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NEWSLETTER #117 JULY 2023

Australia issues a draft report that mitigates the effects of two shortsighted reviews

The latest Cochrane reviews (Traeger et al., 2023; O'Connell et al., 2021), which we critiqued in our March and Maynewsletters, are the focus of a new 115-page draft report prepared by hereco for the Department of Health and Aged Care in Australia (Anon., 2023). Traeger et al., the authors of the review published in March, also are from Australia. The hereco report indicates that, rather than suggest any changes in health care reimbursement policies, their countrymen proposed "to list SCS [spinal cord stimulation] devices . . . at the current benefit, whilst also undertaking further [research]." (hereco, p.9).

The criticisms of hereco echo some of ours, and the report's authors have undertaken a partial remedy: "Cochrane reviews have narrow inclusion criteria and may have omitted a much larger volume of relevant evidence. Therefore, all evidence provided by sponsors and stakeholders, together with evidence excluded from the Cochrane reviews, was collated for this post-listing review (PLR) . . .. Nine additional RCTs [randomized controlled trials] were considered . . .. Two of the nine trials stated they were blinded." (hereco, p. 8).

Although a step in the right direction, this falls far short of a new systematic review; rather, it is described as a "targeted evidence scan" (hereco, p. 23). It improves upon the Traeger and O'Connell reviews, which excluded such studies, by considering four (but only four) RCTs comparing high frequency with conventional SCS, four comparing "alternative approaches" (multicolumn, closed loop, multiplexed, burst) with conventional SCS, and one comparing SCS with dorsal root ganglion stimulation. It also expands the scope of the review to include ischemic pain, which has been the subject of other systematic reviews (NICE 2008).

By considering suggestions from "stakeholders," hereco opens a door, but it does so incompletely; many of the suggestions are dismissed using the same criteria as

Cochrane. For example, hereco perpetuates the simplistic Cochrane notion that “The gold standard for the assessment of any medical treatment is a double-blind randomised controlled trial. . .” (hereco p. 23). Of course, the requirement for blinding excludes trials of not only paresthesia-based SCS but also of interventions such as kidney transplants, parachutes, etc., which are well accepted in the “real world.” Paresthesia-based SCS remains available with contemporary SCS devices and is commonly used but less often included in recent studies than are waveforms that are experimental or not yet in widespread use, which could be considered over-represented in the recent literature.

The Traeger and O’Connell reviews in 2023 and 2021 were the first in 17 years, and neither included our 2005 RCT of SCS vs. reoperation trial (North et al., 2005) or its companion cost-effectiveness study (North et al., 2007). The latter is mentioned by hereco among stakeholder submissions, and the 2004 Cochrane review by Mailis-Gagnon et al. referenced a preliminary publication of our RCT results (Mailis-Gagnon et al., 2007). Our RCT, of course, introduced the important concept of patients crossing over to an expensive alternative such as repeated lumbosacral spine surgery. This concept is not recognized explicitly in the Traeger and O’Connell reviews; thus, the tacit assumption that patients are “treated as intended,” i.e., as randomized, and do not incur additional expense from other treatments is an important shortcoming. Payers surely recognize this expense, however, making this one sense in which their interests align with those of patients who understand the various costs and consequences of undergoing additional surgical procedures.

The hereco report concludes that the evidence for SCS is “uncertain” (hereco, p. 61). While the authors do not recommend that payers in Australia use the Traeger or O’Connell reviews for policy making, other payers might do so. We must continue, and WIKISTIM must facilitate, our efforts on all fronts to produce the highest quality research to reflect the benefits SCS offers to appropriately selected and treated patients.

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