The dangers of dental devices as reported in the Food and Drug Administration Manufacturer and User Facility Device Experience Database

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ABSTRACT

Background. The authors conducted a study to determine the frequency and type of adverse events (AEs) associated with dental devices reported to the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database.

Methods. The authors downloaded and reviewed the dental device–related AEs reported to MAUDE from January 1, 1996, through December 31, 2011.

Results. MAUDE received a total of 1,978,056 reports between January 1, 1996, and December 31, 2011. Among these reports, 28,046 (1.4%) AE reports were associated with dental devices. Within the dental AE reports that had event type information, 17,261 reported injuries, 7,777 reported device malfunctions, and 66 reported deaths. Among the 66 entries classified as death reports, 52 reported a death in the description; the remaining were either misclassified or lacked sufficient information in the report to determine whether a death had occurred. Of the dental device–associated AEs, 53.5% pertained to endosseous implants.

Conclusions. A plethora of devices are used in dental care. To achieve Element 1 of Agency for Healthcare Research and Quality's Patient Safety Initiative, clinicians and researchers must be able to monitor the safety of dental devices. Although MAUDE was identified by the authors as essentially the sole source of this valuable information on adverse events, their investigations led them to conclude that MAUDE had substantial limitations that prevent it from being the broad-based patient safety sentinel the profession requires.

Practical Implications. As potential contributors to MAUDE, dental care teams play a key role in improving the profession's access to information about the safety of dental devices.

Key Words. Dental equipment; dental public health; dental records; informatics; quality of care; safety management.

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Providing dental care to patients demands the use of a dizzying range of devices: endodontic files, endosseous implants, orthodontic brackets, handpieces, and fluoride varnish, just to name a few. These items are essential to the practice of dentistry but are accompanied by the risk for adverse events (AEs), which the Food and Drug Administration (FDA) defines as "any undesirable experience associated with the use of a medical product in a patient."[1] To uphold our profession's responsibility to provide the safest possible care to our patients, we must be vigilant and continually monitor the safety of dental devices and products, which by their very nature, expose our patients to risk. As we described in our previous article,[2] the Agency for Healthcare Research and Quality (AHRQ) of the US Department of Health and Human Services has proposed a 4-element patient safety initiative to minimize patient safety hazards. This model provides a useful framework for dentistry to "identify, understand, and reduce the risk of harm associated with medical errors and health care system–related problems."[3] By continually updating the risks associated with dental devices, we as a profession reaffirm our commitment to Element 1 of the Patient Safety Initiative,[3] Identifying Threats to Patient Safety.

The FDA, which regulates all medical devices and products in the United States, has a postmarket surveillance system to keep track of device problems after it has been brought to market. Here, it is useful to understand the definition of a device as compared with a drug: devices achieve their intended effect without a chemical interaction with, or metabolism by, the body.[4]

Thus, dental floss is a device, whereas lidocaine is a drug. For some devices, such as fluoride varnish, the distinction is subtler. Recalls of dental devices happen frequently. The recalls that have occurred in 2013 include an absorbable collagen wound dressing, which may have been manufactured with excess pyrogens[5]; endodontic canal preparation instruments with incorrect length markings[6]; and orthodontic bracket buccal tubes with incorrect labeling that might lead to unintentional rotation of the molars.[7]

The Journal of the American Dental Association (JADA) articles from 2001[8] and 2013[9] reviewed the background of FDA postmarket device surveillance. What is salient for the work we present here is that the Manufacturer and User Facility Device Experience (MAUDE) database contains both individual voluntary reports from health care providers and consumers, and individual mandatory reports from manufacturers and user facilities, dating back to August 1, 1996. Once manufacturers or distributors become aware of device-related AEs like deaths, serious injury, or malfunctions, they are obligated to report the AE to the FDA within 30 days. Similarly, user facilities, described as "a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility, or an outpatient diagnostic facility which is not a physician's office," have 10 days to report the AE to the FDA.[10] MAUDE contains a narrative description of the reported event, information about the occupations of the reporters, information about patient problems and device problems, and the results of manufacturers' evaluations and conclusions about reported events.

Since its inception, MAUDE has received millions of reports, a number of which involve dental devices. The 2001 JADA article on the FDA's postmarket device surveillance[8] presented an analysis of the data collected from August 1996 through June 1999, which included reports of two deaths, 18,406 injuries, and 9,942 device malfunctions. These dental device reports represented 10.5% of all of the device reports during that time frame. Endosseous implants represented the most dental device reports at that time. The more recent 2013 JADA article on FDA postmarket surveillance focused primarily on drug-related reports and did not quantify the device reports, but at the same time, it reinforced the value of continual mining of the device-related AE reports.[9] The device-related AEs uncovered through that work included detachment or fracture of dental needle components; osseointegration failure or loss of endosseous dental implants; and fracture, overheating, or malfunction of dental instruments, for example, high-speed handpieces.

Building upon these previous articles, we determined the frequency and type of dental AEs reported to FDA by reviewing reports submitted to MAUDE from January 1, 1996, through December 31, 2011. In so doing, we were able evaluate the strengths and weaknesses of MAUDE reports for identifying threats to dental patient safety.

By quantifying the frequency and type of dental AEs reported into MAUDE since its inception, we aimed to update the dental profession's understanding of device-related threats to dental patient safety, thereby contributing to Element 1 of AHRQ's Patient Safety Initiative. In parallel, we evaluated the strengths and weaknesses of MAUDE as a source of device-related patient safety information. The importance of this undertaking is best understood in context: dentistry does not have the extensive patient safety literature that medicine has accumulated. In fact, it has been noted that there are few studies or reports related to errors or AEs that take place in dental practices.[2,11] This may be attributed to a number of causes: harm produced by dental devices may be less severe, follow-up is more difficult in a dispersed ambulatory setting, dentists may fear impact on remunerations, and there may be gaps in dentistry's patient safety culture.[2,11]

METHODS

One can access the MAUDE data in two ways: through an online search available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM or through downloading the data files from the FDA Web site.[12] For our study, we included all the reports from January 1, 1996, through December 31, 2011. We used MySQL database version 5.0.77 and MySQL Workbench version 5.2 to analyze the data. The MAUDE data can be broadly classified as master event data, patient data, device data, and free-text data, all collected via the MedWatch forms described previously. Master event data includes reporting source and event type details, and text data contains textual information from MedWatch. At the time of our search, there were 296 distinct dental product codes cataloged by MAUDE,[13] which we used to create a dental products lookup table to identify the dental products contained within the database.

To better understand MAUDE reporting trends, we first identified and plotted the medical and dental device–associated reports from January 1, 1996, through December 31, 2011. We identified the number of mandatory and voluntary reports, as well as the reports related to death, injuries, and malfunctions, respectively. We also analyzed event locations and the reporters' occupations. To determine dental devices that

ABBREVIATION KEY. AEs: Adverse events. **AHRQ:** Agency for Healthcare Research and Quality. **DC:** District of Columbia. **FAERS:** FDA Adverse Event Reporting System. **FDA:** Food and Drug Admininstration. **JADA:** The Journal of the American Dental Association. **MAUDE:** Manufacturer and User Facility Device Experience.