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Introduction to the MAUDE Database

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Abstract: The Manufacturer and User Facility Device Experience (MAUDE) database represents a reporting system mandated by the Food and Drug Administration for postmarket surveillance. MAUDE has been made into a searchable online database that includes all reported events in which medical devices may have malfunctioned or caused a death or serious injury. For the clinician considering the use of a new medical device, searching the MAUDE database is useful to search for complications not yet reported in the medical literature.
Key words: MAUDE database

Introduction

Medical devices range from simple latex gloves and elastic bandages to complex programmable pacemakers and laser surgical devices. Medical devices are used in gynecology regularly, both in the clinic and in the operating room. If a product is labeled, promoted, or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug and Cosmetic Act, it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and postmarketing regulatory controls.

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A device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals, and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."[1] This definition provides a clear distinction between a medical device and other FDA-regulated products such as pharmaceuticals.

The Approval Process

PREMARKET EVALUATION AND APPROVAL

In response to several incidents involving patient morbidity owing to medical devices (including the Dalkon Shield in the

1970s), Congress enacted the Medical Device Amendments of 1976 to enable the FDA to regulate safety and effectiveness of medical devices.[2] Before receiving approval to market a new medical device in the United States, the manufacturer must now demonstrate to the FDA that the device is safe and effective. Low-risk devices may only need to undergo "registration and listing" or require only evidence of compliance with manufacturing guidelines.[3] Higher-risk devices must be submitted to the FDA in one of 2 ways: demonstration of "substantial equivalence" [called a 510(k) application] to a previously approved and legally marketed device, or demonstration of safety and effectiveness through a Premarket Approval Application. A Premarket Approval Application requires more clinical data and significantly more resources than a 510(k).[4] The majority of applications come in the form of 510(k). The amount and type of data required for approval depend on the device itself. The application data are reviewed on a regular basis. Recommendations made by the FDA advisory panels consisting of physicians, scientists, and representatives from industry and patient advocate groups are also reviewed.

POSTMARKET SURVEILLANCE

The limitation of the premarket evaluation phase is that rare complications or complications that take time to develop may not be appreciated in clinical trials involving relatively small numbers of patients over a short period of time. Thus, postmarket surveillance is designed to better identify uncommon but potentially serious adverse events related to device use in the general public.[5] As a result of the Safe Medical Devices Act of 1990, there are several systems in place by the FDA for postmarket surveillance.[6] These include registries, facility inspection, analysis of health care databases, and spontaneous reporting systems.

The Manufacturer and User Facility Device Experience Database

The Manufacturer and User Facility Device Experience (MAUDE) database represents a reporting system mandated by the FDA for postmarket surveillance. It includes reports of adverse events involving medical devices that occur after device approval. It allows for postmarket safety monitoring of approved devices. If a device is defective or causes a health risk, the FDA can issue warnings or recalls. MAUDE has been made into a searchable online database. It includes all reported events in which medical devices may have malfunctioned or caused a death or serious injury. MAUDE is updated quarterly and the search page reflects the date of the most recent update. The database is maintained by a division of the FDA and is available for public use under the Freedom of Information Act.[7] It can be accessed at the following web address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm.

The MAUDE database consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. Manufacturers are required to report device-related death, serious injury, or malfunction within 30 days of becoming aware of the event. User facility (hospitals, outpatient diagnostic or treatment facilities, nursing homes, and ambulatory surgical facilities) reports are also required by the FDA within 10 work days.[8] Individual clinicians can report events to the designated person in their user facility or a voluntary report can be submitted to FDA through FDA's "MedWatch"

program at http://www.fda.gov/medwatch/index.html or by phone at 1–800-FDA-1088.[9]

The Utility of MAUDE Database

For the clinician considering the use of a new medical device, searching the MAUDE database is useful for several reasons. First, most clinical trials are performed by experts and conform to rigorously defined protocols that might not translate into what can be expected in widespread use. Second, physicians might be reluctant to publish their own complications because of concerns for medicolegal risk or time constraints. Third, infrequent complications might only occur after large numbers of procedures have been performed. Finally, there is often a significant time lag in event occurrence and subsequent peer review publication.

Many papers have appeared in the medical literature as reviews of MAUDE data. These papers have attempted to summarize adverse events in the database. Pertinent to gynecology, papers reviewing optical access and traditional laparoscopic trocars,[10,11] global endometrial ablation devices,[12,13] midurethral slings,[14] transobturator slings,[15] and breast implants[16] have been published. The benefit to clinicians using these reviews versus individual searches of the database is avoidance of extraneous information that often requires inordinate amounts of sifting-through when accessing MAUDE online. Device malfunctions not associated with patient morbidity make up many of the reports in the online database thus diluting reports of patient morbidity. Duplicate reports often appear, and reports may lack pertinent information "pending investigation" that may or may not appear in subsequent reports.

Reviews of MAUDE published in the medical literature are also limited by the data themselves. Reports in the database often lack sufficient details to clearly establish a causal relationship between complications and use of the device in question. In addition, a relative or absolute degree of risk is difficult to determine for 2 reasons. First, the relative or absolute degree of risk is not known because there is no way to determine whether complications have been underreported. Adverse events are reported both by device manufacturers and facilities, thus duplicate reports may occur and are difficult to discriminate in the database. Similarly, attempts to quantify occurrences of adverse events as a percentage risk are limited by the fact that the absolute number of procedures performed by any given device is not tracked by the FDA and is not available on the database. Some device manufacturers keep statistics on the number of devices sold, but this is only somewhat representative of how many devices have been used. For reusable devices, these numbers are "guestimates" at best. Therefore, any complication rate estimates are subject to significant numerator and denominator limitations. Accordingly, a disclaimer now appears on the FDA website—"MAUDE data are not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices."[7]

For the practicing clinician, MAUDE offers information regarding adverse events related to medical device use, which may not be available in other forums, but must be used in the context of understanding of the underlying limitations.

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