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Letter to the Editor regarding Somerson et al: "Analysis of 4063 complications of shoulder arthroplasty reported to the US Food and Drug Administration from 2012 to 2016"

To the Editor:

We read with interest the article by Somerson et al, "Analysis of 4063 complications of shoulder arthroplasty reported to the US Food and Drug Administration from 2012 to 2016."[7] The authors are to be applauded for their efforts to identify complications of shoulder arthroplasty in the real world environment. This study was described as the first analysis of shoulder arthroplasty failure using the then current FDA Manufacturer and User Facility Device Experience (MAUDE) database. The authors compared their study of 4063 shoulder arthroplasty complications (1673 anatomic and 2390 reverse) reported to the FDA for the years from 2012 to 2016 with those in a recent review by Bohsali et al[2] analyzing 1009 shoulder arthroplasty complications (345 anatomic and 664 reverse) identified in articles published in the 10 years from 2006 to 2015. The authors concluded that "the FDA database reveals modes of shoulder arthroplasty failure that are not emphasized in the published literature."[7] The limitations of the use of this database described in the article were modest, involving only lack of standardization of data entry, possibly overweighting patients who experienced multiple failure modes, and an inability to ascribe the exact etiology of the failure mode (ie, surgeon error vs. device failure). In fact, the FDA MAUDE database has a number of limitations that significantly limit the ability of researchers (and regulators) in using this database to evaluate device complications.

Foremost, the MAUDE database provides no denominator for calculating complication rates. Although Somerson et al are careful to present their statistics as type of complication/overall number of complications, a far more useful number is the number of complications/number of devices implanted. Absent any ability to calculate the true complication rate makes use of this database challenging, to say the least. Device manufacturers often try to create this number by using complications reported/devices sold, but even this number is often inaccurate, as not all distributed devices are actually implanted. Registry data, in contrast, offer reasonably accurate true complication rates, with a true denominator of devices implanted, and better provide the real-world experience sought for by the authors. Even systematic reviews such as Bohsali et al[2] provide this key denominator number to allow the reader to clearly understand the data presented. Although this limitation was not recognized in this article, the lack of a denominator was reported in a similar article regarding the use of MAUDE in the evaluation of elbow arthroplasty.[8]

More worrisome is the quality of the data input into the MAUDE database. It is important to understand that physicians are not required to report complications to this database, and rarely do so. This may be due to liability concern in reported to a database that is not completely immune to subsequent disclosure to a potentially litiginous patient and their attorneys, despite the protections offered by Congress in 21 C.F.R. § 20.63(f).[5] Manufacturers and hospitals are required by law to report complications to the MAUDE database. This reporting however is inconsistent and frequently ends with phrases such as "a full report regarding this complication will follow." Follow-up is virtually nonexistent. This reporting is rarely done stringently or by medical officers associated with the device manufacturers, potentially creating serious flaws in the quality of the data entry. Incomplete reporting by hospitals and manufacturers due to liability concerns has similarly been reported. Buntz noted that of over 17,000 device complaints reported to Bayer regarding the Essure device, only 5093 were reported to the MAUDE database as of June 2015.[3] This failure to report over two-thirds of manufacturer reported complications for the Essure device might well be expected to be pervasive over the database.

Finally, the bulk of MAUDE entries are made not by either manufacturers or physicians, but by patients themselves. While not minimizing the right of patients to report complications with their care, the ability of patients to

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accurately report and categorize their surgical complications would have to be recognized as fairly modest. The use of any ''big data'' in the end is limited by the quality of the data entry, a critical flaw in the use of all these types of data sources. [6] Patient entered data might well be expected to be of poorer quality than even clerical data entry performed for large databases.

In summary, the MAUDE database has serious flaws that significantly exceed the authors' modest discussion of its limitations. Using this database to reflect complications in current US surgical practice may easily create erroneous conclusions. The flaws and inconsistencies in the use of the MAUDE database were well summarized in the LA Times article by Buntz[3] where the MAUDE database was described as ''so antiquated that it can take years for the Agency to detect serious problems.'' Other industry evaluations of the MAUDE database have come to similar conclusions, noting that in regard to researchers ''the MAUDE database is not ideal for these users.''[1] A disclaimer on the MAUDE database site itself states that the data may be ''incomplete, inaccurate, untimely, unverified, or biased.''[4] Understanding these limitations is critical in any use of this database and limits the ability of and other articles in using this database[8] to make conclusions about device-related complications in the United States.

Disclaimer

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