American Society of Interventional Pain Physicians

" The Voice of Interventional Pain Management "

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Re: Request for suspension of AHRQ of Technology Assessment for Pain Management Injection Therapies for Low Back Pain, Project ID: ESIB0813, Final March 20, 2015

Dear Drs. Kronick, Arnold, and Berliner:

While we were disappointed with the publication of the *Technology Assessment for Pain Management Injection Therapies for Low Back Pain*, which was neither needed nor appropriate, we are now even more disappointed and astonished after reading the first of the series of manuscripts by Chou et al. As you are well aware, this technology assessment provides no new information; it is just a republication of ill-conceived, previously published manuscripts and guidance by Pinto et al (1) and Chou et al (2-4). Consequently, this technology assessment for the Agency for Healthcare Research and Quality (AHRQ) at the request of the Centers for Medicare and Medicaid Services (CMS) by Chou's group is a travesty. It is neither a scientific breakthrough, nor a clarification of issues. Rather, it promotes the self interests of a certain group of people.

While 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 technology assessment does not help achieve that mission. All the developments, from assignment to execution to publication, of this technology assessment are inappropriate.

This technology assessment is fundamentally inconsistent with the Institute of Medicine (IOM) standards for systematic reviews (5). The inconsistencies are:

- Lack of confirmation for a new review (i.e., it is the same review by the same individuals reaching the same conclusions)
- Inclusion of authors with financial conflicts of interest and professional and intellectual bias
- Lack of clinical expertise
- Inappropriate design and methodologic quality assessment of the manuscripts with injection of prejudice
- Lack of qualitative synthesis
  In addition, the manuscript also deviates from the standards of placebo and nocebo. Extensive research on placebo and nocebo and the importance of these aspects in pain have been published worldwide, specifically from the National Institutes of Health (NIH). There is also a movement to incorporate appropriate placebo responses in clinical management.
  - In this systematic review, the authors unilaterally convert all active control trials to placebo control trials, raising not only methodological, but also ethical, issues.

The most glaring and fundamental flaw relates to how the authors unintentional converted placebo trials to active control trials.

As well-known professionals at AHRQ and respected scientists, you are aware that active control trials are totally different from placebo control trials. It is synonymous to comparing skim milk to whole milk as the placebo control (and water to whole milk, placebo control). No one considers a surgical intervention or drug to be a placebo.

The scientists who understand the study design know that absolute effect size can only be measured in a true placebo control trial, not a fake placebo or one converted from active control to placebo control for convenience.

The technology assessment claims that therapeutic effects in the epidural space are primarily related to corticosteroids; however, neither this manuscript, nor the previously published manuscripts provide any evidence for this position. Further, the only evidence they do provide is a self-serving statement that local anesthetics are placebos. In fact, there is overwhelming evidence of the therapeutic efficacy of local anesthetics on a long-term basis, sometimes even better than steroids. There is also significant evidence that physiologic changes occur when inert substances are injected into active structures, let alone a therapeutic substance such as local anesthetic. Multiple systematic reviews and numerous appropriately performed studies have shown epidural injections of local anesthetic alone, or of local anesthetic and steroids, are effective (6-9). Local anesthetic alone and local anesthetic and steroids have been shown to be equally effective except in very rare circumstances where the addition of steroids to the local anesthetic showed some improvement (9,10).

Their conflicts include past funding of $1.4 million from the American Pain Society 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.

Just remember issues we are facing; 16,917 deaths a year with opioids, 17,000 deaths a year due to NSAIDs, over 100,000 hospitalizations, and lumbar surgery leading to 1,286 deaths a year. Compare these to this issue of only 131 deaths from 10-20 years.

If we recall, 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. 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 look at the standards they have established and their impact on health care: positive or negative outcomes and cost-utility.

At this time, we request the AHRQ withdraw this publication and remove it from public review until further information is gathered and an independent assessment is performed.

Hopefully, as everyone believes, AHRQ is not too powerful to be accountable.

If you have any questions, please feel free to contact us.

Thank you.

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