The FDA MAUDE Database
Who reports & what biases does this create?

Lindsay Calderon, PhD, MPH
Eastern Kentucky University

FDA MAUDE Database

- **MAUDE: Manufacturer and User Facility Device Experience**
- **Intended to safeguard patient safety.** This database is the main instrument used by the FDA in post-market surveillance of medical devices.

FDA MAUDE Database

There are many types of devices:

- **Some are only used externally,**
- **Some are implanted into the patient and**
- **Some have moving and electrical parts.**

FDA MAUDE Database

Device classification depends on the intended use of the device and also upon indications for use:

- **Class I:** For some devices, the exempt of a [510(k)] and marketing clearance from FDA is not required.
- **Class II:** Certain Class II devices are also exempt from 510(k) and premarket approval.
- **Class III:** Requires undergoing a premarket approval (PMA).

FDA MAUDE Database

- The devices which have a significant potential for adverse patient safety events are those which are implanted and have movable and/or electrical parts.

Who is Reporting ??

Study by Kavanagh KT, Brown RE, Kraman SS, Calderon LE & Kavanagh SP, published in Patient Related Outcome Measures in 2019 attempted to answer this question.

- The reporter's occupation and source of the MAUDE medical device report were determined for acquisition dates Jan 1, 1997 to Dec 31, 2018.
- A total of 7,766,737 adverse event records were analyzed.

USA Health Watch

Who is Reporting ??

Major Findings:

- 96.6% (N = 7,504,512) of reports originated with the manufacturer. Manufacturer reports may be spurred by warranty claims and lawsuits which contain little useful clinical information.

Who is Reporting ??

Major Findings:

- 96.6% (N = 7,504,512) of reports originated with the manufacturer. Manufacturer reports may be spurred by warranty claims and lawsuits which contain little useful clinical information.
- Patients (patients/family/friend) were the next most frequent submitter of reports directly to the FDA (N = 33,276), almost five times as often as physicians.

Who is Reporting ??

Major Findings:

- 96.6% (N = 7,504,512) of reports originated with the manufacturer. Manufacturer reports may be spurred by warranty claims and lawsuits which contain little useful clinical information.
- Patients (patients/family/friend) were the next most frequent submitter of reports directly to the FDA (N = 33,276), almost five times as often as physicians.
  - Nurses submitted reports (N = 18,850) directly to the FDA 2.77 times as often as physicians.

USA Health Watch

Who is Reporting ??

Major Findings:

- 96.6% (N = 7,504,512) of reports originated with the manufacturer. Manufacturer reports may be spurred by warranty claims and lawsuits which contain little useful clinical information.
- Patients (patients/family/friend) were the next most frequent submitter of reports directly to the FDA (N = 33,276), almost five times as often as physicians.
  - Nurses submitted reports (N = 18,850) directly to the FDA 2.77 times as often as physicians.
  - Attorneys were listed as the occupation in 2.04% of reports (N = 156,490) submitted 0.8% directly to the FDA.

USA Health Watch

Who is Reporting ??

- Only 0.49% of physician reports were submitted directly to the FDA (N = 6,794), representing 0.09% of total MAUDE reports.

USA Health Watch

MAUDE Data Integrity

MAUDE data is largely unstructured.

- Manufacturer names are not standardized.
  For example: Johnson & Johnson is entered as:
  -- Johnson & Johnson
  -- Johnson&Johnson
  -- Johnson and Johnson
  -- J&J
  -- J & J
- Free field entry for patient history and symptoms usually lacks specifics and quantitative data or laboratory results.
- Duplicate records are very common.

USA Health Watch

Why is this important?

- Clinical data is entered in an unstructured field and often has little specific or clinically important data. Laboratory test results and other quantitative measures are usually absent.

- For example, in another study, “less than 4% of 14,714 records (was found), reported the data/lab reports of cobalt elevation or toxicity to support the claim.” -- Kavanagh, et al. Journal of Patient Safety, 2018.

USA Health Watch

Mandatory Reporting ?

- Manufacturers and facilities must report all adverse events which cause severe harm to the FDA.
- However, the definition of “Severe Harm” is not defined and up to the manufacturer or facility.
- Health care professionals are NOT required to report harm or fatalites to the FDA. Although, there is an easy way to do so thought the FDA’s Medwatch webpage.

https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Mandatory Facility Reporting

- Facilities made only 1.3% (N = 110,863) of the reports in the MAUDE database. This questions the compliance and effectiveness of the regulatory reporting requirement

USA Health Watch

Should Provider Reporting Be Mandatory ?

- There are a number of logistical problems.
- Many implantable devices have problems which present years later.
- For a report to be useful, the type of medical device must be known. However, with the exception of the surgeon, the treating physician & primary care doctor may not know what type of device was implanted.

USA Health Watch

Mandatory Reporting ?

- A Unique Device Identifier needs to be present on the device (if possible) and readily accessible in the medical record. Otherwise, the MAUDE record will not be able to relate to a device or a product code. This is a huge problem in post market surveillance.

USA
Health Watch

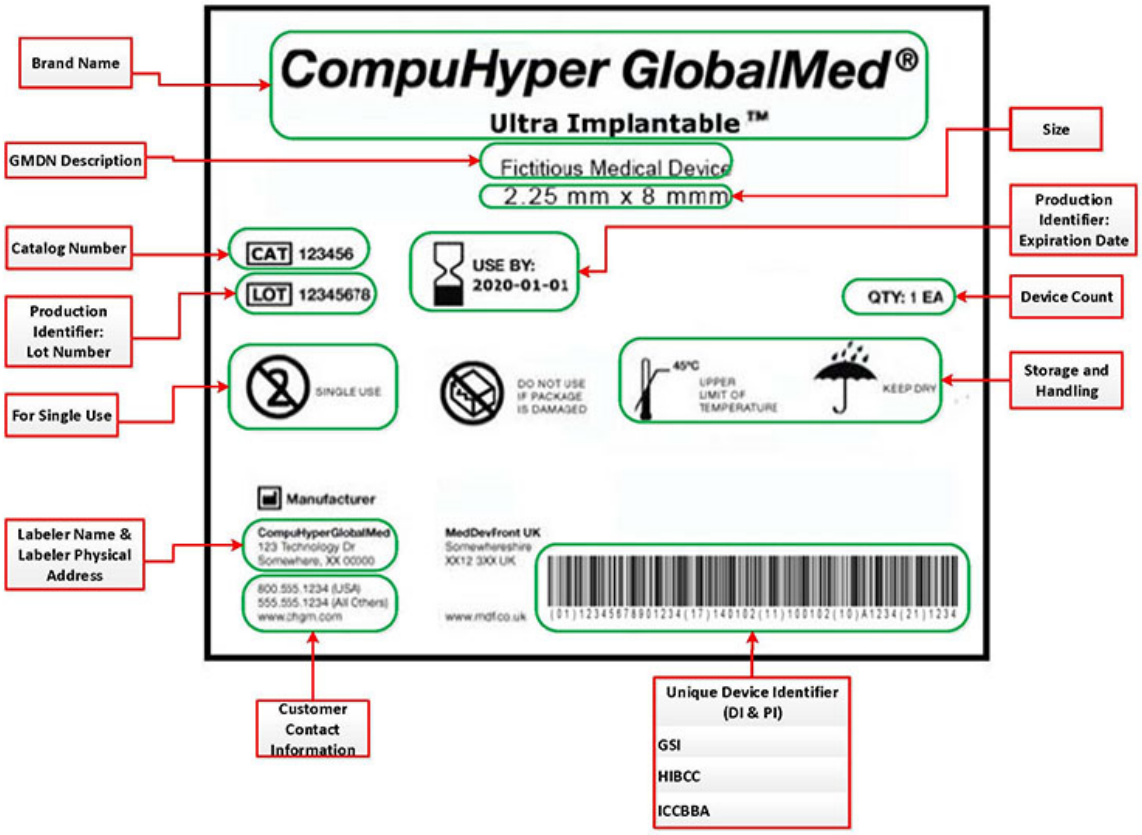
Unique Device Identifier - UDI

Labels required on Device & Packaging

- Class I UDI Labels not enforced
- Class II & III devices: A device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. In addition, single use implantable devices are not included in this exemption.

USA Health Watch

Unique Device Identifier - UDI



https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-basics

Unique Device Identifier - UDI

Implantable Devices

- However, the requirements appear to exclude placing the UDI on many implantable devices because of the following exceptions:
  (1) Any type of direct marking would interfere with the safety or effectiveness of the device.
  (2) The device cannot be directly marked because it is not technologically feasible.

- UDI labels are required on implantable device packaging.

Unique Device Identifier - UDI

- Implantable devices are a problem since they are used for years and an UDI is not placed on many devices.
- Thus, even when the device is removed the serial number, model and make may still be in doubt.

Informing Patients - UDI

- Any household device, even a toaster, the consumer is given written information on the operation and risks of the device upon purchase.
- The same needs to be true with medical devices.
- The patient should be given written material on the make and model number of the implanted device, including potential problems and who to report them to.

Informing Patients - UDI

- There needs to be easy access to the UDI in the patient's medical record. This will allow both the primary care provider and patient to accurately identify the type of device which has been implanted and may be associated with the patient's adverse events.
- However, medical records may not be easily accessed by a provider who is not in the same healthcare system and the location of the UDI data within the EMR (electronic medical record) may be difficult to access.

Conclusion

- The FDA needs objective, unbiased, complete data relating to any adverse device-related incident.
- Physicians & healthcare providers bring a unique perspective and can provide vital information which is critical to post-market surveillance of approved devices.
- Unfortunately, reports from healthcare providers, especially physicians, rarely submit a report directly to the FDA.

USA Health Watch

Conclusion

- The current reporting process is unstructured and time-consuming.
- Building reporting functions into electronic medical records, including ready access to a device's Unique Device Identification (UDI) code, could encourage reporting and improve the quality of MAUDE adverse event reports.
- In addition, educational institutions and professional associations should educate students and physicians on the importance of submitting reports to the FDA and how to access and input data into MedWatch.

Questions