

Understanding FDA's Manufacturer & User Facility Device Experience (MAUDE) Database

Purpose of MAUDE Database

The Manufacturer and User Facility Device Experience (MAUDE) database represents a reporting system maintained by the U.S. Food and Drug Administration (FDA) for post market surveillance. MAUDE, which is used to view individual device adverse event reports that physicians or manufacturers have submitted to the FDA, is searchable online. It includes events reported to FDA in which medical devices may have malfunctioned or caused serious injury or death.

FDA Reporting Requirements

When a medical device complaint is reported to the manufacturer, it is the manufacturer's responsibility to determine if the complaint meets FDA regulations for a Medical Device Report (MDR) submission, as described by FDA medical device reporting regulation 21 CFR § 803. If the manufacturer determines that the complaint is a reportable adverse event, it is required to submit an MDR to the FDA for review and subsequent posting to the MAUDE database. When looking at orthopaedic devices specifically, in certain cases it may be determined that the reason for the device adverse event is multifactorial. A high percentage of adverse event reports may not be attributable to the devices themselves, but rather to complications, such as infection. Furthermore, if multiple components were potentially involved in the singular device adverse event, FDA requires that a separate MDR be submitted for each component that may have cause or contributed to death or serious injury. (i.e. femoral component, tibial tray, polyethylene insert, patella insert, and bone cement were revised during a single revision case for infection, thus five separate MDRs can potentially be submitted to FDA.)

Cautions when Evaluating MAUDE Data

1. FDA Statement on Utilization of MAUDE Data

Because the MAUDE database does not include any specific sales volume data for any device or component, Medical Device Reports are not scientifically valid or reliable for calculation of adverse event rates or comparison of adverse events between products. While it may be useful in identifying potential signals about product issues that may need to be further investigated

by manufacturers, it is not reliable in determining the risks of individual devices. In certain cases, manufacturers have utilized the MAUDE database to compare adverse event rates across both devices and manufacturers. This practice is specifically discouraged by the FDA. In fact, the following statement is posted directly on the FDA website:

"MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices."¹

2. Differences in Manufacturer Reporting Procedures

While physicians may report events to FDA, manufacturer reporting is required and most events within the MAUDE database are reported by manufacturers. Reporting protocols can vary from manufacturer to manufacturer. Variability in reporting practices can affect the number of adverse event reports found within the MAUDE database for different manufacturers.

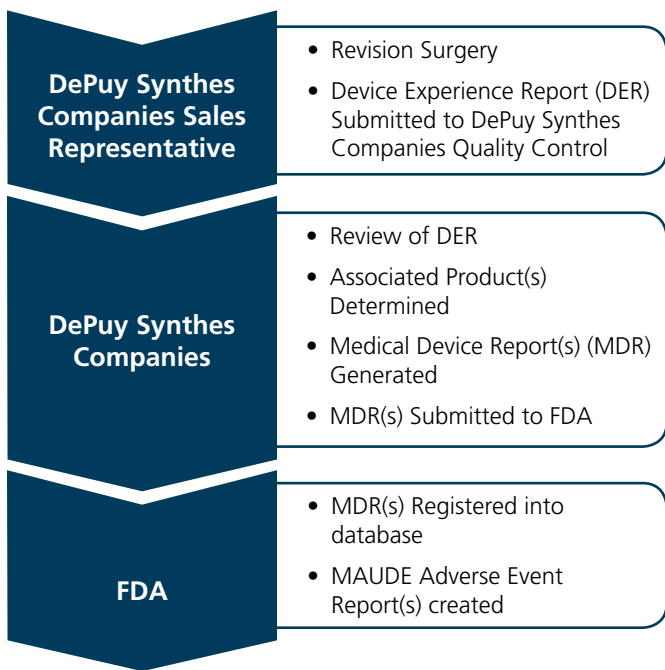
DePuy Synthes Companies Reporting Procedure

As illustrated in Chart 1, the evolution of a MAUDE Adverse Event Report is a multi-step process.

DePuy Synthes Companies Case Report - Revision Due to Infection (Revision Surgery Occurred on 01/08/17)

- Revision surgery completed
- Device Experience Report (DER) submitted to DePuy Synthes Companies Customer Quality (Complaint Handling Department) noting infection, for example, as the reason for revision
- Review of Device Experience Report completed by DePuy Synthes Companies
- Components (femoral, tibial tray, polyethylene insert, patella insert, bone cement) involved in the adverse event are determined and complaint entered into DePuy Synthes Companies Complaints database

Chart 1



- For reportable incidents, DePuy Synthes Companies submits MDRs to cover each component. In this case, DePuy Synthes Companies submitted 5 MDRs. (Separate MDR submitted for each associated component)
- In turn, FDA registers five Medical Device Reports within the MAUDE database
- Subsequently, five MAUDE Adverse Event Reports* were generated and posted on the FDA website for a singular event of infection (Figure 1 - Screen shot of FDA MAUDE website)

As illustrated within this case report, the number of *Adverse Event Reports* found within the MAUDE database can be higher than the actual number of adverse events reported to the manufacturer. The discrepancy between the number of MAUDE *Adverse Event Reports* posted versus the number of adverse events reported to the manufacturer can lead to potential misinterpretation of MAUDE data.

* Report numbers 1818910-2017-10735, 1818910-2017-10737, 1818910-2017-10739, 1818910-2017-1042, 1818910-2017-1044

Five separate Adverse Event Reports generated from one revision case for infection



Figure 1

Conclusion

The MAUDE database provides a convenient, centralized location for reporting adverse events with medical devices. It is important however, to thoroughly understand FDA's statement on the utilization of this data, along with the multitude of factors that can potentially contribute to the varying number of *Adverse Event Reports* found amongst different devices and manufacturers.

References:

1. FDA U.S. Food and Drug Administration. Retrieved from: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

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