The safety and effectiveness of medical procedures and treatments are the concern of all health care professionals, payers, policy makers, and public consumers of these services. Even before the 2001 report from the Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century*,1 the American Osteopathic Association (AOA) had promoted and fostered documentation of the quality, safety, and effectiveness of osteopathic medicine, including osteopathic manipulative treatment (OMT), in its accredited colleges, in hospitals, and in the private practices of its members. In 1999, the National Quality Forum (NQF) formed as a private, not-for-profit membership organization to use a consensus-based process to develop and implement a national strategy for health care quality measurement and reporting.2 In 2002, based on the available literature and expert opinion at the time, and because of OMT’s documented record of safety, the NQF accepted the AOA’s recommendation to list disability or death from spinal manipulation as a reportable serious adverse event (SAE), as it is unexpected, unintended, measurable, and preventable.

Many organizations and states have used the information and recommendations gathered by the Institute of Medicine and NQF to institute policies, statutes, and laws pertaining to patient safety, standard quality measures, and reporting of SAEs. In 2004, the state of New Jersey, for example, passed the Patient Safety Act, which “requires every health care facility licensed by the Department of Health and Senior Services to report every serious preventable adverse event, defined as an adverse event that is preventable and results in a patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge.”3 In California, legislation (SB 1301) was enacted in July 2007 based on the NQF recommendations. One of the 28 adverse events defined by the Health and Safety Code, Section 1279.1, is “A patient death or serious disability due to spinal manipulative therapy performed at the health facility.”4 However, not only has there been a paucity of SAEs from spinal manipulation reported by states and other health care facilities, but in 2011, the NQF recommended to remove this SAE because it “targets a specific group of healthcare providers” and “is related to individual provider behavior rather than facility safety systems.”5

To ensure that all osteopathic physicians are competent in using OMT safely and appropriately, the American Association of Colleges of Osteopathic Medicine and the National Board of Osteopathic Medical Examiners include documentation of competency in OMT by all osteopathic medical students and all physicians who elect to pursue osteopathic licensure and board certification.6-8 In addition, osteopathic physicians who pursue further training in OMT can access continuing medical education courses through local, regional, and national osteopathic conferences and specialty groups, such as the American Academy of Osteopathy.

Because of the safety and effectiveness of OMT, 2 AOA position papers,9,10 one of which has become a national clinical practice guideline,10 promote the use of OMT for neck and back pain, respectively. In addition, several large prospective clinical trials have demonstrated the safety and effectiveness of OMT as an adjunct to standard medical care.11-14

Based on a review of articles over 6 decades,15 SAEs from OMT are estimated to be so rare that a prospective, randomized, placebo-controlled clinical trial to evaluate the actual incidence in clinical practice would be cost prohibitive, requiring thousands of OMT patient encounters. Thus, gathering data on SAEs is more pragmatic through a practice-based research network (PBRN). The DO-Touch.NET PBRN, which was established in 2010 and is centered at the A.T. Still University Kirksville College of Osteopathic Medicine in
Missouri, consists of 43 osteopathic physicians from across the country. Under the direction of Brian F. Degenhardt, DO, the DO-Touch.NET PBRN investigated the incidence and types of patient-reported adverse events immediately after OMT.

In this issue of the JAOA, Degenhardt et al\textsuperscript{16} report on their survey findings from more than 880 patients, totaling more than 1800 office encounters with clinicians using osteopathic manipulative procedures (all except 2 clinicians were US-trained and licensed DOs; one was an MD and the other a foreign-trained osteopath). To limit reporting bias, the patients reported any adverse events immediately after OMT directly to the researchers. Adverse events were generally mild (eg, pain/discomfort), and no SAE was reported.\textsuperscript{16} It is the largest prospective study on patient-reported adverse events from OMT as provided by clinicians in the PBRN. Adverse events from manual therapy performed by nonosteopathic clinicians have been documented primarily after procedures similar to high-velocity, low-amplitude OMT.\textsuperscript{17,18} Surprisingly, Degenhardt et al\textsuperscript{16} describe a very different adverse event profile from high-velocity, low-amplitude techniques and the various OMT procedures used. Overall, the incidence of adverse events from OMT as reported by Degenhardt et al\textsuperscript{16} is far less than has been estimated by previous publications using retrospective data. The value of PBRN research can readily be seen and appreciated. Further data are anticipated along these lines as this PBRN continues to analyze its large patient survey database. (doi:10.7556/jaoa.2018.031)

References


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