

## Medical Reversals: The Challenge of Replacing Outdated Medicine

Healthcare in the U.S. has achieved significant milestones over the past several decades, including advances in clinical research, diagnostic and therapeutic technologies, and medical treatment. However, while improvements in diagnostic and treatment modalities offer additional options to patients, they, likewise, have the potential to be more costly. Additionally, newer treatments typically go through rigorous safety testing and approval processes, resulting in additional time to review and evaluate them against existing treatment methodologies to determine their relative effectiveness. When a medical practice or test is determined to either: (1) be less effective than current treatment options or, (2) actually cause more harm than “*traditional*” or existing practices, it can fall from favor—a situation termed *medical reversal*.<sup>1</sup>

Studies regarding the incidence and prevalence of *medical reversals* have only really begun to gain traction in the medical literature over the past few decades. A recent study found that reversal is common; examination of 10 years of original research articles revealed that over 40% (146 of the reviewed articles) identified reversal of an established medical practice. These 146 reversals impacted several classes of medical practice, from medications to diagnostic and screening tests, as well as medical procedures and treatment technology.<sup>2</sup> Similarly, in 2011, a review of all of the articles published in the *New England Journal of Medicine* in 2009 found that 13% of the articles constituted a reversal of medical practice. The most common reason underlying the adoption of a reversed practice was confidence in the pathophysiological rationality of the concepts underlying the proposed practice or model.<sup>3</sup> Further, a 2013 project by the BMJ Group evaluated the effectiveness of certain medical treatments based on the results of randomized controlled trials, and found that approximately (1) 50% were of unknown effectiveness; (2) 11% were shown to be beneficial; (3) 3% likely to be ineffective or harmful; and (4) the remaining treatments fell somewhere in the middle of the effectiveness spectrum.<sup>4</sup>

The incidence rates of medical reversals appearing in published medical literature have the potential to have a negative impact on the U.S. healthcare system and the practice of medicine. Aside from the potential harm an unproven medical practice can have on patients—either

by worsening a medical condition or delaying more effective treatment—once it becomes prevalent in medical practice, it can be difficult to replace, resulting in the potential for a loss of trust by patients in their medical provider.<sup>5</sup> The U.S. medical system, currently navigating through an era of healthcare reform, constitutes an environment whereby quality improvement and evidence-based medicine is considered the “gold standard” for medical care. In this type of healthcare milieu, high rates of medical reversals documented in the literature have the potential to cast doubt over current device and treatment approval processes, as well as the validity of medical decision-making.

One perspective from which to address this issue is for every medical specialty to discourage the use of the top five commonly utilized (and expensive) tests or treatments that lack sufficient evidence to show “*meaningful benefit*” to the patient population that would typically receive them.<sup>6</sup> However, the *National Institute for Health and Clinical Excellence (NICE)*, charged with the responsibility of identifying opportunities for disinvestment in low value practices, notes that, although disinvestment in these medical practices may increase efficiency and quality of care, it likely won’t garner all of the cost savings needed to meet the reduced spending goals called for under healthcare reform.<sup>7</sup> In addition, the process of convincing the medical field to disengage with highly utilized practices has been proven to be difficult, e.g., one study that reviewed the literature citations for controversial medical treatments found that specialty journals tended to show a publication bias towards studies that had been contradicted by well-designed randomized trials when the reversed practice was beneficial to that specialty.<sup>8</sup>

Medical reversals can impact healthcare delivery in a variety of ways, and have begun to amass more interest in recent years, most notably with regard to improving healthcare efficiency and reducing unnecessary costs in an overburdened and expensive healthcare system. In 2010, the *Archives of Internal Medicine* initiated a series of articles entitled “*Less is More*,” for the purpose of drawing attention to circumstances when “*less*” medical care may actual have a better outcome.<sup>9</sup> As the U.S. healthcare delivery system continues to work

through the challenges of healthcare reform, the effective utilization of medical reversal data and evidence-based medical practice, in an effort to contain costs and improve efficiency, is likely going to continue to gain momentum over the next several years.

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<sup>1</sup> “Medical Reversal: Why we must Raise the Bar Before Adopting New Technologies”, by Vinay Prasad and Adam Cifu (2011), Yale Journal of Biology and Medicine, Vol. 84, p. 471-472

<sup>2</sup> “A Decade of Reversal: An Analysis of 146 Contradicted Medical Practices”, by Prasad et al. (August 2013), Mayo Clinical Proceedings, Article in Press, p. 3 -4

<sup>3</sup> “The Frequency of Medical Reversal”, by Prasad et al. (October 11, 2011), Archives of Internal Medicine, Vol. 171, No. 18, p. 1676

<sup>4</sup> “What Conclusions has *Clinical Evidence* Drawn About What Works, What Doesn’t Based on Randomised Controlled Trial Evidence?”, BMJ Publishing Group, 2013,

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<http://clinicalevidence.bmj.com/x/set/static/cms/efficacy-categorisations.html> (Accessed August 11, 2013)

<sup>5</sup> *Ibid*, Prasad and Cifu, 2011, p. 473-474; “Reversals of Established Medical Practices: Evidence to Abandon Ship”, by Prasad et al. (January 4, 2012), Journal of the American Medical Association, Vol. 307, No. 1, p. 38

<sup>6</sup> “Medicine’s Ethical Responsibility for Health Care Reform – The Top Five List”, by Howard Brody (2010), The New England Journal of Medicine, Vol. 362, No. 4, p. 284

<sup>7</sup> “Disinvestment From Low Value Clinical Interventions: NICEly Done?” by the National Institute for Health and Clinical Excellence, 2011, BMJ, Vol. 343, p. 1, 3

<sup>8</sup> “Persistence of Contradicted Claims in the Literature”, by Tatsioni, et al. (December 5, 2007), Journal of the American Medical Association, Vol. 298, No. 21, p. 2525

<sup>9</sup> “Less is More: How Less Health Care Can Result in Better Health”, by Deborah Grady and Rita F. Redberg (May 10, 2010), Archives of Internal Medicine, Vol. 170, No. 9, p. 749-750



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