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NEWSLETTER #111 JANUARY 2023

No Conflct, No Interest

In our November newsletter, we noted that the *Journal of the American Medical Association* (JAMA), an early leader in the promotion of evidence-based medicine, had just published the results of a spinal cord stimulation (SCS) outcomes study with important methodological shortcomings that peer reviewers should have caught (Hara et al. 2022). Similarly, JAMA editors have led efforts to define conflict of interest (CoI) and potential bias arising from industry sponsorship of research (Angell 2008, DeAngelis et al. 2008). In December, however, *JAMA Neurology* published an analysis of “big data” proxy SCS outcomes (Dhruva et al. 2023) that has raised concerns not only about the methodology used in this analysis but also about CoI on the part of the authors.

In this paper, Dhruva et al. distinguish “industry funded” from “independent evaluations” as if to suggest that their work falls in the latter category. A companion editorial (Shirvalkar et al. 2023) notes that Dhruva et al. are "*relatively* [emphasis added] free from such conflicts of interest." In fact, however, most of the authors are affiliated with a large health insurance company that has expanded its business to subsume health care providers, thus entering the health care delivery arena on a broad front. Insurance companies have long qualified as industries within the “financial activities supersector” (US Bureau of Labor Statistics 2023) and, as such, can be expected to promote distinct economic interests and incentives that the affiliated authors have an obligation to acknowledge (Herman 2022).

In their paper, however, Dhruva et al. not only fail to point out this conflict, they attempt to underscore their tenuous conclusions by 1) dismissing several previously published SCS cost-effectiveness studies because they were sponsored by the medical device industry and 2) ignoring the very existence of recent SCS cost studies and meta-analyses that were not sponsored by industry yet show that SCS is cost-effective over the long term (Niyomsri et al. 2020, Rojo et al. 2021).

Because of its relatively high initial cost, SCS generally requires a few years to achieve fiscal neutrality, i.e., to “pay for itself” by reducing health care expenditures associated with “conventional medical management” and reoperation. This time-to-cost-neutrality is not the concern of a patient in whom previously intractable pain is relieved; an insurer, however, whose relationship with any given patient might well end before the company can reap the cumulative cost savings, can be expected to have a different perspective (Villaroel et al. 2014). Indeed, Shirvalkar et al’s. companion editorial notes that Dhruva et al. ". . . may have detected a significant non–QALY-adjusted difference between SCS and CMM if their analyses was [sic] extended by 12 more months (to 3 years),” a significant omission in this context.

Dhruva et al. acknowledge, and the companion editorial mentions, that the study "unfortunately lacks direct pain or function measures." This is another vitally important omission that is not obviated by being listed as a study limitation. The advantages of composite or holistic outcome measures are clear (Piltsis et al. 2021), but these composites do not ignore direct measures of pain intensity and of function. Pain, after all, is the most common chief complaint of all patients and is so important that it became the “fifth vital sign” (Campbell 2016) used by payers (viz., Medicare) as a quality measure and (for some time) as a determinant of reimbursement (Lee et al. 2017). The fact that the word “pain” appears more than 100 times in the Dhruva paper makes it even more remarkable that the authors downplay it as an outcome measure in favor of indirect, ultimately economic measures, such as opioid use and aggregate health care use. The vast literature on SCS that uses pain as a primary outcome measure, and thus is directly relevant to real-world clinical problems, cannot be summarily dismissed in this manner if a study wishes to be taken seriously.

In addition, Dhruva et al. report that “among matched patients, during the first 12 months, patients treated with SCSs [sic] had higher odds of chronic opioid use. . . compared with patients treated with CMM.” Downplaying or ignoring the fact that this difference disappeared “during months 13 to 24,” the authors conclude that “SCS placement was not associated with a reduction in opioid use. . . at 2 years.” This failure to note a positive effect of SCS on opioid use in their sample is matched by their failure to acknowledge multiple prior publications that contradict their conclusion (e.g., North et al. 2021, Hayek et al. Cui bono, Neuromodulation in press). (By the way, WIKISTIM enables anyone to find additional papers on the subject – a search for “opioid” in our SCS database yields 38 hits, most considering opioid use as an outcome.) The failure of Dhruva et al. to acknowledge contrary prior art, a failure also present in the study by Hara et al. that we reviewed in November, adds to our concerns about the quality of these papers, the validity of their conclusions, and the review process.

The phrase “no conflict, no interest,” was used by William Brody, then president of the Johns Hopkins University, to recognize that CoI is unavoidable: “A bias is born when a scientist has an idea and sets out to make that idea work,” (Brandt 2005). Brody defined the goals of a CoI management policy: “Protecting the safety and welfare of human research subjects; safeguarding the integrity of scientific research; making sure that technology developments and scientific discoveries move quickly from the university to industry; making sure that student training is not subverted to the priorities of outside corporations; ensuring open communication among physicians and scientists, unencumbered by consulting arrangements; assuring the reputational integrity of the university; maintaining the dedication of the faculty to the aims of the university" (Brody 2005). In another context, however, the same phrase has been widely attributed to venture capitalist John Doerr and taken to mean that he was interested in investing only when he had information that gave him an advantage over other investors, i.e., when he benefitted from what might well be considered a conflict of interest (Blodgett 2011). Careful peer review and prudent editorial decisions are necessary to prevent the publication of research that was motivated by an unacknowledged CoI, and irony abounds when the reports of such research attack other, duly acknowledged, potential conflicts while obfuscating their own.

JAMA has long recognized the importance of managing CoI, along with following the principles of evidence-based medicine, and we all agree that high quality evidence should inform policy. The Dhruva paper comes from authors with close ties to the insurance industry, which sets reimbursement policy, and it is fair and indeed vital to ask whether this in fact is an example of "policy-based evidence" (Marmot 2006). Does this study serve the insurance industry's interests or the interests of patients in pain?

Cui Bono? YOU Do!

We are pleased that Elsevier has made our letter to the editor, **SCS and Evidenced-Based Medicine--Cui Bono,** which is now online in Neuromodulation, free for viewing and download until February 24, 2023.

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Deep Brain Stimulation (now 7349 citations)

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Contact

The Neuromodulation Foundation, Inc.
117 East 25th Street
Baltimore, MD 21218

wikistim@gmail.com