American Society of Interventional Pain Physicians®

Fact Sheet on AHRQ Technology Assessment for Low Back Pain Therapies: Intellectual Bias and Conflicts

The American Society of Interventional Pain Physicians (ASIPP) is a not-for-profit professional organization founded in 1998 comprised of over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States. ASIPP also has affiliated state societies in all 50 states and Puerto Rico.

Physicians in the United States are drowning in a regulatory tsunami from the Health Insurance Portability and Accountability Act (HIPAA), numerous components of the Affordable Care Act (ACA) including electronic medical records (EMRs), the Physician Quality Reporting System (PQRS), value-based payment system, electronic prescribing, the statutory monopoly of the American Medical Association (AMA), Current Procedural Terminology (CPT), and Relative Value Scale Update Committee (RUC) with numerous codes, and now the ICD-10 implementation with unfunded mandatory requirements. In addition to the many factors contributing to the extinction of independent practitioners, we are now facing technology assessments and systematic reviews which are intellectually biased by taxpayer funding to benefit only a few.

Background

In 1989, the Agency for Healthcare Policy and Research (AHCPR) was created as an arm of the Department of Health and Human Services (DHHS).[1] AHCPR has undertaken a number of initiatives, including creation of the National Guideline Clearinghouse (NGC) designed to summarize the available medical evidence on the appropriate treatments for various conditions.[1] They produced 15 guidelines at a cost of $750 million. In the mid 1990s, controversies arose after an agency-sponsored research team concluded that there was insufficient evidence to support certain spinal surgeries, and on the basis of that, the agency issued practice guidelines for the treatment of back pain.[2] Strong opposition from spine surgeons, along with broader questions about the value of the research that the agency had funded, and other factors, led to pressure to eliminate the agency.[2]

Ultimately, AHCPR was retained but its funding for fiscal year 1996 was reduced from prior levels. It was renamed the Agency for Healthcare Research and Quality (AHRQ). Since then, its overall budget has generally been maintained, at least in nominal terms, or increased.[1]

In the United States, there are now multiple organizations performing the same functions duplicatively without communication among them. They include NIH, Institute of Medicine, USPSTF, and AHRQ and its multiple effectiveness program centers.

1 U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. www.ahrq.gov

2 Gonzalez EG, Materson RS. The guidelines, the controversy, the book. In Gonzalez ER, Materson RS (eds). The Nonsurgical Management of Acute Low Back Pain. Demos Vermande, New York, 1997, pp 1-4.

AHRQ Mission

AHRQ's mission is "to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used." This injection therapy technology assessment does not help achieve that mission. All stages, from assignment to execution to publication of this technology assessment are inappropriate.

Technology Assessment for Low Back Pain Therapies

In March 2015, after a long wait, AHRQ published a Technology Assessment for pain management injection therapies for low back pain.[3] When they inquired with us about the need for it to be performed by Chou and his associates, ASIPP informed them that there was neither a need nor was it appropriate for them to perform such an assessment. In spite of this they went on to perform the Technology Assessment. As one would expect, their reported results where the same as their previous publications. AHRQ claims that this was performed at the request of the Centers for Medicare and Medicaid Services and they are not responsible for the contents. Instead, they say the authors are responsible. This review is of poor quality and will harm patients by potentially affecting their ability to obtain meaningful treatment that is today the standard of care for pain patients. It is neither a scientific breakthrough, nor clarification of issues. Rather it is merely the promotion of the self-interests of a certain group of people with the help of AHRQ.

The same is published in the Annals of Internal Medicine.[4]

Intellectual Bias and Conflicts of Interest

We were greatly disappointed with these reviews and the intellectual bias exerted through the unscientific nature of this systematic review and the failure to follow the guidance provided by the Institute of Medicine (IOM).[5] Local anesthetics have been used as therapeutic agents in billions of individuals for over 100 years. In fact, much of the literature shows that local anesthetics are as effective as a local anesthetic and steroids in many cases except in rare circumstances.

The most glaring and fundamental flaw relates to how they converted active trials to placebo-control trials, which was not meant to be by the authors. Active control trials are totally different

3 Chou R, Hashimoto R, Friedly J, et al. Pain Management Injection Therapies for Low Back Pain. Technology Assessment Report ESIB0813Rockville, MD: Agency for Healthcare Research and Quality; March 20, 2015. http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/id98TA.pdf

4 Chou R, Hashimoto R, Friedly J, et al. Epidural corticosteroid injections for radiculopathy and spinal stenosis: A systematic review and meta-analysis. Ann Intern Med 2015; 163(5):373-81. http://www.ncbi.nlm.nih.gov/pubmed/26302454

5 Eden J, Levit L, Berg A, Morton S (eds); Committee on Standards for Systematic Reviews of Comparative Effectiveness Research; Institute of Medicine. Finding What Works in Health Care. Standards for Systematic Reviews. The National Academies Press, Washington, DC, 2011.

ASIPP®
American Society of Interventional Pain Physicians®
81 Lakeview Drive, Paducah, KY 42001 Phone: 270-554-9412 Fax: 270-554-5394 Internet: www.asipp.org E-mail: asipp@asipp.org

from placebo control trials. It is synonymous to comparing water to whole milk as the placebo control (and skim milk to whole milk, active control trial). No one considers any surgical intervention or drug to be a placebo.

Their conflicts include funding in the past from the American Pain Society of $1.4 million for publication of guidelines. It is well known that the pharmaceutical companies are major contributors to the American Pain Society. Also, they are generating funds for multiple private enterprises by selling flawed opinions.

Other Low Back Pain Therapy Modalites

An important fact to consider is that epidural injections have an excellent risk-benefit ratio compared to opioids and NSAIDs, which are responsible for almost 17,000 deaths a year and numerous hospitalizations. Lumbar surgery alone is responsible for approximately 1,300 deaths a year, while deaths over the past two decades related to epidural injections were 131 - significantly less than any other modality.

Changes Without Evidence

The normal level of cholesterol was dropped from 240 to 200, blood sugar was dropped from 140 to 126, T scores for osteoporosis from -2.5 to -2.0, and systolic blood pressure from 160 to 140, and recently 120. The number of patients with hyperlipidemia increased by 86%, diabetes by 14%, hypertension by 35%, and osteoporosis in women by 85%. Now, 50% of Medicare Part B dollars are spent on drugs. Maybe the researchers need to start looking at the standards they have established and their impact on health care: positive or negative outcomes and cost-utility.

However, this issue is not limited to interventional pain management or low back pain. The AHRQ seems to be functioning ineffectively.

Future Actions

1. FINANCIAL CONFLICTS OF INTEREST AND INTELLECTUAL BIAS

AHRQ must follow IOM guidance on financial conflicts of interest and potenial intellectual bias (Eden J, Levit L, Berg A, Morton S [eds]; Committee on Standards for Systematic Reviews of Comparative Effectiveness Research; Institute of Medicine. Finding What Works in Health Care. Standards for Systematic Reviews. The National Academies Press, Washington, DC, 2011).

2. COMPOSITION OF PANEL

A proper assessment must include different health technology assessment individuals with at least 50% of the reviewers who are practicing clinicians rather than physician methodologists.

3. APPROPRIATE AND LOGICAL USE OF ACTIVE-CONTROLLED TRIALS AND PLACEBO-CONTROLLED TRIALS

The authors of the previous reviews, including the ones from AHRQ, have erroneously considered all active-control trials as placebo control. This is not supported by any literature. They did this purely to yield their own opinions without any scientific basis and with intellectual bias. The authors must consider extensive literature available on placebos and nocebos, specifically from the National Institutes of Health (NIH) and multiple other agencies.

4. PRE-POSSESSED AND INTELLECTUALLY BIASED METHODOLOGICAL QUALITY ASSESSMENT

The authors must not perform biased, unscientific, prepossessed methodological quality assessment. In the past the authors, including those from Spectrum and AHRQ, utilized pre-possession with a determination to downgrade the studies which were positive in addition to changing active-controlled trials to placebo-controlled trials.

5. UTILIZATION OF APPROPRIATE OUTCOME PARAMETERS

The authors must utilize appropriate outcome parameters to derive clinically relevant outcomes.

6. ANALYTIC METHODS

The authors must utilize quantitative amd qualitative analysis.

If you have any questions, please feel free to contact us one of us: Laxmaiah Manchikanti, MD, at drm@asipp.org; Peter Staats, MD, at peterstaats@hotmail.com; Tim Hutchinson at hutchinsont@gtlaw.com; Monica Prahl Schulteis at schulteism@gtlaw.com; Jeff Mortier at jmortier@rmvbllp.com; or Jeff MacKinnon at jmackinnon@rmvbllp.com.