Editors' Note: We are publishing all previously posted dialogue about intraoperative spinal monitoring. Evidence-based medicine (EBM) is a laudable goal, but it is clear that well-intentioned authorities will have strongly held opinions based on their review of the same evidence. The concluding letter by Gronseth, arguably our specialty's leading figure in EBM, does not "give the answer" but does suggest a way forward.

Robert C. Griggs, MD, and Megan Alcauskas, MD

**EVIDENCE-BASED GUIDELINE UPDATE:
INTRAOPERATIVE SPINAL MONITORING
WITH SOMATOSENSORY AND
TRANSCRANIAL ELECTRICAL MOTOR
EVOKED POTENTIALS: REPORT OF THE
THERAPEUTICS AND TECHNOLOGY
ASSESSMENT SUBCOMMITTEE OF THE
AMERICAN ACADEMY OF NEUROLOGY
AND THE AMERICAN CLINICAL
NEUROPHYSIOLOGY SOCIETY**

John P. Ney, David N. van der Goes, Seattle: Nuwer et al.¹ consolidated the best evidence available on the use of evoked potentials during spinal operations. However, focusing on the value of intraoperative neurophysiological monitoring (IOM) alerts in predicting postoperative motor deficits does not offer new answers to the question "Why use IOM?" The guideline authors agree with the results of a review² that supported IOM as a predictive diagnostic tool with a high level of evidence. Prediction alone is insufficient to warrant use of IOM especially when actual outcomes will be revealed almost immediately following the surgery. Also, short-term prediction is insufficient to justify the costs of the specialized equipment, technicians, and professional oversight necessary for proper IOM performance. The evidence for IOM to alter outcomes is weak with only one non-randomized study³ showing a 52% rate of preventing neurologic deficits from acting on IOM alerts. In the absence of randomized controlled trials, outcomes research from large observational datasets may clarify the utility of IOM as cost-effectiveness becomes a greater factor in medical decision-making.⁴

Author Response: Marc Nuwer, Los Angeles; Ronald Emerson, New York; Robert Minahan, Washington, DC; Alan Legatt, New York; Gloria Galloway, Columbus, OH; Jamie Lopez, Stanford, CA; Thoru Yamada, Iowa City, IA: IOM raises warnings early enough to allow for interventions during spinal cord surgery. We believe clinical experience and animal experiments establish unequivocally that IOM warns of spinal cord injury, and interventions reverse impairment and prevent paraplegia. Our assessment¹ discussed this rationale and cited literature.

The assessment process was constrained narrowly so that only the "prediction" question could be asked. That answer is clear and crucial: IOM accurately warns of neural insults intraoperatively. Spinal cord injury produces irreversible deficits within minutes. The absence of randomized human outcome studies is no accident; in light of overwhelming animal data, it is our opinion that human experiment would be unconscionable.

We emphatically reject Drs. Ney and van der Goes' suggestion that postoperative assessment of paraplegia is an adequate alternative outcome measure because by that time the damage is irreversible.

Regarding cost-effectiveness, assume that spinal cord IOM saves adverse outcome in 0.5% of surgeries.⁵ For a young person who is devastated by preventable paraplegia, costs include diminished quality of life, lifelong medical care, lost opportunity, and social services. The expense of IOM to spare each incidence of paraplegia is not only cost-effective but an overall cost savings.

The best way to treat paraplegia is to prevent it in the first place.

John P. Ney, David N. van der Goes, Seattle: We appreciate the response of Dr. Nuwer et al. to our comments but emphasize that animal studies and personal clinical experience are insufficient to support the claim that evidence of effectiveness is not needed. We agree that permanent motor deficits are an undesirable outcome in any sphere. The effectiveness of IOM is a function of its diagnostic characteristics and the ability to act on IOM alerts to avert

impending neurologic disasters.⁴ The latter is a largely missing piece of the puzzle and, in its absence, those with alternate agendas will attempt to fill the vacuum.

An example is the methodologically flawed article by Traynelis et al.⁶ published 6 days before the updated IOM guidelines. The authors outlined a series of 720 unmonitored cervical surgery patients who developed no new permanent neurologic deficits “saving” the hospital over \$1 million in monitoring costs. Because quadriplegia and paraplegia are relatively rare events, underpowered single-center, retrospective studies can overestimate the safety of spine surgery and undermine the need for IOM. Until there are data that IOM alters outcomes, its use will be decided by the operating surgeon, who is much more likely to read *Journal of Neurosurgery: Spine*⁶ than *Neurology*[®].

Author Response: Marc R. Nuwer, Los Angeles: In their most recent WriteClick post, Drs. Ney and van der Goes suggest that there is a lack of well-designed scientific studies demonstrating that IOM improves outcomes. They are incorrect. Human and animal data show that IOM improves outcomes. Our multi-center study⁵ compared neurologic adverse outcomes in a large group of surgeons before and after adopting evoked potential spinal cord IOM. Major neurologic deficits such as paraparesis and paraplegia decreased by 60% after adopting IOM. In another study, 50 patients without IOM were compared to 50 patients with IOM.⁷ In that study, the formally graded motor scores in follow-up were significantly better in those who had IOM. Drs. Ney and van der Goes would like an unrealistically idealistic, impractical, and unethical controlled outcome study. That will never occur. They will need to accept what studies can be done in a practical manner. They will also need to accept well-designed animal research, as cited in the original assessment, which has unequivocally shown that outcomes are improved by IOM. When Drs. Ney and van der Goes state that IOM literature lacks a demonstration of effectiveness, they show a lack of familiarity with and understanding of the full literature.

Anup D. Patel, Columbus, OH: Drs. Ney and van der Goes suggest that surgeons could get the same information regarding outcomes if they wait to wake up the patient after surgery. They also note that the IOM does not alter outcomes because it is not backed up by randomized trials for outcome. Conducting randomized human trials of IOM during these complicated surgeries is not possible because no surgeon would be willing to participate. Addition-

ally, robust animal data support the recommendations provided in the guidelines.

Eva K. Ritzl, Baltimore: I read Nuwer et al.¹ as well as the comments by Drs. Ney and van der Goes with interest. I applaud the American Academy of Neurology for endorsing an updated practice guideline that highlights the importance of intraoperative signal changes as a marker for neurologic injury during spine surgeries. Establishing that signal changes during spine surgeries reliably detect (impending) neurologic injury can only be achieved by showing that IOM correctly predicts neurologic deficit, as was done here. Randomized studies addressing the question of whether or not use of intraoperative neuromonitoring is able to prevent neurologic disability are clearly unethical. The data Nuwer et al. have compiled are therefore the logical and important first step toward evidence-based guidelines for IOM:

1. A signal change predicts a neurologic deficit (see updated Practice Guidelines for IOM).
2. The signal change occurs during the surgery, in time for corrective action to be taken.
3. A permanent spinal cord injury can be avoided if the signal recovers with the corrective action. (This is the logical conclusion if 1 and 2 are correct.)
4. Permanent spinal cord injury incurs a very high cost (in dollars as well as in human suffering).

Nuwer et al. did not consolidate the best but rather the most stringent evidence available on the use of evoked potentials during spinal operations. In the data compiled,¹ IOM predicted an outcome that would have otherwise been revealed immediately after the surgery. But this is not the point. The point is that neurophysiologists, surgeons, and all other members of the operating team need to know with confidence that a signal change implies real danger to the patient's neural structures. This review provides further important evidence that they can.

Author Response: Ronald G. Emerson, New York: The use of IOM to prevent paraplegia during certain spine surgeries is unequivocally supported by a large body of human literature, animal literature, and clinical experience. A rigid orthodoxy, that deems animal experimentation “inadequate” and instead demands human experimentation that could never ethically be performed, is itself flawed and unhelpful. Rather than promote best practice, it encourages “alternate agendas” of the sort cited by Drs. Ney and van der Goes.

Stanley A. Skinner, David Rippe, Minneapolis: Drs. Ney and van der Goes do not dispute that uncovered spinal cord conduction block during moni-

toring predicts postoperative spinal cord injury (SCI). They rightfully insist that monitoring must also prevent SCI. Therefore, those who monitor patients must identify injury when it occurs, relate the presumed injury to a procedural context, and implement a context-driven intervention.

We—and others—have reported these tactics during decompression at spinal cord level.⁸ We lost motor evoked potential (MEP) in 15 patients: 4/5 with unrecovered MEP had postoperative SCI; 10/10 patients with recovered MEP through specific interventions had no deficit. The understudied problem of false-positive MEP monitoring must be considered.⁹ However, if only 1/10 of our MEP-recovered patients “truly” avoided catastrophic SCI, the monitoring effort was vindicated.

Also, cost-effectiveness analyses¹⁰ suggest that the lifetime cost of 1 avoided paraplegic age 25 is about \$977,000. The avoidance of paraplegia in 1 patient age 50 may pay for about 250 monitored cases. Patient caregivers, who act also as research scientists, operate under a special burden. The enrollment of patients into randomized trials demands a state of “therapeutic equipoise” between the studied interventions (or noninterventions). Only a “genuine doubt” of efficacy can bioethically justify randomization.¹¹

Author Response: Gary S. Gronseth, Kansas City, KS: Is Drs. Ney and van der Goes’ call for evidence for the effectiveness of IOM similar to asking for a randomized controlled trial on parachutes?¹² Everyone dies when jumping from an airplane at altitude without a parachute, so we know there are no confounders affecting outcomes. Without confounding, the observation of 1 person surviving provides strong evidence of parachute benefit: survival 100% (95% confidence interval 20.7% to 100%).

By contrast, there are many confounding factors that affect spinal surgery outcomes. Thus, many observations under controlled circumstances are needed to infer a benefit from IOM. The inference from the diagnostic accuracy evidence that IOM¹ could be beneficial is reasonable but not compelling. Unintended consequences from the use of diagnostic tests can harm patients.¹³ For example, surgeons using IOM might attempt riskier procedures. Animal studies provide evidence that if IOM shows changes, it is prudent to act. From the broader perspective of whether IOM vs no IOM affects outcomes, the animal data are inadequate.

Differences in opinion and evidence that some surgeons do not use IOM⁶ indicate equipoise. Based on the evidence, it is reasonable to use IOM. It is also reasonable to perform a randomized trial to determine whether IOM really helps patients.

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