

Robotic Surgical Incident Reporting Leads To More Questions Than Answers

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This column appears in the upcoming January/February print issue of Surgical Products.

Some questions simply lead to more questions. No questions lead to definitive answers without data and evidence leading the way.

That thought came into my mind when I read a recent [San Francisco Chronicle article](#) [1] about adverse-event reporting in healthcare, specifically as it relates to Intuitive Surgical's da Vinci robotic surgery system. The piece took aim at a U.S. database that serves to list reports of injuries and deaths submitted to the Food and Drug Administration (FDA). It characterized the database's records as "sometimes vague, incomplete, and unverified by the agency." There is no disputing the fact that incidents are not being reported, details are missing, and the database lacks information about incidents reported and referenced elsewhere. Oh, and it also mentioned how the FDA has no authority to force doctors to report adverse events.

The word "disaster" was uttered by one healthcare professional quoted in the article, while a chief scientist at the FDA readily admitted the agency is "well aware of under-reporting of adverse events."

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Published on Surgical Products (<http://www.surgicalproductsmag.com>)

This makes me wonder... To what level of certainty can someone speak to the safety of products on the market today?

Without clear and accurate data, there is simply no definitive answer to that question.

That's an unsettling fact for healthcare professionals, who are taught to gather as much (good) information as possible before offering a diagnosis, prescribing treatment, or making any other decision. While information about products can be gleaned from other sources (including clinical research results), poor reporting adverse-event reporting skews the data and paints an inaccurate picture of the safety and effectiveness of various products.

Again, this article took aim at the reporting (or lack thereof) of injuries and incidents involving Intuitive Surgical's da Vinci robotic surgery system. It referenced a recent Bloomberg review of unreported robotic surgery incidents as evidence of a lack of complete and accurate data regarding the safety of the system.

I'm more concerned about the inadequacy of the reporting process than I am about what information isn't being reported. After all, how can something be properly evaluated without a proper process in place to do so?

And while it's uncertain whether there's more to the story about how safe the da Vinci system is, it is evident some of the means in place to arrive at that conclusion are incredibly flawed.

What's your take? E-mail me at mike.schmidt@advantagemedia.com [2] or respond on Twitter @MikeSchmidt_SP.

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