

# Reporting on Adverse Events: Triumph of Marketing Over Science?

Recent studies suggest that the reporting of adverse events and complications in randomized controlled trials (RCTs) of new treatments and technologies—and even old ones—is often scandalously incomplete.

In an editorial in *Archives of Internal Medicine*, John P.A. Ioannidis, MD, suggests that this may be a product of marketing and conflicts-of-interest. In the quest to bring products to market, the developers of new technologies and treatments often concentrate on the reporting of efficacy and effectiveness in RCTs—and leave information about harms and adverse events for future studies. This effectively buries information about potential harm—to the detriment of patients seeking medical treatment.

Ioannidis points out that balancing harm against efficacy is vital in assessing any treatment. His observations apply across medicine but are particularly relevant to spine care. (See Ioannidis, 2009.)

“Most newly introduced treatments usually have small, incremental benefits, if any, against already available interventions, and differences in the profile of harms should play a key role in treatment choices,” he suggests.

He offers six potential reasons why reporting on adverse events is often incomplete.

- The study ignored adverse events.
- The study neglected the collection of information about adverse events.
- The study failed to report on adverse events—even if it did study them.
- The study restricted reporting on adverse events.
- The study distorted reporting of adverse events.
- The study silenced evidence on harms (he cites the cases of Vioxx and Neurontin).

The reporting of adverse events in spine care is particularly challenging. Since spine surgery procedures vary substantially from individual to individual, some adverse events are difficult to categorize and systematize. Only recently have scientists

offered standardized protocols for reporting adverse events. And, of course, there is no systematic surveillance of adverse events related to new treatments and technologies in the current regulatory system.

And there are few incentives for reporting on adverse events. In a litigious medicolegal system, the reporting of adverse events is sometimes punished and stigmatized rather than encouraged and rewarded.

Ironically, most spine care providers and researchers want to see accurate and comprehensive data on adverse events.

In a 2006 article proposing standardized measurement of adverse events in spine surgery, Sohail Mirza, MD, and colleagues pointed out that surgeons “focus intensely” on the avoidance of adverse events in regular morbidity and mortality conferences. Yet this has not translated into a similar focus in published trials, according to Mirza et al. They noted that “discussions of adverse occurrences in the surgical literature are often dismissive or defensive, leaving lessons buried...” (See Mirza et al., 2006.)

Ioannidis offers a novel suggestion. Perhaps it is time to switch gears in randomized trials. Since advances in efficacy are increasingly marginal, perhaps the focus should shift to the comprehensive reporting of information about complications, adverse events, and harms. These could be elevated to primary outcome measures, with outcomes on efficacy and effectiveness taking a secondary role.

## References:

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