Washington State Health Care Authority, HTA Program
Key Questions and Background
Spinal Injections

Introduction

HTA has selected Spinal Injections for review. An independent vendor will systematically review the available evidence on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input about available evidence. Key questions guide the development of the evidence report. They are posted for public review and comment. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Key Questions - Draft

Spinal injections are used to treat chronic back or neck pain with or without radiculopthy when more conservative care has not provided relief. Spinal injections include epidural injections, facet joint injections, medial branch blocks, sacroiliac joint injections, and intradiscal steroid injections. When used in adult patients with chronic back or neck pain:

1. What is the evidence of efficacy and effectiveness of spinal injections? Including:
    a. Short term and long term measures, including measures related to:
       repeated spinal injections
       multilevel spinal injections
       bilateral vs. unilateral spinal injections
    b. Impact on clinically meaningful physical function and pain,
    c. Impact on quality of life, patient satisfaction
    d. Opiod use, return to work and any other reported surrogate measures

2. What is the evidence of the safety of spinal injections? Including:
    a. Adverse event type and frequency (mortality, major morbidity, other)
    b. Dural or arachnoid puncture;
    c. Infection;
    d. Epidural or intradural hematoma
    e. Allergic reaction
    f. Nerve or spinal cord injury
    g. Artery/vein damage/puncture
    h. Arachnoiditis

3. What is the evidence that spinal injections have differential efficacy or safety issues in sub populations? Including consideration of:
    a. Gender
    b. Age
    c. Psychological or psychosocial co-morbidities
    d. Diagnosis or time elapsed from fracture
    e. Other patient characteristics or evidence based patient selection criteria
    f. Provider type, setting or other provider characteristics

g. Payor/ beneficiary type: including worker's compensation, Medicaid, state employees

4. What evidence of cost implications and cost-effectiveness of spinal injections? Including:
    a. Direct costs over short term and over expected duration of effect
    b. Comparative costs

Technology Background

Disease: Back and neck pain are common conditions, with sixty to eighty percent of U.S. adults afflicted at some time during their life. Back pain, and then neck pain, are the most common causes of disability and loss of productivity. Approximately 90% of low back pain is of the nonspecific type, and a similar majority of neck pain is non-specific. Most patients' symptoms resolve satisfactorily within a relatively short time span (within six weeks).

In 5 – 10% of patients, pain does not satisfactorily resolve and the symptoms can be disabling and the social and economic impact of chronic pain is enormous. Discovering the cause for nonspecific low back and neck pain symptoms remains challenging. Some psychosocial risk factors for the progression to chronicity have been identified, but the origin and neurophysiologic pain sensations are poorly understood.

Treatments: Chronic pain treatment may include pharmacological treatment, physical therapy, psychological care and coping skills, exercise, education, antidepressants, cognitive behavioral therapy and supported self-management, spinal manipulations, electrical stimulation, injections, implanted devices, and other surgical treatment. Treatment strategies generally begin with the least invasive and low risk interventions and progress if the treatments are not effective. Treatment often involves a combination of interventions.

Technology:

Spinal injections are usually performed after appropriate non-surgical treatments have been given a fair trial and have not provided adequate relief. The injection is performed under X-ray guidance, (fluoroscopy). This allows visualization of the spine to ensure accurate needle placement; contrast agents may also be used to assist in needle placement. Spinal injections are intended to provide relief by injecting a local anesthetic and/or an anti-inflammatory agent, typically into spinal joints or the space around the spinal nerves and joints. Significant questions remain about the safety, efficacy and effectiveness (particularly long term), and the cost effectiveness of SI.

Washington State Health Care Authority

Clinical Expert Conflict Disclosure

Introduction

The HTCC Workgroup is a public service workgroup established to safeguard the public interest by identifying medical tests and treatments where evidence shows they are safe, effective, and cost-effective. Balance, independence, objectivity and scientific rigor are a basis for public trust and crucial to the credibility and integrity of decisions.

Guiding Principle

Conflict of Interest decisions must be disclosed and balanced to ensure the integrity of decisions while acknowledging the reality that interests, and sometimes even conflicting interests, do exist. Individuals that stand to gain or lose financially or professionally, or have a strong intellectual bias need to disclose such conflicts.

> *For example,* the fact that a member or stakeholder is a health care provider that may use a service under review creates a potential conflict. However, clinical and practical knowledge about a service is also useful, and may be needed in the decision making.

Procedure

Declaration of real or potential conflicts of interest, professional, intellectual, or financial is required prior to membership or provision of written or verbal commentary. Participants must sign a conflict of interest form; stakeholders providing comment must disclose conflicts.

The HTCC Chair or HCA Administrator shall make a decision, in his/her sole discretion, as to whether a conflict of interest rises to the level that participation by the conflicted participant could result in a loss of public trust or would significantly damage the integrity of the decision.

HCA defines conflict of interest as any situation in which a voting member or anyone who provides written or verbal testimony regarding products, services, or technologies discussed or voted on during the workgroup meeting, has a relationship with a manufacturer of any commercial products and / or provider of services discussed or voted on during the meeting. Relationship extends to include immediate family member(s) and / or any entity in which the member or person testifying may have an interest.

A relationship is considered as:

1. Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $10,000.
2. Equity interests such as stocks, stock options or other ownership interests in excess of $10,000 or 5% ownership, excluding mutual funds and blinded trusts.
3. Status of position as an officer, board member, trustee, owner or employee of a company or organization representing a company, association or interest group.
4. Loan or debt interest; or intellectual property rights such as patents, copyrights and royalties from such rights.
5. Manufacturer or industry support of research in which you are participating.
6. Any other relationship that could reasonably be considered a financial, intellectual, or professional conflict of interest.
7. Representation: if representing a person or organization, include the organization's name, purpose, and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).
8. Travel: if an organization or company has financially paid your travel accommodations (e.g. airfare, hotel, meals, private vehicle mileage, etc).

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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		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner	X	
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

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

Editor-in-Chief, Pain Practice, This is the official journal of the World Institute of Pain (WIP). WIP sponsors the certification examination in Interventional Pain Practice (Fellow of Interventional Pain Practice: FIPP). Board Examiner for FIPP examinations.

	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).		X

7. If yes, 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  3-9-2011 Craig T. Hartrick, MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Curriculum Vitae

Concerning: **Craig T. Hartrick, M.D., D.A.B.P.M., F.I.P.P.**

Home Address: 2408 Park Ridge
Bloomfield Hills, Michigan 48304-1487

Office Address 1: William Beaumont Hospital,
Anesthesiology Research
3601 W. 13 Mile Road
Royal Oak, Michigan 48073 USA
ph: (248) 898-1907; fax: (248) 898-8358

Office Address 2: William Beaumont Hospital,
Anesthesiology Research
44201 Dequindre Road
Troy, MI 48085 USA
ph: (248) 964-3440; fax: (248) 964-3112

Office Address 3: Oakland University William Beaumont School of Medicine
525 O'Dowd Hall
Rochester, Michigan 48309 USA
ph: (248) 370-2728

Email: chartrick@beaumont.edu
hartrick@oakland.edu

Employment: **Discipline Director, Pharmacology,**
Oakland University William Beaumont School of Medicine,
Rochester, Michigan
www.oakland.edu

Director, Anesthesiology Research,
Research Institute, William Beaumont Hospital,
Royal Oak, Michigan
www.beaumonthospitals.com

Editor-in-Chief, *Pain Practice*
Official Journal of the World Institute of Pain
Winston-Salem, North Carolina
www.painpractice.org

Anesthesiologist
South Oakland Anesthesia Associates, PC
Practicing at the William Beaumont Hospitals,
Affiliated - Oakland University
Royal Oak and Troy, Michigan
www.beaumont.edu

Born: Pontiac, Michigan, USA - May 24, 1954

Medical Licensure: Michigan 44416

Education:

Undergraduate Education:

Michigan State University
B.S. Chemical Engineering - 1976
Minor: Biomedical Engineering
Elected Tau Beta Pi

Medical Education:

Wayne State University
M.D. - 1980
Diplomate National Board of Medical Examiners

Postgraduate Education:

Internship: Pediatrics 1980-81
Wayne State University
Children's Hospital of Michigan
Residency: Anesthesiology 1981-83
Providence Hospital
Southfield, Michigan
Fellowship: Pain and Regional Anesthesia 1983-4
University of Cincinnati
Fellowship Mentors:
P.Prithvi Raj, M.D. (Pain Medicine);
Phillip O. Bridenbaugh, M.D. (Regional Anesthesia);
Donald D. Denson, Ph.D. (Research).

Board Certifications:

Diplomate, American Board of Anesthesiology – 1984
Voluntary Recertification - 2009

American Board of Anesthesiology:
Certificate of Added Qualifications in Pain Management – 1993
Added Qualifications Recertification - 2003

Diplomate, American Board of Pain Medicine – 1994

Fellow, Interventional Pain Practice - 2003

Board Examiner: World Institute of Pain
Interventional Pain Practice (FIPP): 2004-present
Memphis (04-08); NYC (2009); Budapest (04-10); Cleveland (2010)

Practice Experience and Positions:

Oakland University – Rochester, Michigan

William Beaumont Hospital Department of Anesthesiology - Royal Oak and Troy, MI

Professor of Biomedical Sciences; Discipline Director, Pharmacology; and Co-Director, Neuroscience Course
Biomedical Sciences, Oakland University William Beaumont School of Medicine (OUWBSOM)

Professor of Anesthesiology, Oakland University William Beaumont School of Medicine (OUWBSOM)

Clinical Professor in the School of Health Sciences, Oakland University (Pharmacology)

Director, Anesthesiology Research:
Beaumont Hospitals
2001 – present

Director, Chronic Pain Medicine Section:
Beaumont – Royal Oak
1988 – 2000

Director, Neuropathic Pain Project:
Beaumont Research Institute – Royal Oak
2000 - 2005

Director, Pain Services:
Beaumont Hospitals - institution-wide
2007 – 2009

Providence Hospital Department of Anesthesiology – Southfield, MI

Assistant Director, Pain Clinic – 1984 - 1988

Pain Fellowship Coordinator: 1984 – 1988

Editor:

Editor-in-Chief: Pain Practice, Wiley-Blackwell: 2006 - present

Associate Chief Editor: Pain Practice, Blackwell Science: 2004 - 2005

Editorial Boards:

Editorial Board: *Pain Practice*, Blackwell Science: 2003-2004

Editorial Advisory Board: *MD Consult Pain Medicine*, Elsevier Science: 2003-05

Editorial Boards (continued):

Editorial Board: Opioid Management of Pain
Prime National Publishing: 2004-2010

Advisory Board: PainPathways Magazine; www.painpathways.org

Reviewer:

Societies: Practice Guidelines

Clinical Practice Guideline and Evidence:
American Pain Society-American College of Physicians
Guidelines for the Management of Low Back Pain
Peer Reviewer – 2006, 2007

Low Back Pain Guidelines Primary Care:
American Pain Society-American College of Physicians
Peer Reviewer – 2007

APS-AAPM Clinical Guidelines for the Use of Opioids for Chronic Non-cancer Pain
American Pain Society and American Academy of Pain Medicine – Peer Reviewer – 2007, 2008

APS Low Back Pain Guidelines: Interventional, Surgical, Interdisciplinary Techniques
American Pain Society – Peer Reviewer – 2008

Societies: Scientific Meetings

American Society of Anesthesiologists:
Annual Meeting Abstracts
Pain and Local Anesthesia – 2003, 2004

American Society of Anesthesiologists:
Annual Meeting Abstracts
Chronic and Cancer Pain – 2006, 2007, 2008, 2009

Twenty-ninth Annual Resident and Fellow Research Forum, William Beaumont Hospital: 1999

Oakland University/Beaumont Biomedical Research Symposium – Judge: 2011

Study Sections: Grants

American Institute of Biological Sciences (PRMRP-05)
Chronic Pain and Orthopaedic Injury Evaluation Panel:
Congressionally Directed Peer Reviewed Medical Research Program
Department of Defense – 2005

Reviewer (continued):

Study Sections: Grants (continued)

American Institute of Biological Sciences (PRMRP-06)
Chronic Pain and Fatigue Research/Fibromyalgia:
Congressionally Directed Peer Reviewed Medical
Research Program
Department of Defense - 2006

American Institute of Biological Sciences
Combat Casualty Care: Chronic Pain Management:
Department of Defense
US Army – 2007

American Institute of Biological Sciences
Airway Management: *Department of Defense*
US Army – 2007

American Institute of Biological Sciences
Chronic Pain: *Department of Defense*
US Army – 2008

American Institute of Biological Sciences
Chronic Pain: *Department of Defense*
US Army – 2010

Journals

BMC Medical Research Methodology, Biomed Central:
2005

Journal of Immunological Methods, Elsevier: 2005

Journal of Neuroimmunology, Elsevier: 2003

Journal of Clinical Anesthesia, Elsevier: 2002-2010

Pain Practice, Blackwell Science: 2002-2005

MD Consult – Pain Medicine, Elsevier: 2002-2005

Pain Digest, Springer-Verlag: 1996-1999

Opioid Management of Pain, Prime: 2004-2009

Journal of Pain, Elsevier: 2005-2010

Journal of Postgraduate Medicine,
Medknow Publications: 2007-2008

BMC Anesthesiology, BioMed Central: 2008

Journal of Brachial Plexus and Peripheral Nerve Injury, BioMed Central: 2008

Reviewer (continued):

Journals (continued):

Expert Reviews in Clinical Pharmacology, Future Medicine: 2009

Drugs, Adis, Wolters Kluwer Health: 2009

BMC Musculoskeletal Disorders, BioMed Central: 2010

Advances in Therapy, Springer Healthcare: 2010 - 2011

Current Drug Safety, Bentham Science: 2011

Expert Opinion on Pharmacotherapy, Informa Healthcare: 2011

Moderator/Facilitator:

Local Anesthesia and Pain
Local Anesthetics: Clinical and Animal Studies
American Society of Anesthesiologists
October 22, 1996

Critical Care and Trauma
Acute Lung Injury and Liver
American Society of Anesthesiologists
October 19, 1998

Local Anesthesia and Pain
Poster-Discussion
American Society of Anesthesiologists
October 21, 1998

Residents' and Fellows' Research Forum Day
Research Institute
William Beaumont Hospital
June 16, 1999

Local Anesthesia and Pain
Basic Science I
American Society of Anesthesiologists
October 14, 2003

Local Anesthesia and Pain
Clinical Science I
American Society of Anesthesiologists
October 25,2004

Chronic and Cancer Pain
Basic Science and Clinical
American Society of Anesthesiologists
October 17, 2006

Moderator/Facilitator (continued):

Publication of Clinical Trials
Moderator – Topical Seminar
4th World Congress – WIP (Budapest)
September 28, 2007

Chronic and Cancer Pain
Poster Discussion: Clinical
American Society of Anesthesiologists
October 13, 2007

"Advances in Pain Management: Emerging Strategies and Clinical Innovations" Poster Maze: Post-Congress Symposium - American Pain Society, 27th Annual Meeting
Penn State College of Medicine
Tampa, Florida – May 10, 2008

Conference Program: Sessions 1 and 2
13th Annual Advanced Interventional Pain Conference
World Institute of Pain
Budapest, Hungary - September 8, 2008

Regional Anesthesia and Acute Pain
Acute Pain Basic Science
American Society of Anesthesiologists
October 21, 2008

Regional Anesthesia and Acute Pain
Moderator - Oral Presentations: Pain, Basic Science
American Society of Anesthesiologists
October 20, 2008

Publication of Clinical Trials
Moderator – Topical Seminar
5th World Congress – WIP (New York)
March 14, 2009

Interventional Pain Techniques Review Course
Moderator
14th Annual Advanced Interventional Pain Conference
World Institute of Pain
Budapest, Hungary – September 1, 2009

Chronic and Cancer Pain
Scientific Posters: Basic Science
American Society of Anesthesiologists
October 17, 2009

Regional Anesthesia and Acute Pain
Poster Discussion: Basic Science and Pharmacology
American Society of Anesthesiologists
October 17, 2009

Moderator/Facilitator (continued):

Regional Anesthesia and Acute Pain
Basic Science and Local Anesthetic Pharmacology
American Society of Anesthesiologists
October 18, 2009

Regional Anesthesia and Acute Pain
Making Regional Anesthesia Better
American Society of Anesthesiologists
October 21, 2009

Neurobiology of Pain Processing
Moderator, Plenary Lectures
12th Annual Pain Management Symposium
Cleveland Clinic Foundation
Coronado, California – March 6, 2010

Regional Anesthesia and Acute Pain
Scientific Posters: Basic Science and Pharmacology
American Society of Anesthesiologists
October 16, 2010

Regional Anesthesia and Acute Pain
Scientific Posters: Ultrasound Guided Regional Anesthesia Advances
American Society of Anesthesiologists
October 16, 2010

Regional Anesthesia and Acute Pain
Oral Presentations: Measuring Pain and Outcome
American Society of Anesthesiologists
October 19, 2010

Regional Anesthesia and Acute Pain
Poster Discussion: Hyperalgesia and the Progression to Chronic Pain
American Society of Anesthesiologists
October 20, 2010

Topical Seminar
Why Formal Pain Medicine Education and Board Certification Matter
6th World Congress – World Institute of Pain
Seoul, S. Korea – May 1, 2011

Invited Lectures:

" Cervical Plexus Block for Carotid Surgery"
Anatomy, Physiology and Technique of Regional Anesthesia
Northwest Indiana Anesthesia Seminar
Indiana University School of Medicine
Gary, Indiana - April 28, 1984

"Intercostal Block"
Anatomy, Physiology and Technique of Regional Anesthesia
Northwest Indiana Anesthesia Seminar
Indiana University School of Medicine
Gary, Indiana - April 28, 1984

"Epidural Anesthesia"
Anatomy, Physiology and Technique of Regional Anesthesia
Indiana University School of Medicine
Gary, Indiana - April 28, 1984

"Narcotics"
Anesthesia: Pre- and Postoperative Nursing Management
PAR Workshop - University Hospital
University of Cincinnati - May 6, 1984

"Chronic Pain Syndromes and their Management"
Dearborn County Hospital
Dearborn County Medical Society
Lawrenceburg, Indiana - June 8, 1984

"The Concept of a Pain Clinic"
Saint Joseph's CME Programs
St. Joseph Mercy Hospital, West
Mt. Clemens, Michigan - February 4, 1987

"The Use of TENS in the Treatment of Pain"
Pain: New Perspectives and Management
Tenth Annual Anesthesia Symposium
Mt. Carmel Mercy Hospital
Mercy College
Detroit, Michigan - September 17, 1988

"Infrared Thermographic Evaluation of Postsurgical Groin Pain"
Pain: New Perspectives and Management
Tenth Annual Anesthesia Symposium
Mt. Carmel Mercy Hospital
Mercy College
Detroit, Michigan - September 17, 1988

"Pain Management"
Third Annual Medical Staff and Alumni Meeting
William Beaumont Hospital
Royal Oak, Michigan - September 21, 1991

Invited Lectures (continued):

"Pain Management"
Blue Cross and Blue Shield of Michigan
Continuing Medical Education Series
Southfield, Michigan - January 28, 1994

"Pediatric Pain Management"
CME Programs
Bay Medical Center
Bay City, Michigan - March 2, 1994

"Pain Management"
Blue Cross and Blue Shield of Michigan
Continuing Medical Education Series
Southfield, Michigan - January 28, 1994

"Pediatric Pain Management"
CME Programs
Bay Medical Center
Bay City, Michigan - March 2, 1994

"The Acute Pain Management Service"
CME Programs
Bad Axe Medical Center
Bad Axe, Michigan - April 15, 1994

"How to Manage the Difficult or Impossible
Pain Patient"
Workshop: World Society of Pain Clinicians
Sixth International Congress - Pain Clinic
Medical College of Georgia
Atlanta, Georgia - April 18, 1994

"Pediatric Pain Management"
CME Programs
Department of Pediatric Hematology-Oncology
Hurley Hospital - Cancer Center
Flint, Michigan - June 14, 1994

"Regional Anesthesia for Pediatrics"
CME Department
Michigan Capital Medical Center
Michigan State University
East Lansing, Michigan - November 3, 1994

"The Evaluation of the Chronic Pain Patient"
Grand Rounds - Continuing Medical Education
Mount Clemens General Hospital
Mt. Clemens, Michigan - September 8, 1995

"Pediatric Pain Management - Comforting Kids"
Pain Management Service
Children's Hospital Medical Center
University of Akron
Akron, Ohio - March 21, 1996

Invited Lectures (continued):

"Pediatric Pain Management / Regional Anesthesia"
Grand Rounds - Department of Anesthesia
St. Vincent Medical Center
Toledo, Ohio - September 19, 1996

"Pediatric Pain"
Grand Rounds - Nursing Department
Children's Hospital
Ohio State University
Columbus, Ohio - October 1, 1996

"Managing Pediatric Pain"
Grand Rounds
Doctors Hospital
Ohio University Medical School
Columbus, Ohio - November 21, 1996

"Preemptive Analgesia"
Practical Updates in Anesthesiology
Michigan Society of Anesthesiologists
University of Michigan
Puerto Vallarta, Mexico - February 7, 1997

"Pain Management"
Department of Pediatrics
Saint John Hospital and Medical Center
Detroit, Michigan - March 19, 1997

"Pain Measurement in Pediatrics"
Grand Rounds
Mount Clemens General Hospital
Mt. Clemens, Michigan - December 12, 1997

"Pain: Prevention/Management"
Department of Pediatrics
Hurley Hospital
Flint, Michigan - Jan. 29, 1998

"Pediatric Pain Measurement"
Department of Pediatrics
St. Joseph Mercy Hospital
Pontiac, Michigan – June 15, 1999

"Opioids in the Emergency Department"
Purdue Frederick Medical Education
Purdue Pharma L.P./Abbott Pharmaceuticals
Auburn Hills, Michigan – November 2, 1999

"Pain Receptors"
Merck Visiting Professor Seminar
Royal Oak, Michigan – April 9, 2003

Invited Lectures (continued):

"Multimodal Pain Therapy"
Detroit COX-2 Medical Advisory Board
Pfizer/Pharmacia
Birmingham, Michigan – September 10, 2003

"Multimodal Postoperative Pain Management"
American Society of Health-System Pharmacists
Annual Meeting
New Orleans, Louisiana – December 8, 2003

"Pathophysiology of Postoperative Pain: Multimodal Analgesia"
Merck Medical Education
Indianapolis, Indiana – June 16, 2004

"Pathophysiology of Chronic Pain: Rheumatoid Arthritis"
Merck Medical Education
Birmingham, Michigan – June 23, 2004

"Secondary Hyperalgesia and the Development of Chronic Pain"
Merck Medical Education
Greenville, South Carolina – August 19, 2004

"Evaluating New Postoperative Analgesics"
Introduction and Moderator:
Introducing a New Drug into Practice: Clinical Considerations
American Society of Regional Anesthesia and Pain Medicine - Annual Fall Pain Meeting
Phoenix, Arizona – November 12, 2004

"Point-Counterpoint: Introducing a New Drug into Practice – Clinical Considerations"
58th Postgraduate Assembly in Anesthesiology
New York State Society of Anesthesiology
New York, New York – December 11, 2004

"Chronic Pain: An accident waiting to happen"
Pain Topics in the Tropics II: Scientific seminar
World Institute of Pain
San Juan, Puerto Rico – January 29, 2005

"Pain: Myths and Mystery"
Medical Alumni Reunion Day
Wayne State University
Detroit, Michigan – May 7, 2005

"New Drugs for Pain Management"
23rd Annual Pain Symposium
Texas Pain Society
Texas Tech University Health Sciences Center
Lubbock, Texas – June 11, 2006

Invited Lectures (continued):

"Neurokinin-1 antagonism in the Prevention of Postoperative Nausea and Vomiting"
General Surgery Grand Rounds
Botsford Hospital
Farmington, Michigan – September 12, 2006

"NK-1 Antagonists and PONV"
Merck Medical Education
Birmingham, Michigan – September 13, 2006

"Multimodal PONV Prophylaxis: NK1 Antagonism"
Merck Medical Education
South Bend, Indiana – October 25, 2006

"Multimodal Perioperative Pharmacopeia for GYN Surgery: Pain and Nausea"
OB-GYN Visiting Professor Program: Grand Rounds
Grand Rapids Medical Education & Research Center
Michigan State University
Grand Rapids, Michigan - January 17, 2007

"Postoperative Nausea and Vomiting: NK-1 antagonism versus multimodal antiemetic prophylaxis"
Merck Medical Education
Birmingham, Michigan – April 26, 2007

"What makes a good investigator/investigation?"
4th World Congress – World Institute of Pain
Budapest, Hungary – September 28, 2007

"Clinical Implications of Recent Advances in Analgesics"
Advances in Pain Management: Emerging Strategies and Clinical Innovations - Penn State College of Medicine Pre-Congress Symposium - American Pain Society 27th Annual Meeting
Tampa, Florida – May 7, 2008

"Publication of Clinical Pain Research: Observational Studies"
5th World Congress – World Institute of Pain
New York, New York – March 14, 2009

"Anesthesiology and Pain Management"
New Frontiers in Neuroscience: 2009
Beaumont Cancer Institute, Brain and Spine Institute, and the Department of Neurosurgery
Birmingham, Michigan – April 24, 2009

"Susceptibility to the Development of Posttraumatic Chronic Pain"
ALGOS 2009 – International Symposium: WIP
Myconos Island, Greece – June 18, 2009

Invited Lectures (continued):

"Clinical Trial Quality Assessment: A Case Study - Tapentadol"
The Uses of Pain Medications: Angels and Demons
Pain Management Academy of Puerto Rico
San Juan, Puerto Rico - October 24, 2009

"Interpreting Analgesic Trials"
12th Annual Pain Management Symposium
Cleveland Clinic Foundation
Coronado, California – March 8, 2010

"Evidence Assessment in Analgesic Trials: Beyond the RCT"
11th National Congress on Pain
Istanbul, Turkey – May 22, 2010

"Why Formal Pain Medicine Education and Board Certification Matter: Undergraduate and Medical School Pain Education"
Topical Seminar
6th World Congress – World Institute of Pain
Seoul, S. Korea – May 1, 2011

"Abuse, Misuse, and Diversion"
Refresher Course: Clinical Update
6th World Congress – World Institute of Pain
Seoul, S. Korea – April 28, 2011

Various lectures on Research Methodology, Pain and Local Anesthetics - Departments of Anesthesiology, Pharmacy, Plastic Surgery, Pediatrics, Physical Medicine and the Research Institute at William Beaumont Hospital, 1988-present

Workshops:

"Brachial Plexus Model"
American Society of Regional Anesthesia
Ninth Annual Meeting
San Diego, California - March 15-17, 1984

"Transforaminal Neuroplasty"
23rd Annual Pain Symposium
Texas Pain Society/WIP
Texas Tech University
Lubbock, Texas – June 10, 2006

Societies:

American Academy of Pain Medicine
American Pain Society
  Basic Science SIG
  Clinical Trials SIG
American Society of Anesthesiologists
American Society of Regional Anesthesia
International Anesthesia Research Society
International Association for the Study of Pain
  Neuropathic Pain SIG
Michigan Society of Anesthesiologists
Michigan State Medical Society
Oakland County Medical Society
Society for Neuroscience
World Association Medical Editors
World Institute of Pain

Hospital and Medical School Committees:

Pain Management Committee (past)
Chairman (founding chair 1999 - 2009):
William Beaumont Hospital - Royal Oak, Troy, Grosse Pointe

Animal Care Committee (current; since 1996)
Vice Chair: 2008 - present
William Beaumont Hospital - Royal Oak

Physician Well-Being Committee (past)
William Beaumont Hospital – Royal Oak

Transfusion Committee (past)
Providence Hospital

Ad Hoc Credentials Committee – Chair (past)
William Beaumont Hospital – Royal Oak

Investigator Initiated Clinical Research Support Task Force
William Beaumont Research Institute (current)

Residency Education Committee – Anesthesiology
William Beaumont Hospital – Royal Oak (current)

Curriculum Committee
Oakland University William Beaumont School of Medicine
Rochester, Michigan (current)

Medical Society Committees:

Secretary, Board of Directors
World Institute of Pain Foundation: 2009 - present

World Institute Pain
Liaison to the Executive Board: 2006 - present

American Pain Society
Clinical Practice Guidelines Committee: 2005 - present

Education Committee: Chair - 2010 – present
WIP Foundation

Board of Governors
Wayne State University Medical Alumni – term: 2007-2010
MARD Committee (2009-10);
Career Night Committee (2007-11)

American Pain Society
Clinical Trials SIG – Education Committee: 2005

American Society of Anesthesiologists
Local Anesthesia and Pain: 2003, 2004

American Society of Anesthesiologists
Pain Management Committee: 2005 - 2007

American Society of Anesthesiologists
Chronic and Cancer Pain: 2006 - 2009

Michigan State Medical Society
Pain Management Task Force - past

Michigan Society of Anesthesiologists
Scientific and Academic Affairs Committee - past

Michigan Society of Anesthesiologists
Pain Medicine Committee - past

Michigan Society of Interventional Pain Physicians
Board of Directors - past

Past Chair:
BCBS Liaison Committee for Pain Reimbursement
Michigan Society of Anesthesiologists

Advisory Boards:

Endo Pharmaceuticals National Peri-operative Analgesia Advisory Board – 2003

Pfizer/Pharmacia – Detroit COX-2 Medical Advisory Board - 2004

Endo Pharmaceuticals National Anesthesiology Advisory Board – 2004

Cadence Advisory Panel – 2006, 2007

Adela Advisory Board (Anesiva) – 2008

Shire New Products Advisory Board – 2008

Incline Advisory Board - 2010

Additional Certification:

Academy of Neuromuscular Thermography Course: Orlando, Florida (C Wexler, MD) - 1986

Percutaneous Electrothermal Treatment of Discogenic Pain Course: Palo Alto, California (J Saal, MD) - 1999

Advanced Neurostimulation Techniques - Medtronic Neurophysiologic Research Laboratory: Minneapolis, Minnesota (T Deer, MD, R Levy, MD) – 1999

Nucleoplasty (Percutaneous Disc Decompression) with Coblation Course – ArthoCare (D Dobritt, DO) – 2002

CITI Human Subject Protection Certification University of Miami – 2005, (recertification: 2008, 2010).

Essentials for IACUC Members – ResearchTraing.org (recert. 2010)

Working with the IACUC – ResearchTraining.org (recert. 2010)

ACLS (latest recertification: 2010)

Teaching:

Pain Fellowship Director, Providence Hospital, 1985-1988

Oakland University: BIO491 ST: Clinical Genetics Research (Jointly with Dr. Douglas Wendell) teaching a bedside-to-bench clinical research laboratory course for undergraduate students (2007-current).

Curriculum Development: Discipline Director (Master Educator)- Pharmacology
Oakland University William Beaumont School of Medicine

Curriculum Development: Course Co-Director - Neuroscience
Oakland University William Beaumont School of Medicine

Oakland University: HS491/BIO491: Summer Course – Diabetes
Course development jointly with OUWBSM faculty (2010)

Oakland University: Pharmacology: HS331, HS531 - School of Health Sciences (Jointly with Dr. Richard Rozek): TBL in Pain Course development (2010 - present)

Awards:

Citation Award: American Pain Society Abstracts - 1989

President's Medal: WIP and WIP-Section of Pain Practice - 2006

Media:

PBS Documentary – Fibromyalgia: Fitting the Pieces Together (S. Ostalecki)
Chapter 4. Neural Mechanism & Referred Pain Patterns – Craig Hartrick, MD (September 2009)

Hartrick CT. Susceptibility to chronic postsurgical pain. Podcast: American Society of Anesthesiologists Annual Meeting <http://www.asahq.org/Annual-Meeting/Podcasts.aspx>

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Journal of Contemporary Neurology 1998;3(1):1-6. (http://www.mitpress.mit.edu)

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Pain Digest 1998;8(2):137-138.

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Reviewer's Report, 11 Jul 2005: Pre-publication history for: Lack of interchangeability between visual analogue and verbal rating pain scales: a cross sectional description of pain etiology groups. Irene Lund, et al.
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Reviewer's Report: 25 June 2008: Pre-publication history for: Determination of the efficacy and side-effect profile of lower doses of intrathecal morphine in patients undergoing total knee arthroplasty. Hassett P, et al. ***BMC Anesthesiology*** 2008, 8:5 (doi:10.1186/1471-2253-8-5) http://www.biomedcentral.com/1471-2253/8/5/prepub

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Creating an Integrated Undergraduate Biomedical Science Course for Pre-Medical Students Transitioning into Medical Schools Adopting Competency Based Curriculum
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63. Viscusi E, Hartrick C, Frenkl T, Gammaitoni A, Peloso PM, Ko AT, Morgan L, Mehta A, Papanicolaou D:
Perioperative Use of Etoricoxib in Patients Undergoing Total Abdominal Hysterectomy
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Development Of A Fully Integrated One Semester Basic Science Course For The M1 Year
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Chapters/Monographs:

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   Pain Due to Trauma, in
   Practical Management of Pain, ed. PP Raj,
   Year Book Medical Publishers, Chicago, pp. 296-311, 1986.

2. Pither CE, Hartrick CT:
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4. Hartrick CT:
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   Practical Management of Pain, Second Ed., ed. PP Raj, Mosby-Yearbook Medical Publishers, Inc., Chicago, 409-433, 1992.

5. Hartrick CT:
   Managing the Difficult Pain Patient, in
   Management of Pain-A World Perspective, eds. PP Raj, S Erdine, D Niv, S Raja, International Proceedings Division, Monduzzi Editore, Bologna, Italy, 330-333, 1995.

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   Pharmacologic management of acute and chronic pain in trauma patients, in
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7. Hartrick CT:
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8. Hartrick CT:
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Chapters/Monographs(continued):

9. Hartrick CT:
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10. Hartrick CT:
Management of Chronic Pain, in **Orthopaedic Physical Therapy Secrets**, 2nd Edition, eds. Placzek JD, Boyce DA, Hanley and Belfus, Inc., Philadelphia, pp. 247-254, 2006.

11. Miaskowski C, Blair M, Chou R, D'Arcy Y, Hartrick C, Huffman L, Maleki J, Manworren R:
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12. Hartrick CT, Manvelian G:
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Iontophoretic transdermal fentanyl (Ionsys), in **The Essence of Analgesia and Analgesics**, eds. Sinatra R, Jahr J, Cambridge University Press, New York, pp. 455-458, 2010.

Textbook:

1. **Evidence-based Interventional Pain Medicine according to Clinical Diagnoses**, eds. Van Zundert J, van Kleef M, Mekhail N, Hartrick CT, Wiley-Blackwell, London, 2011 (in press).

Research Activity:

Total Cumulative Grant Funding as Principle Investigator: $4,000,000

Principal Investigator (non-commercial - cumulative grants total over $250,000):

Percutaneous model for sciatic inflammatory neuritis in the rat: William Beaumont Hospital – intramural
Unrestricted grant: Pfizer ($36,000)

A novel, immune-mediated, rodent model for CRPS1: William Beaumont Hospital – intramural
Grant: DeRoy Testamentary Foundation ($5,000)

Biochemical characterization and stimulated nitric oxide production in peripheral monocytes in patients with neuropathic pain.

Neuroselective sensory electrodiagnostic evaluation of a topical gel containing gabapentin, ketoprofen and dextromethorphan.

Acute pain measurement in older adult patients using a simplified system for observational pain measurement.

Acute pain measurement in the pediatric patients: Perioperative comparison of several observational pain scales.

Acute pain measurement in the adult patient: Psychometric distinctions between NRS-11 and the VAS.

Pain Management Medical School Grant: The efficacy of rofecoxib for postoperative analgesia following hysteroscopy/dilatation and curettage.
Unrestricted grant - Merck ($18,000)

Outcome Studies in the prediction of treatment response for chronic pain patients: Neuropathic, Myofascial and Spinal Pain protocols – Beaumont Foundation/SOAA ($57,000) and Oakland University ($14,000).

The effect of initial local anesthetic dose with continuous interscalene analgesia on postoperative pain and diaphragmatic function in patients undergoing arthroscopic shoulder surgery – Beaumont Foundation/SOAA ($36,000).

The use of Emend (aprepitant) in the prevention of postoperative nausea following DepoDur (Depofoam encapsulated epidural morphine): an Observational study - intramural

Susceptibility to the development of chronic pain following extremity injury ($15,000 Oakland University/Beaumont Hospital; and Beaumont Foundation/SOAA - $79,000)

Principal investigator on the following multicenter phase II and phase III clinical trials: (commercial - cumulative grants total: $3.7 Million)

A Phase 2, Randomized, Placebo-Controlled, Double-Blind Study of Sustained-Release Encapsulated Morphine Administered Epidurally For the Treatment of Post-Operative Pain in Patients Undergoing Hip Arthroplasty Procedures under general anesthesia (Depotech)

A Phase 2, Randomized, Placebo-Controlled, Dose Finding, Double-Blind Study of Sustained-Release Encapsulated Morphine Administered Epidurally For the Treatment of Post-Operative Pain in Patients Undergoing Hip Arthroplasty Procedures (Depotech)

A Phase 2, open-label, long-term effectiveness and safety study of oxymorphone extended release tablets in patients with cancer or neuropathic pain (Endo)

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose Ranging Study to Evaluate the Safety and Efficacy of a Single Epidural Dose of Sustained-Release Encapsulated Morphine (SKY0401) in the Management of Post-Operative Pain in Patients Undergoing Hip Arthroplasty (SkyePharma)

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose Ranging Study to Evaluate the Safety and Efficacy of a Single Epidural Dose of Sustained-Release Encapsulated Morphine (SKY0401) in the Management of Post-Operative Pain in Patients Undergoing Lower Abdominal Surgery (SkyePharma)

A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Dose Ranging Study to Evaluate the Safety and Efficacy of a Single Epidural Dose of Sustained-Release Encapsulated Morphine (SKY0401) in the Management of Post-Operative Pain in Patients Undergoing Knee Arthroplasty (SkyePharma)

A Phase 2, Multicenter, Multi-Dose, 13 Week Double-Blind Study of the Comparison of the Safety and Efficacy of Dirame (Schedule I) and Placebo in Combination with NSAID Therapy in the Treatment of Moderate to Severe Hip or Knee Pain in Osteoarthritis with a 52-week Open-Label Extension (Shire)

A Phase 2, Single Dose Sequential Two Cohort Trial Designed to Evaluate the Efficacy and Safety of a Single Dose of 15, 30, or 45 mg Controlled-Release Hydrocodone (HCD) in Postoperative Orthopedic Patients (Purdue)

Research Activity (continued):

Multicenter Trials (continued):

A Phase 2, Multicenter, Randomized, Double-Blind, Placebo and Active Controlled Comparison of the Safety and Efficacy of Dirame (Propiram Fumarate: Schedule I), Oxycodone (5 mg) and Placebo in the Treatment of Moderate to Severe Pain After Total Hip Replacement Surgery. (Shire)

A Phase 2, Open-Label, Dose Escalating/De-Escalation Study of Sustained-Release Encapsulated Morphine Administered Epidurally for the Treatment of Post-Operative Pain in Patients Undergoing Total Hip Arthroplasty (SkyePharma)

A Phase 2, Multi-Center Clinical Study to Monitor the Clinical Performance of the PORT-A-CATH II Intraspinal Low Profile Implantable Access System in Delivering Preservative-Free Morphine to the Intrathecal Space in Patients with Chronic Pain of Malignant or Non-Malignant Origin (Deltec)

Phase 2, Evaluation of the Safety Profile of Oral Tramadol Hydrochloride for the Treatment of Painful Conditions in Children and Adolescents Aged Seven To Sixteen Years (RW Johnson)

A Phase 2, Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Clinical Study of the Safety and Efficacy of BOTOX (Botulinum Toxin Type A) Purified Neurotoxin Complex in Patients with Chronic Low Back Pain Associated with Paraspinal Muscle Spasm (Allergan)

A Phase 2, Double-Blind, Placebo-Controlled, Single Dose Evaluation of the Safety and Efficacy of Hydromorphone Hydrochloride Extended Release 24 mg Capsules in Acute Post-Operative Pain (Purdue-Frederick)

A Phase 2, Double-Blind, Placebo-Controlled, Single Dose Evaluation of the Safety and Efficacy of Hydromorphone Hydrochloride Extended Release 24 mg Capsules following total hip and total knee arthroplasty (Purdue-Frederick)

A Phase 2, Multiple Dose Multicenter Study Evaluating The Efficacy And Safety Of Hydrocodone/Acetaminophen (HA) With Naltrexone (NTX) In Post-Operative Orthopedic Patients (Purdue)

A Phase 2, Double-Blind, Multicenter Study Of The Safety And Efficacy Of Parecoxib Followed By Valdecoxib Compared To Placebo For Treatment Of Post Surgical Pain In Patients Who Have Coronary Bypass Graft Via Median Sternotomy (Pfizer/Pharmacia)

Research Activity (continued):

Multicenter Trials (continued):

A Pivotal Clinical Study To Evaluate The Safety And Effectiveness of MR Guided Focused Ultrasound Surgery In The Treatment Of Uterine Fibroids (InSightec)

A Phase 2, Safety evaluation of D-TRANS fentanyl with naltrexone HCl in opioid tolerant patients (Alza/Johnson & Johnson)

A Phase 2, Open-label safety evaluation of D-TRANS fentanyl with naltrexone HCl in opioid tolerant patients (Alza/Johnson & Johnson)

A Phase 2, Comparison of the Safety and Efficacy of Patient Controlled Analgesia Delivered by Fentanyl HCl Transdermal System (E-TRANS) Versus Morphine IV Pump for Pain Management after Primary Unilateral Total Hip Replacement (Ortho-McNeil)

A multicenter, double-blind, placebo-controlled, randomized study of the analgesic efficacy and safety of valdecoxib 20mg qd and valdecoxib 20mg bid compared to placebo over multiple days for management of acute postsurgical pain in patients undergoing anterior cruciate ligament (ACL) reconstruction (Pfizer)

A Phase 3, double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of a single epidural dose of sky0401 in the management of post-operative pain in patients undergoing hip arthroplasty with regional anesthesia (Skye Pharma/Endo)

A Phase 2, Multicenter, Randomized, Double-Blind, Parallel-group, Placebo-Controlled Study of 2 mg/kg Bolus Plus 24-hour 0.05 mg/kg/hr Infusion of Pexelizumab in Patients Undergoing Coronary Artery Bypass Grafting with Cardiopulmonary Bypass (PRIMO-CABG II) (Proctor and Gamble)

An Observational, Multicenter, Prospective Study of Resource Utilization in the Management of Post-operative Pain using Intravenous (IV) Patient-Controlled Analgesia (PCA) (Ortho-McNeil)

A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group, Phase II Study to Evaluate the Safety and Efficacy of Oral Dosing with GW679769 (50 mg or 150 mg) for Three Consecutive Days When Administered with a Single Intravenous Dose of Ondansetron Hydrochloride for the Prevention of Post-operative Nausea and Vomiting and Post-discharge Nausea and Vomiting in Female Subjects with Known Risk Factors for Post-operative Nausea and Vomiting Who are Undergoing Laparoscopic/Laparotomic Surgical Procedures Associated with an Increased Emetogenic Risk (GlaxoSmithKline)

Research Activity (continued):

Multicenter trials (continued):

A Randomized, Double-Blind, Placebo-Controlled, Multi-centre Phase 3 Study to Evaluate the Safety and Efficacy alvimopan 0.5 mg Twice Daily for 12 weeks for the Treatment of Opioid-Induced Bowel Dysfunction in Adults taking Opioid Therapy for Persistent Non-Cancer Pain (GlaxoSmithKline)

A Randomized, Double-Blind, Placebo-Controlled, Multi-centre Phase 3 Study to Evaluate the long term Safety of alvimopan 0.5 mg Twice Daily for 12 months for the Treatment of Opioid-Induced Bowel Dysfunction in Adults taking Opioid Therapy for Persistent Non-Cancer Pain (GlaxoSmithKline)

A phase 3 multicenter, randomized, double-blind, parallel group study to evaluate the safety and efficacy of the intravenous formulation of the neurokinin-1 receptor antagonist GW679769 for the prevention of postoperative nausea and vomiting in female subjects at high risk for emesis (GlaxoSmithKline)

An observational study to characterize the burden of illness associated with laxative use in subjects using opioids for the management of persistent pain (GlaxoSmithKline)

A randomized, double-blind, active and placebo controlled, parallel group, multicenter study to evaluate the efficacy and safety of multiple doses of CG5503 (tapentadol)immediate release (IR) formulation in the treatment of acute pain from total hip replacement followed by an voluntary open label extension (Johnson & Johnson)

A randomized, double-blind, placebo-controlled, Multicenter study to evaluate the cardioprotective effects of MC-1 in patients undergoing high-risk coronary artery bypass graft (CABG) surgery (Medicure)

A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of dexmedetomidine for sedation during monitored anesthesia care (Hospira)

A phase 3, randomized, double-blind, placebo-controlled, Multicenter, parallel-group, multiple-dose study of the analgesic efficacy and safety of intravenous acetaminophen versus placebo over 48 hours for the treatment of postoperative pain after gynecologic surgery (Cadence)

A randomized, double-blind, active and placebo controlled, parallel group, multicenter study to evaluate the efficacy and safety of multiple doses of CG5503 (tapentadol)immediate release (IR) formulation in the treatment of acute pain from arthritis in patients awaiting joint replacement surgery (Johnson & Johnson)

Research Activity (continued):

Multicenter Trials (continued):

A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of dexmedetomidine for the prevention of delirium following hip fracture surgery (Hospira)

A phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of dexmedetomidine for sedation following CABG (Hospira)

An Exploratory Phase 2, multicenter, randomized, placebo-controlled, parallel group, double-blind study to assess the safety, tolerability, efficacy and pharmacokinetics of 4975 in patients undergoing primary unilateral total hip arthroplasty (Anesiva)

A phase 2, multicenter, randomized, placebo-controlled, parallel-group, double-blind study to evaluate the tolerability, safety and pharmacokinetics of 4975 in patients undergoing primary unilateral total knee arthroplasty (Anesiva)

A Phase III Randomized, Double-Blind, Placebo-Controlled, Multi Center, Parallel-Group, Repeated-Dose Study of the Analgesic Efficacy and Safety of Intravenous Acetaminophen Versus Placebo for the Treatment of Postoperative Pain After Abdominal Laparoscopic Surgery (Cadence)

Protocol # 6003/ Study of a Urethral Catheter Coated with Eluting Silver Salts: SUCCESS (BARD)

The E-Stim Trial: A Randomized, Double-Blind, Multicenter Trial Comparing The Efficacy Of The Empi Select™ Transcutaneous Electrical Nerve Stimulation (TENS) To A Control For The Treatment Of Chronic Lower Back Pain (Empi)

A Double-Blind, Placebo-Controlled, Multicenter Trial To Study The Efficacy And Tolerability Of MK-0663/Etoricoxib In The Treatment Of Pain After Abdominal Hysterectomy (Merck)

An Open Label Pilot Study Of The Analgesic Efficacy And Safety Of Q8003 And Of The Conversion From IV Morphine PCA Analgesia To Q8003 Or To Percocet In Patients Who Have Undergone Primary Unilateral Total Knee Arthroplasty (QRx Pharma)

A Prospective, Multi-Center, Observational Registry Of Patients Using Prescription Medications Containing Oxycodone Immediate Release For The Treatment Of Pain (Ortho-McNeil)

Research Activity (continued):

Multicenter Trials (continued):

A Phase 3b Multicenter, Double-Blind, Randomized Withdrawal Efficacy And Safety Study Of Pregabalin In The Treatment Of Patients With Inadequately Treated Painful Diabetic Peripheral Neuropathy (Protocol A0081242)(Pfizer)

Bupivacaine Effectiveness And Safety In Saber Trial (BESST) (C803-025)(Durect Corp.)

A Randomized, Open-Label Study of Pragmatic Trial Methods for Testing the Effectiveness of NUCYNTA® (tapentadol) Immediate-Release (IR) or Oxycodone IR on Work Outcomes in the Treatment of Employed Subjects With Low Back Pain (Ortho-McNeil)

Spinal Injections (indidivual speakers = 2 minutes; groups = 10 minutes)

	#	Name	Representing	COI	PPT
Group #1	1	Paul Dreyfuss, MD		Yes	Yes
	2	Ray Baker, MD	North American Spine Society (NASS)	Yes	Yes
	3	Way Yin, MD		Yes	Yes
	4	Nikolia Bogduk, MD		Yes	Yes
	5	Richard Rosenquist, MD		Yes	Yes
	6	John Carrino, MD		Yes	Yes
Individual Presenters	7	Carolyn Marquardt, MD	Northwest Spine & Sport Physicians	Yes	No
	8	Andrew J. Cole, MD	Northwest Spine & Sport Physicians	Yes	No
	9	Jason Attaman, DO		Yes	No
	10	Jeffrey Roh, MD		Yes	No
	11	Llewellyn N. Packia Raj, MD		Yes	No
	12	Irene Young, MD		Yes	No
	13	Yung J. Lee, DO	Northwest Spine & Sport Physicians	Yes	No
	14	Elin Bjorling	American Pain Foundation	Yes	No
	15	Deryk Lamb	American Pain Foundation	Yes	No
	16	Trent L. Tredway, MD		Yes	No
	17	Michael Hatzakis, Jr., MD		Yes	No
	18	Alison Stout, DO		Yes	No

Washington State Health Care Authority

Paul Dreyfuss, MD – SI

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		x
2.	Equity interests such as stocks, stock options or other ownership interests		x
3.	Status or position as an officer, board member, trustee, owner	x	
4.	Loan or intellectual property rights		x
5.	Research funding		x
6.	Any other relationship, including travel arrangements		x

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

I am immediate past president of the International Spine Intervention Society (Board Position)

	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).	x	

7. If yes, Provide Name and Funding Sources: I represent the International Spine Intervention Society, but have received no funding to be able to present on March 18th.

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 _____ 2.18.11 Paul Dreyfuss, MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Ray Baker, MD – SI

Washington State Health Care Authority

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		X
2.	Equity interests such as stocks, stock options or other ownership interests	X	
3.	Status or position as an officer, board member, trustee, owner	X	
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

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

- Warrants (<3% of company) in Nocimed, Laurimed, and Relievant MedSystems. I received a total of $14,000 in the past 12 months as dividends.
- Board of Directors, Immediate Past President of North American Spine Society
- Board of Directors, President-elect of International Spine Intervention Society.

	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).	X	

7. If yes, Provide Name and Funding Sources:I will represent the North American Spine Society. I will not receive any funding or monies for preparing or presenting at the meeting.

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] 2/22 RAY M. BAKER

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

Washington State Health Care Authority

Way Yin, MD – SI

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	X	
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner	X	
4.	Loan or intellectual property rights		X
5.	Research funding	X	
6.	Any other relationship, including travel arrangements		X

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

#3: Owner, Bellingham Spine Pain Specialists, PC, Bellingham, WA (medical practice)

#3: Managing Member, Northwest Ambulatory Surgery Center, Bellingham, WA

#5: Research grant: International Spine Intervention Society (2008; $10,000 total, none current)

#1: Consultant, Spinal Restoration, Inc., Austin, TX. (2010 to present < $10,000)

#1: Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) – (no compensation)

	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).	X	

#7: President, Board of Directors, International Spine Intervention Society (no compensation) – presenting as a representative of this society (no compensation for work or travel or other costs related to HTA presentation)

#7: Task force member (Value, Performance measures, Registry), North American Spine Society (no compensation)

#7: Noridian Administrative Services, LLC work group (no compensation)

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 _____ 2/18/11 WAY YIN, MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

Washington State Health Care Authority

Nikolia Bogduk, MD – SI

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		x
2.	Equity interests such as stocks, stock options or other ownership interests		x
3.	Status or position as an officer, board member, trustee, owner	x	
4.	Loan or intellectual property rights		x
5.	Research funding		x
6.	Any other relationship, including travel arrangements		x

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

Founding Member, International Spine Intervention Society

However, as a Staff Specialist working exclusively in a Public Hospital, I derive no income from any procedures, and my involvement in learned societies has been in the interests of conducting research and promoting evidence-informed practice.

	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).		x

7. If yes, 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 Nikolai Bogduk 28-2-11 NIKOLAI BOGDUK

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Richard Rosenquist, MD -SI

Washington State Health Care Authority

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		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner	X	
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

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

Member American Society of Regional Anesthesia and Pain Medicine Board of Directors

Chair, American Society of Anesthesiologists Committee on Pain Medicine

	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).		X

7. If yes, 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.

Richard W. Rosenquist 03/01/2011 Richard W. Rosenquist, M.D.

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

John Carrino, MD – SI

Washington State Health Care Authority

Disclosure

Any unmarked topic will be considered a "Yes"

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

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

General Electric Medical Advisory Board for Pain Management (non-paid position)

	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).		x

7. If yes, 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 John A Carrino 3/3/2011 John A. Carrino

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

Washington State Health Care Authority

Carolyn Marquardt, MD - SI

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		x
2.	Equity interests such as stocks, stock options or other ownership interests		x
3.	Status or position as an officer, board member, trustee, owner		x
4.	Loan or intellectual property rights		x
5.	Research funding		x
6.	Any other relationship, including travel arrangements		x

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).		x

7. If yes, 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 Carolyn Marquardt 2-20-11 _____

_____

Signature *Date* *Print Name*

Andrew J. Cole, MD – SI

Washington State Health Care Authority

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:

1, 6 Medtronic Corp – 2x/y speak on non-op management of LBP – medical/surface pd.
2. Shares owned in Overlake Hospital ASC.

	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)		✓

7. If yes, 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 _____ 2/24/11 Andrew J. Cole, MD
Signature Date Print Name

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

Jason Attaman, DO - SI

Washington State Health Care Authority

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		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements	X	

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

OTHER RELATIONSHIP: I am a fellowship trained and board

	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).		X

7. If yes, 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 _____ 2/24/11 Jason G. Attaman, DO, FAAPMR

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

Washington State Health Care Authority

Jeffrey Roh, MD - SI

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:

1) Stryker, 2) Advanced Biologics, 3) Orthopedics International, 4) USPTO, 5) Stryker

	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).	✓	

7. If yes, Provice Name and Funding Sources: I am the chair of credentials committee and the chair of spine services at Evergreen Hospital.

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] MD, 3/3/11

Signature *Date*

Jeffrey Roh, MD

Print Name

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,

Llewllyn Packia Raj - ST

Washington State Health Care Authority

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		x
2.	Equity interests such as stocks, stock options or other ownership interests	x	
3.	Status or position as an officer, board member, trustee, owner		x
4.	Loan or intellectual property rights		x
5.	Research funding		x
6.	Any other relationship, including travel arrangements		x

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).		x

7. If yes, 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* 3/4/11 *Date* Llewllyn Packia Raj *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,

Washington State Health Care Authority

Irene Young, MD – SI

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		X
2.	Equity interests such as stocks, stock options or other ownership interests	X	
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

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

Overlake Surgery Center

	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).		X

7. If yes, 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 _____ 2/21/11 Irene Young MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,

Washington State Health Care Authority

Yung J. Lee, DO - SI

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).		✓

7. If yes, 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 _____ 3/3/11 Yung J. Lee

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,

Elin Bjorling, PhD - SE

Washington State
Health Care Authority

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		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

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).	X	

7. If yes, Provide Name and Funding Sources;

See APF's Annual Report for a full list of APF funding sources;
http://www.pa.nfoundation.org/learn/publications/files/2009-annual-report.pdf

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 _____ 3/4/2011 Elin Bjorling, Ph.D.
Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Deryk Lamb - SII

Washington State Health Care Authority

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		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

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).		X

7. If yes, 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* 3.4.11 *Print Name* DERYK LAMB

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742.

Washington State Health Care Authority

Trent Tredway, MD – SI

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	X	
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

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

Synthes Spine : Honorarium

Medtronic: Honorarium

	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).		X

7. If yes, 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 Trent L. Tredway, MD (e-sign) 3/1/11

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,

Michael Hatzakis, Jr, MD - SI

Washington State Health Care Authority

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		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements		X

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).		X

7. If yes, 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 _____ 2/27/2011 Michael Hatzakis Jr MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

Washington State
Health Care Authority

Alison Stout, DO - SI

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		X
2.	Equity interests such as stocks, stock options or other ownership interests		X
3.	Status or position as an officer, board member, trustee, owner		X
4.	Loan or intellectual property rights		X
5.	Research funding		X
6.	Any other relationship, including travel arrangements	*	

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

* No travel arrangements for this HTCC meeting. Numerous other travel arrangements for various societies. Sent email to Denise Santoyo for clarification of this. None of these are in excess of economy class airfare, ground transfers, hotel; the sum of all does not exceed $10,000 over the last 5 years.

	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).		X

7. If yes, 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* 3/3/2011 *Date* Alison Stout D.O. *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

Spinal Injections: Public Comments for HTCC Review

Ray Baker, MD
Nikolai Bogduk, MD
John Carrino, MD
Paul Dreyfuss, MD
Richard Rosenquist, MD
Way Yin, MD

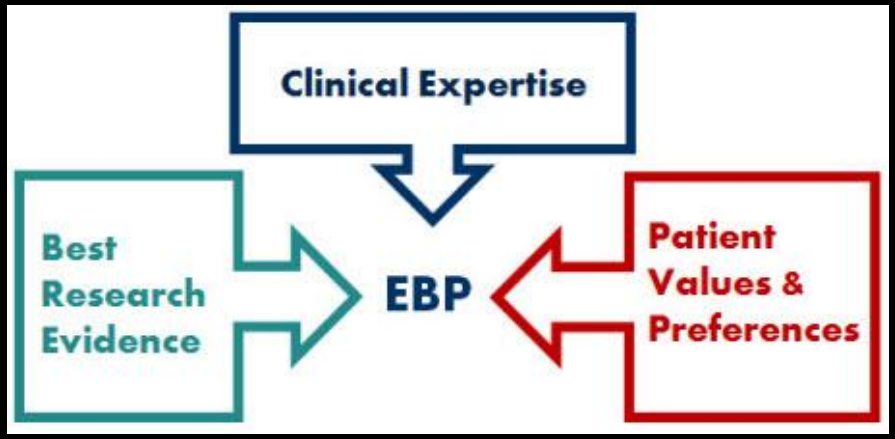
Introduction

- HTCC members have expertise in evidence based medicine, epidemiology, public health, and the scientific method
- HTCC members are active practicing clinicians
- All members are interested in helping to provide the best care possible to Washington State's patients
- The decisions that are made today will affect almost 4 million WA State residents

The HTCC has used the true Sackett definition of EBM in making prior decisions

EBM Definition

- EBM is a distillation of clinical experience informed by the results of clinical trials
- Evidence based practice (EBP) involves integrating clinical expertise, patient values, and the best research evidence into the decision making process for patient care



As defined by Sackett, EBM involves more than systematic reviews and RCTs

- The best available evidence is used, not restricted to Level 1 or 2 studies
- RCTs are not the only form of evidence, or the only form of admissible evidence

Systematic Reviews have Limitations

- They do not paint the full picture of the original literature
- They can be limited (e.g. *Spectrum including only Level 1 or 2 studies*)
- They can be flawed or biased, and evaluation of the literature is subjective
  - How to reconcile multiple systematic reviews with differing conclusions?

Because of methodological idiosyncrasies, systematic reviews understate both the effectiveness and relevance of spinal injections

Systematic reviews do not prove that procedures are ineffective; they only lament that the literature is lacking in the types of studies that the authors happen to want

RCTs have Limitations

- RCTs only determine if a treatment is better than placebo, or if a treatment is better than another treatment
  - Once a treatment has been shown not to be a placebo, it *cannot* be impugned for "not working."
- RCTs *cannot* determine how well a treatment works
  - Population studies are needed to demonstrate the magnitude of the treatment effect

RCTs have Limitations

- An absence of evidence cannot be equated with evidence of ineffectiveness
- RCTs are expensive and difficult to carry out
  - Although spinal fusions, artificial discs, and other treatments have ‘deep pocket’ sponsors, spinal injections do not
  - Attempted RCT for lumbar RF had a budget of over $400k

RCTs have Limitations

- Although RCT data is desired by reviewers, funding for RCTs in this and other fields have not been provided by guideline or evidence review organizations, states, or the federal government
- The lack of multiple RCTs for spinal injections is understandable and is consistent with most other treatments in medicine

Patients are the Bottom Line

- We need to preserve appropriate patient access to care while we allow for studies to be performed assessing the role and magnitude of the treatment effect

We Applaud the HTCC's Application of True EBM in their Prior Decisions

- The HTCC has found in favor of numerous treatments despite conflicting / negative / or low grades of evidence from the evidence vendor
  - Lumbar Fusion
  - Lumbar Artificial Disc Replacement
  - Ultrasound in Pregnancy
- We applaud the HTCC's application of true EBM in their prior decisions which included understanding the evidence in *context* of the patient's clinical situation

Commentary of APS guidelines and Spectrum HTA Report on Spinal Injections

- The inclusion/exclusion criteria of the APS Guidelines and Spectrum report allowed for *only* a limited number of valid conclusions, which are not in agreement with other guidelines that have used a broader range of evidence
- The grading scheme used by Spectrum, and the inclusion/exclusion criteria used by APS and Spectrum (use of RCTs primarily) would render the evidence for *nearly all spinal treatments (surgical and non-surgical) as low or very low*

Spectrum Grading Methodology

Domain	Definition/Criterion
Quality	• At least 80% of the studies are LoE I or II
Quantity	• There are at least three studies which are adequately powered to answer the study question
Consistency	• Study results would lead to a similar conclusion (similar values, in the same direction) in at least 70% of the studies

SoE	Description	Further Research Impact	Domain Criterion Met		
			Quality	Quantity	Consistency
1	**High**	Very unlikely to change confidence in effect estimate	+	+	+
2	**Moderate**	Likely to have an important impact on confidence in estimate and *may* change the estimate	+	-	+
			+	+	-
3	**Low**	Very likely to have an important impact on confidence in estimate and *likely* to change the estimate	+	-	-
			-	+	+
4	**Very Low**	Any effect estimate is uncertain	-	+	-
			-	-	+
			-	-	-

Evidence Equivalent to Other Txs

- For chronic pain, the evidence for spinal injections is equal to or superior to existing conservative treatments and therapies
  - physical therapy, chiropractic care, acupuncture, psych services, medication management, etc.
- The evidence for most spinal injections is equal to or superior to that of lumbar fusion and disc arthroplasty

Surgery Sparing

- There is evidence that spinal injections – in certain disease conditions (e.g. cervical and lumbar radicular pain) – *may actually have surgery sparing effects*
  - In one study, 71% of patients in treatment group cancelled surgery v. 33% control group ($p<.004$)
  - Of these, 80% did not have surgery 5 years later (Riew, et al JBJS 2000/2006)

- In the Spectrum report the level of evidence for lumbar transforaminal epidural steroid injections was downgraded from “low to moderate” to “low” *after* inclusion of a recent 6 arm randomized controlled trial in which benefit from epidural steroid injections was shown *not* to be attributable to a systemic effect of the corticosteroids, a local effect of the anesthetic or a placebo response. (Ghahreman A. Pain Med 2010; 11:1149-1168)
- This may represent bias

Spectrum Research violated basic conflict of interest policies by using Dr. Chou as a contributor to the technology assessment on spinal injections

- Dr. Chou was the primary author of the APS guideline which was critical of spinal injections.
- Dr. Chou has an obvious academic and intellectual bias to be consistent with his prior publications.
- By recruiting Dr. Chou as a contributor to their report and by using the APS guidelines as the foundation for their report, Spectrum violated the public trust by *not* performing an independent review of all spinal injection literature, as demanded by their contract.

APS Guidelines-Note
Spine 2009;34:1066–1077

- Clinical practice guidelines are “guides” only and may not apply to all patients and all clinical situations. As part of a shared decision-making approach, it may be appropriate for the clinician to inform a patient that a particular recommendation may not be applicable, after considering all circumstances pertinent to that individual.

Spectrum Disclosure/Note

- Spectrum's report states "Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the *context* of individual patient circumstances and resource availability."
- We implore you to keep this dictum in mind

Spinal Injections in the context of existing spinal treatments

Diagnostic Injections

- Diagnostic injections were not evaluated in Spectrum's technology assessment on *therapeutic* spine injections
- It is well accepted that they can provide accurate structure-specific diagnostic information not otherwise obtainable.
  - e.g. a negative block can save a patient from surgery based on a misdiagnosis

- Diagnostic Injections are a vital part of the spinal armamentarium
  - This includes diagnostic intraarticular facet injections, medial branch blocks, intraarticular sacroiliac joint injections, sacral lateral branch blocks and selective spinal nerve injections

Spinal injections facilitate physical therapy when patients cannot tolerate activity based exercise strategies or plateau with treatment

- Spinal injections are an important alternative to surgery
  - If other conservative treatments fail, and spine injections are eliminated, far more patients are likely to undergo spinal surgery, including fusion and artificial disc replacement (which the HTCC has endorsed)
  - The failure, complication rates and costs of these surgeries should be considered in any decision to limit or eliminate spinal injections

Patients refusing more aggressive approaches, such as surgery, will be relegated to ongoing disability and suffering, or maintained on chronic opioids or other medications

The HTCC should not evaluate the evidence in isolation

The context of your decision, in light of patients' residual options, must be considered as you have done in the past

Spinal injections are safe overall, and *no evidence suggests that spinal injections are less safe than surgical interventions*.

Although assumed to be safe, conservative therapies have not been studied in this particular context. There is no evidence that spinal injections are *LESS* safe than conservative care.

Multi-Society Supported Procedure Recommendations:

The multi-society group includes:

- American Association of Neurological Surgeons
- American Academy of Pain Medicine
- American Academy of Physical Medicine and Rehabilitation
- American College of Radiology
- American Society of Anesthesiologists
- American Society of Neuroradiology
- American Society of Spine Radiology
- Congress of Neurological Surgeons
- International Spine Intervention Society
- North American Spine Society
- Society of Interventional Radiology

The recommendations of these societies and the scientific rationale for their recommendations was submitted to the HTCC on November 24, 2010 and is a matter of public record

We trust the HTCC:

- Will not find multi-society input biased or conflicted
- Will respect and utilize the multi-society consensus document in understanding application of the literature in context.

If the HTCC considers medical society input as biased, they should also consider the potential for bias created by the $1.2 million contract issued to Spectrum to perform evidence analysis for the state of WA

The multi-society group supports:

- The use of injection procedures as *diagnostic tests*
  - Including intraarticular facet injections, medial branch blocks, intraarticular sacroiliac joint injections, sacral lateral branch blocks and selective cervical, thoracic, lumbar, and sacral spinal nerve injections

The multi-society group supports:

Certain spinal injection procedures as *therapeutic interventions*:

- Lumbar transforaminal epidural injections
- Sacroiliac joint injections
- Cervical interlaminar epidural injections

Context

- Injections come into play when conservative care has failed.
  - In this context, there is no choice to revert to conservative care, for conservative care has manifestly failed.
- The only choice, the only conflict, is between injections and surgery.
  - There is no proven surgery for facet joint or sacroiliac joint pain.
  - Lumbar transforaminal injections have been shown to help prevent lumbar decompressive surgery with 5 year follow-up

ON CONTEXT

PATIENTS

PAYORS

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

PAYORS

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

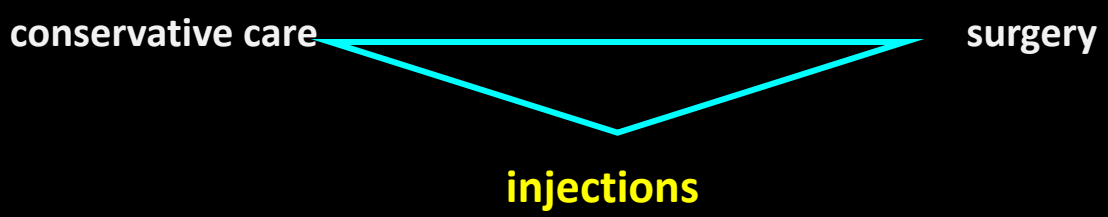
conservative care ——— surgery

PAYORS

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

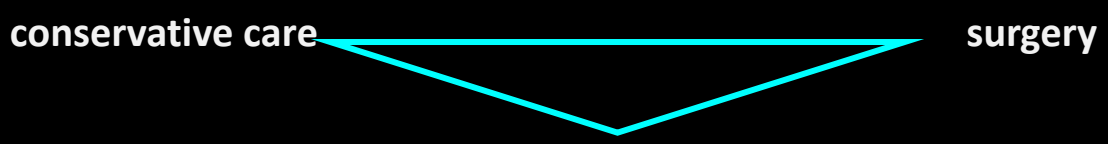


PAYORS

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN



injections

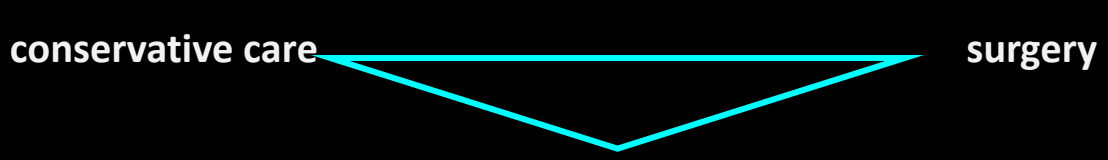
PAYORS

EFFECTIVENESS

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN



EFFECTIVENESS

PAYORS

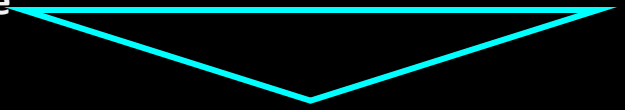
Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care



surgery

injections

PAYORS

EFFECTIVENESS

certain procedures

some situations

cost-effective

and safe

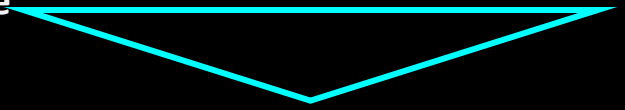
Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care



surgery

injections

PAYORS

EFFECTIVENESS

~~therapeutic MBB~~

~~intradiscal steroids~~

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

EFFECTIVENESS

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic ✓ ✓ ✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

EFFECTIVENESS

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic ✓ ✓ ✓

sacroiliac ✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care

surgery

injections

PAYORS

EFFECTIVENESS

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic ✓ ✓ ✓

sacroiliac ✓

cervical interlaminar ✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

EFFECTIVENESS

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic ✓ ✓ ✓

sacroiliac ✓

cervical interlaminar ✓

lumbar transforaminal ✓ ✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

ABUSE

EFFECTIVENESS

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic	✓ ✓ ✓	lumbar transforaminal	✓ ✓
sacroiliac	✓	cervical interlaminar	✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

ABUSE

EFFECTIVENESS

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic	✓ ✓ ✓	lumbar transforaminal	✓ ✓
sacroiliac	✓	cervical interlaminar	✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

ABUSE

INDICATIONS

EFFECTIVENESS

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic	✓ ✓ ✓	lumbar transforaminal	✓ ✓
sacroiliac	✓	cervical interlaminar	✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

ABUSE

EFFECTIVENESS

INDICATIONS

No conservative care available

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic	✓ ✓ ✓	lumbar transforaminal	✓ ✓
sacroiliac	✓	cervical interlaminar	✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

ABUSE

EFFECTIVENESS

INDICATIONS

No conservative care available

Failed conservative care

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic	✓ ✓ ✓	lumbar transforaminal	✓ ✓
sacroiliac	✓	cervical interlaminar	✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

ABUSE

EFFECTIVENESS

INDICATIONS

No conservative care available

Failed conservative care

No repeat without prior benefit

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic	✓ ✓ ✓	lumbar transforaminal	✓ ✓
sacroiliac	✓	cervical interlaminar	✓

Multi-Society Group

PATIENTS

BACK PAIN NECK PAIN

RADICULAR PAIN

conservative care — surgery

injections

PAYORS

ABUSE

EFFECTIVENESS

INDICATIONS

No conservative care available

Failed conservative care

No repeat without prior benefit

Benefit substantial and lasting

~~therapeutic MBB~~

~~intradiscal steroids~~

diagnostic	✓ ✓ ✓	lumbar transforaminal	✓ ✓
sacroiliac	✓	cervical interlaminar	✓

Multi-Society Group

Systematic reviews do not make decisions.

Committees make decisions.

It is the Committee that brings to the process understanding, insight, and humanity.

Valid procedures can be misused or abused

- Physician specialty societies have recognized that utilization of spinal injection procedures has increased dramatically and these procedures have frequently been used inappropriately
  - Society concerns regarding misuse were confirmed with OIG reports in a Medicare population, looking at facet injections (OEI-05-07-00200, Sept 2008):
    - 63% of facet injections did not meet MC program requirements
    - 38% had documentation errors (27% no documentation, 11% insufficient documentation)
    - 31% had coding errors
    - 8% were medically unnecessary

Many of these improprieties occurred due to increased numbers of providers performing the procedures without adequate training or controls, or without image guidance

Coding Error Rates by Specialty

High specialty-specific coding error rates among non-interventional specialties were found, especially in office based settings (error rates over 60% by specialty):

- Neurosurgery: 100%
- General Surgery: 100%
- Pathology: 100%
- ARNP: 100%
- Emergency Medicine: 100%
- Physician Assistants: 100%
- General Practice: 100%
- Internal Medicine: 87%
- Family Practice: 78%
- Neurology: 73%
- Rheumatology: 71%
- Orthopedic Surgery: 64%
- General Anesthesiology: 63%

- Coding error rates were lowest in practices specializing in spine interventions:
  - Interventional Pain Management: 12%

Effectiveness is how well a procedure works in the general community – not in highly selected samples of patients who volunteer for studies.

- But that effectiveness is clouded by patients who would not benefit, yet receive the treatment.
- Inappropriate use of spinal injections occurs when practitioners do not follow best practice.

- Other insurers have recognized the importance of this phenomenon. They recognize that it is not the procedure that is at fault, but the practitioners who abuse it.
- To combat this abuse insurers have applied restrictions to the use of procedures.
- This is what the multi-society group recommends to the Committee and has effectively done with Noridian Administrative Services (Medicare Contractor)

- Twelve stakeholder medical societies (including the 11 represented by this multi-society group) forged a groundbreaking working relationship with Noridian Administrative Services (NAS) – a Medicare Contractor that processes claims and determines coverage for Medicare beneficiaries in 11 Western States, including Washington

- Together, we instituted appropriate safeguards against the abuse of injections while preserving appropriate patient access to care, and to allow those practitioners who are ethical and responsible to care for their patients.

Dr. Bernice Hecker, a medical director for Noridian Administrative Services (NAS), stated:

- “Cooperation between NAS and the medical societies or their representatives has occurred and was fruitful in forming a Local Carrier Decision (LCD) on facet joint injections and RF neurotomy. Coverage decisions have been evidence-based and, when deficits in such knowledge were appreciated, a “best practice” model was used”
- “NAS has now permanently established a Pain Management Workgroup composed of experienced clinicians from practices across the West and Midwest. We deem these providers to be experts in the field and this expertise is most useful”
- “NAS and the workgroup are currently involved in the production of another LCD on epidural steroid injections with plans for several additional coverage policies, including surgical policies.”

- The multi society group shares the concerns of WA State and other state and Federal agencies and are working to help prevent misuse and abuse.
  - Controlling abuse requires establishing administrative controls, restrictions, and requirements.
  - Controlling abuse does *not* involve the blunt force of non-coverage decisions for validated procedures.

- Restrictions are not an administrative device to cut costs.
- They are a reaffirmation of what constitutes correct and best practice, with respect to indications and repetitions.
- Observing these restrictions eliminates abuse and restores the effectiveness of procedures.

"Automobiles do not kill. Bad drivers kill."

- The solution is not to ban cars; it is to apply sensible traffic rules.
- In pain medicine, the solution is to implement sensible 'traffic' rules.

Despite requests for a more focused scope, the topic today remains impossibly broad.

- Prior HTA spine topics have involved 3-5 primary RCTs
- Today's topic involves 46 RCTs
- There are an additional 172 pertinent references cited in the 299 page evidence vendor report

This places an inordinate burden on the HTCC to thoroughly evaluate such a comprehensive body of literature in such a limited time frame.

- We appreciate that the HTCC is not allotted adequate time for deliberations.
- In fact, no additional time has been allotted to the committee to compensate for the broad scope of material.
- However, there is a fair option for the committee to consider.

RCW 70.14.110(3)

- Vote for coverage with restrictions that are currently in place by Medicare and private payers in the state of WA
- This is appropriate as there is *not* "substantial evidence regarding the safety, efficacy and cost-effectiveness of the technology to support a *contrary* determination" as established by RCW 70.14.110(3)
- Furthermore, RCW 70.14.110(3) states that "formal assessments and determinations shall be consistent with decisions made under the federal Medicare program and in expert treatment guidelines, *including those from specialty physician organizations* and patient advocacy organizations"

Spine Injections are covered procedures

- National Policies:
  - Including, but not limited to: CMS, Aetna, Cigna, Humana, United Health Care cover therapeutic epidural steroid injections, diagnostic and therapeutic sacroiliac Joint injections and primarily diagnostic facet Injections (Humana covers therapeutic facet injections)

Spine Injections are covered procedures

- Local Policies:
  - Including, but not limited to: Premera, BCBS, Regence, Medicare (Noridian) for WA state cover therapeutic epidural steroid injections, diagnostic and therapeutic sacroiliac joint injections and diagnostic and therapeutic facet Injections

The coverage policies that are currently in place for Medicare (LCDs) and major third party payers in the state of WA provide reasonable restrictions to prevent abuse, yet allow appropriate patient access to care.

We request the HTCC adopt these currently available and responsible coverage policies as outlined in the remaining slides

Current Coverage Policies for Medicare (NCD and LCD) and Third Party Payers

Imaging Guidance and Diagnostic Injections

- Spine injection procedures should be performed under fluoroscopic or CT guidance. Ultrasound guidance is not a covered image guidance modality.
- Diagnostic procedures provide valuable information not obtained through other methods. These covered procedures include medial branch blocks, facet injections, sacroiliac joint injections, lateral branch blocks and selective spinal nerve injections.

Current Coverage Policies for Medicare (NCD and LCD) and Third Party Payers

Sacroiliac and Facet Joint Injections

- Sacroiliac and facet joint injections can be performed only if there is failure of conservative care for a minimum of 6 weeks
- Sacroiliac and facet joint injections should not be repeated unless the prior injection provided ≥50% relief with functional improvement for a minimum of 6 weeks
- No more than 4 steroid injections/year should be performed into the same joint

Current Coverage Policies for Medicare (NCD and LCD) and Third Party Payers

Cervical and Lumbar Epidural Injections

- Epidural steroid injections should not be performed unless there is failure of conservative care for a minimum of 3 weeks
- No more than 2 epidural steroid injections should be performed *unless* there is ≥50% pain relief with functional improvement for at least 6 weeks
- No more than 3 epidural injections are indicated in any 6 month period with no more than 6 epidural steroid injections/yr

Thank you for your attention and consideration of our viewpoints and perspective

Washington State Senate

Senator Doug Ericksen
Republican Whip
42nd Legislative District

Olympia Address:
PO Box 40442
Olympia, WA 98504-0442

(360) 786-7682
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E-mail: Doug.Ericksen@leg.wa.gov

March 8, 2011

RE: March 18, 2011 HTCC Meeting, Statement for Spinal Injections

I understand the process the Health Technology Clinical Committee goes through to determine which medical procedures are safe, cost-effective and provide the greatest benefit to the individual patient. One such procedure entails the treatment of patients suffering from spine-related pain with minimally invasive, appropriately performed spinal injections.

I can personally attest to the effectiveness of this procedure, as I went through it myself. I found it to be incredibly beneficial to my overall health.

The discontinuation of medical coverage for this procedure would affect all state employees and Medicaid/L&I patients. If patients are not covered, they will be remanded to either costly surgery or chronic narcotics, neither of which are acceptable options when an appropriately administered spinal injection is at least as effective as conservative care.

I encourage the Committee to listen to the testimony of experts in this specialty field like Dr. Way Yin as you make your decisions. I appreciate your strong consideration.

Sincerely,

Doug Ericksen

Senator Doug Ericksen
42nd Legislative District

3/4/2011

Washington HTA

Dear Dr. Budenholzer,

I recently had the pleasure of speaking with Josh Morse, of Washington L&I, about the problems the state of Washington faces with the increased utilization of interventional pain management procedures. We discussed my work as a utilization reviewer for L&I. Josh believes that my experience translates into useful insights into the increased utilization of injections as well as new perspectives on how to appropriately apply these medically necessary treatments.

As we approach the problem of increased utilization it is imperative that we look at the global picture and identify three fundamental trends:

Three Trends:

- There has been a large increase in the utilization of interventional pain procedures.
- From a global perspective it appears that outcomes are poor.
- There is strong evidence to support certain interventional procedures.

If we agree on the aforementioned three trends, we can then identify three problem areas that need to be addressed:

Three Problems

- Which procedures have efficacy? – This complex question is beyond the scope of this letter. At present we have no good published standard of care. The ASIPP guidelines appear to support essentially all procedures. The ACOEM and ODG Guidelines have been criticized for being inaccurate and written without authority. It is my understanding that an alternate evidenced based approach is currently being prepared that could help us move toward a standard.
- Appropriate utilization – There appears to be a difference of opinion within the pain community as to what constitutes appropriate care. From my experience performing utilization reviews, certain procedures are performed out of their appropriate context and at a higher frequency than indicated. A good example is lumbar medial branch blocks. This test is only diagnostic. Therefore, it should legitimately be performed on up to two occasions leading to potentially curative treatment. Unfortunately some practitioners perform these injections on a regular basis despite there being no clear medical evidence to justify their approach.
- Patient selection – It is essential that patients are selected appropriately. When injections are preformed on patients without the correct medical indications or those with a high potential for secondary gain, the outcomes will remain poor. That failure is not a failure of the injection, but a failure of the physician to prescribe the correct treatment for that individual patient.

If those three problems need to be addressed, the following three solutions might be a point to start the discussion:

Three Solutions

- Utilization Standard - Adopt a utilization standard that describes appropriate procedure utilization. This publication needs to have the support of experts in the fields.

- Data Mining - Perform data mining on utilization and outcomes by individual practitioners. If over analyzed, this data can be confusing. A good starting point would be to look at the ratio of different procedures performed versus the number of office visits. Another tracking measure could be the utilization of fluoroscopy during procedures. A final statistical measure to watch could be the reduction in opiate utilization or increased returned to work rates by patients who have procedures performed by a specific practitioner.

- Audit Quality – Randomly audit procedures after they are paid for. It is easy for a practitioner to produce an operative report demonstrating a perfect procedure. This written note should be accompanied by saved fluoroscopic images that can be reviewed by a peer matched physician to verify the technical accuracy of the injection.

In my Chicago based pain management practice we achieve excellent outcomes using an evidence guided approach to injective and complimentary therapies. We are proud of our very high returned to work rate that gives the insurance community an easy mechanism to follow the outcomes from our interventional pain management procedures.

It would be an honor to assist Washington use the medical literature to develop treatment standards.

Thank you for your time,

Andrew J. Engel, MD

773-283-3131

Rep. Cody,

I personally feel spinal injections have low efficacy, cost too much, and are over utilized.

Steven H. Litsky MD

Am. Brd. Phys. Med. & Rehab.

Trustee, Pierce Count. Med. Society

Agency Medical Director Comments

Agency Experience:

Spinal Injections

March 18, 2010

Spinal Injections: Background

- Up to 75% of the population will have an episode of pain at some point in life
- Spinal injections are used to treat and/or isolate the source of back or neck pain, typically when:
  - It has become chronic (more than 3 or 6 months w/o relief), and
  - Conservative measures have failed to provide relief
- Spinal injections include:
  - Injections into the epidural space via various approaches (e.g., caudal, transforaminal)
  - Facet joint injections; medial branch blocks
  - Injections into spinal discs
- Locations and methods of injections include:
  - Fluoroscopically guided injections in the epidural space, sometimes through the foramen
  - Paravertebral injections to the tissue surrounding nerve roots

Agency Concerns

Safety Concerns (Low)

Spinal injections are invasive techniques to infiltrate tissues in the vicinity of major nerves of the CNS with anesthetic or anti-inflammatory agents. Though risk is reportedly low, infection and allergic reactions are safety concerns.

Efficacy Concerns (Medium)

The efficacy of spinal injections is rated medium. It is unclear what effect spinal injections may have on long term improvement in back pain and function.

Cost Concerns (Medium)

Back pain is common among Washington insured. The cost-effectiveness of spinal injections is unknown, yet the volume of utilization significant and rising.

Coverage Overview: All Agencies

- Currently covered by UMP, Medicaid and Labor and Industries
- UMP and Medicaid: No limits and prior authorization is not required

Coverage Overview: L&I

- Epidural injections may be authorized when:
  - There is evidence of nerve root irritation or radiculopathy;
  - The intent is to identify the involved nerve root(s), or to reduce inflammation of same
- Epidural steroid injections are limited to:
  - 3 in the first 30 days
  - No more than 6 per episode
- Must be under fluoroscopic guidance, or performed in an accredited facility

Coverage Overview: L&I

- Facet joint injections are covered:
  - When provided by qualified specialists in orthopedics, neurology, and anesthesia.
  - Injections must be performed in an accredited hospitals under radiographic control.
  - Not more than four facet injection procedures are authorized in any one patient.

Utilization Cost- All Agencies

	2006	2007	2008	2009	4 Year Total
Procedures	34,298	33,994	39,667	44,128	152,087
Patients	9,010	9,072	10,025	11,078	36,846
Avg Cost L&I per patient	$2231	$2353	$2336	$2161	$2268*
Avg Cost DSHS per patient	$517	$503	$520	$523	$648**
Avg Cost UMP per patient	$1429	$1418	$1507	$1491	$1925**

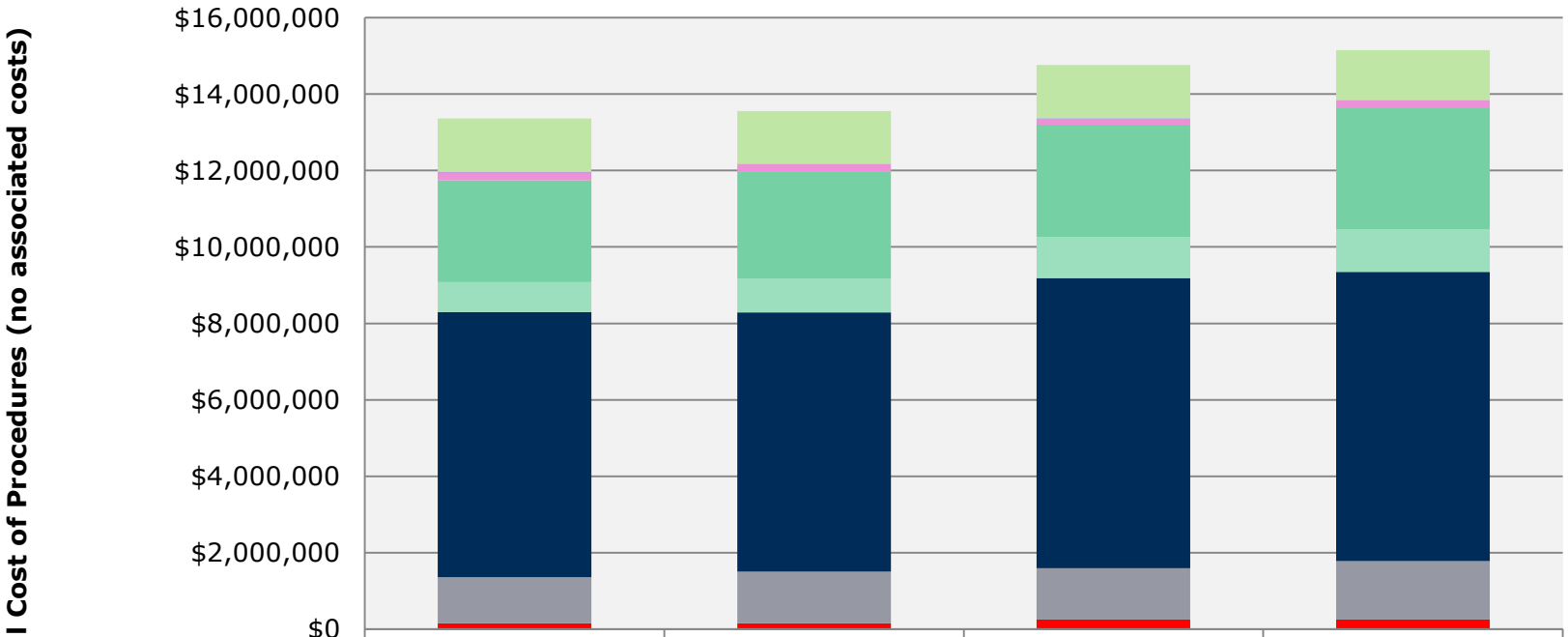
*Avg per patient per year
**Avg per patient per 4 years

Utilization Cost- All Agencies

Direct Costs (millions)	2006	2007	2008	2009	4 Year Total
Total	$13.1	$13.3	$14.5	$14.9	$55.7
L&I	$10.4	$10.4	$10.8	$10.6	$42.1
DSHS	$1.3	$1.3	$1.5	$1.8	$6.0
UMP	$1.4	$1.56	$2.2	$2.4	$7.7

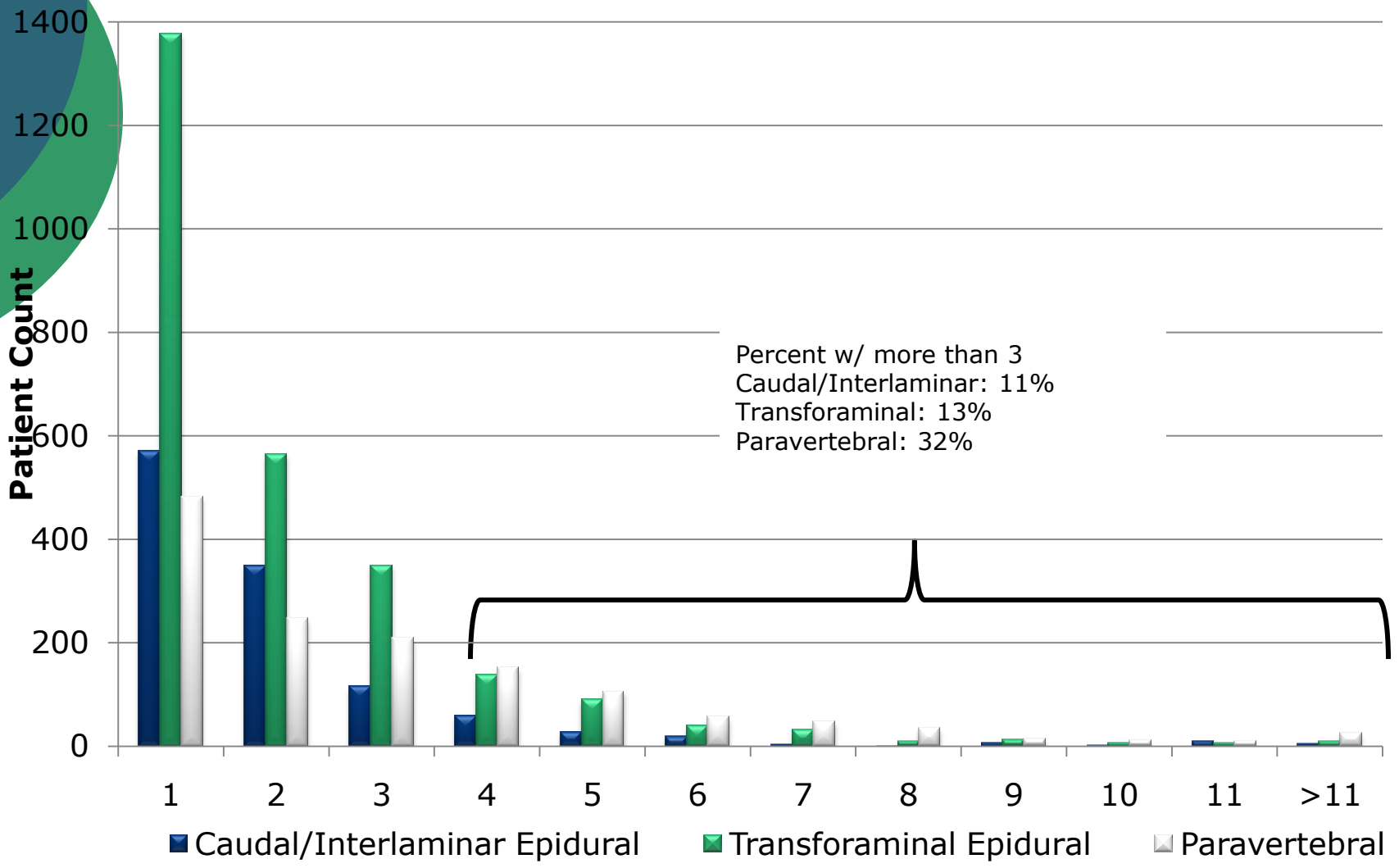
Agency Utilization

Combined Agency Costs of Spinal Injections by Type, 2006-2009

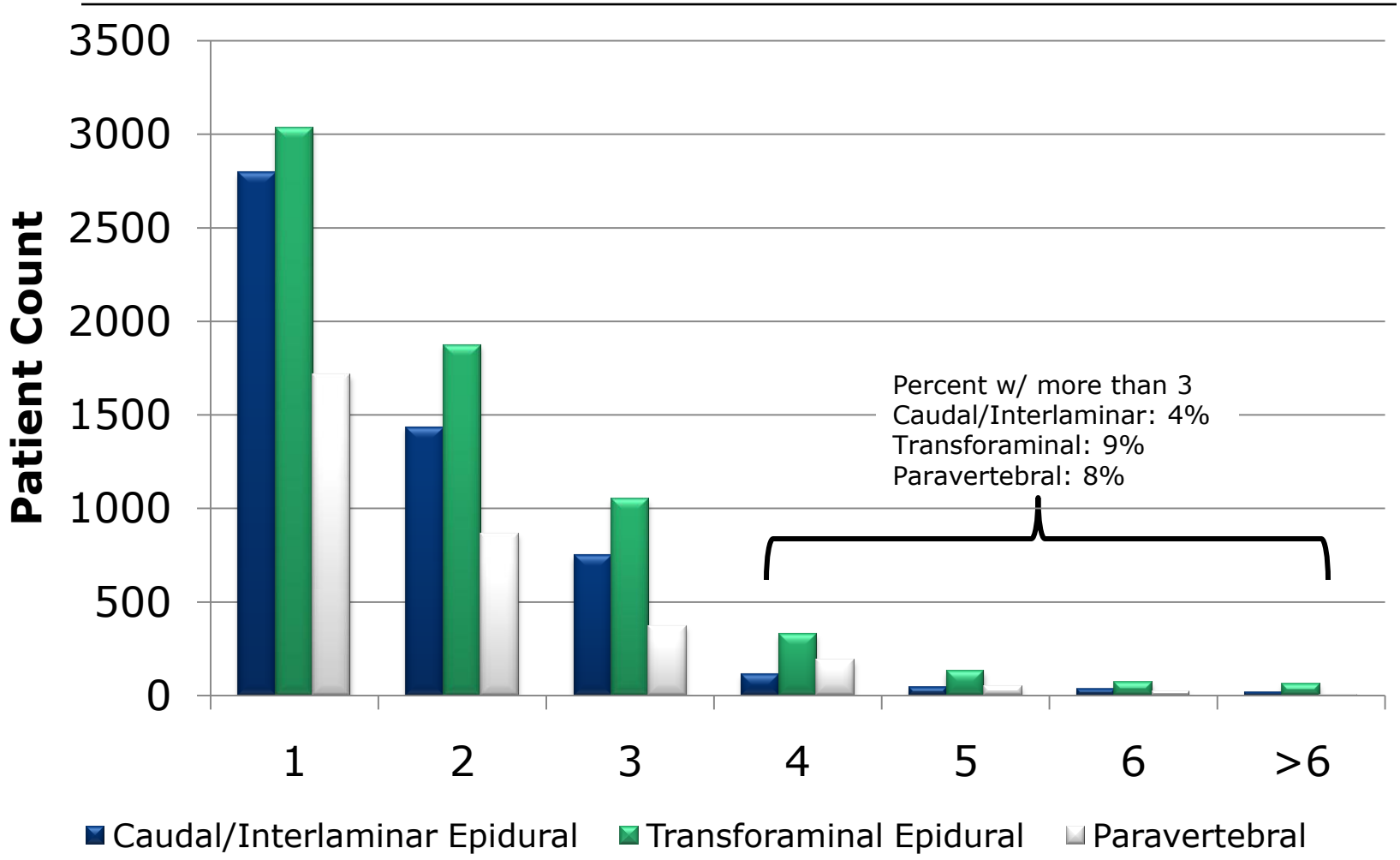


	2006	2007	2008	2009
Fluoroguide	$1,397,395	$1,385,257	$1,398,461	$1,305,842
Epidurography	$3,947	$3,310	$6,536	$9,263
Nerve Block L/T	$212,863	$192,683	$162,356	$207,319
Facet/Paravertebral L/S	$2,662,436	$2,801,054	$2,935,520	$3,173,577
Facet/Paravertebral C/T	$790,647	$886,974	$1,078,891	$1,112,482
Epidural/Foraminal L/S	$6,935,437	$6,785,690	$7,585,933	$7,563,214
Epidural/Foraminal C/T	$1,199,986	$1,346,630	$1,345,572	$1,528,725
Sacroiliac Joint Injection	$157,067	$156,273	$252,041	$253,153

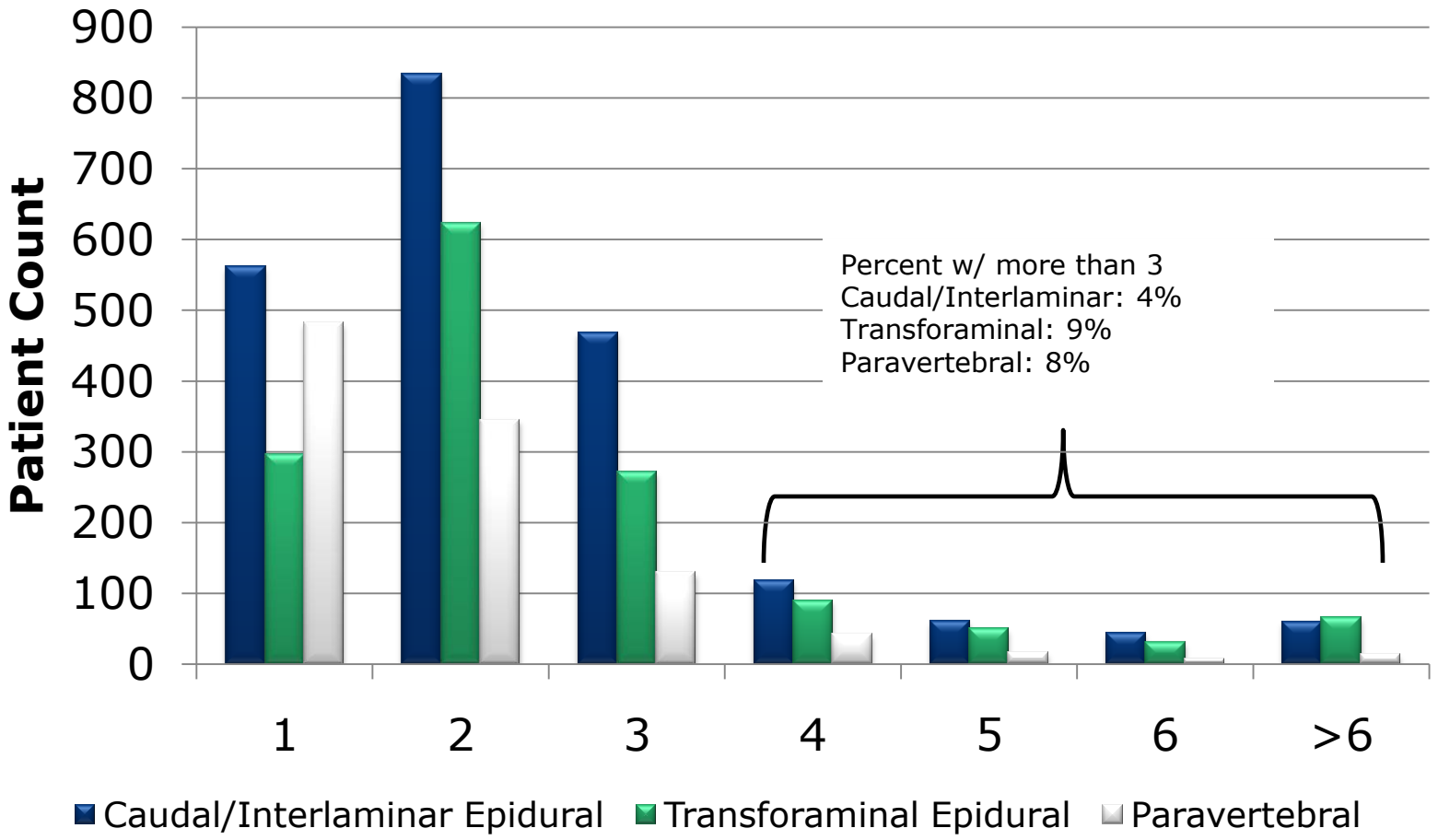
UMP L/S Injections Utilization by Procedure Codes, 2006-2009,



L&I L/S Injections by Procedure Codes, 2006-2009



DSHS L/S Injections by Procedure Codes, 2006-2009



Increase in Utilization

- Spinal injection costs increased in all agencies between 6 and 16% from 2008 to 2009
- 6.1% increase in L&I despite 15% decrease in claim volume
- 76% of utilization, $42 million, is in workers' compensation

Case Examples

Age	Gender	Injection Count	Days Injected	Time Span	Injection Types
81	F	6	6	1.5 yr	Epidural L/S
49	M	9	4	8 months	Facet L/S (6) Epidural L/S (3)
70	M	4	4	1.5 yr	Epidural L/S
75	F	13	13	2.5 yr	Epidural L/S
57	F	4	3	2 months	Facet L/S (2) Epidural L/S (2)
51	F	32	24	3.75 yr	Sacroilliac (20) Epidural L/S (10) Epidural C/T (2)
77	F	18	18	3.5 yr	Facet C/T (7) Facet L/S (2) Epidural C/T (4) Epidural L/S (5)
66	F	12	12	3.5 yr	Facet L/S(3) Epidural L/S (9)

Summary

- The best evidence from the Spectrum report shows only 'mixed results' for the most common spinal injections for back pain with sciatica or radiculopathy including:
  - Lumbar caudal or interlaminar epidural steroid injections
  - Transforaminal steroid injections
- A large body of evidence appears to show no benefit from a variety of different injection techniques for a number of conditions including:
  - Spinal stenosis
  - Low back pain without sciatica or radiculopathy
  - Failed back surgery syndrome
  - Facet joint pain
  - Discogenic back pain

AMDG Considerations

1. Is there a category of injections where coverage with conditions makes sense?
2. If there is, should it be only for monoradiculopathies and/or for multiple levels?
    1. Single root injections for monoradiculopathies?
    2. Injections for multiple roots (bilateral or multiple levels)?
3. Is there any evidence for coverage of any injection for chronic, non-radicular back pain?

AMDG Recommendations

- Based on the available evidence and agency experience the AMDG recommends:
- Coverage with conditions for of spinal injections
- Limitations of coverage
  - 1 Epidural steroid injection for radiculopathy when:
    - Conservative treatment has failed
    - There is documentation of clinical evidence of sciatica or radiculopathy (e.g., altered sensation, inability to heel-toe walk)
    - Additional injections may be covered the first injection is demonstrated to provide relief (pain and function) for the expected duration
- Non-covered
  - Therapeutic facet joint injections
  - Therapeutic intradiscal injections
  - Any injections for chronic, non-radicular back pain

Spinal Injections Technology Assessment

Presented by:

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Health Technology Clinical Committee Meeting
Washington State Health Technology Assessment Program
Seattle, Washington
March 18, 2011

SPECTRUM RESEARCH

Scope of Report

This report evaluates relevant published research describing the use of spinal injections for chronic back or neck pain

Background

Spinal injections

- typically considered only after failure of conservative treatment
- injection of anti-inflammatory agent (steroid) and local anesthetic into spine or surrounding nerves and joints
- injection often monitored with fluoroscopic or CT visualization
- deliver treatment directly to pain source (theoretical advantage)

Key Questions

When used in adult patients with chronic neck or back pain:

1. What is the evidence of efficacy and effectiveness of spinal injections?

2. What is the evidence of safety of spinal injections?

3. What is the evidence that spinal injections have differential efficacy or safety issues in subpopulations?

4. What is the evidence of cost implications and cost effectiveness of spinal injections?

Inclusion and exclusion criteria: participants

Inclusion:

Adults with lumbar or cervical spinal pain

Exclusion:

Children

Acute major trauma

Cancer

Infection

Cauda equina syndrome

Fibromyalgia

Spondyloarthropathy

Osteoporosis

Vertebral compression fracture

Inclusion and exclusion criteria: intervention

Inclusion: lumbar and cervical intraspinal injections, limited to:

Epidural injections

Facet joint injections

Sacroiliac joint injections

Intradiscal injections

Exclusion:

Extraspinal injections

Chemonucleolysis

Radiofrequency denervation

Intradiscal electrothermal therpay

Coblation nucleoplasty

Literature Search

1. Total Citations
Key questions 1-3 (n = 2738)
Key question 4 (n = 22)

2. Title/Abstract exclusion
Key questions 1-3 (n = 2667)
Key question 4 (n = 20)

3. Retrieved for full-text evaluation
Key question 1 (n =72)
Key question 4 (n = 2)

4. Excluded at full–text review
Key questions 1-3 (n = 19)
Key question 4 (n = 0)

5. Publications included
Key questions 1-3 (n = 1 SR; n = 22 RCTs)
(n = 7 cohort studies)
(n = 24 case series)
Key question 4 (n = 2 economic analyses)

Key Question 1

What is the evidence of efficacy and effectiveness of spinal injections?

Inclusion:

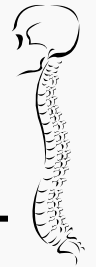
RCTs published in English.

For lumbar injections:

- RCTs ≤ 2008 as reported in the APS/ Chou et al (2009) SR
- RCTs ≥ 2008

Exclusion:

- Unreported diagnosis
- < 75% of patients had excluded diagnosis
- Study type other than RCT
- Abstracts, letters, editorials



Key Question 1

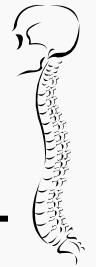
What is the evidence of efficacy and effectiveness of spinal injections?

Outcomes

1. **Pain relief**
2. **Physical function**
3. Opioid use
4. Return to work
5. Quality of life
6. Patient satisfaction

Positive outcome: spinal injections *beneficial* compared with control intervention

Negative outcome: *no clear benefit* of spinal injections compared with control intervention



Key Question 1

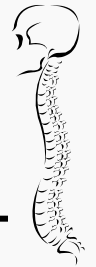
What is the evidence of efficacy and effectiveness of spinal injections?

Comparisons include 5 variables:

1. Injection type
2. Injection approach (epidural only)
3. Diagnosis
4. Control intervention
   a. Placebo
   b. Active control
5. Study quality

Key Question 1

	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

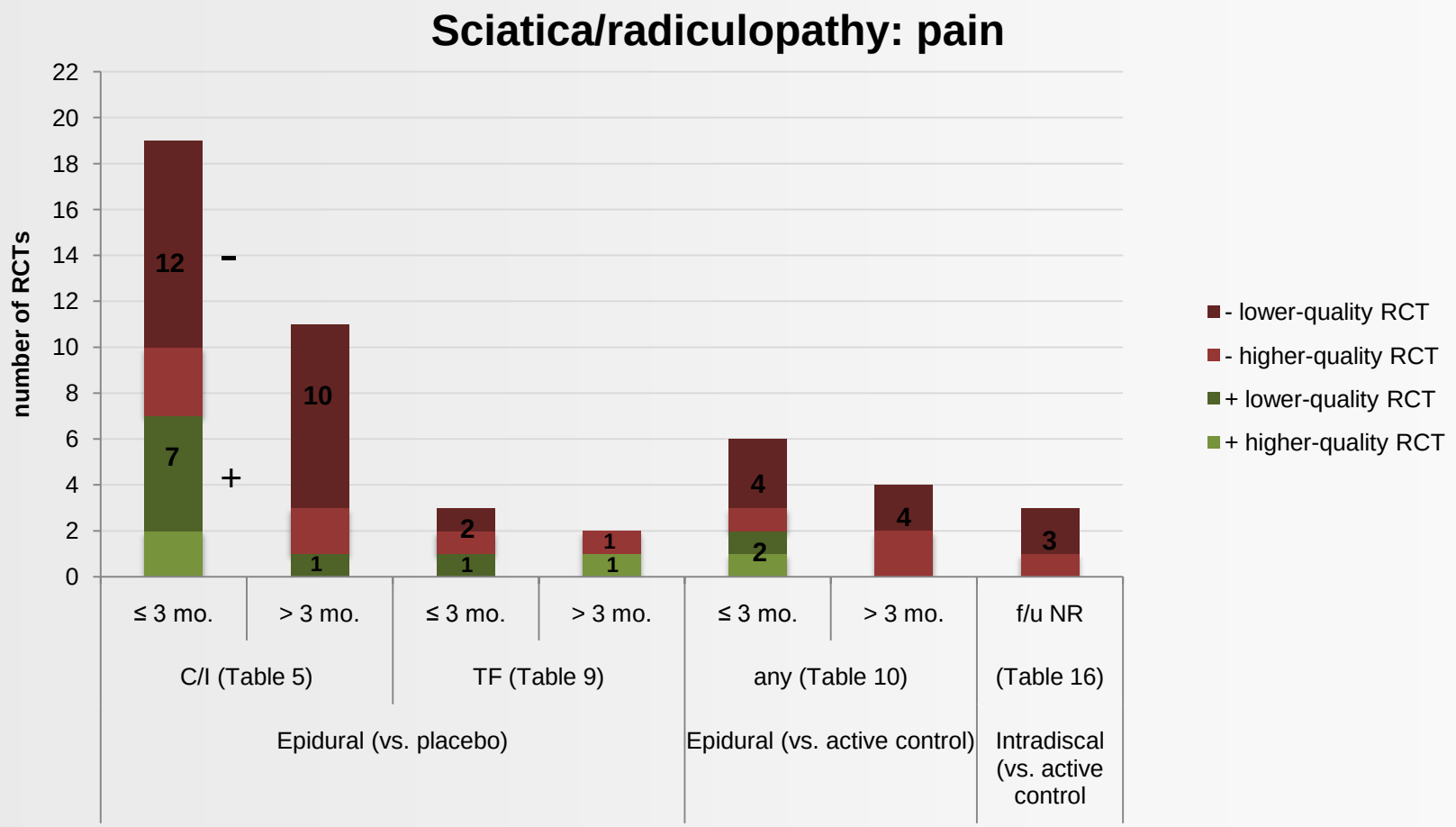


Key Question 1

Lumbar spinal injections

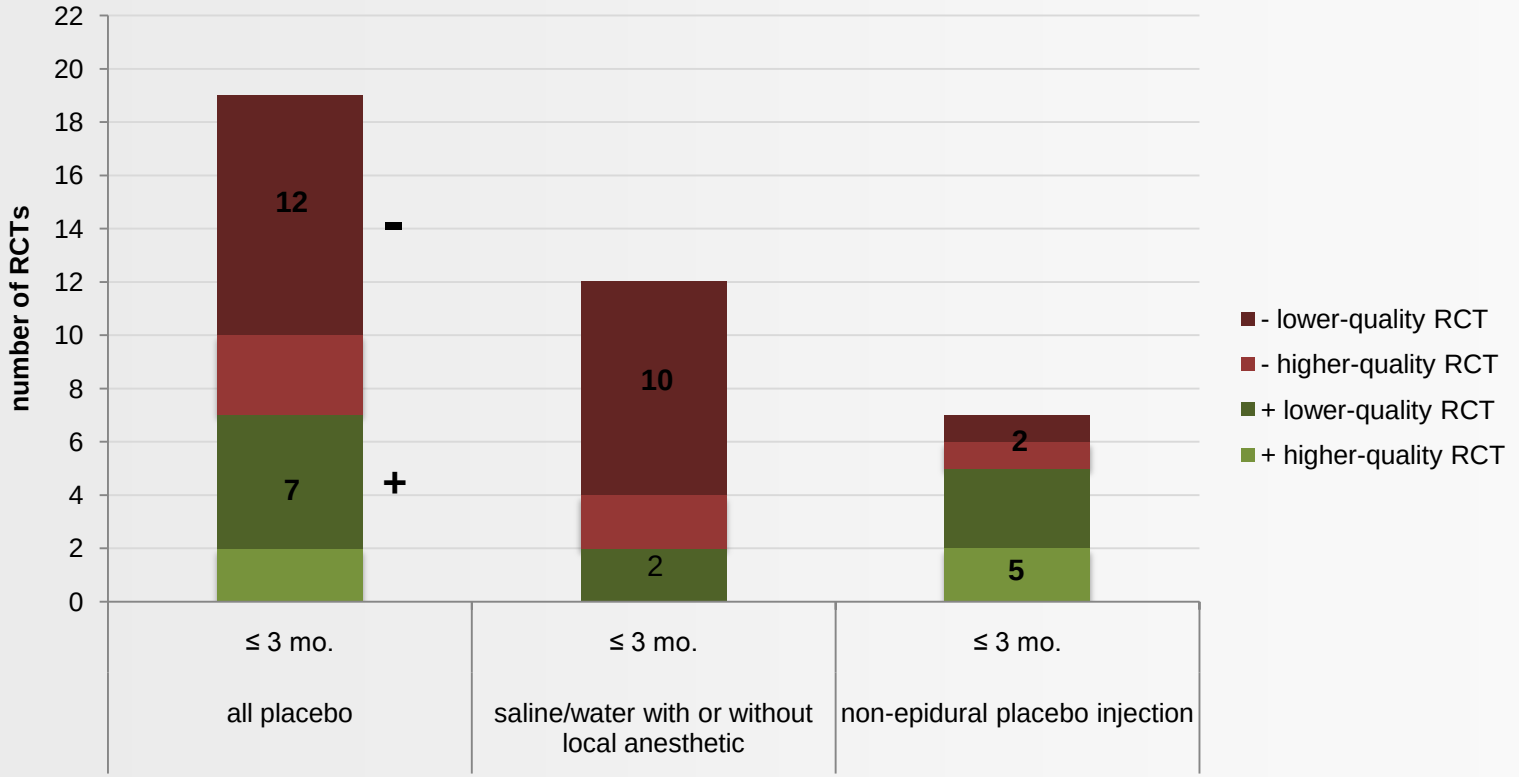
(tables 5-16 in report)

Key Question 1



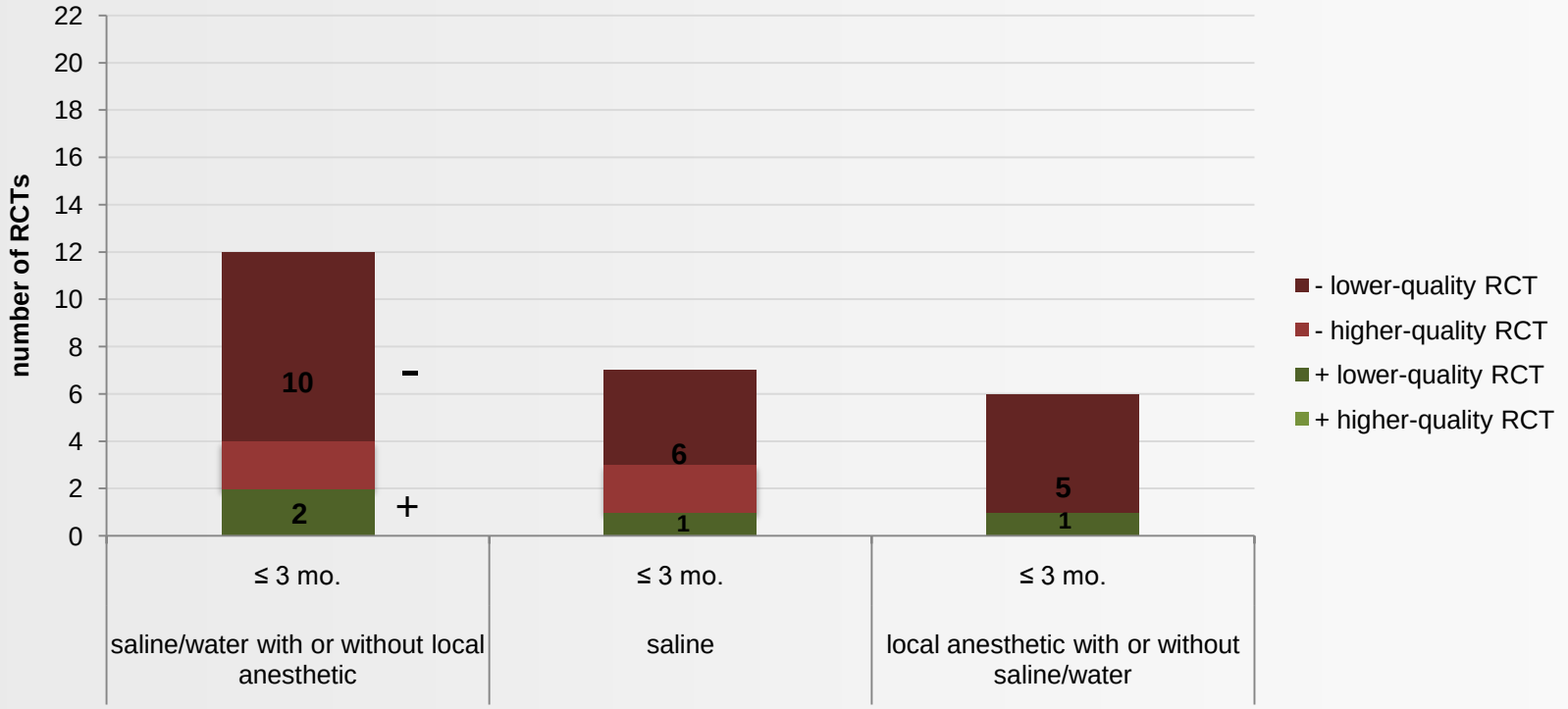
Key Question 1

Epidural injections for sciatica/radiculopathy: pain
BREAKDOWN OF PLACEBO-CONTROLLED TRIALS

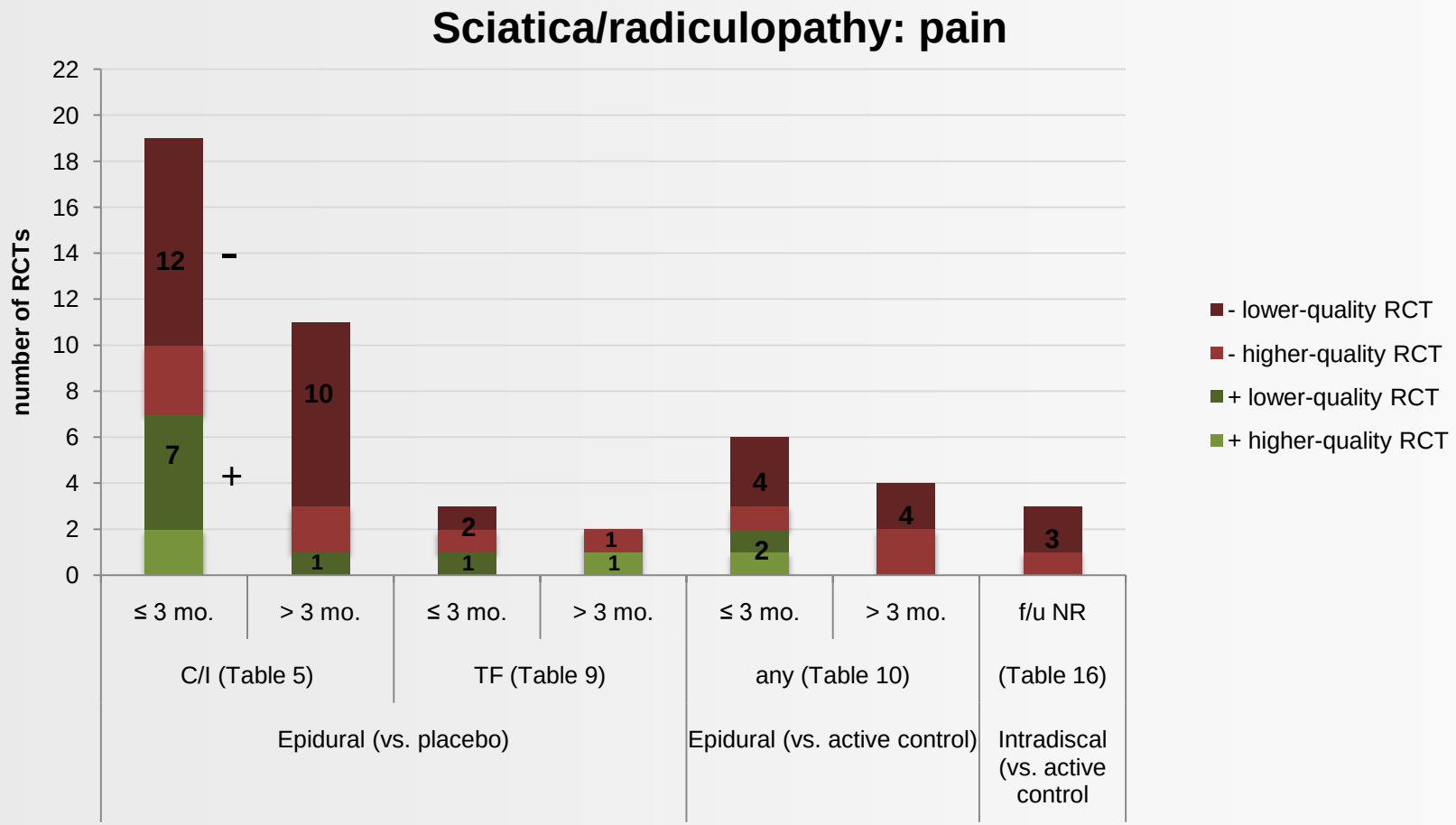


Key Question 1

Epidural injections for sciatica/radiculopathy: pain
BREAKDOWN OF EPIDURAL PLACEBO-CONTROLLED TRIALS

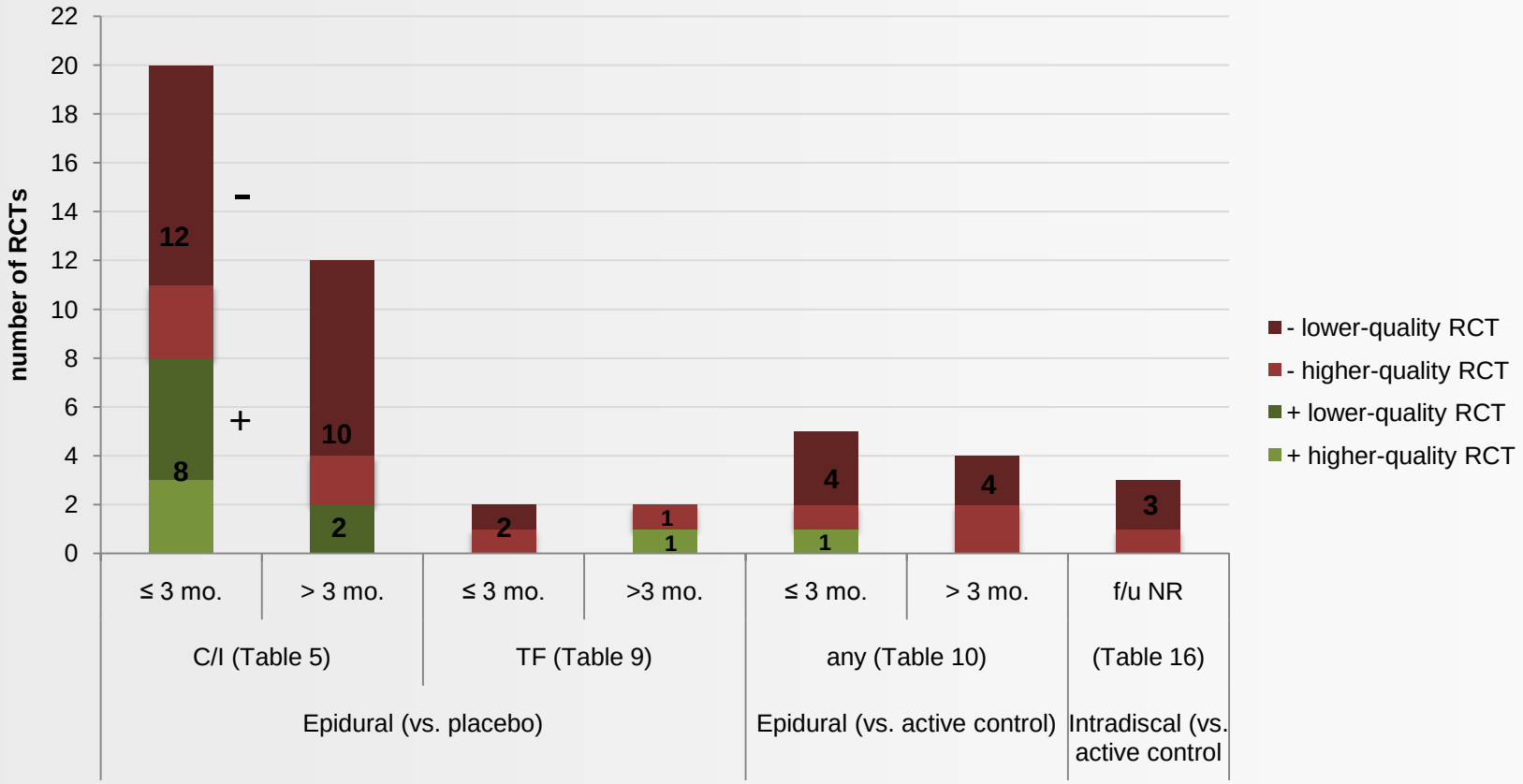


Key Question 1



Key Question 1

Sciatica/radiculopathy: function

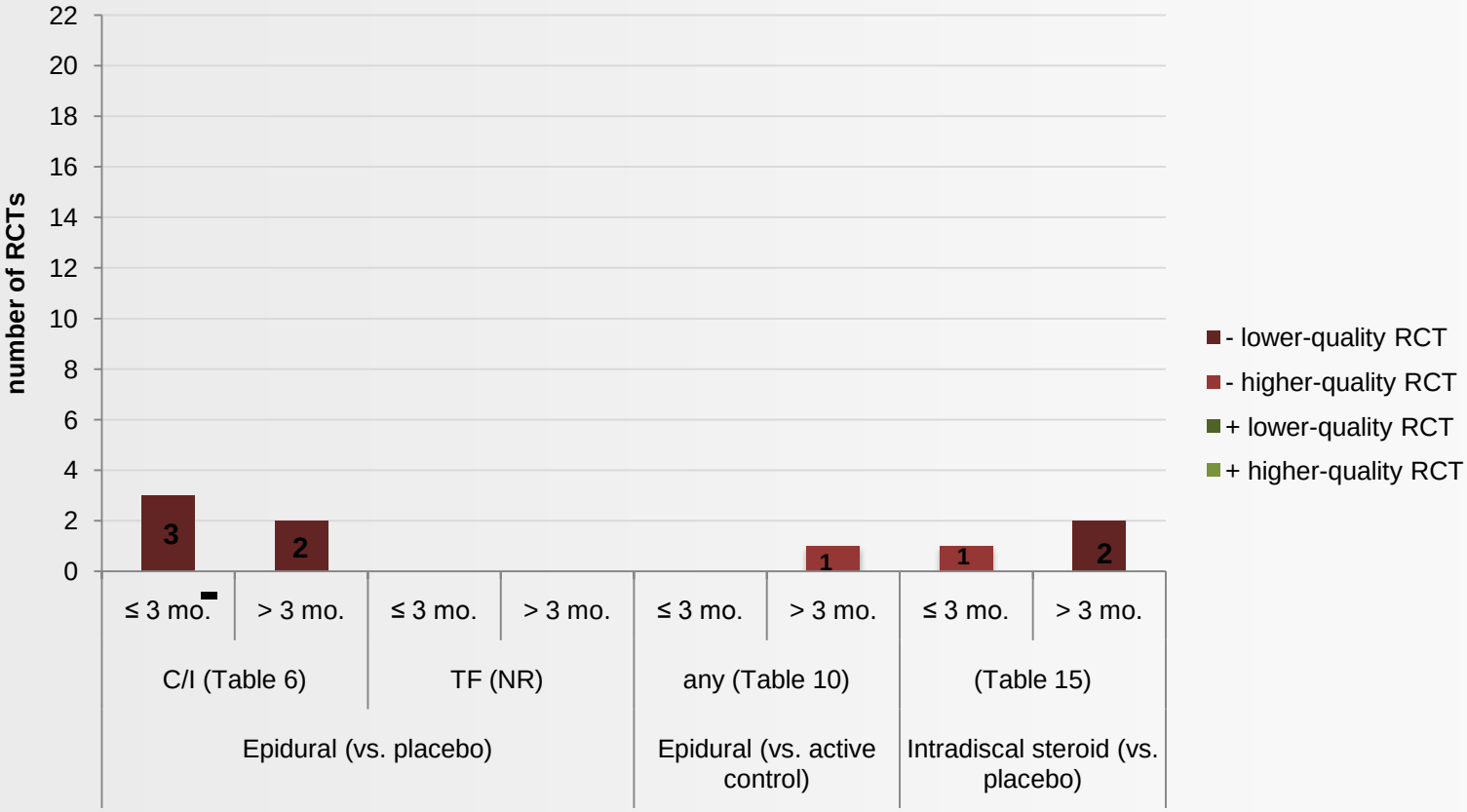


Key Question 1

	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

Key Question 1

LBP (discogenic): pain & function

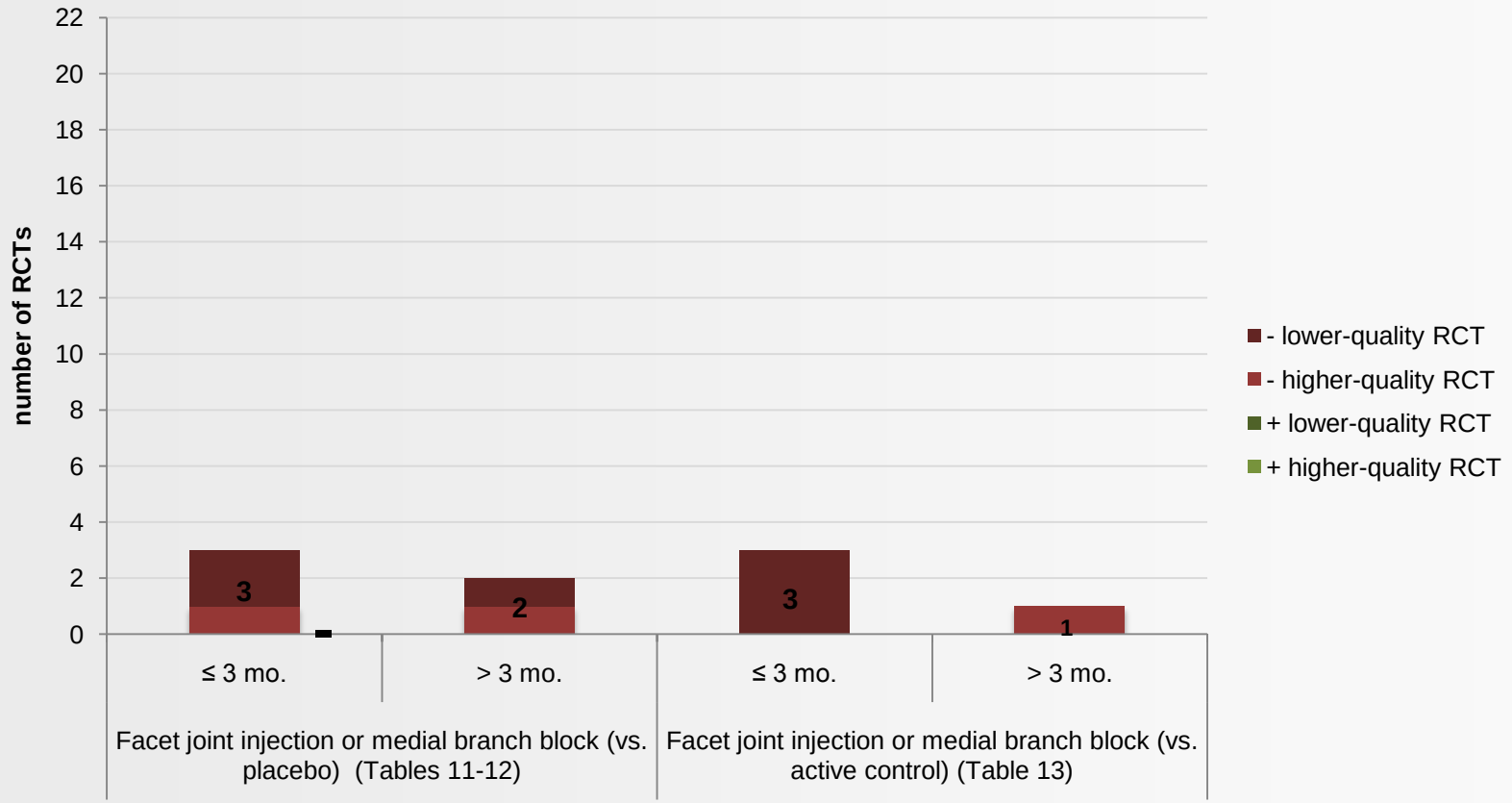


Key Question 1

	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

Key Question 1

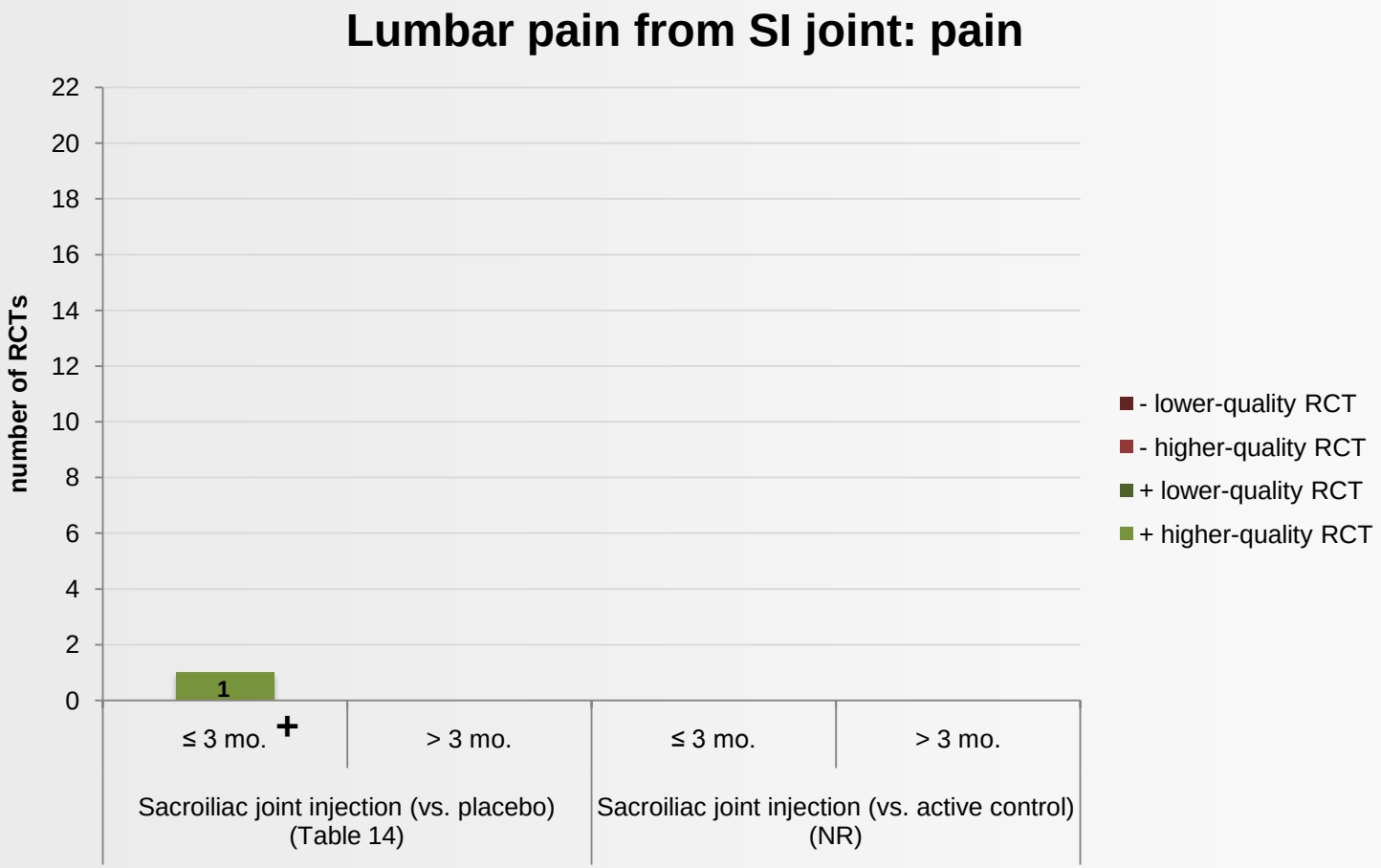
Lumbar pain from facet joint: pain & function



Key Question 1

	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

Key Question 1

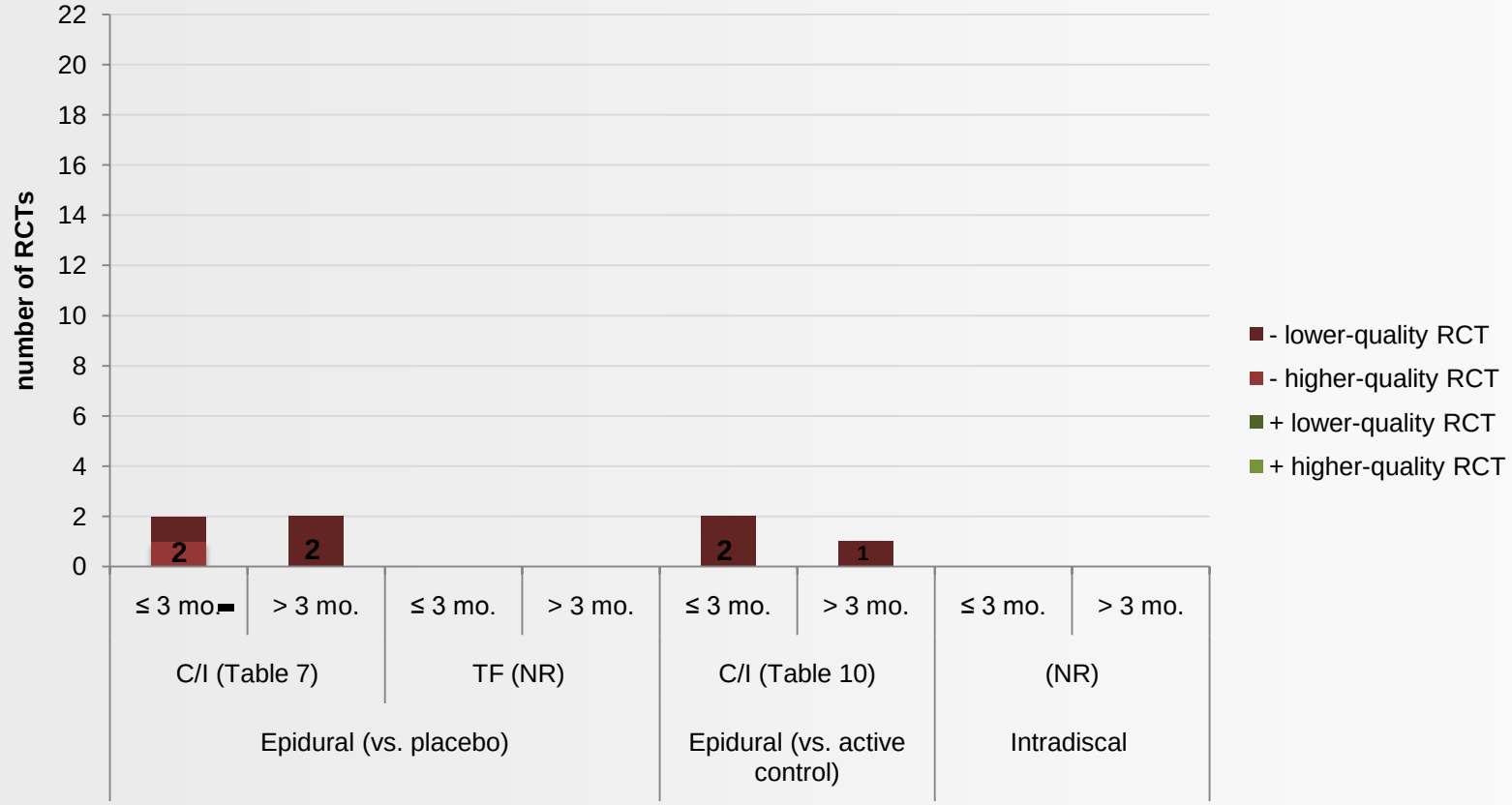


Function: not reported.

Key Question 1

	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

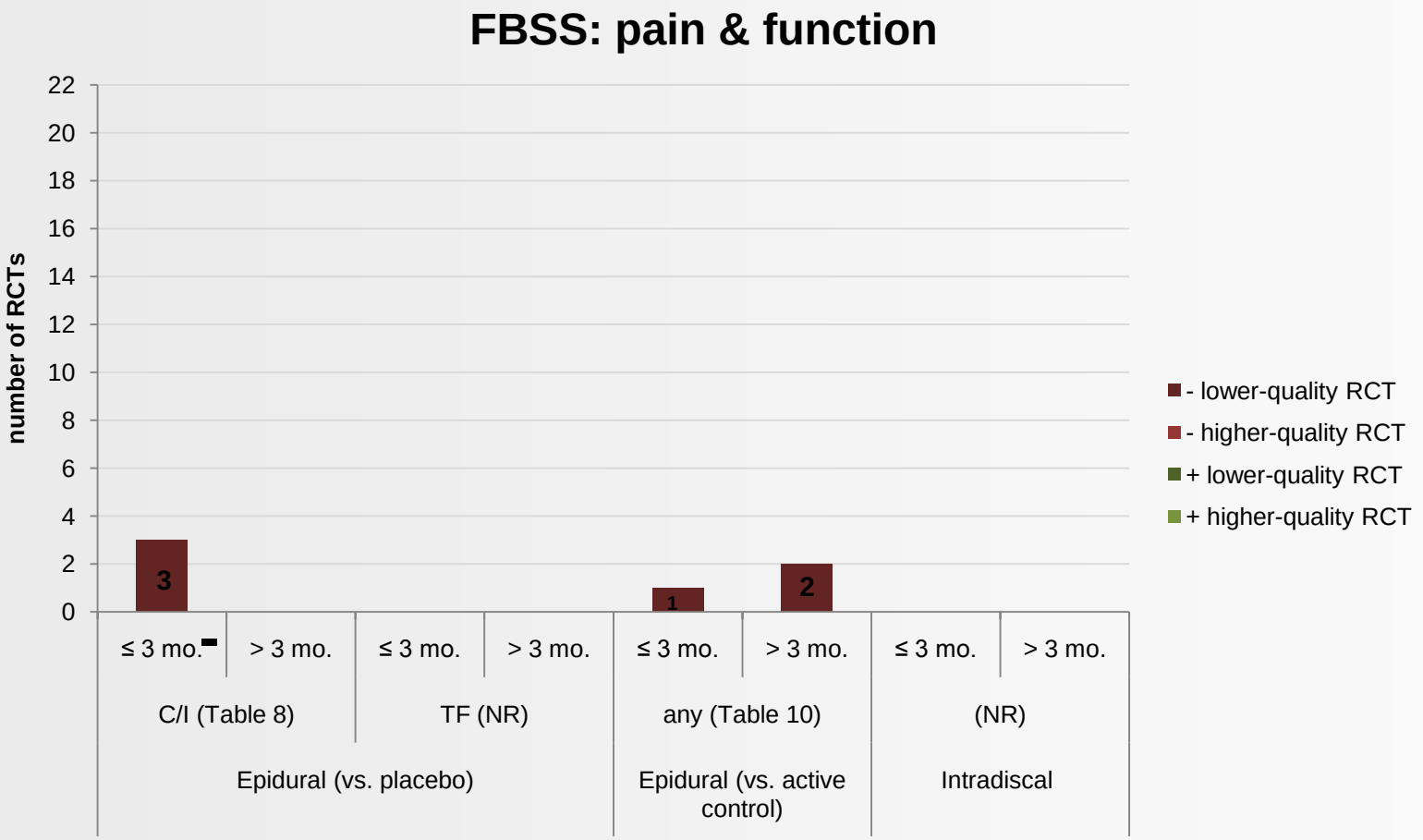
Key Question 1

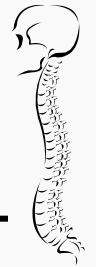


Key Question 1

	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

Key Question 1





Key Question 1

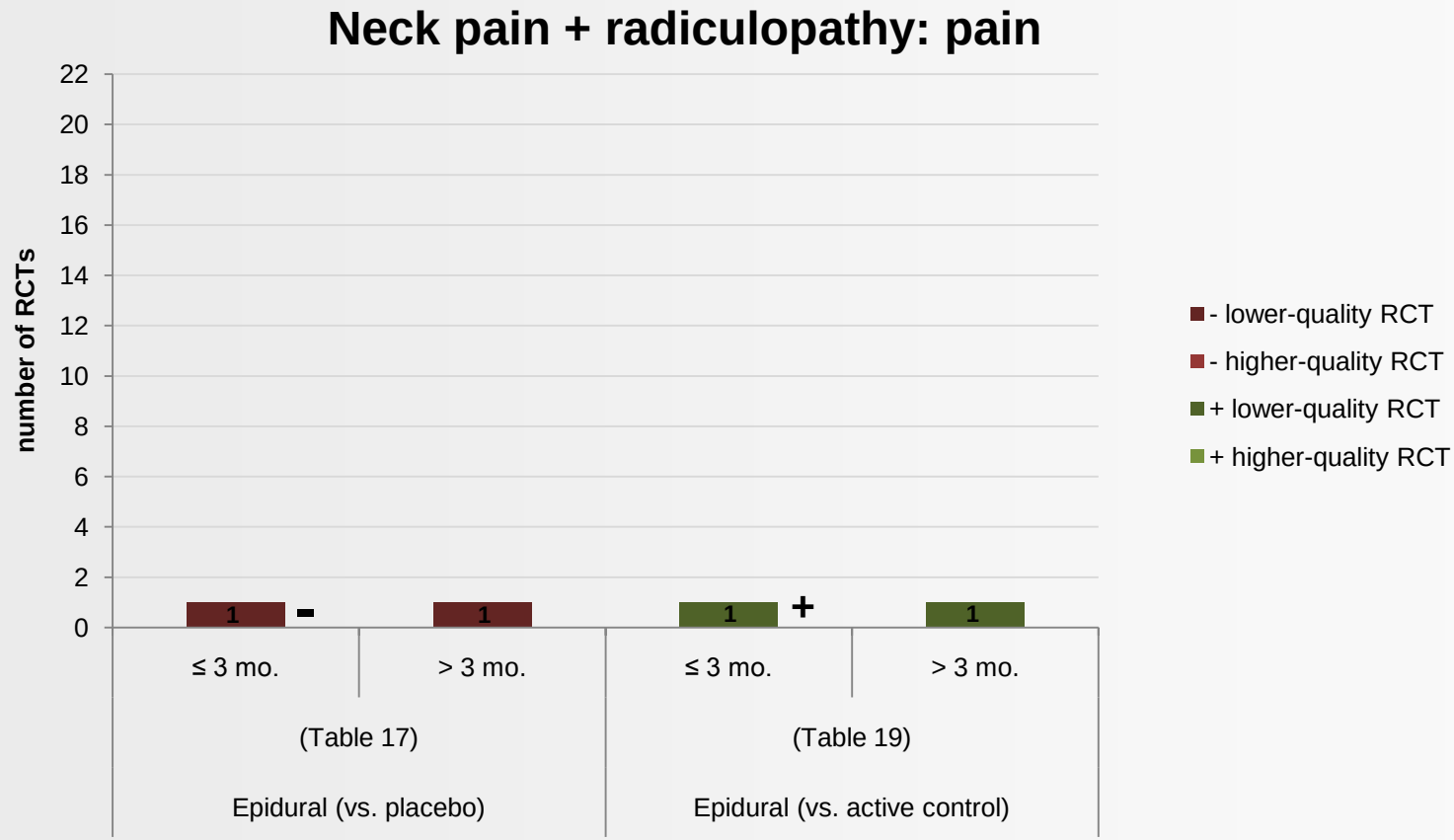
Cervical spinal injections

(tables 17-21 in report)

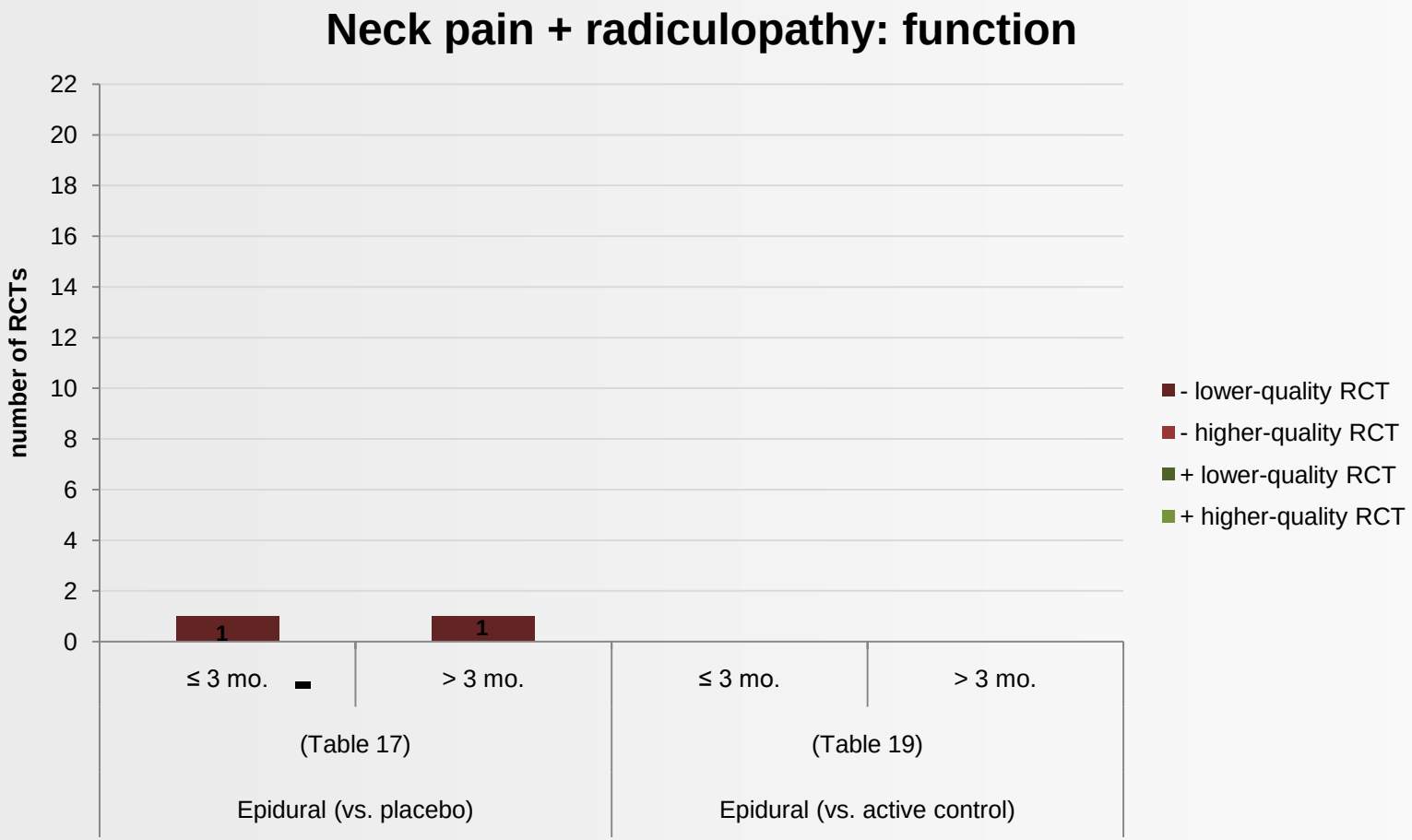
Key Question 1

	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

Key Question 1



Key Question 1

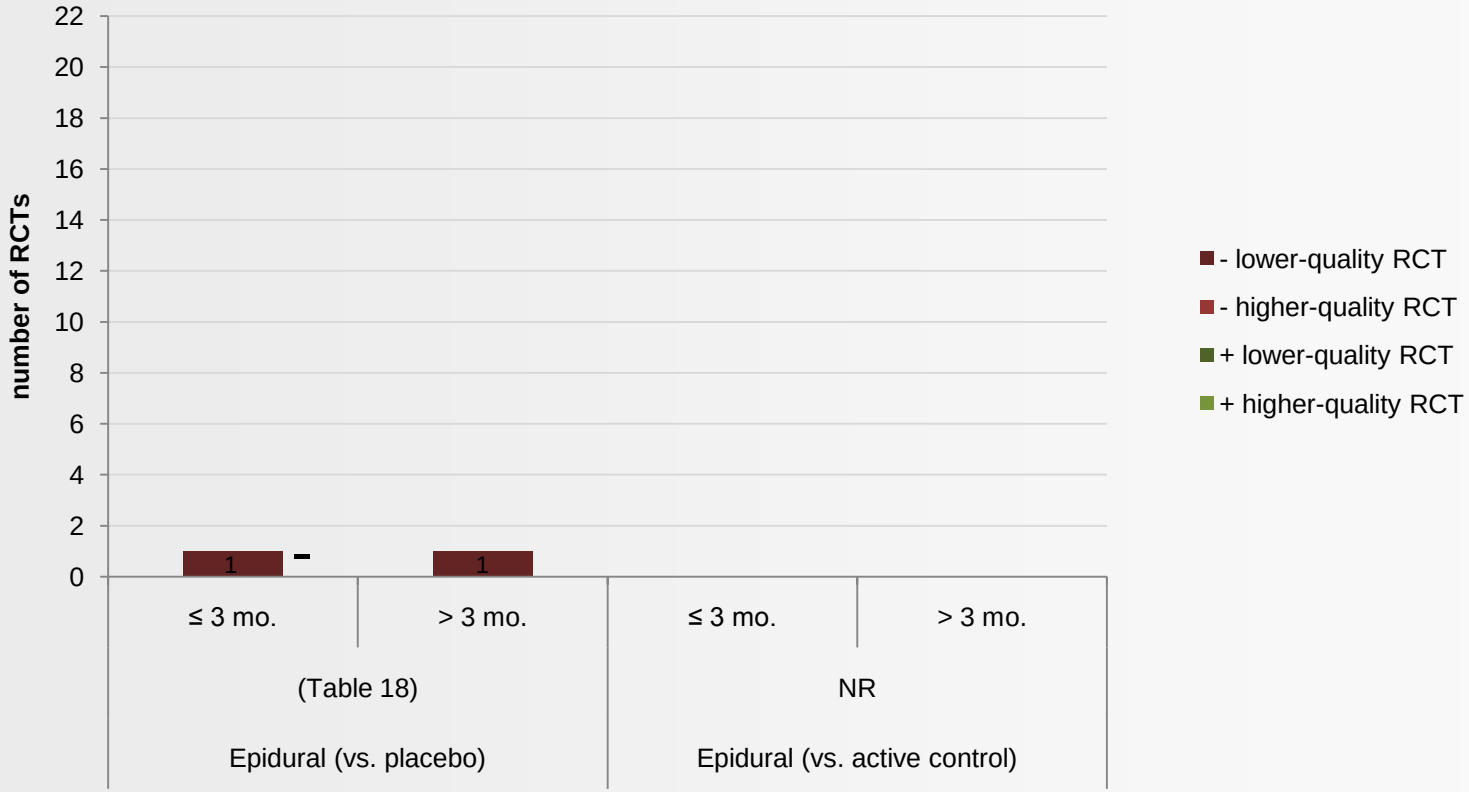


Key Question 1

	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

Key Question 1

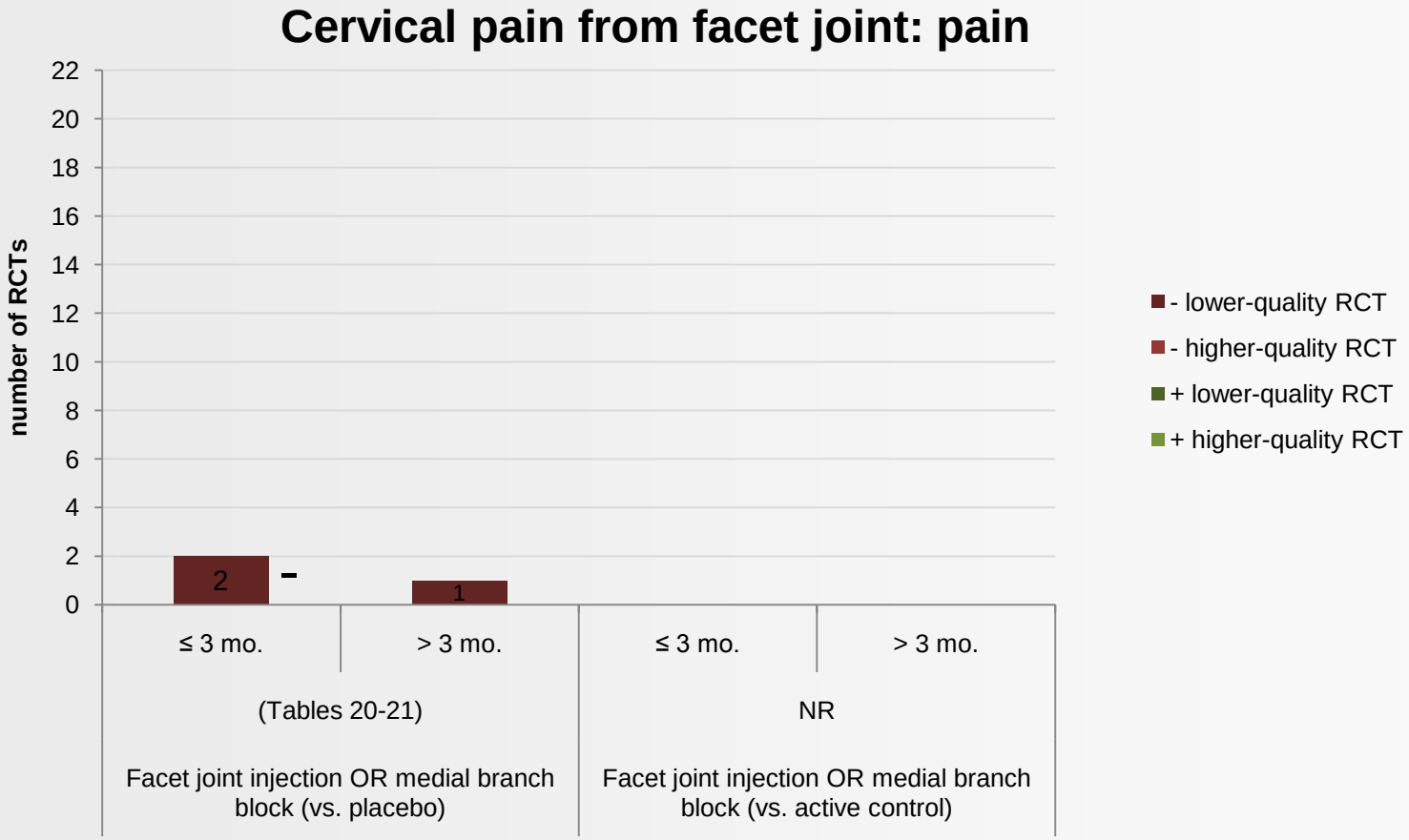
Cervical pain (unspecified): pain & function



Key Question 1

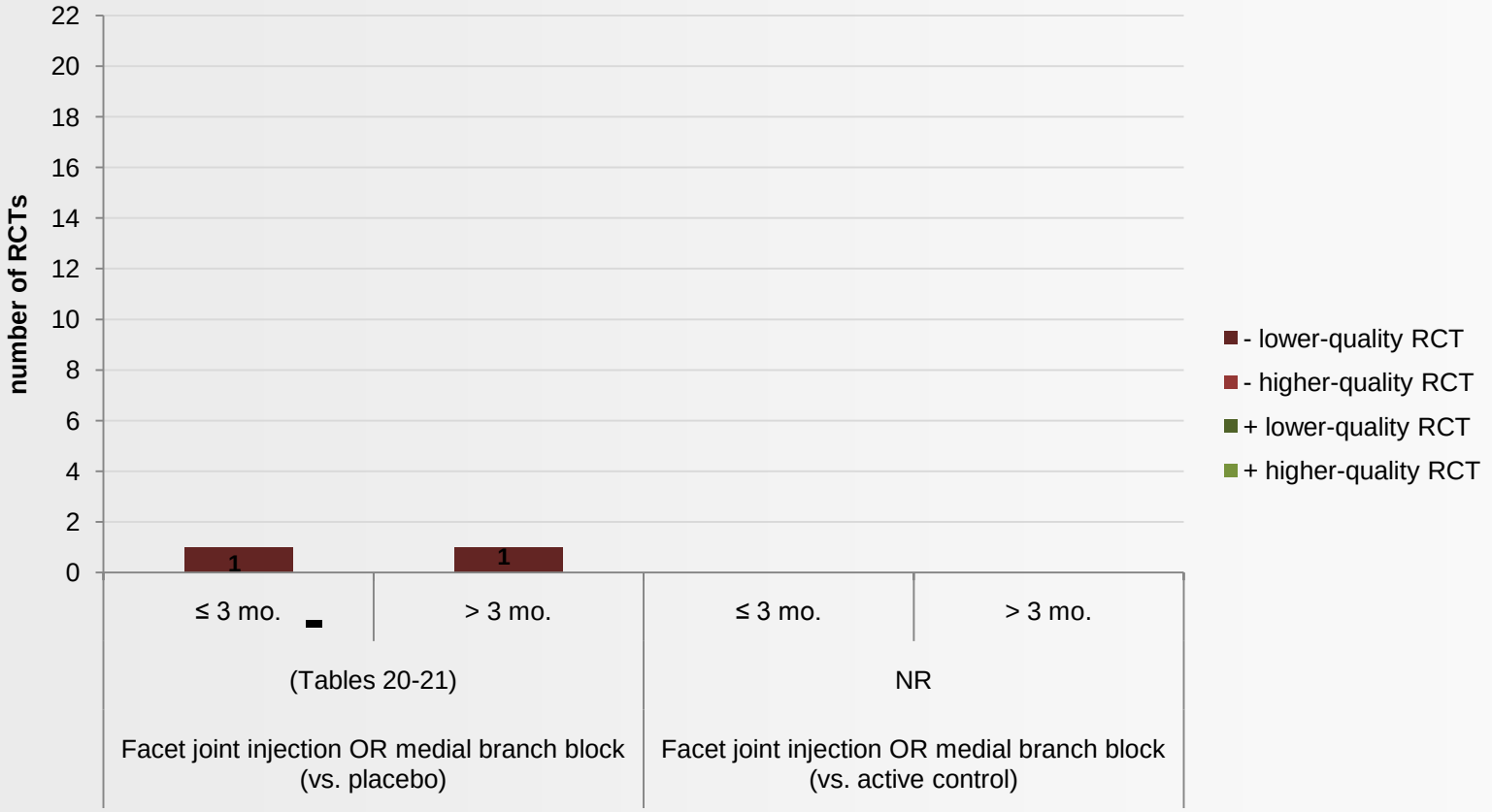
	Epidural steroid injection				Intradiscal steroid block		SI joint block	Facet/m. branch steroid injection	
	Caudal/interlaminar		Transforaminal						
	v. placebo	v. active	v. placebo	v. active	v. placebo	v. active	v. placebo	v. placebo	v. active
Sciatica/ radiculopathy	(+/-) short (-) long	(+/-) short (-) long	(+/-) short (+/-) long	See C/I		(-) f/u NR			
Lumbar pain • (discogenic)	(-) short (-) long	(-) long			(-) short (-) long				
• (facet)								(-) short (-) long	(-) short (-) long
• (SI)							(+) short PAIN only		
Stenosis	(-) short (-) long	(-) short (-) long							
FBSS (prior surgery)	(-) short	(-) short (-) long							
Cervical radiculopathy	(-) short (-) long	(+) short (+) long PAIN only							
Cervical pain • (unspecified)	(-) short (-) long								
• (facet)								(-) short (-) long	

Key Question 1



Key Question 1

Cervical pain from facet joint: function

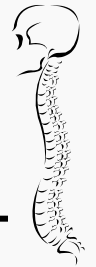


Key Question 2

What is the evidence of safety of spinal injections?

Safety outcomes:

1. Major complications
2. Minor complications
3. Vascular puncture
4. Radiation exposure to physician



Key Question 2

What is the evidence of safety of spinal injections?

Inclusion:

RCTs + APS SR as included in Key Question 1

Case series designed to report complications (n ≥ 100)

Exclusion:

Case reports

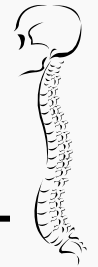
Key Question 2

Major complications: lumbar spinal injections

SoE = HIGH (major complications are rare)

	RCTs (APS/Chou SR + 14 RCTs)	Case series (6 studies)
Death attributed to procedure	0/1146 patients	0/10,416 injections
Paralysis	0/1146 patients	0/10,416 injections
Dural puncture	1/1556 injections or patients	1/10,416 injections
Subarachnoid puncture	1/1556 injections or patients	1/10,416 injections
Angina pectoris	1/1556 injections or patients	0/10,416 injections

Case reports of serious complications (section 4.2.6)



Key Question 2

Major complications: cervical spinal injections

SoE = HIGH (major complications are rare)

	RCTs (5 RCTs)	Case series (4 studies)
Death attributed to procedure	0/326 patients	0/7240 injections or patients
Paralysis	0/326 patients	0/7240 injections or patients
Dural puncture	0/710 injections or patients	2/6330 patients
Subarachnoid puncture	3/710 injections or patients	NR
Life-threatening anaphylactice reaction	NR	1/7240 injections or patients
Grand-mal seizure	NR	1/7240 injections or patients
Local hematoma	NR	1/7240 injections or patients

Key Question 2

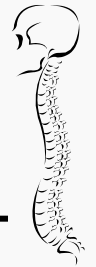
Minor complications

SoE = HIGH (minor complications are more common but are generally transient in nature)

Overall rate of minor complications: 0.06% - 16.3% injections or patients
(19 RCTs, 14 case series)

Pain at injection site
Increased radicular pain, numbness, and/or weakness
Nerve root irritation
Superficial infection
Sympathetic blockade
Facial flushing

Vasovagal reaction/ fainting
Headache
Gastric complaints
Dizziness
Pruritis
Irregular menstrual periods
Insomnia



Key Question 3

Is there evidence of differential efficacy or safety issues with use of spinal injections?

Inclusion:

Comparative clinical studies (RCTs, cohort studies with concurrent controls)

Exclusion:

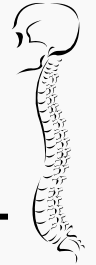
Non-clinical studies (e.g., technical reports)

Case reports

Unreported diagnosis

< 75% of patients had excluded diagnosis

Key Question 3



No strong evidence of differential efficacy or safety in subpopulations based on the following characteristics:

- Injection approach (lumbar epidural) (8 RCTs, 2 retrospective cohort studies)
- Diagnosis (1 RCT, 4 retrospective cohort studies)
- Baseline pain and dysfunction (1 RCT, 1 prospective & 3 retrospective cohort studies)
- Injectate characteristics (1 RCT)
- Sex (3 retrospective cohort studies)
- Age (3 retrospective cohort studies)
- Imaging (2 retrospective cohort studies)

Key Question 4

What is the evidence of cost implications and cost effectiveness of spinal injections?

Economic conclusions

SoE = VERY LOW (no evidence of cost effectiveness)

	Study characteristics	Conclusions
Price 2005 (NHS HTA) QHES = 78/100	1 RCT (Arden 2005) Lumbar epidural steroid versus saline injections for chronic sciatica **Trial conclusions:** Early benefit in outcomes (3 weeks) not sustained at or after 6 weeks Total benefit of epidural steroid injection: ~ 2.2 days of full health (NNT for 75% improvement = 11.4)	£354,171/QALY for ≤3 injections£167,145/QALY for 1 injection **NHS conclusions:** Cost-effectiveness ratios are higher than the NICE thresholds.

Economic conclusions

SoE = VERY LOW (no evidence of cost effectiveness)

	Study characteristics	Conclusions
Karppinen 2001 QHES = 49/100	RCT Lumbar epidural steroid versus saline injections for chronic sciatica **Trial conclusions:** Early benefit in outcomes (4 weeks) not sustained at or after 3 months	No QALY calculated. Epidural steroid injections result in therapy and medication cost savings at 4 weeks ($54/pt); no differences in medical costs or sick leave. No cost savings at 1 year.

Points to consider

Efficacy

On one hand…	On the other hand…
1. Large number of RCTs.	1. Heterogeneity relating to injection types & approaches, diagnoses, control groups, and study quality.
2. No clear benefit of epidural steroid injections in sciatica patients.	2. Heterogeneity between control interventions makes interpretation of results somewhat challenging.

Points to consider

Efficacy

On one hand…	On the other hand…
3. In general, no benefit of spinal injections for other types of back pain; fewer trials reporting.	3. Possible benefit in the following cases (1 study each): • LBP from the SI joint treated with SI joint blocks • Cervical radiculopathy treated with epidural steroid injections

Points to consider

Safety

On one hand…	On the other hand…
1. Major complications are rare.	1. Major complications have been reported in case reports; incidence unclear.
2. Minor complications are more common.	2. Minor complications are generally transient in nature.

Points to consider

Cost effectiveness

1. Based on 2 RCTs: epidural versus placebo injections in patients with LBP + sciatica.
2. Higher quality study showed no cost benefit.
3. Short-term cost- benefit (3-4 weeks) in lower quality study not sustained.
4. Other injection types not evaluated.


Questions?

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 these 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-effective[1] as expressed by the following standards. [2]

- 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 harms.[3]

- 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.
- 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.

[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

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 evidence[4] 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.

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 at 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.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
CMS National Policy Decisions – WA HTA Centers for Medicare and Medicaid Services Page: 46		▪ The Centers for Medicare and Medicaid Services have no published National coverage determinations (NCD) for any spinal injections		N/A
Guidelines – WA HTA Page: 27 *American Pain Society (APS)* *Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain (Chou et al)*	2009	For patients with nonradicular low back pain, the APS is unable assess the benefit of epidural steroid injection, facet joint steroid injection, medial branch block, or sacroiliac joint injection based on insufficient or poor evidence (Grade I). Corticosteroid facet joint injection is not recommended based on moderate evidence. Intradiscal steroid injection is not recommended for treatment of nonradicular low back pain based on good evidence (Grade D). For patients with radicular low back pain, the APS found moderate evidence for short-term (through three months) benefit from epidural steroid injections based on fair evidence (Grade B). Physicians should discuss the risks and benefits of epidural steroid injection, and such discussions should include the lack of evidence for long-term benefit of epidural steroid injections. A recommendation for epidural steroid injection for patients with symptomatic spinal stenosis is not offered based on insufficient or poor evidence (Grade I). Intradiscal steroid injection was not found to be more effective than chemonucelolysis for patients with symptomatic spinal stenosis, and no recommendation is given (Grade C).		
Guidelines – WA HTA Page: 27 *American Society of Interventional Pain Physicians* *Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain (NGC:007428)*	2009	The recommendation for caudal epidural steroid injection in managing lumbar spinal pain with disc herniation and radiculitis or discogenic pain without disc herniation or radiculitis is 1A or 1B, indicating a strong recommendation where the benefits outweigh the risks of treatment. In addition, the recommendation for caudal epidural steroid injection for patients with post-lumbar laminectomy syndrome and spinal stenosis is 1B or 1C, also indicating a strong recommendation.The recommendation for use of cervical interlaminar epidural injection for disc herniation and radiculitis to achieve short-term relief is 1C. For patients seeking long-term relief, the recommendation is 2B (weak recommendation), indicating benefits are balanced with risks and burdens of		

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
		treatment. In patients with spinal stenosis and discogenic pain without disc herniation and radiculitis the recommendation is 2C (very weak, with uncertainty in estimates of benefits, risk, and burden of treatment). The recommendation for lumbar transforaminal epidural injections is 1C. Intraarticular facet joint injections are not recommended.Cervical, thoracic, and lumbar facet joint nerve blocks are recommended to provide both short-term and long-term relief in the treatment of chronic facet joint pain (recommendation 1B or 1C).		
Guidelines – WA HTA Page: 28 *Institute for Clinical Systems Improvement* *Assessment and management of chronic pain (NGC:007602)*	2009	Epidural steroid injections and facet joint injections are classified as level I (standard, first-line) therapeutic procedures, and are recommended as part of a comprehensive treatment plan that includes pharmacologic, rehabilitative, and psychological interventions. Evidence is limited when such procedures are used alone.		
Guidelines – WA HTA Page: 28 *American College of Occupational and Environmental Medicine* *Chronic pain NGC:007160*	2008	Epidural glucocorticosteroid injection is recommended as a treatment option for subacute radicular pain syndromes, and as an option for second-line treatment of acute flare-ups of spinal stenosis associated with true radicular or radiculomyelopathic symptoms based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). Epidural glucocorticosteroid injection is not recommended to treat chronic neck pain or for dorsal spine symptoms that predominate over leg pain based on evidence that harms and cost exceed benefits to the patient (Evidence Rating C: limited evidence). The ACOEM makes no recommendation regarding the use of facet joint injection for flare-ups of neuropathic pain or chronic low back pain (Evidence Rating I: insufficient evidence). Facet joint injection is not recommended for any radicular pain syndrome, chronic non-specific axial pain, and repeat injections are not recommended for patients who failed to achieve lasting functional improvements after a prior injection for neuropathic or chronic low back pain based on evidence that treatment is ineffective or that costs or harms outweigh benefits to the patient (Evidence Rating B: moderate evidence).		

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Guidelines – WA HTA Page: 28 *Institute for Clinical Systems Improvement* *Adult low back pain (NGC:006888)*	2008	ICSI recommends epidural steroid injection only after conservative treatment has failed and to avoid surgical intervention. ICSI finds limited evidence for the efficacy of epidural steroid injection, but indicates it may allow patients to progress with conservative treatments. Epidural steroid injection should be performed under fluoroscopy with contrast in order to prevent treatment failure.		
Guidelines – WA HTA Page: 28 *Work Loss Data Institute* *Low back - lumbar & thoracic (acute & chronic) (NGC:006562)*	2008	Epidural steroid injection and sacroiliac joint injections are recommended as part of a comprehensive treatment plan for low back pain. Specifically, epidural steroid injection is recommended to avoid surgery for severe cases with radiculopathy, but does not offer long-term functional benefit. “Series of three” epidural steroid injections, facet joint injection (multiple series, thoracic, and medical branch blocks), and intradiscal steroid injection were considered but are not recommended.		
Guidelines – WA HTA Page: 29 *Work Loss Data Institute* *Neck and upper back (acute & chronic) (NGC:006563)*	2008	Epidural steroid injection is recommended as part of a comprehensive treatment plan for radicular pain. Specifically, epidural steroid injection is recommended to avoid surgery in severe cases with neurologic findings. Facet joint injection was considered but is not recommended.		
Guidelines – WA HTA Page: 29 *Work Loss Data Institute* *Pain (chronic) (NGC:006564)*	2008	Epidural steroid injection is recommended as part of a comprehensive treatment plan. Facet blocks are classified as under study by the Institute and are not currently recommended.		
Guidelines – WA HTA Page: 29 *American Academy of Neurology* *Assessment: use of epidural steroid injections to treat radicular lumbosacral pain. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology (NGC:005580)*	2007	The American Academy of Neurology indicates the use of epidural steroid injections may result in a small magnitude of improvement in radicular lumbosacral pain when evaluated 2-6 weeks post-injection, but the recommendation is classified as a level C (possibly effective) due the small number of relevant studies, highly select patient population, and variation in comparison treatments in the evidence base. Epidural steroid injections are not recommended for radicular lumbosacral pain due to a lack of evidence for improvement of function, need for surgery or long-term pain		

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
		relief beyond 3 months. This recommendation is classified as level B (probably ineffective based on Class I-III evidence). There was insufficient evidence to make a recommendation regarding the use of epidural steroid injections to treat cervical radicular pain.		
Guidelines – WA HTA Page: 29 *American College of Occupational and Environmental Medicine* *Low back disorders (NGC:006456)*	2007	The use of epidural glucocorticosteroid injection is recommended as a second-line treatment of acute spinal stenosis flare-ups, and as a treatment option for acute or subacute radicular pain syndromes lasting at least 3 weeks after treatment with NSAIDs and when pain is not trending towards spontaneous resolution. Both treatments are recommended based on low potential harm to the patient and low costs (Evidence Rating I: insufficient evidence). The use of facet joint injections is not recommended for acute, subacute, chronic low back pain, and radicular pain syndrome based on evidence that the treatment is ineffective or that harms and cost exceed benefits to the patient (Evidence Rating B: moderate evidence). Sacroiliac joint corticosteroid injection is recommended as an option for patients with specified known cause of sacroiliitis (Evidence Rating C: limited evidence). The use of epidural glucocorticosteroid injection is not recommended for acute, subacute, or chronic low back pain in the absence of radicular signs and symptoms (Evidence Rating C: limited evidence).		
Guidelines – WA HTA Page: 30 *American College of Physicians and the American Pain Society* *Diagnosis and treatment of low back pain: a joint clinical practice guideline*	2007	Epidural steroid injection is an option for patients with prolapsed lumbar disc with persistent radicular symptoms who have not responded to noninvasive therapy. No specific recommendation is given for this or any other injection therapy of interest.		
Guidelines – WA HTA Page: 30 *North American Spine Society* *Diagnosis and treatment*	2007	The NASS recommends nonfluoroscopically-guided interlaminar epidural steroid injection as a treatment option for short-term symptom relief in patients with neurogenic claudication or radiculopathy. A single radiographically-guided transforaminal injection may also provide short-term symptom relief for patients with radiculopathy (Grade B: fair evidence).		

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
of degenerative lumbar spinal stenosis (NGC:005896)		A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections may provide long-term symptom relief in patients with radiculopathy or neurogenic intermittent claudication, but evidence supporting this recommendation is of poor quality.		
Guidelines – WA HTA Page: 30 *EuroCOST: European evidence-based guideline COST B13 Working Group on Guidelines for Chronic Low Back Pain* *European guidelines for the management of chronic nonspecific low back pain*	2006	Epidural steroid injection, facet joint injection, and facet nerve blocks are not recommended based on a lack of evidence or conflicting evidence. Intradiscal injections are not recommended for the treatment chronic nonspecific low back pain based on evidence they are not effective (level B: moderate evidence).		
Guidelines – WA HTA Page: 30 *American Association of Neurological Surgeons; Congress of Neurological Surgeons* *Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: injection therapies, low-back pain, and lumbar fusion (NGC:005374)*	2005	Lumbar epidural injections and facet injections are recommended as treatment options for temporary, symptomatic relief in some patients with chronic low back pain, but epidural injections are not recommended for long-term relief of pain, based on Class III evidence (unclear clinical certainty). Facet injections are not recommended as long-term treatment for low back pain based on Class I evidence (high clinical certainty).		

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

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

	Spinal Injections
Safety Outcomes	**Safety Evidence**
Mortality	
Morbidity	
Cervical Spine Injections ▪ Major Complications ▪ Minor Complications	
Lumbar Spine Injections ▪ Major Complications ▪ Minor Complications	
Vascular Puncture	
Radiation Exposure to the Physician	
Other Adverse Events	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Type of Steroid	
MRI Findings	
Pre-injection Pain Intensity	
Approach of Epidural Steroid Injection	
Diagnosis / Indication	
Opioid Use	
Functional Outcomes	
Pain Relief / Reduction	
Quality of Life	
Patient Satisfaction	
Other Patient Outcomes	

Special Population / Considerations Outcomes	Special Population Evidence
Sex	
Age	
Provider Characteristics	
Patient Selection	
Payer or Beneficiary Type	
Cost	**Cost Evidence**
Cost Implications	
Direct and indirect - Short terms - Over expected duration of use	
Repeat Procedures	
Cost Effectiveness	

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.

Clinical Committee Findings and Decisions

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.

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?