# Analysis of the Food and Drug Administration MAUDE Database for Approved Devices in Obstetrics and Gynecology

**Joseph M. Maurice, M.D., M.S., FACOG, and Sheena Galhotra, M.D.**

*OBJECTIVE: To evaluate the accuracy of the Manufacturer and User Facility Device Experience (MAUDE) database for devices approved via premarket (PMA) and 510(k) approval processes, and to compare the accuracy of death and injury reports.*

*STUDY DESIGN: A retrospective observational study.*

*RESULTS: Death and injury reports were collected from November 1, 2002, to April 25, 2018, from the MAUDE database. This collection of raw data was subsequently adjusted to improve accuracy. There was an 87% drop in number of adjusted death reports as compared to raw death reports ($p=0.004$). There was a 98% drop in the number of adjusted injury reports as compared to raw injury reports ($p=0.002$).*

*CONCLUSION: Death reports in the MAUDE database are more accurate than injury reports, whether approved by the PMA or 510(k) process, and more likely to contain an actual death, as compared to an actual injury report. Raw death reports overestimated deaths 7.9 times as compared to adjusted death reports; injury reports overestimated total injuries by 71.9 times as compared to adjusted injury reports. This warrants a call for a more accurate national device registry with concurrent robust statistical analysis so trends of potentially harmful devices can be identified.* (J Reprod Med 2020;65:3–7)

***Clinicians have an incomplete awareness of the postmarket surveillance process and an even lesser interpretation of its significance.***

**Keywords:** equipment and supplies, FDA, MAUDE Database, medical device, public health, public health service, registries, USFDA, USPHS, United States Food and Drug Administration, United States Public Health Service.

The U.S. Food and Drug Administration (FDA) is the federal agency within the U.S. Department of Health and Human Services (HHS) responsible for protecting the public health. Their authority incorporates medical device oversight. Specifically, the FDA Center for Devices and Radiological Health (CDRH) is primarily responsible for medical device review and approval for human use.[1] In addition to medical device approval, the CDRH incorporates a number of processes where problems with a device may be detected after introduction to the general population. These include registries,

From the Division of Minimally Invasive Gynecologic Surgery, Department of Obstetrics and Gynecology, Rush University Medical Center, Chicago, Illinois.

This study is IRB exempt, date 7/7/2017, ID 17061502.

Address correspondence to: Joseph Maurice, M.D., M.S., FACOG, Department of Obstetrics and Gynecology, Rush University Medical Center, 1653 W. Congress Parkway, 218 Kellogg, Chicago, IL 60612 (joseph_m_maurice@rush.edu).

*Financial Disclosure*: The authors have no connection to any companies or products mentioned in this article.

0024-7758/20/6501-02–0003/$18.00/0 

facility inspection, analysis of health care databases, and spontaneous reporting systems.[2] In 2009 the Manufacturer and User Facility Device Experience (MAUDE) database was created.[3] Medical device reporting found on the MAUDE website is one way in which medical devices are monitored after FDA approval.[3]

The approval process for medical devices used in Obstetrics and Gynecology has been described previously.[4] Devices are approved primarily via two pathways: *premarket approval* (PMA) and *premarket notification*, more commonly referred to as *510(k)*.[5-7] Compared to the PMA process, the 510(k) process is generally less stringent, less expensive, and faster.[8] After a device has been approved for human use in the general population, a process for continuing review, known as postmarket surveillance, is employed to assess patient safety. The MAUDE database collects reports during postmarket surveillance from various sources regarding patients affected by medical devices.

The MAUDE database collects medical device reporting for three types of suspected adverse events: deaths, injuries, and malfunctions.[1-3] The MAUDE database contains mandatory medical device reporting submitted to the FDA by manufacturers, importers, and device user facilities, as well as voluntary reports from health care professionals, legal professionals, patients, and consumers.[1-3] The database is updated monthly.[8] Clinicians have an incomplete awareness of the postmarket surveillance process and an even lesser interpretation of its significance. It is important for all clinicians to understand the benefits and limitations of this postmarket surveillance process and the MAUDE database. The primary objective of this paper is to highlight the process of postmarket surveillance and to educate clinicians about the MAUDE database's utility, limitations, and drawbacks.

### *Materials and Methods*

This retrospective observational study was exempted by the Institutional Review Board at Rush University Medical Center, Chicago, Illinois. We identified devices used in Obstetrics and Gynecology from November 1, 2002, to April 25, 2018, from the FDA Product Classification Database.[1] This database contains medical product and device names with associated descriptive information.[1] A unique, three-letter product code is assigned to each device. Each product code encompasses a group of similar medical devices and is assigned to a review panel. For instance, product code HET contains laparoscopic equipment and accessories; all products in this code are approved by the Obstetrics and Gynecology review panel. Using the advanced search feature on the MAUDE database website, we reviewed 243 product codes from the Obstetrics and Gynecology review panel. Devices that were 510(k) exempt, categorized under the Humanitarian Device Exemption, or approved for emergency use authorization were excluded from review. After removing the exempted devices, 154 product codes in the Obstetrics and Gynecology review panel were identified. This encompassed a total of 3,656 devices. These devices were then classified into their respective approval processes: PMA or 510(k). We also identified devices used in the field of Obstetrics and Gynecology yet approved by the General Surgery or Urology review panels. For instance, product code LMF reviewed by the General Surgery review panel and product code GBM reviewed by the Urology review panel were included in our database. LMF denotes absorbable collagen hemostatic agents with thrombin, and GMB denotes urethral catheters. Both of these products are used ubiquitously in Obstetrics and Gynecology. The reports of deaths and injuries of these devices were downloaded from the MAUDE website and imported into Microsoft Office Excel (Microsoft Corporation, Redmond, Washington).

The downloaded death and injury reports were considered raw data. Due to suspicion of a high level of inaccuracy of the reports, the MAUDE data were individually screened. Each report was reviewed for accuracy, relevancy, and duplication. For example, if an entry was listed as a "death" and, upon review, no death was identified, that entry was not included in the adjusted number. Additionally, when there were multiple reports of the same event, the duplicate reports were excluded in the adjusted number. Finally, reports with inadequate data were also excluded. After the initial screening, the majority of the product codes had fewer than 100 reports of death or injury. For the small number of product codes with greater than 100 reports, only the most recent 100 were reviewed and, when appropriate, were included in the adjusted data.

Statistical analysis was performed using the Statistical Package for the Social Sciences Software

(IBM SPSS Statistics for Windows, Version 24.0; IBM Corp., Armonk, New York, USA). Categorical variables were expressed as number (percentage). Chi-squared analysis was used to calculate statistical significance, and a p value of less than 0.05 was considered statistically significant.

### *Results*

A total of 209 product codes were considered pertinent to the field of Obstetrics and Gynecology. This encompassed 12,019 devices: 589 approved by PMA and 11,430 approved by 510(k) (Figure 1). Table I shows the breakdown between the raw and adjusted number of death reports for the PMA and 510(k) device approval processes. Table II shows adjusted number of injury reports for the PMA and 510(k) device approval processes.

In our scope of inquiry, there were some product codes that had an excessively large number of reports (>500). With the guidance of our statistician, we generated distribution graphs for both death and injury data and determined that the majority of product codes can be described by limiting the review to the first 100 accurate entries. In the death reports, this revealed that 72.4% of product codes had no reported deaths, and the majority of product codes (89.5%) had 5 or fewer deaths. Cumulatively, 97.6% of death reports are described by using 100 as the cutoff. The trend for MAUDE injury reports revealed that 47% of the product codes had no reported injuries, and the majority of the product codes (65.2%) had 5 or fewer injuries. Cumulatively, 83.3% of injury reports are described by using 100 as the cutoff. Analysis without this adjustment produced significantly skewed data and disproportionally represented a small number of product codes over the majority of others.

**Table I** *Raw and Adjusted Death Reports from MAUDE Database According to Approval Process*

| | Raw deaths | Adjusted deaths | Total |
|---|---|---|---|
| PMA, n (%) | 350 (20.2) | 26 (11.9) | 376 |
| 510(k), n (%) | 1,382 (79.8) | 192 (88.0) | 1,574 |
| Totals* | 1,732 | 218 | 1,950 |

*p=0.004.

Table I depicts the raw and adjusted death reports from the MAUDE database according to approval process. There were 1,732 raw death reports, of which 350 were attributed to PMA approval process and 1,382 were attributed to 510(k) approval process. The adjusted death reports generated a total of 218 death reports, of which 26

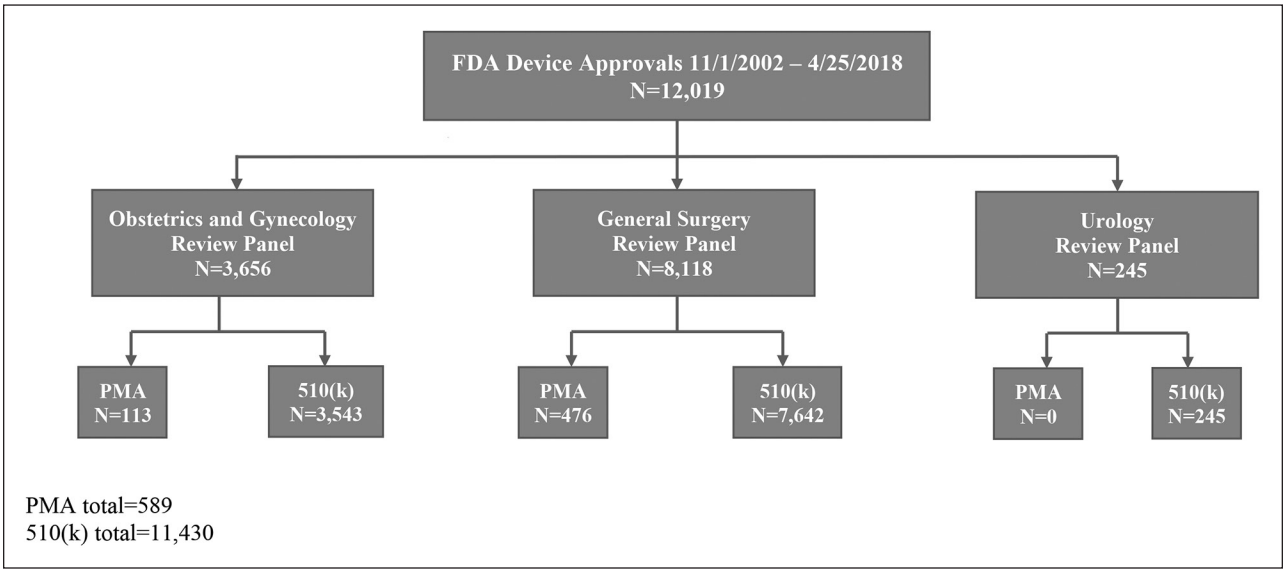


**Figure 1** Identified product codes from the FDA product classification database were searched from November 1, 2002, to April 25, 2018, to identify devices used in Obstetrics and Gynecology. Product codes reviewed by the General Surgery and Urology review panels for devices utilized in Obstetrics and Gynecology were included.

**Table II** *Raw and Adjusted Injury Reports from MAUDE Database According to Approval Process*

| | Raw injuries | Adjusted injuries | Total |
|---|---|---|---|
| PMA, n (%) | 36,033 (22.3) | 440 (19.5) | 36,473 |
| 510(k), n (%) | 125,343 (77.7) | 1,814 (80.5) | 127,157 |
| Totals* | 161,376 | 2,254 | 163,630 |

*p=0.002.

were attributed to the PMA approval process and 192 were attributed to the 510(k) approval process (Table I). Table II depicts the raw and adjusted injury reports from the MAUDE database according to approval process. There were 161,376 raw injury reports, of which 36,033 were approved via PMA process and 125,343 were attributed to the 510(k) process. The adjusted injury reports generated a total of 2,254 reports, of which 440 were approved via the PMA approval process and 1,814 were approved via the 510(k) process (Table II). There was an 87% drop in number of adjusted death reports as compared to raw death reports (p=0.004). There was a 98% drop in the number of adjusted injury reports as compared to raw injury reports (p=0.002).

Analyzing each approval process, the percentage of deaths attributed to PMA-approved devices decreased from 20.2 to 11.9%, and the proportion of deaths attributable to 510(k)-approved devices increased from 79.8 to 88.0% (p=0.004) (Table I). The number of injury reports, both in the raw and adjusted data, far exceeded the number of death reports. The percentage of injuries attributed to PMA-approved devices decreased from 22.3 to 19.5%, and the proportion of injuries attributed to 510(k)-approved devices increased from 77.7 to 80.5% (p=0.002) (Table II). The dichotomy of reports was interesting. There were 7.9 times more deaths in the raw data than in the adjusted data, and 71.6 times more injuries in the raw data as compared to adjusted data.

### *Discussion*

There was a statistically significant decrease in the number of raw death reports as compared to the adjusted death reports (p=0.004). There was also a statistically significant decrease in the number of raw injury reports as compared to adjusted injury reports (p=0.002). There were 7.9 times more deaths in the raw reports as compared to the adjusted reports, and 71.6 times more injury reports in the raw data when compared to the adjusted data. Regarding the two device approval processes, deaths were overestimated by the more rigorous PMA approval process and underestimated by the less stringent 510(k) process, although not statistically significantly. Raw injury reports were similarly overestimated by both the PMA and 510(k) processes, although less egregiously. As a result, raw death reports in the PMA category appear more potentially dangerous as compared to the raw death reports in the 510(k) process. Raw injury reports are less distorted than raw death reports and, as a result, conceal the potential danger of the 510(k) approval process. Generally speaking, death reports in the MAUDE database are more accurate than are injury reports, whether approved by the PMA or 510(k) process. This inaccuracy has the potential of incorrectly labeling a PMA-approved device as harmful.

The FDA implemented the MAUDE database in 1990 as a part of the Safe Medical Devices Act.[9] The database contains "incomplete, inaccurate, untimely, unverified, or biased data."[9] It is also well known that the incidence and prevalence of an event cannot be determined, and, as a result, interpretation is limited.[1,10] Additionally, data are kept only from the past 10 years, thus meaningful evaluation of a device over a longer time frame is limited. Finally, there is a disproportionate gap between the introduction of a device into the general population and its postmarket surveillance, potentially delaying reports of deleterious devices.[7]

Confounding variables with the MAUDE database include reports populated from various sources, including, but not limited to, physicians, health care workers, administrators, attorneys, and patients themselves. These sources do not have a uniform reporting process. The burden of reporting by manufacturers appears rigorous and compulsory, but a closer look reveals that it is riddled with flaws. Manufacturers are not required to report deaths or serious events if they themselves decide that the use of the device and event are unrelated.[7,11] When manufacturers do report an issue to the MAUDE database, generally speaking, there is minimal investigation and analysis between the event and outcome, and, if any postapproval study performed, it is generally of poor quality.[7,11]

When comparing the FDA approval process of

new drugs to new devices, the dichotomy is stunning. In 1937, as a result of the deaths from the use of the medication sulfanilamide–ethylene glycol, the regulatory approval process for drugs underwent substantive change.[10,12] For devices, it was not until 1976, with the mortality and morbidity associated with use of the Dalkon Shield intrauterine device, that regulations were enacted.[10,12] Yet, even with the changes in the device approval process, significant gaps remain. A review of high-risk cardiovascular devices revealed that less than 33% were evaluated in randomized clinical trials.[13] Even with Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act in 1976, and the Safe Medical Devices Act in 1990, the FDA does not review many devices, including high-risk devices.[6] As a result, manufactures are left to themselves to prove that devices are safe.[5] Unlike drugs, device approval does not require human trials before use.[7,13] The FDA should evaluate devices with the same vigorous analysis as they do for drug approvals.[6,10,14]

This is the first paper to analyze the entire MAUDE database for devices used in Obstetrics and Gynecology and provide meaningful framework for data analysis and discussion. Our recommendations are limited in scope but provide a framework for further study and a call to action for a better reporting system. The authors agree that a national device registry with concurrent robust statistical analysis be created so physicians can search the FDA and identify potentially harmful devices and discuss these concerns with their patients.[3] The National Evaluation System for health Technology (NEST) reflects the FDA's commitment to meaningful change within the postmarket surveillance system and adopts regulatory practices and reporting systems similar to those used in the aviation and nuclear power industries.[15,16]

### *Acknowledgment*

We acknowledge Louis Fogg, Ph.D., for his assistance in analyzing the data.

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