.0 [3.0, 23.0]	 <p>SoE for each: INSUFFICIENT</p>
Dragoo 2013†	28.9	25.2	8	33.2	14	9	37.4%	-4.3 [-24.0, 15.4]	
Subtotal (95% CI)			31			32	100.0%	6.5 [-9.9, 22.9]	
Heterogeneity: Tau ² = 86.07; Chi ² = 2.35, df = 1 (P = 0.12); I ² = 58%									
Test for overall effect: Z = 0.78 (P = 0.44)									
1.1.3 Long-term									
Vetrano 2013*	91.3	9.9	23	77.6	19.9	23	100.0%	13.7 [4.6, 22.8]	 <p>SoE: INSUFFICIENT</p>
Subtotal (95% CI)			23			23	100.0%	13.7 [4.6, 22.8]	
Heterogeneity: Not applicable									
Test for overall effect: Z = 2.96 (P = 0.003)									

*Vetrano: PRP vs. ESWT
†Dragoo: LR-PRP + DN vs. DN




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- ### Patellar Tendinopathy: PRP vs. Control (4 of 4 slides)
- No evidence:
 - Function success
 - Pain success
 - Secondary outcomes
 - HR-QoL (1 RCT, PRP vs. ESWT):
 - No difference (short-, intermediate-term)
 - Pain during sports (1 RCT, PRP vs. dry needling):
 - No difference (short-, intermediate-term)
 - Better outcome with PRP (long-term)
-
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Rotator Cuff Tendinosis and/or Partial Tear: PRP vs. Control (1 of 2 slides)

- Evidence base: 2 RCTs + 1 retrospective cohort study
 - N=39-40 per RCT
- Control group:
 - Saline injection: 1 RCT
 - Dry needling: 1 RCT (compared PRP + DN vs. DN alone)
- Minimum symptom duration: 3-6 months
- Number of injections: 2 (reported by 1 RCT only)



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Rotator Cuff Tendinosis and/or Partial Tear: PRP vs. Control (2 of 2 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Function SPADI (0-100)	Short-term	2 RCTs N=72	Imprecision (-1)	<ul style="list-style-type: none"> • MD -13.5 (95% CI -24.8, -2.2) (Rha) • Median 27.6 vs. 45.3, p=NS (Kesikburun) Conclusion: Greater functional improvement with PRP vs. control.	⊕⊕⊕○ MODERATE
	Intermediate-term	2 RCTs N=72	Imprecision (-1)	<ul style="list-style-type: none"> • MD -11.8 (95% CI -22.5, -1.1) (Rha) • Median 21.7 vs. 40.9, p=NS (Kesikburun) Conclusion: Greater functional improvement with PRP vs. control.	⊕⊕⊕○ MODERATE
	Long-term	1 RCT N=40	Imprecision (-2)	Median 14.6 vs. 15.4, p=NS Conclusion: No difference between groups.	⊕⊕○○ LOW

Insufficient evidence: Short- and intermediate-term pain
 No evidence: Function success, Pain success, Pain, long-term Function, long-term Pain
 Secondary outcomes: no differences between groups in any outcome

- Recovery, return to sport (intermediate-term): 1 RCT, ABI vs. DN

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Summaries

- Rotator Cuff Tendinosis and/or Partial Tears:
 - PRP vs. Control: Better function with PRP in the short- and intermediate-term (moderate SoE), but no difference by long-term (low SoE).
- Achilles Tendinopathy
 - PRP vs. Control: no differences between groups in function in the short-term (moderate SoE), or intermediate- or long-term (low SoE).
- Patellar Tendinopathy
 - PRP vs. Control: no differences between groups in pain or function in the short-term (low SoE).

Plantar Fasciitis

Plantar Fasciitis: PRP vs. Control (1 of 3 slides)


- Evidence base: 5 RCTs + 3 prospective cohort study
 - N=21-60 per RCT
- Control group:
 - Steroid injection: 3 RCT
 - Prolotherapy: 1 RCT (compared PRP + DN vs. DN alone)
 - ESWT or conservative care: 1 RCT (two control groups)
- Minimum symptom duration: 4-12 months
 - 4 months: 2 RCTs
 - 6 months: 1 RCT
 - 12 months: 1 RCT
- Number of injections: 1-2



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Plantar Fasciitis: PRP vs. Control (2 of 3 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Function (various measures)	Short-, intermediate-term	4 RCTs N=134	RoB (-1) Imprecision (-1)	<u>Conclusion:</u> No difference between groups: <ul style="list-style-type: none"> • 3 RCTs (N=94): no difference • 1 RCT (N=40): better outcome with PRP vs. steroid (Monto) 	⊕⊕○○ LOW
	Long-term	2 RCTs N=86	RoB (-1) Imprecision (-1)	<u>Conclusion:</u> Significantly greater improvement with PRP vs. steroid as evaluated by the AOFAS Ankle and Hindfoot scale: <ul style="list-style-type: none"> • MD 13.4 (95% CI 4.6, 22.3), 1 RCT (N=46, 60 heels) (Jain) • Median: 92 vs. 56 MD NR/NC†, p<0.01‡, 1 RCT (N=40) (Monto) 	⊕⊕○○ LOW



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Plantar Fasciitis: PRP vs. Control (3 of 3 slides)


Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Pain VAS (0-100)	Short-, intermediate-term	4 RCTs N=174	RoB (-1) Imprecision (-1)	<u>Conclusion:</u> No difference between groups: <ul style="list-style-type: none"> 3 RCTs (N=114): no difference 1 RCT (N=60): better outcome with PRP vs. steroid (Tiwari) 	⊕⊕○○ LOW

- Insufficient evidence:
 - Long-term function success
 - Long-term pain
- No evidence:
 - Short-, intermediate-term function success, Pain success, Pain, long-term Function, long-term Pain
- Secondary outcomes:
 - Symptoms (1 RCT, PRP vs. steroid):
 - No difference between groups (short-, intermediate-term)
 - Better outcome with PRP (long-term)
 - Disability (1 RCT, PRP vs. prolotherapy):
 - No difference between groups (short-, intermediate-term)

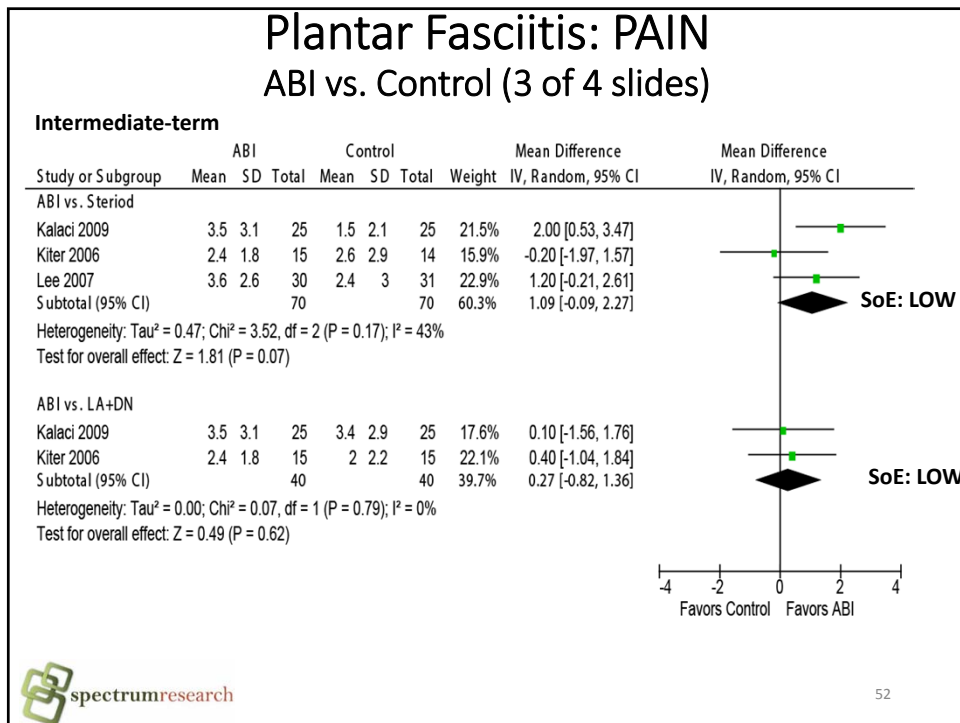
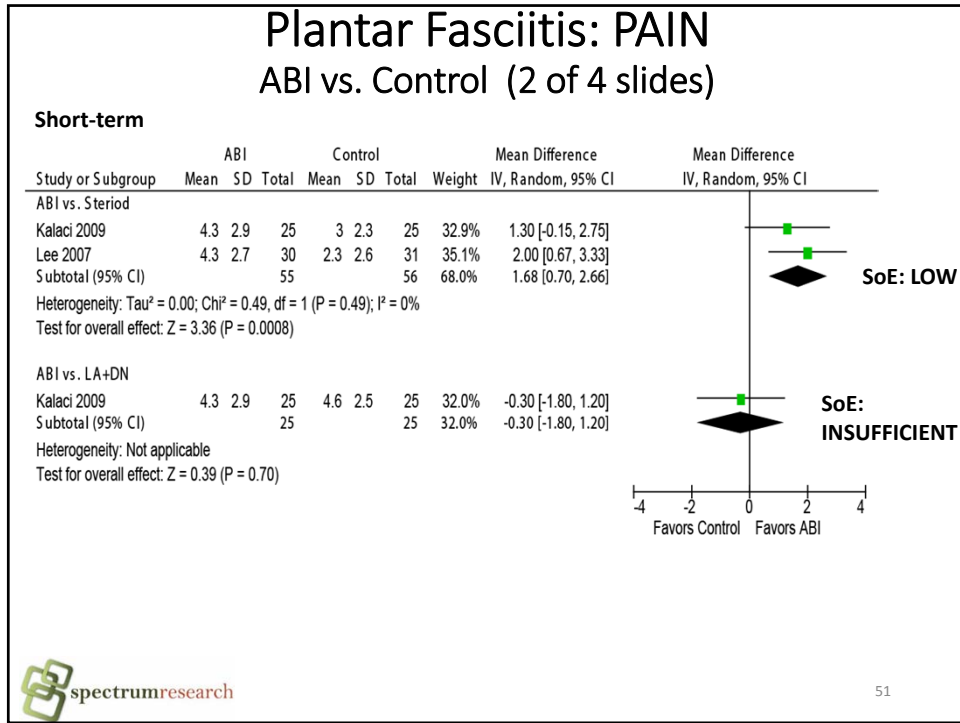
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Plantar Fasciitis ABI vs. Control (1 of 4 slides)

- Evidence base: 3 RCTs
 - N=44-75 per RCT
- Control group:
 - Steroid injection: 3 RCTs
 - Anesthetic injection + dry needling: 2 RCTs (two control groups)
- Minimum symptom duration: 6 months (reported by 2 studies)
- Number of injections: ≤3 (reported by 1 study)



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Plantar Fasciitis: ABI vs. Control (4 of 4 slides)

- Insufficient evidence:
 - Function (intermediate-term)
- No evidence:
 - Function (short-, long-term)
 - Function success
 - Pain success
- Secondary outcomes:
 - Symptoms:
 - No difference (intermediate-term): 1 RCT, ABI vs. steroid, ABI vs. anesthetic + dry needling (2 comparisons)
 - Repeat injections:
 - No difference between groups (short-term) (1 RCT, ABI vs. steroid)
 - Mixed results (intermediate-term) (1 RCT, 2 comparisons):
 - Worse outcome with ABI vs. steroid patients
 - No difference between ABI and anesthetic + dry needling



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Summary


- Plantar Fasciitis
 - In general, outcomes were the same with PRP or ABI versus control groups.
 - PRP vs. Control: Short- and intermediate-term pain and function results were similar between groups, although long-term function scores were better with PRP than steroid injections (Low SoE for all).
 - ABI vs. Control: Short-term pain was worse with ABI versus steroid, though intermediate-term pain was similar between groups (Low SoE).



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Acute Injuries

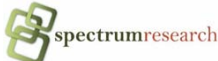
Acute muscle injury
 Achilles tendon rupture
 Ankle sprain
 Temporomandibular joint dislocation
 Osteochondral lesion of the talus



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Acute Muscle Injury: PRP + conservative care vs. control (1 of 2 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Function (various measures)	Intermediate-term	1 RCT N=80	Imprecision (-2)	MD -3 (95% CI -12, 7) <u>Conclusion:</u> No difference between groups as evaluated by HOS-Overall (0-100 (best)).	⊕⊕○○ LOW
Pain (various measures)	Intermediate-term	1 RCT N=80	Imprecision (-2)	<u>Conclusion:</u> No difference between groups as evaluated the following HOS scales (0-100 (best)): • HOS-Soreness: MD -2 (95% CI -11, 7) • HOS-Pain: MD 1 (95% CI -9, 10)	⊕⊕○○ LOW



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Acute Muscle Injury: PRP + conservative care vs. control (2 of 2 slides)

- Insufficient evidence:
 - Short-term function and pain; intermediate-term function
- No evidence:
 - Long-term function
 - Function success
 - Pain success
- Secondary outcomes:
 - Return to sports
 - Mixed results (short-term) (3 RCTs):
 - Better outcome with PRP + CC vs. CC (2 RCTs)
 - No difference between groups (1 RCT)
 - Other outcomes, no difference between groups:
 - Recovery; patient satisfaction (short-term) (1 RCT)
 - Symptoms; HR-QoL; return to sport (intermediate-term) (1 RCT)
 - Re-injury (short-, intermediate-, long-term) (1 RCT)

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Other injuries

- Ankle Sprain: PRP vs. saline (1 RCT, N=33)
 - Function; Pain:
 - No difference between groups (short-term)- Insufficient SoE
 - No evidence for any other outcome
- TMJ Dislocation: ABI vs. intermaxillary fixation (1 RCT, N=32)
 - Recurrent dislocation:
 - Greater risk of dislocation following ABI vs. IMF (long-term)- Insufficient SoE
 - No evidence for any other outcome
- Osteochondral Lesions of the Talus: PRP vs. HA (1 quasi RCT, N=29)
 - Function; Pain:
 - Better outcomes with PRP vs. HA (short-, intermediate-term)- Insufficient SoE
 - No evidence for any other primary outcome

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Osteoarthritis

Knee osteoarthritis
Hip osteoarthritis
Temporomandibular osteoarthritis



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Knee OA

PRP vs. HA (1 of 12 slides)


- Evidence base: 6 RCTs and 4 cohort studies
 - N=92-192 per RCT
- Minimum symptom duration: 3-6 months
- Radiographic classification: mild to moderate
 - Doesn't necessarily correlate with symptom severity
- 2-3 injections per procedure

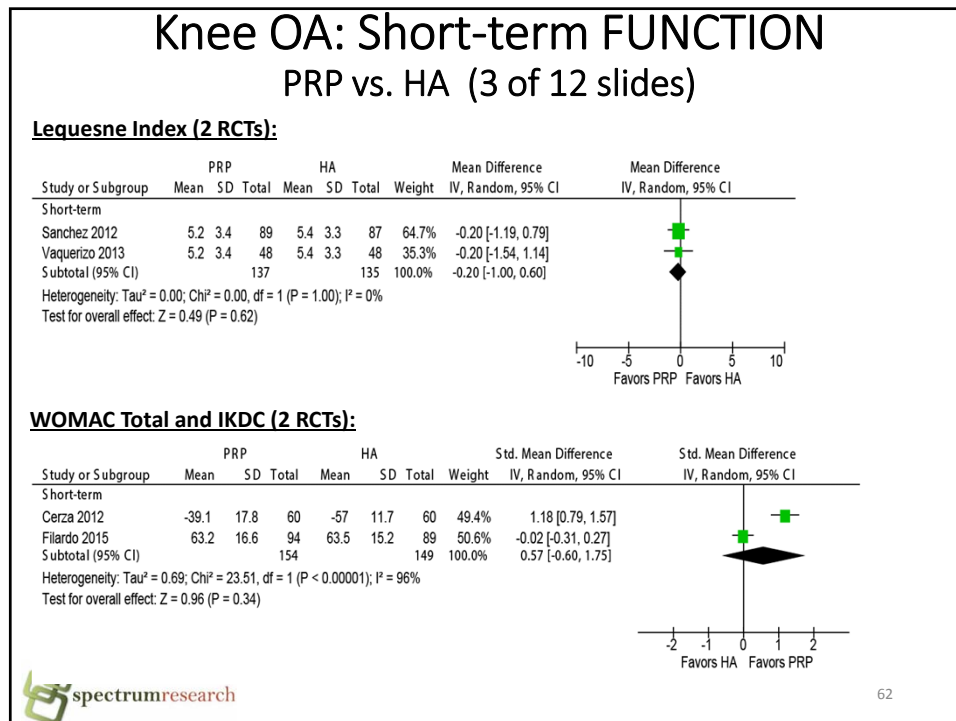


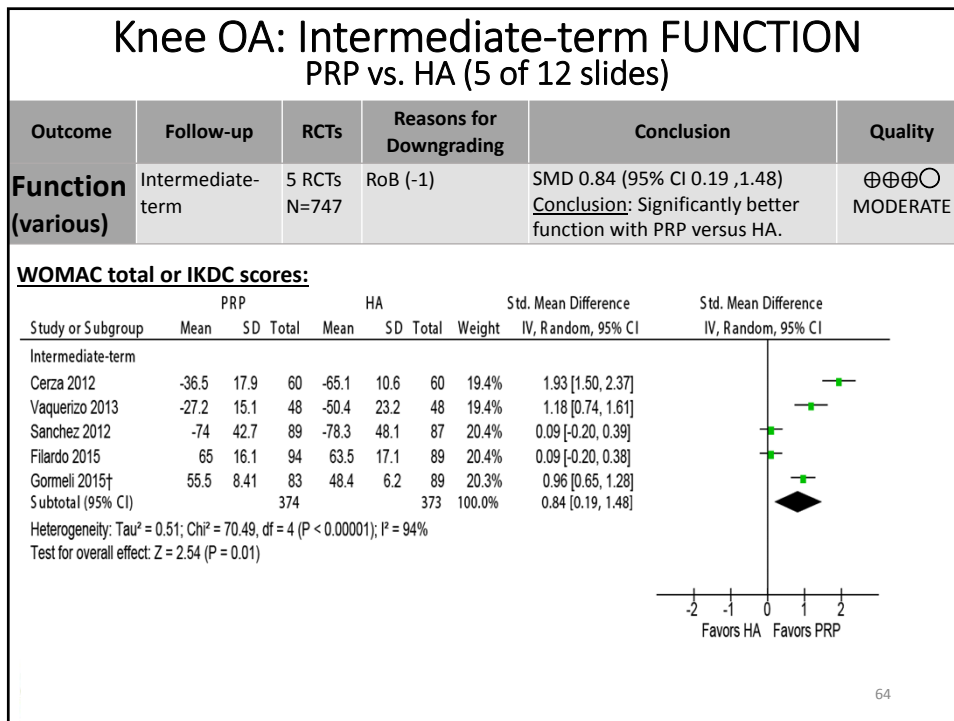
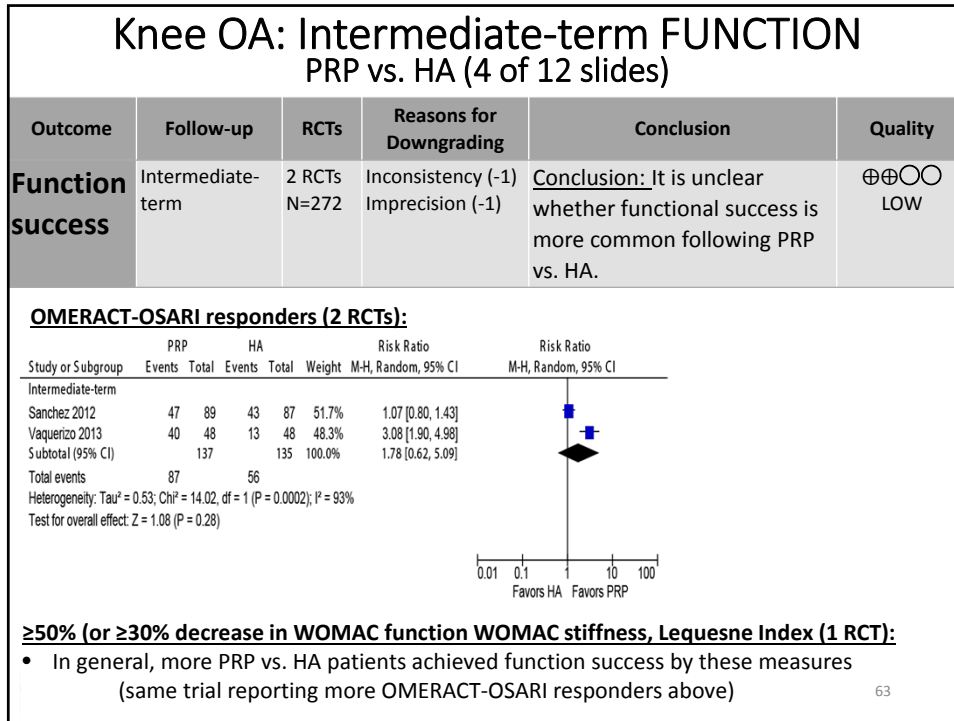
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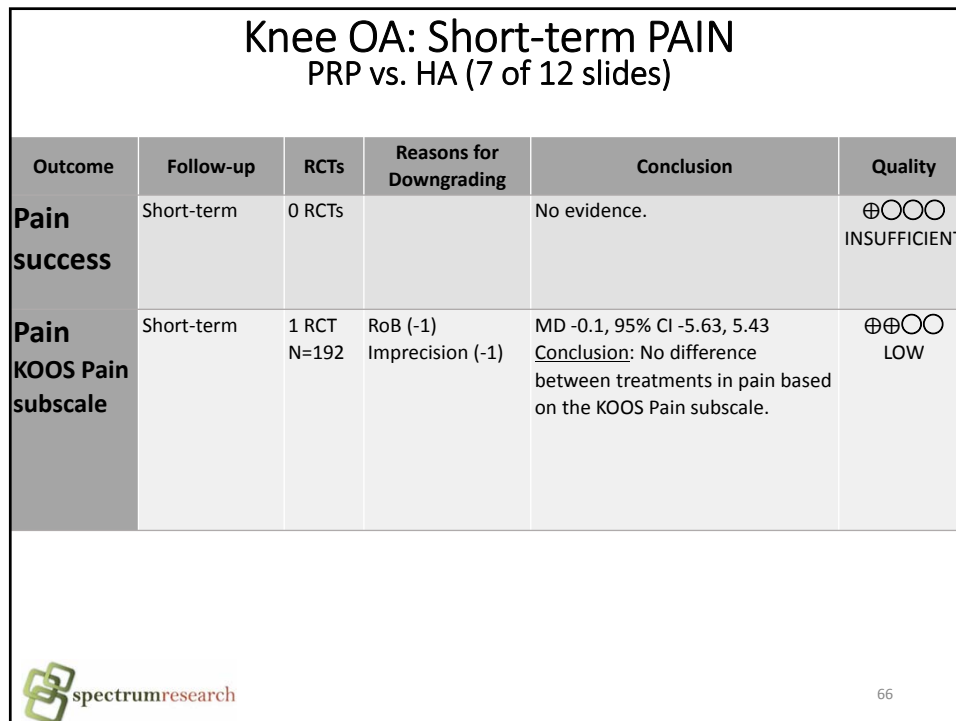
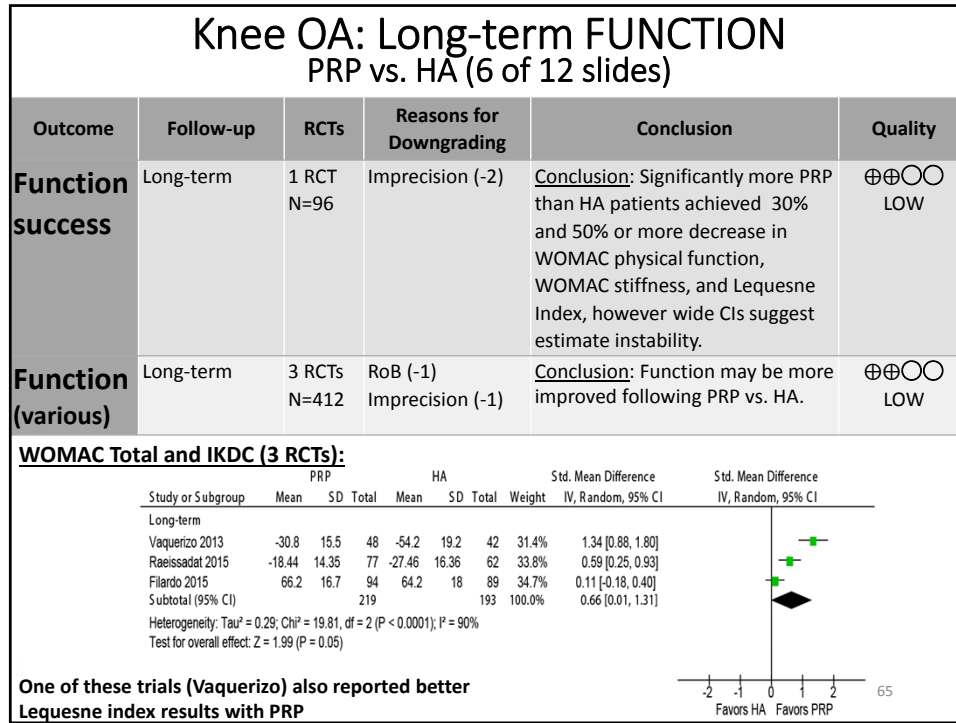
Knee OA: Short-term FUNCTION PRP vs. HA (2 of 12 slides)

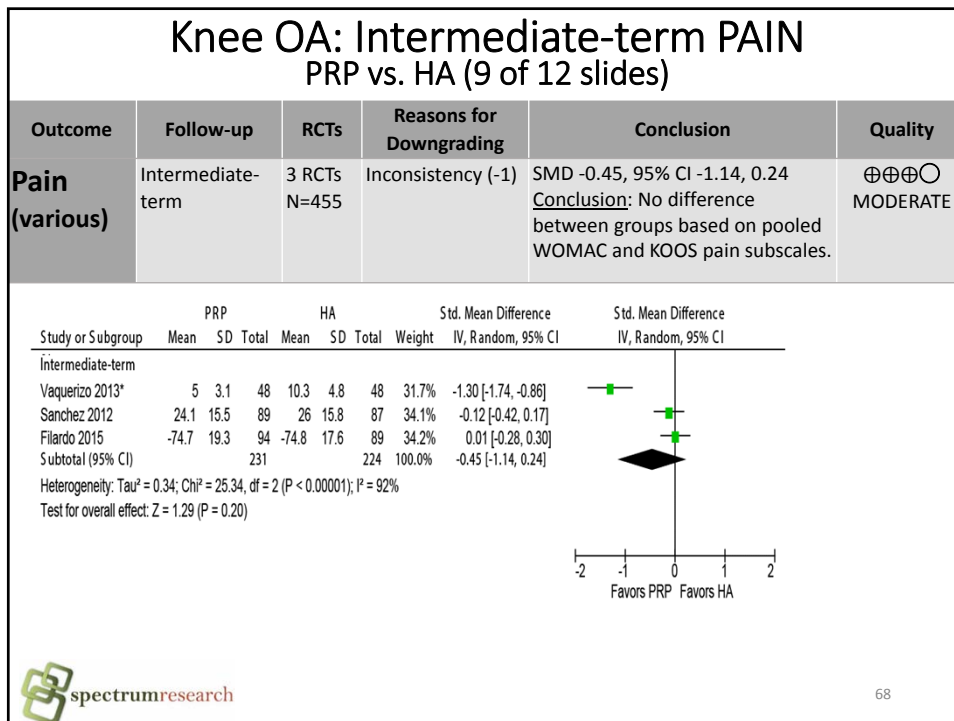
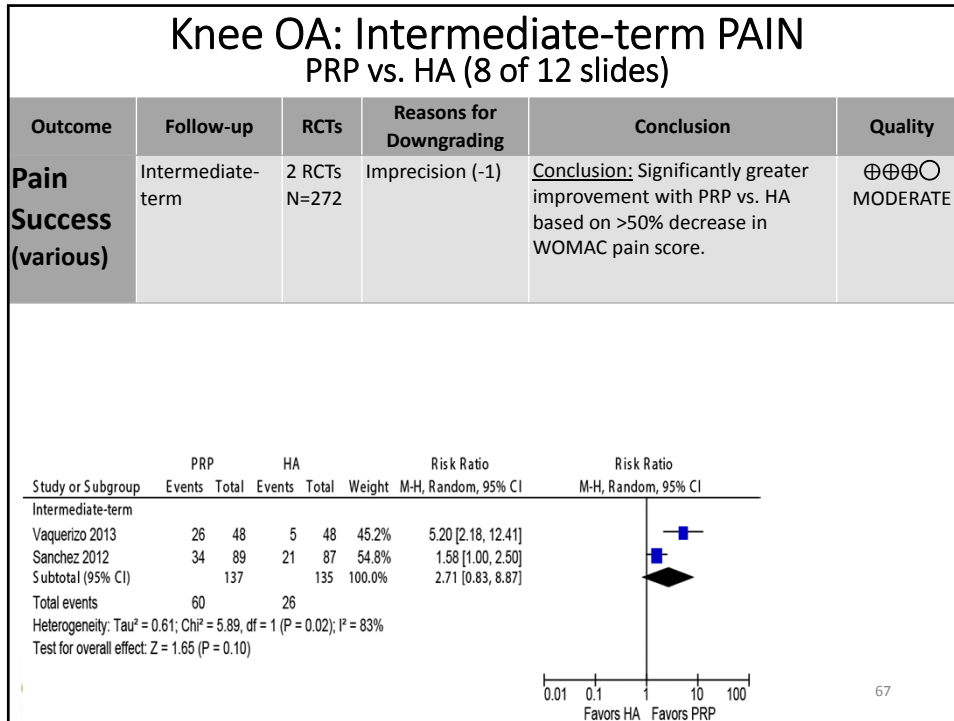
Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Function success	Short-term	0 RCTs		No evidence.	⊕○○○ INSUFFICIENT
Function (various)	Short-term	4 RCTs N=575	RoB (-1)	<p><u>Conclusion:</u> No difference between groups based on the following:</p> <ul style="list-style-type: none"> Lequesne Index: MD -0.20 (95% CI -1.0, 0.60); 2 RCTs (N=272) (Sanchez 2012, Vaquerizo). WOMAC, IKDC: SMD 0.57 (95% CI 0.60, 1.75), 2 RCTs (N=303) (Cerza, Filardo). KOOS subscales or Tegner scores : no difference between groups in 1 trial (Filardo) 	⊕⊕⊕○ MODERATE


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Knee OA: Long-term PAIN PRP vs. HA (10 of 12 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Pain Success (WOMAC pain scores)	Long-term	1 RCT N=96	Imprecision (-2)	<p><u>Conclusion:</u> Significantly more PRP than HA patients achieved pain success:</p> <ul style="list-style-type: none"> ≥30% decrease: RR 4.9 (95% CI 2.1, 11.5) ≥50% decrease: RR 13.3 (95% CI 1.81, 95) 	⊕⊕○○ LOW

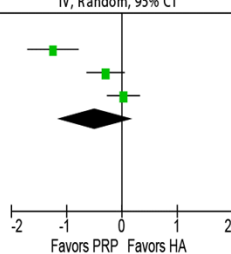

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Knee OA: Long-term PAIN PRP vs. HA (11 of 12 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Pain (various)	Long-term	3 RCTs N=412	RoB (-1) Inconsistency (-1)	<p>SMD -0.49 (95% CI -1.16, 0.18)</p> <p><u>Conclusion:</u> No difference between groups based on pooled WOMAC and KOOS pain subscales.</p>	⊕⊕○○ LOW

Study or Subgroup	PRP			HA			Weight	Std. Mean Difference	
	Mean	SD	Total	Mean	SD	Total		IV, Random, 95% CI	IV, Random, 95% CI
Long-term									
Vaquerizo 2013*	6.3	3.3	48	10.7	3.7	42	31.6%	-1.25	[-1.70, -0.80]
Raeissadat 2015	4.03	3.36	77	5.08	3.73	62	33.8%	-0.30	[-0.63, 0.04]
Filardo 2015	-74.9	19.3	94	-75.4	19	89	34.6%	0.03	[-0.26, 0.32]
Subtotal (95% CI)			219			193	100.0%	-0.49	[-1.16, 0.18]


Heterogeneity: Tau² = 0.32; Chi² = 21.56, df = 2 (P < 0.0001); I² = 91%
 Test for overall effect: Z = 1.42 (P = 0.16)




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Knee OA: Secondary Outcomes PRP vs. HA (12 of 12 slides)


- Secondary Outcomes
 - HR-QoL:
 - Short-term: no difference between groups (1 RCT)
 - Intermediate-term: same or better (varied by outcome measure) (2 RCTs)
 - Long-term: better with PRP (2 RCTs)
 - Patient satisfaction:
 - Intermediate-, long-term: no difference between groups (1 RCT each)
 - Medication use:
 - ≥6 months: no difference between groups (1 RCT)



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Knee Osteoarthritis: PRP vs. Saline (1 of 2 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Function (various measures)	Short-term	1 RCT N=78	RoB (-1) Imprecision (-1)	Conclusion: Better function with PRP (% change from baseline): <ul style="list-style-type: none"> • WOMAC total score (-57% versus 12%), • WOMAC stiffness score (-47% versus 2.0%) • WOMAC physical function score (-56% versus 11%) 	⊕⊕○○ LOW
	Intermediate-term	2 RCTs N=204	RoB (-1) Imprecision (-1)	Conclusion: Better function with PRP (% change from baseline): <ul style="list-style-type: none"> • WOMAC total score: -47% versus 20%, p<0.05 (Patel) • WOMAC stiffness score: -47% versus 10%, p<0.05 (Patel) • WOMAC physical function score 46% versus 20%, p<0.05 (Patel) IKDC: MD 19.0 (95% CI 16.2, 21.8) (Gormeli)	⊕⊕○○ LOW




- No evidence: Long-term function, Function success

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Knee Osteoarthritis: PRP vs. Saline (2 of 2 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Pain (various measures)	Short-term	1 RCT N=78	RoB (-1) Imprecision (-1)	Mean % change from baseline: -63% vs. 18% (p <0.05) <u>Conclusion:</u> LP-PRP resulted in significantly improved pain versus saline.	⊕⊕○○ LOW
	Intermediate-term	1 RCT N=78	RoB (-1) Imprecision (-1)	<u>Conclusion:</u> LP-PRP resulted in significantly improved pain compared with saline based on: <ul style="list-style-type: none"> WOMAC pain (% change): -50% vs. 25%, p <0.05 VAS (0-10): MD -2.3 (95% CI -2.7, -1.8) 	⊕⊕○○ LOW


- No evidence: Long-term pain, Pain success
- Secondary outcomes:
 - Patient satisfaction (intermediate-term): higher in PRP group
 - HR-QoL (intermediate-term): better in PRP group



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Knee OA: Other comparators


- PRP vs. steroid (1 RCT, N=41)
 - Function; Pain:
 - Better results with PRP (short-, intermediate-term)- Insufficient SoE
 - No evidence for any other primary outcome
- PRP vs. Exercise ± TENS (2 RCTs, N=45-65)
 - Function; Pain:
 - No clear difference between groups (short-, intermediate-term)- Insufficient SoE
 - No evidence for any other primary outcome



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Hip Osteoarthritis: PRP vs. HA (1 of 2 slides)


Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Function Harris Hip Score (0-100)	Short-term	1 RCT N=104	RoB (-1) Imprecision (-1)	MD -4.3 (95% CI -10.6, 1.99) <u>Conclusion:</u> No difference between groups.	⊕⊕○○ LOW
	Intermediate-term	1 RCT N=104	RoB (-1) Imprecision (-1)	MD -5.5 (95% CI -12.0, 0.92) <u>Conclusion:</u> No difference between groups.	⊕⊕○○ LOW
	Long-term	1 RCT N=104	RoB (-1) Imprecision (-1)	MD -6.8 (95% CI -14.1, 0.51) <u>Conclusion:</u> No difference between groups.	⊕⊕○○ LOW

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Hip Osteoarthritis: PRP vs. HA (2 of 2 slides)

Outcome	Follow-up	RCTs	Reasons for Downgrading	Conclusion	Quality
Pain VAS (0-10)	Short-term	1 RCT N=104	RoB (-1) Imprecision (-1)	MD 0.0 (95% CI -0.84, 0.84) <u>Conclusion:</u> No difference between groups.	⊕⊕○○ LOW
	Intermediate-term	1 RCT N=104	RoB (-1) Imprecision (-1)	MD 0.25 (95% CI -0.59, 1.09) <u>Conclusion:</u> No difference between groups.	⊕⊕○○ LOW
	Long-term	1 RCT N=104	RoB (-1) Imprecision (-1)	MD 0.16 (95% CI -0.78, 1.1) <u>Conclusion:</u> No difference between groups.	⊕⊕○○ LOW

- No evidence: Function success, Pain success
- Secondary outcomes:
 - Medication use (short-, intermediate-, long-term): no difference between groups

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TMJ Osteoarthritis: PRP vs. HA

- 1 RCT (N=50)
- Function, pain
 - No differences between groups (short-, intermediate-, long-term)- Insufficient SoE
- No evidence:
 - Function success
 - Pain success
 - Secondary outcomes

Summary

- Osteoarthritis
 - Only knee osteoarthritis had evidence of benefit with PRP
 - PRP vs. HA: No short-term differences between groups in pain (low SoE) or function (moderate SoE). By the intermediate-term, function scores were better and pain success more common in the PRP (moderate SoE for both) (although there were no differences between groups in function success (low SoE) or pain scores (moderate SoE)). In the long-term, pain and function success was more common and function scores were better with PRP (but there were no differences between groups in pain scores) (low SoE for all).
 - PRP vs. Saline: Short- and intermediate-term pain and function scores were better with PRP (low SoE for all).
 - Hip osteoarthritis:
 - PRP vs. HA: No differences between PRP and HA groups in short-, intermediate-, or long-term function or pain scores (low SoE).

KQ2: Harms and Complications

Tendinopathies

Plantar Fasciitis

Acute Injuries

Osteoarthritis



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Harms and Complications

- All included comparative studies were evaluated for harms
- No case series met the inclusion criteria
 - $N \geq 100$, specifically designed to evaluate harms
- Serious adverse events:
 - Across all included studies, there was no evidence of any serious harms in any intervention or control group.
 - SoE: LOW or INSUFFICIENT
- Non-serious adverse events:
 - The most common non-serious adverse event was injection-site pain (both during and after the injection) and was more common with PRP or ABI than other injections.
 - Otherwise, the majority of non-serious adverse events occurred relatively infrequently.
 - SoE: LOW or INSUFFICIENT

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KQ3: Differential Efficacy and Safety

- No evidence: tendinopathies, plantar fasciitis, acute injuries, hip OA, TMJ OA
- Insufficient evidence:
 - Knee OA, PRP vs. HA (1 RCT, N=122)
 - Patients with early OA reported better function (IKDC) and better quality of life (EQ VAS) than those with advanced OA with PRP injection.
 - Knee OA, PRP vs. Saline (1 RCT, N=123)
 - Patients with early OA reported better function (IKDC) and better quality of life (EQ VAS) than those with advanced OA with PRP injection.

KQ4: Cost Effectiveness

No evidence.

Summaries

- Safety
 - No serious adverse events reported (low or insufficient SoE).
 - Non-serious adverse events:
 - Injection-site pain (both during and after the injection) and was more common with PRP or ABI than other injections.
 - Otherwise non-serious events occurred relatively infrequently.
- Differential efficacy and safety
 - Insufficient quality or no evidence
- Cost-effectiveness
 - No evidence

Questions?

FINAL Key Questions and Background

Autologous Blood or Platelet-Rich Plasma Injections

Background

Platelet-rich plasma (PRP) and whole blood injections are treatments that have been utilized for a variety of healing applications in sports medicine and orthopedic medicine. Conditions where PRP or whole blood injections are commonly utilized include refractory acute or chronic ligament injuries, muscle strain injuries, cartilage injuries, osteoarthritis, and tendinopathies. In particular, the use of PRP and blood injections in sports medicine have seen a recent increase in public exposure, as many professional athletes have elected to receive these treatments, especially PRP, for sports-related injuries.

The rationale behind PRP and autologous blood injections (ABI) is to increase the concentration of growth-factor rich platelets around the injured area. These growth factors include platelet-derived growth factor (PDGF), insulin-like growth factors (IGF-I and IGF-II), and vascular endothelial growth factor (VEGF). This influx of platelets is thought to promote the healing process by enhancing regeneration and increasing angiogenesis. In particular, PRP preparations contain a concentration of platelets that is at least four-fold higher than that in blood to approximately one million platelets per microliter, a concentration that is thought to be clinically active. These therapies are outpatient procedures and utilize the patient's own blood to obtain the PRP or whole blood used in the injection. PRP is prepared by centrifugation of autologous blood to separate out the platelet-carrying buffy coat layer from platelet-poor plasma, red blood cells and white blood cells; the buffy coat layer and some of the plasma are then isolated and re-centrifuged to obtain the PRP to be used in the injection. Platelet-activating factors like thrombin may be added to PRP to stimulate platelets to release growth factors and increase recruitment of tissue repair factors. No such additional processing occurs for whole blood injections after venipuncture. It is common to add local anesthetic to PRP and whole blood samples to reduce pain at the injection site. Injection is usually performed under ultrasound guidance, and can be repeated if needed.

Despite the increased use of PRP and whole blood injections for healing applications, the efficacy and safety for PRP and whole blood injection treatments are not well established. In particular, there are additional issues regarding PRP: while the technology to obtain PRP is FDA-approved, PRP itself is currently not indicated for direct injection. Additionally, the number of PRP-preparation systems and lack of standardization for the platelet concentration of PRP also make establishing true efficacy difficult.

Policy Context

Platelet-rich plasma (PRP) and whole blood injections are proposed for a variety of healing applications. Concerns are considered medium for safety, medium/high for efficacy and medium for cost-effectiveness.

Scope of This HTA

To systematically review, critically appraise, analyze and synthesize research evidence evaluating the comparative efficacy, effectiveness, and safety of PRP in adults for treating musculoskeletal soft tissue injuries, tendinopathies, osteoarthritis, or low back pain. The differential effectiveness and safety of PRP for subpopulations will be evaluated, as will the cost effectiveness.

Population: Patients with musculoskeletal soft tissue injuries, tendinopathies, osteoarthritis, or low back pain.

Interventions: Autologous PRP or whole blood injections (that used in conjunction with other procedures such as surgery will be excluded)

Comparators: Alternative treatment(s), placebo, or no treatment

Outcomes: Function (primary), pain (primary), time to recovery, return to normal activities (sports, work, or activity level), quality of life, patient satisfaction, recurrence, medication use, secondary procedures (e.g., surgery), adverse events (primary), cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcomes

Key Questions

In patients with musculoskeletal soft tissue injuries, tendinopathies, osteoarthritis, or low back pain:

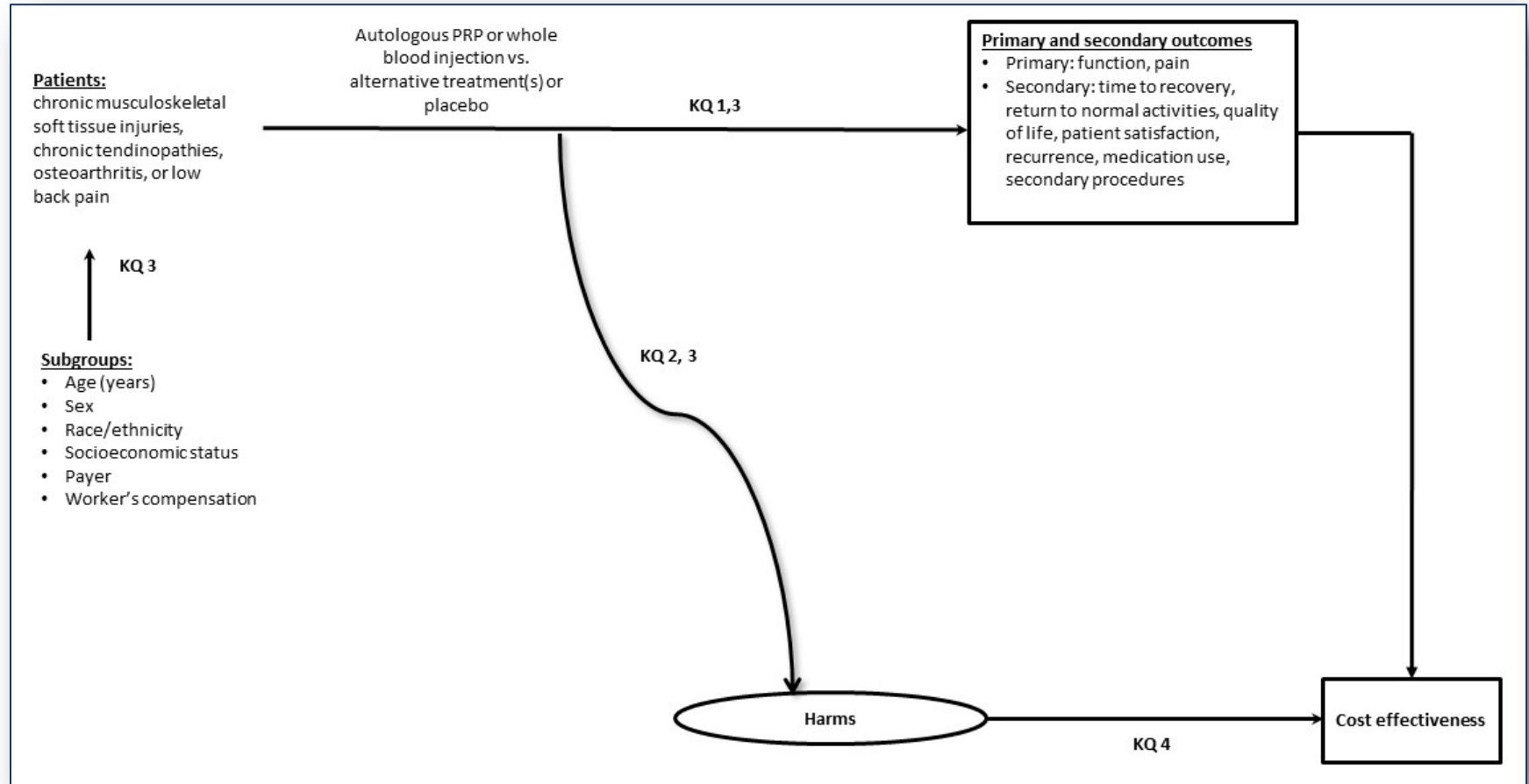
1. What is the evidence of the short- and long-term efficacy and effectiveness of autologous PRP or whole blood injections compared with alternative treatment options or no treatment/placebo?
2. What is the evidence regarding short- and long-term harms and complications of autologous PRP or whole blood injections compared with alternative treatment options or no treatment/placebo?
3. Is there evidence of differential efficacy, effectiveness, or safety of autologous PRP or whole blood injections compared with alternative treatment options no treatment/placebo? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation?
4. What is the evidence of cost-effectiveness of autologous PRP or whole blood injections compared with alternative treatment options?

Summary of Inclusion And Exclusion Criteria

Study Component	Inclusion	Exclusion
Population	Patients with any of the following conditions: <ul style="list-style-type: none"> • musculoskeletal soft tissue injuries • tendinopathies • osteoarthritis, or • low back pain: 	<ul style="list-style-type: none"> • Cutaneous wounds • Bone fractures • Neurosurgery • Ophthalmological conditions • Cosmetic conditions • Maxillofacial surgery • Urological conditions • Cardiothoracic conditions • Dental conditions
Intervention	Autologous PRP or whole blood injections*	<ul style="list-style-type: none"> • PRP or whole blood injections used in conjunction with other procedures (i.e., surgery) • Other biologics (growth factor injections, etc.) • Whole blood injections for OA*
Comparator	<ul style="list-style-type: none"> • Alternative treatment(s) • Placebo 	
Outcomes	<ul style="list-style-type: none"> • Function (primary) • Pain (primary) • Time to recovery • Return to normal activities (sports, work, or activity level) • Quality of life • Patient satisfaction • Recurrence • Medication use • Secondary procedures (e.g., surgery) • Adverse events (primary) 	<ul style="list-style-type: none"> • Non-clinical outcomes
Study Design	Focus will be on studies with the least potential for bias. Key Question 1-2: <ul style="list-style-type: none"> • High quality systematic reviews will be considered if available. • Randomized controlled trials (RCTs) • High quality non-randomized comparative studies Key Question 2: <ul style="list-style-type: none"> • KQ2: High-quality non-comparative studies (case series) designed specifically to evaluate harms/adverse events. Key Question 3: <ul style="list-style-type: none"> • RCTs which present results for both intervention and comparator such that they are stratified on patient or other characteristics of interest. Key Question 4: <ul style="list-style-type: none"> • Only full, formal economic studies (i.e., cost-effectiveness, cost-utility, cost-minimization, and 	<ul style="list-style-type: none"> • Indirect comparisons • Noncomparative studies (case series) (except as described to evaluate harms) • Incomplete economic evaluations such as costing studies • Studies with fewer than 10 patients per treatment group • Case reports • Studies in which <80% of patients have a condition of interest

Study Component	Inclusion	Exclusion
Publication	<p>cost-benefit studies) will be considered.</p> <ul style="list-style-type: none"> • Studies published in English in peer reviewed journals or publically available FDA reports 	<ul style="list-style-type: none"> • Abstracts, editorials, letters • Duplicate publications of the same study which do not report on different outcomes • Single reports from multicenter trials • White papers • Narrative reviews • Articles identified as preliminary reports when results are published in later versions

Analytic Framework



Public Comment & Response

No comments were received.

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective¹ as expressed by the following standards²:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms³:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

¹ Based on Legislative mandate: See RCW 70.14.100(2).

² The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

³ The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence⁴ using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

⁴ Based on GRADE recommendation: <http://www.gradeworkinggroup.org/FAQ/index.htm>

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document:

What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
Injection site pain	
Efficacy – Effectiveness Outcomes	Efficacy / Effectiveness Evidence
Function	
Function success	
Pain	
Pain success	
Surgery (need for)	
Composite (eg. Function success and no surgery)	

Full recovery	
Quality of life (QoL)	
Return to activities	
Satisfaction	
Medication use	
Special Population / Considerations Outcomes	Special Populations/ Considerations Evidence
Early vs advanced osteoarthritis	
Cost Outcomes	Cost Evidence
Cost	
Cost effectiveness	

Medicare Coverage and Guidelines

From page 93 of the Final Report

Centers for Medicare Service (CMS): National Coverage Determination for Blood-Derived Products for Chronic Non-Healing Wounds

The Centers for Medicare and Medicaid Services (CMS) has determined that PRP – an autologous blood-derived product – will be covered only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds and only when (certain) conditions are met.

From page 80 of Final Report- Table 2 Summary of Clinical Guidelines

Guideline	Evidence Base	Recommendation	Rating/ Strength of Recommendation
Colorado Division of Workers Compensation Cumulative Trauma Conditions: Medical Treatment Guidelines (2010) ²⁶²	NR	In patients with lateral or medial epicondylitis and symptoms lasting longer than 6 months: <ul style="list-style-type: none"> • There is good evidence to support PRP injections (2 injections optimum) • There is some evidence to support ABI (2 injections optimum) 	NR

Guideline	Evidence Base	Recommendation	Rating/ Strength of Recommendation
<p>ACOEM Ankle and Foot Disorders (2011)^{175*} Knee Disorders (2011)^{176*} Elbow Disorders (2012)^{177*}</p>	NR	<p>ACOEM recommends both PRP injections and ABI for the following pathologies:</p> <ul style="list-style-type: none"> • Chronic lateral epicondylitis <p>ACOEM does not recommend –</p> <p>PRP injections for the following pathologies:</p> <ul style="list-style-type: none"> • Achilles tendinopathy <p>ABI for the following pathologies:</p> <ul style="list-style-type: none"> • Plantar fasciitis <p>ACOEM provides no recommendation for –</p> <p>PRP injections and ABI for the following pathologies:</p> <ul style="list-style-type: none"> • Ankle sprain • Knee sprains • Anterior and posterior cruciate ligament tears • Meniscal tears • Patellar tendinosis/tendinopathy • Anterior knee pain • Acute or subacute lateral epicondylitis <p>PRP injections only for the following pathologies:</p> <ul style="list-style-type: none"> • Plantar fasciitis 	<p>Limited (C)† for both PRP and ABI</p> <p>Moderate (B)†</p> <p>Limited (C)†</p> <p>Insufficient (I)† for both PRP and ABI</p> <p>Insufficient (I)†</p>
<p>ICMS Section VII: Platelet Rich Plasma (PRP) Guidelines (2011)¹¹²</p>	<p><u>Tendinopathies</u> 3 studies (type NR) 1 animal study <u>Ligament Sprains</u> 1 study (type NR) <u>Muscle Sprains</u> 1 study (type NR) <u>Joints</u> 1 study (type NR)</p>	<p>ICMS suggests the need for further research on the effects of PRP injections on the following pathologies:</p> <ul style="list-style-type: none"> • Tendinopathies • Ligament sprains • Muscle strains • Joints • Intervertebral discs 	NR
<p>Hsu et al. Platelet-rich Plasma in Orthopaedic Applications: Evidence-based Recommendations for Treatment (2013)¹¹⁰</p>	<p><u>Cartilage Injuries</u> 3 level I studies 1 level II study <u>Chronic Tendinopathies</u> 4 level I studies 1 level III study <u>Rotator Cuff Repair</u> 5 level I and level II studies <u>Achilles Tendon Repair</u></p>	<p>Hsu et al. recommends the use of PRP injections in the following pathologies:</p> <ul style="list-style-type: none"> • Elbow epicondylitis refractory to standard nonsurgical treatment <p>Hsu et al. suggests the need for further research on the effects of PRP on the following pathologies:</p> <ul style="list-style-type: none"> • Cartilage injuries • Chronic tendinopathies (excluding elbow epicondylitis refractory to standard nonsurgical treatment) • Rotator cuff repair • Achilles tendon repair 	NR

Guideline	Evidence Base	Recommendation	Rating/ Strength of Recommendation
	1 level II study 1 level III study		
<p>Work Loss Data Institute</p> <p>Ankle & Foot (acute & chronic) (2013)^{296*}</p> <p>Elbow (acute & chronic) (2013)^{297*}</p> <p>Hip & Pelvis (acute & chronic) (2013)^{298*}</p> <p>Low Back – Lumbar & Thoracic (acute & chronic) (2013)^{299*}</p> <p>Pain (acute & chronic) (2013)^{300*}</p> <p>Shoulder (acute & chronic) (2013)^{301*}</p>	NR	<p>Work Loss Data Institute recommends the use of both PRP injection and ABI for the following pathologies:</p> <ul style="list-style-type: none"> • Acute and chronic elbow disorders (not further defined) <p>Work Loss Data Institute does not recommend–</p> <p>PRP injection for the following pathologies:</p> <ul style="list-style-type: none"> • Ankle and foot disorders (not further defined). • Low back pain (lumbar and thoracic) • Chronic pain, unless used in a research setting <p>ABI for the following pathologies:</p> <ul style="list-style-type: none"> • Ankle and foot disorders (not further defined). <p>Work Loss Data Institute provides no recommendation for –</p> <p>PRP injections for the following pathologies:</p> <ul style="list-style-type: none"> • Hip and pelvis injuries (not further defined) • Shoulder disorders (not further defined) <p>ABI for the following pathologies:</p> <ul style="list-style-type: none"> • Shoulder disorders (not further defined) 	NR
<p>AAOS</p> <p>Treatment of Osteoarthritis of the Knee (2013)³⁴</p>	2 studies of low SOE 1 study of moderate SOE	AAOS cannot make a recommendation for or against the use of PRP and/or growth factor injections for patients with symptomatic osteoarthritis of the knee.	Inconclusive‡

Clinical Committee Findings and Decisions

Efficacy Considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
 - Direct outcome or surrogate measure
 - Short term or long term effect
 - Magnitude of effect
 - Impact on pain, functional restoration, quality of life
 - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
 - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
 - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
 - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

- 1) Does the committee have enough information to identify conditions or criteria?
 - Refer to evidence identification document and discussion.
 - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
 - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
- 2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
 - What are the known conditions/criteria and evidence state
 - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical Committee Evidence Votes

First Voting Question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective				
Safe				
Cost-effective				

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, it is

Not Covered Covered Unconditionally Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next Step: Proposed Findings and Decision and Public Comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

- 1) Based on public comment was evidence overlooked in the process that should be considered?
- 2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next Step: Final Determination

Following review of the proposed findings and decision document and public comments:

Final Vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.