

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

Nutan B. Hebballi, BDS, MPH; Rachel Ramoni, DMD, ScD;
Elsbeth Kalendarian, DDS, MPH, PhD;
Veronique F. Delattre, DDS;
Denice C. L. Stewart, DDS, MHSA; Karla Kent, PhD;
Joel M. White, DDS, MS; Ram Vaderhobli, DDS, MS;
Muhammad F. Walji, PhD

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

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.

JADA 2015;146(2):102-110

<http://dx.doi.org/10.1016/j.adaj.2014.11.015>

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 pyrogens⁵; endodontic canal preparation instruments with incorrect length markings⁶; 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 2001⁸ and 2013⁹ 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 surveillance⁸ 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 to 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 Administration. JADA: The Journal of the American Dental Association. MAUDE: Manufacturer and User Facility Device Experience.

TABLE 1

Characteristics of dental adverse event reports found in MAUDE* (N = 28,046).	
TYPES OF REPORTS	NO. (%) REPORTS
Mandatory Reports	26,691 (95.2)
Manufacturer report	23,583
Distributor report	2,968
User facility report	140
Voluntary Reports	1,355 (4.8)
ADVERSE EVENT TYPES	
Injuries	17,261 (61.5)
Malfunctions	7,777 (27.7)
Other	2,630 (9.4)
Invalid Data/No Data	312 (1.1)
Death	66 (0.23)

* MAUDE: Manufacturer and User Facility Device Experience Database.

contributed to deaths, we further analyzed the death reports reported to FDA during our study period. We calculated the 20 dental devices most commonly associated with AEs, as well as the top 10 problems associated with dental devices. Finally, as we found that endosseous implants were by far the highest-ranking device associated with AE reports, we also explored the top 10 endosseous implant-related problems.

RESULTS

There were a total of 1,978,056 reports deposited into MAUDE from January 1, 1996, through December 31, 2011; 28,046 (1.41%) of these reports were associated with dental devices, 26,691 of which were mandatory (23,583 manufacturer's reports, 2,968 distributor's reports and 140 reports from the user facilities) and 1,355 of which were voluntary reports (Table 1). Among the 28,046 dental device-associated reports, we found a total of 66 deaths, 17,261 injuries, and 7,777 device malfunctions (Table 1). The balance of 2,942 reports did not provide any information about the event, reported the event to be "other," or had invalid data as noted by FDA.

Of the 28,046 AEs reported, 17,387 (62.0%) were submitted by dentists; 8,994 of these reports were submitted by dentists to the manufacturers; 4,368 were submitted to the distributors; and 4,025 were submitted voluntarily to MAUDE by the dentists. A large number of reports did not provide details on AE location: 14.0% of reports indicated the location as being "other"; 6.6% of reports left the location field blank, had either invalid data, or location marked as "no information"; and 4.6% of reports had location marked as "not applicable." The next most common reporters were physicians (4.4%). Other reporters included patients, dental assistants,

TABLE 2

Reporters of dental adverse events found in MAUDE* (N = 28,046).	
TYPE OF REPORTER	FREQUENCY (%)
Dentist	17,387 (62.0)
Other	3,917 (14.0)
Unknown/Invalid Data/Blank/No Information	1,860 (6.6)
Not Applicable	1,280 (4.6)
Physician	1,240 (4.4)
Patient	863 (3.1)
Dental Assistant	668 (2.4)
Attorney	215 (0.8)
Nurse	176 (0.6)
Risk Manager	143 (0.5)
Other Health Care Professional	134 (0.5)
Patient Family Member or Friend	42 (0.1)
Health Professional	30 (0.1)
Service Personnel	16 (0.1)
Pharmacist	15 (0.1)
Biomedical Engineer	11 (0)
Physician Assistant	11 (0)
Radiological Technologist	10 (0)
Dental Hygienist	6 (0)
Other Caregiver	5 (0)
Phlebotomist	4 (0)
Medical Equipment Company Technician Representative	3 (0)
Service and Testing Personnel	3 (0)
Medical Technologist	2 (0)
Respiratory Therapist	2 (0)
Speech Therapist	2 (0)
Medical Assistant	1 (0)

* MAUDE: Manufacturer and User Facility Device Experience Database.

TABLE 3

Location of dental adverse events as reported in MAUDE* (N = 28,046).	
EVENT LOCATION	FREQUENCY (%)
Blank	13,097 (46.7)
Other	6,490 (23.1)
No Information/Invalid Data/Not Applicable	3,589 (12.8)
Outpatient Treatment Facility	3,137 (11.2)
Unknown	1,036 (3.7)
Hospital	367 (1.3)
Home	240 (0.9)
Outpatient Diagnostic Facility	54 (0.2)
Ambulatory Surgical Facility	29 (0.1)
Nursing Home	4 (0)
Public Venue	2 (0)
Clinic-Walk-in, Other	1 (0)

* MAUDE: Manufacturer and User Facility Device Experience Database.

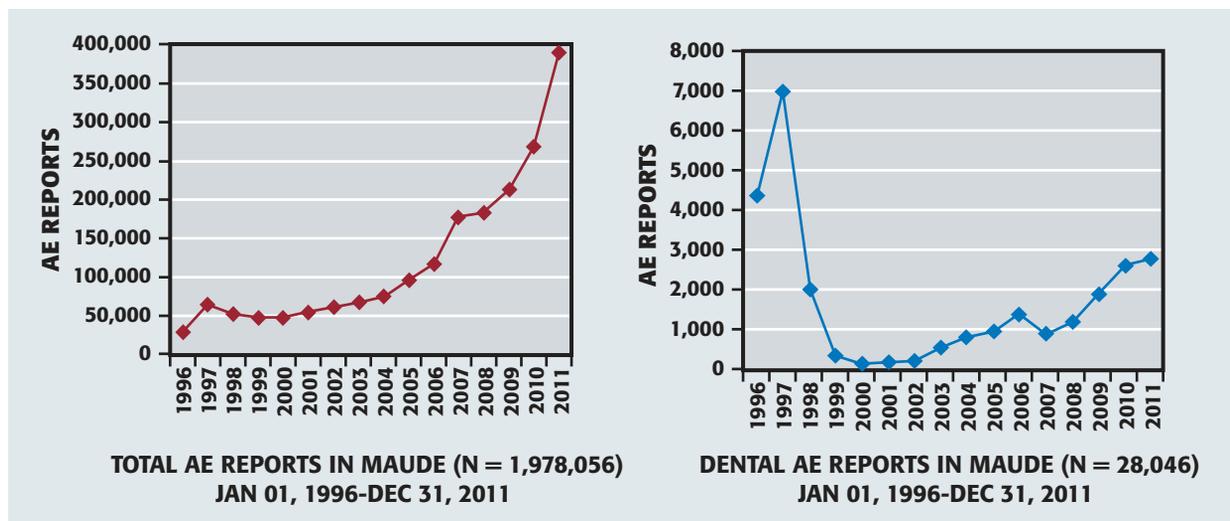


Figure 1. Device-associated adverse event yearly reporting trends. AE: Adverse event. MAUDE: Manufacturer and User Facility Device Experience.

dental hygienists, attorneys, biomedical engineers, physician assistants, radiological technologists, and patient family members or friends, among others (Table 2). The categories we report are those maintained by the FDA. Very little specific information on event location was contained within the reports (Table 3). Reports do show, however, that 1.3% of the dental AEs occurred in a hospital.

Annual MAUDE reporting trends. As MAUDE is composed of both dental and nondental (for example, other medical device-associated AE) reports, we were interested to observe the respective reporting trends as shown in Figure 1. Both nondental and dental AE reports experienced a peak in 1997. The likely explanation for this spike is that a backlog of earlier events was reported; we contacted the FDA to seek an explanation and were told that the agency “cannot speculate on the reason that FDA received more AE reports in 1996-1997” (personal communication, email, February 10, 2014). We then examined the death, injury, and malfunction dental device reporting trends, respectively (Figure 2). There were a total of 66 death reports associated with dental devices during the time range we considered. These reports peaked in 2004 ($n = 14$), which should be interpreted in light of the fact that 2004 is the date of the report, rather than the date of death from an AE. There were no deaths reported between 1999 and 2000.

Detailed analysis of death reports. Upon further analysis of the 66 deaths reported, we found that 52 of the 66 reported deaths were confirmed deaths based on the information provided by the reporter, and the remaining were either misclassified or had insufficient information to determine whether a death had occurred

in association with a dental device. An example of insufficient information is when the description contained no clear indication of patient death. Of the 52 confirmed deaths, 46 cases were from mandatory reports and 6 were from voluntary reports. In 23 reports, (11 men and 12 women), the sex was clearly mentioned in the description but the remaining 29 reports did not have any sex information. Seven of the 52 reports did not indicate a specific device associated with the death. Twenty-five of the 52 death reports described neurologic damage associated with denture adhesives. The remainder of the death-associated devices were TMJ implants, denture cleansers, bone graft, distractor, and dental implants. We should emphasize that this information is based solely on the MAUDE reports and does not constitute proof that a particular dental device caused a person’s death.

Dental devices associated with adverse events. The top 20 dental devices associated with AEs are shown in Table 4. By far, the most commonly represented devices were endosseous dental implants: 53.5% of the AE reports concerned these types of device. To put this in perspective, consider that the next most common device, denture adhesives, represented only 5.0% of the device-associated reports.

Dental device events summary. A total of 3,175 dental device-related problem descriptions were reported to the FDA between January 1, 1996, and December 2011. The events were distributed across 129 different FDA-defined categories.¹⁴ Over a third, 1,213 (38.2%) events, concerned failure of dental implants to osseointegrate. The remaining top 9 event categories are shown in Figure 3. It is notable that the ninth most common event category was “unknown.”

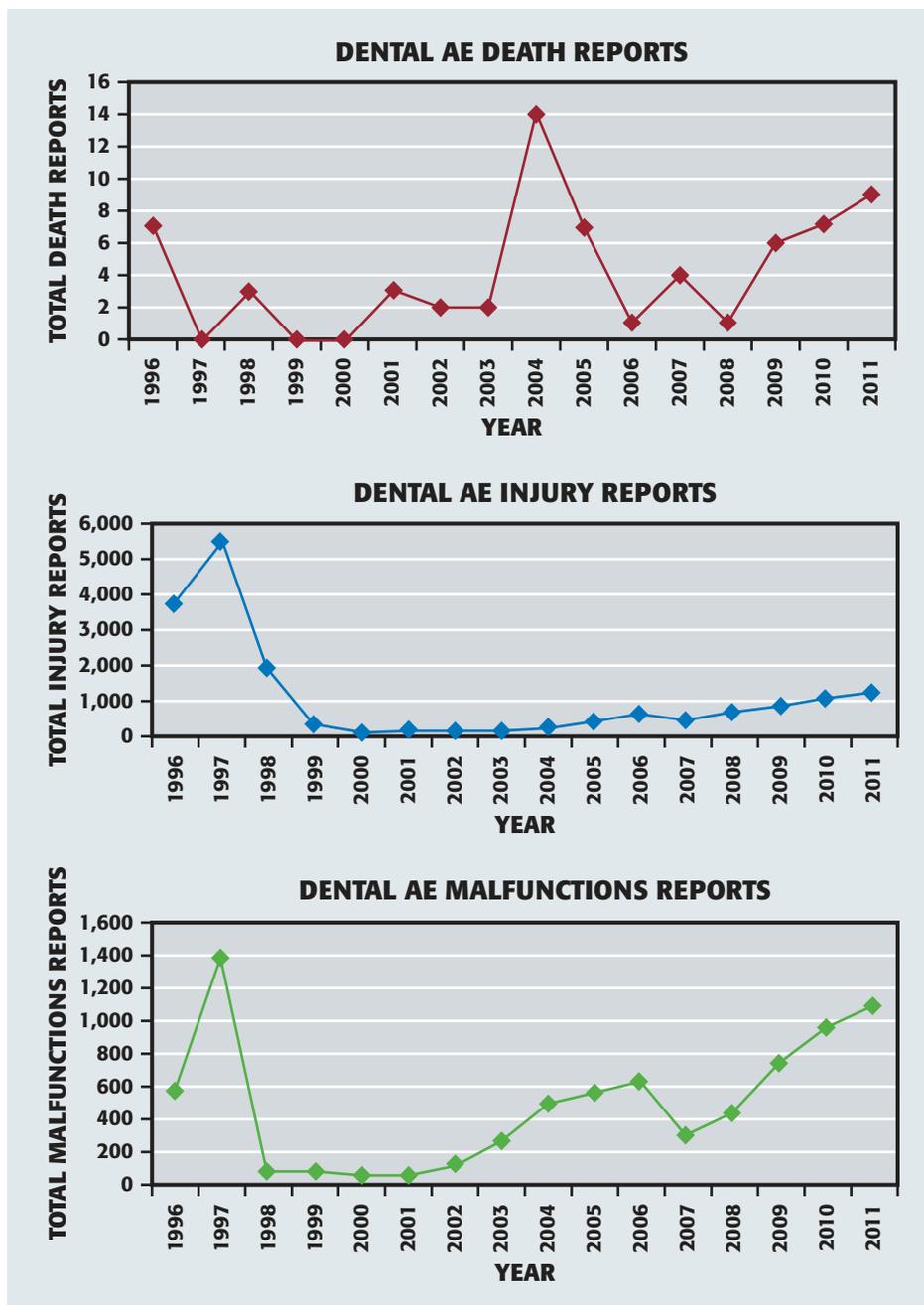


Figure 2. Trends of reported deaths, injuries, and malfunctions associated with dental devices. AE: Adverse event.

Endosseous implant-associated events. As 53.5% of AEs concerned endosseous dental implants, we further analyzed the events described. We found that there were 27 different types of problems associated with endosseous implants, the most common of which (77.3%) was failure to osseointegrate, followed by loss of

if the adhesive is used beyond the recommended levels. In turn, high zinc levels can lead to copper deficiency, which is most commonly manifested through neurologic and hematologic disease. These findings were supported by additional articles.^{16,17} In 2010, several manufacturers issued warnings and stopped or modified

osseointegration, and so on. Figure 4 contains the top 10 problems associated with endosseous dental implants.

DISCUSSION

Knowledge of threats to patient safety empowers our profession to protect our patients. Despite substantial limitations, MAUDE is the only consolidated source of this knowledge about dental devices. As such, it serves not only as a safety sentinel but a reminder that dentistry, like medicine, is inherently and sometimes, surprisingly, risky. The practice of dentistry is replete with obvious sources of risk, such as dental burs and needles, but sometimes, these risks lurk where we might least expect them. Consider the many reports to MAUDE associated with denture adhesives. At first glance, use of these products might not seem to be fraught with peril, but as described in “Denture Cream: An Unusual Source of Excess Zinc, Leading to Hypocupremia and Neurologic Disease,” published in the journal *Neurology* in 2008,¹⁵ the zinc in some denture adhesives can lead to excess zinc ingestion

production of zinc-containing denture adhesives, but zinc-containing denture adhesives were not totally phased out. A 2013 article in the American Journal of Stem Cells described pancytopenia, a reduction in the red blood cells, white blood cells, and platelets, in a 34-year-old patient with a partial denture who used zinc-containing denture adhesive, which resolved with copper therapy and discontinuation of the denture adhesive.¹⁸ A prosthodontist in Baltimore, MD, captured the problem well when interviewed about the risks of denture adhesives, “In 30 years I’ve never seen a patient who had these (neurologic) problems. On the other hand, maybe I’ve missed it. Now we’re all looking for it.”¹⁹ Resources like MAUDE help us to amass and share our collective knowledge about potential, but perhaps unseen, risks to our patients. In some cases, these incidents may have been encountered but not recognized or reported as an adverse event.

The importance of MAUDE as a source of knowledge about threats to patient safety should not obscure its limitations. The content of the reports is not extensively validated, there may be more than 1 report per event, and the severity of the event (apart from the extreme of death or injury) is not classified. Furthermore, from the data stored in MAUDE, we cannot infer a causal association between the dental devices and AEs. Although MAUDE contains narrative reports that attempt to describe the incident, our initial analyses suggest that they are insufficient to determine the causes or factors contributing to a particular adverse event. In addition, the coded data relating to problems associated with endosseous dental implants, for example, are intriguing as they appear to suggest that many of the AEs may be due to technique or biological issues rather than directly attributable to the device. However, great caution is required to adequately interpret data derived from MAUDE. To best serve a health care system managed by people who continually seek to learn how to prevent AEs, the event report should contain the results of root cause analysis, an approach used across various industries to identify factors that contributed to an event. Importantly, such an analysis should be conducted near the time of the event by people with contextual knowledge, as root cause analysis “cannot be used on archival records with any degree of accuracy.”²⁰

Another considerable limitation is that MAUDE appears to be an underutilized resource; its contents are sparse relative to the size of the dental profession. According to Kaiser Family Foundation State Health Facts, as of November 2012, there were 195,941 professionally active dentists in the US.²¹ MAUDE contains only 17,387 reports of dental device-associated AEs submitted by dentists from August 1, 1996, through December 31, 2011. It would be improbably optimistic to assume that these events represent the sum total of

TABLE 4

Top 20 devices associated with dental adverse events.	
DEVICE NAME	FREQUENCY (%)
Endosseous Dental Implant (Root Form)	15,267 (53.5)
Ethylene Oxide Homopolymer and/or Carboxymethylcellulose Sodium Denture Adhesive	1,426 (5.0)
Bone-Cutting Instrument and Accessories (Driver Wire and Bone Drill Manual)	1,278 (4.5)
Dental Hand Instrument (Endodontic File)	815 (2.9)
Bone Plate	760 (2.7)
Dental Cement	630 (2.2)
Ultrasonic Scaler	565 (2.0)
Dental Hand Piece and Accessories	523 (1.8)
Total Temporomandibular Joint Prosthesis	505 (1.8)
Intraoral Dental Drill	458 (1.6)
Carboxymethylcellulose Sodium and/or Polyvinyl Methylether Maleic Acid Calcium-Sodium Double Salt Denture Adhesive	455 (1.6)
Dental Injecting Needle	306 (1.1)
Orthodontic Appliance and Accessories	288 (1.0)
Bone-Cutting Instrument and Accessories (Bone Drill Powered)	283 (1.0)
Intraoral Source X-Ray System	252 (0.9)
Intraoral Devices for Snoring and Obstructive Sleep Apnea	243 (0.9)
Dental Bur	217 (0.8)
Bone Grafting Material—Synthetic	209 (0.7)
Bone Grafting Material With Biological Component	186 (0.7)
Resin Tooth Bonding Agent	182 (0.6)

device-associated AEs in American dental practices. Indeed, as reported in a 2013 JADA article authored by RR, EK, and MW, we found that 34% (95% confidence interval, 22%-48%) of randomly selected patient charts from an academic dental center with both teaching and faculty practices contained at least 1 AE,²² a number of which were device-related, for example, fractured removable partial denture, fractured implant. None of these were voluntarily reported to MAUDE by the clinic. There may be multiple reasons why dental device-related AEs go unreported in MAUDE, including lack of awareness and the inherent difficulty in submitting voluntary reports. One approach to addressing this problem might be to incorporate semiautomated reporting into electronic health records, and another might include instituting mandatory reporting by dental clinics. Precedent for mandatory patient safety reporting includes the District of Columbia’s (DC) Medical Malpractice Amendment Act passed in 2006, which included “mandatory adverse event reporting” (DC Code § 7-161 [2007]).²³ Further, DC Municipal Regulations, title 17, chapter 42 (dentistry), §4212.5

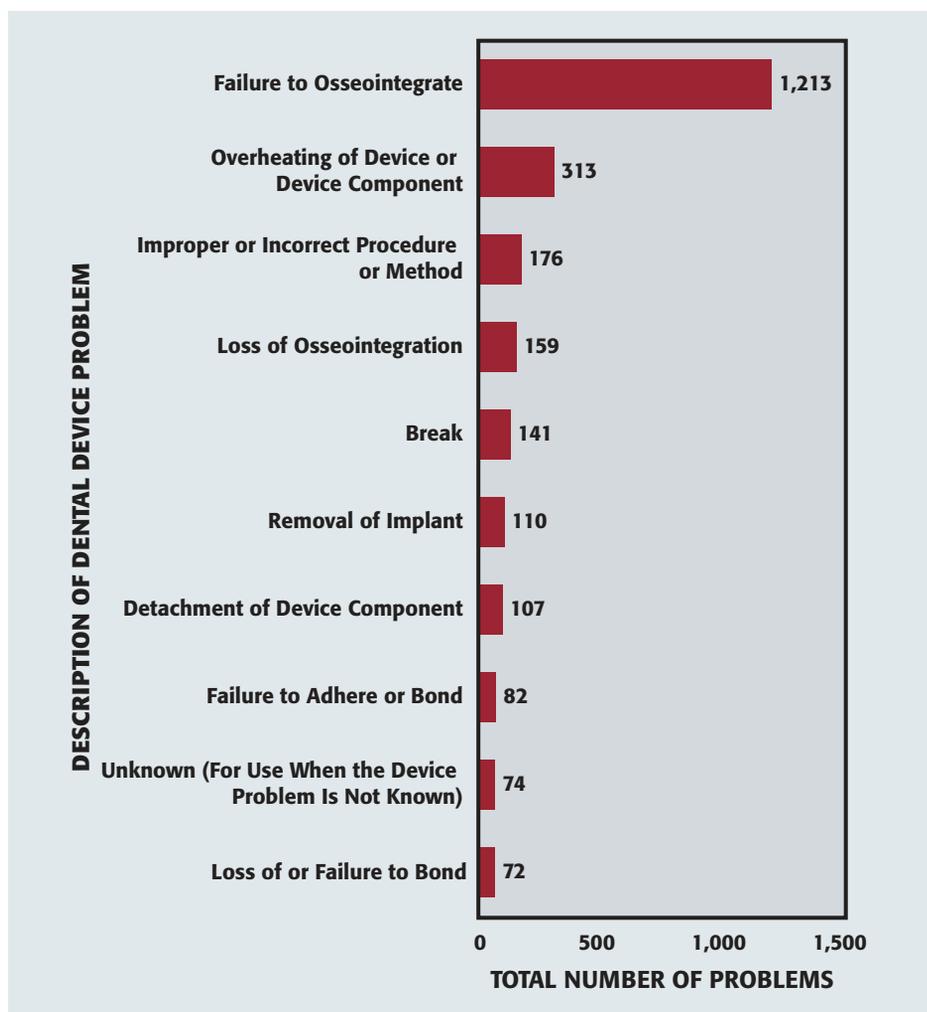


Figure 3. Top 10 device problems associated with dental adverse events in the Manufacturer and User Facility Device Experience Database.

requires dentists to report to the DC Board of Dentistry any deaths, disabling incidents, or hospitalizations caused by administration of local anesthesia or nitrous oxide.²⁴

Finally, MAUDE should not be used to evaluate rates of AEs or to compare AE rates across devices.²⁵ Indeed, in addition to having potentially more than 1 report per event, there may be a reporting bias due to, for instance, the fact that endosseous implants are relatively expensive, leading dentists to approach the manufacturer to replace failed implants, with the manufacturer, in turn, reporting the failure to MAUDE. Our results should be interpreted with this in mind, and readers should not conclude, for example, that endosseous dental implants are associated with more injuries than are dental burs because there are more MAUDE reports about dental implants than burs. This information contained in

MAUDE serves as a starting point to explore device-associated AEs, and would, of course, be useful in terms of tracking patient safety trends, but such surveillance would require a different approach to event ascertainment.

By design, MAUDE limits its purview to device-related events. Such a focus is of indisputable value to an agency concerned with regulating devices, but there exists a range of other threats to dental patient safety, as can be corroborated by a review of media reports, the literature, and other information sources. Consider, for example, cases of osteonecrosis of the jaw after dental extractions among patients who take oral bisphosphonates for osteoporosis; this event, theoretically, would be reported to the FDA's Adverse Event Reporting System (FAERS),²⁶ which focuses on drug and therapeutic biological products. Yet, other

sources of information about threats to dental patient safety may be gleaned from the literature and from media reports.^{27,28} Dental practices would likely be better served by a single source that consolidated a range of threats to patient safety, rather than having to consult various sources like FAERS, MAUDE, the scientific literature, and the media, with each dental practice having to conduct the search anew.

MAUDE is an important, if imperfect, contributor to our profession's knowledge about threats to patient safety. As a group, we, the authors of this report, are interesting in cataloging threats to patient safety in fulfillment of Element 1 of AHRQ's Patient Safety Initiative. Indeed, we are working to address this gap by creating a central repository to catalog the range of AE types that occur in the dental office with the support of an Ro1 from the National Institute of Dental and

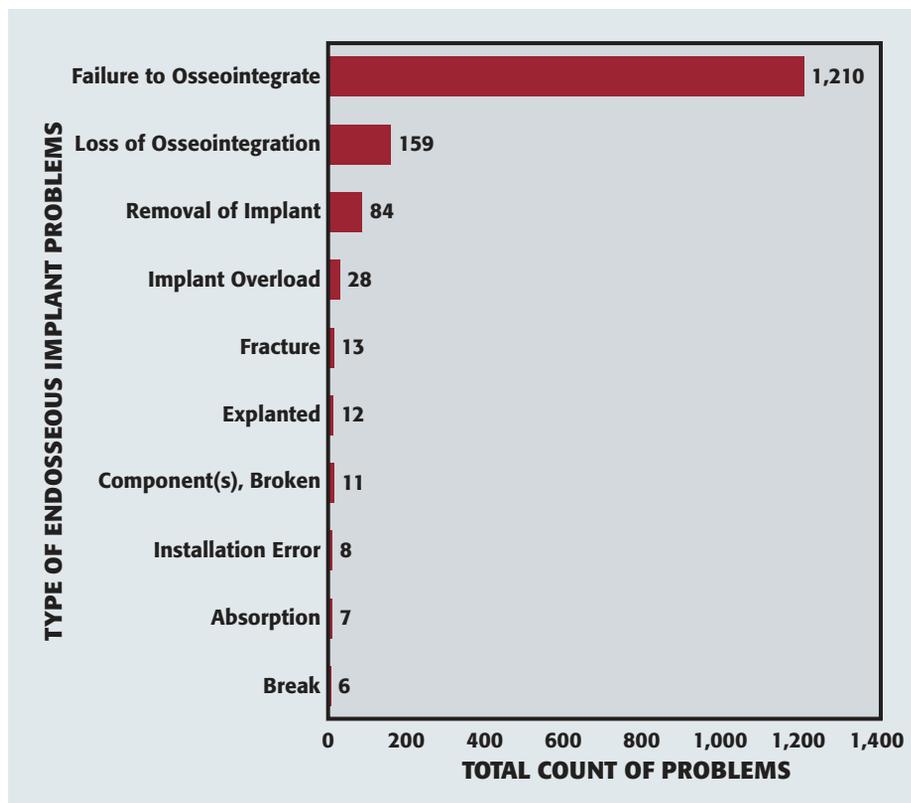


Figure 4. Top 10 endosseous implant-related problems in the Manufacturer and User Facility Device Experience Database.

Craniofacial Research, entitled, Developing a Patient Safety System for Dentistry.²⁹ In so doing, we are drawing upon MAUDE reports associated with dental devices, as well as the scientific literature, the media, and information gleaned from our electronic health records. Those readers who are affiliated with a dental practice must also contribute to this effort by ensuring that well-documented reports of device-associated events are submitted to MAUDE. ■

Dr. Hebballi is a research associate, Department of Diagnostic and Biomedical Sciences, University of Texas Health Science Center School of Dentistry at Houston, Houston, TX.

Dr. Ramoni is an assistant professor, Department of Oral Health Policy and Epidemiology, Harvard School of Dental Medicine, Boston, MA.

Dr. Kalenderian is chair, Department of Oral Health Policy and Epidemiology, Harvard School of Dental Medicine, Boston, MA.

Dr. Delattre is a professor, Department of General Dentistry and Public Health, University of Texas Health Science Center School of Dentistry at Houston, Houston, TX.

Dr. Stewart is a senior associate dean, Clinical Affairs, and a professor, Department of Community Dentistry, Oregon Health & Science University, School of Dentistry, Portland, OR.

Dr. Kent is Director of Quality Improvement, and a professor, Department of Integrative Biosciences, Oregon Health & Science University, School of Dentistry, Portland, OR.

Dr. White is a professor, Department of Preventive and Restorative Dental Sciences, School of Dentistry, University of California, San Francisco, CA.

Dr. Vaderhobli is an associate director, LMC/UCSF AEGD post-graduate residency program, and an associate professor, Department of Preventive and Restorative Dental Sciences, School of Dentistry, University of California, San Francisco, CA.

Dr. Walji is the associate dean, Technology Services and Informatics, and an associate professor, Department of Diagnostic and Biomedical Sciences, University of Texas Health Science Center School of Dentistry at Houston, 7500 Cambridge St, Suite 4184, Houston, TX 77054, e-mail muhammad.f.walji@uth.tmc.edu. Address correspondence to Dr. Walji.

Disclosure. None of the authors reported any disclosures.

Research reported in this article was supported by the National Institute of Dental and Craniofacial Research of the National Institutes of Health under Award Ro1DE022628.

Drs. Hebballi, Ramoni, and Kalenderian share co-first authorship.

1. US Food and Drug Administration. What is a serious adverse event? Available at: <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm>. Accessed June 16, 2014.
2. Ramoni RB, Walji MF, White J, et al. From good to better: toward a patient safety initiative in dentistry. *JADA*. 2012;143(9):956-960.
3. AHRQ's Patient safety initiative: building foundations, reducing risk. Interim report to the Senate Committee on Appropriations. Rockville, MD: Agency for Healthcare Research and Quality; 2003. AHRQ Publication #04-RG005.
4. US Food and Drug Administration. Classification of products as drugs and devices and additional product classification issues. Available at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm#_Toc294261432. Accessed December 9, 2014.
5. US Food and Drug Administration. Class 2 Device recall CollaPlug Absorbable Collagen Wound Dressing for Dental Surgery. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=117050>. Accessed June 15, 2014.
6. US Food and Drug Administration. Class 2 Device Recall Lightspeed LSX Files. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=115470>. Accessed December 9, 2014.
7. US Food and Drug Administration. Class 2 Device Recall Bracket Buccal Tube. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=116926>. Accessed June 15, 2014.
8. Fuller J, Parmentier C. Dental device-associated problems: an analysis of FDA postmarket surveillance data. *JADA*. 2001;132(11):1540-1548.
9. Zavras AI, Rosenberg GE, Danielson JD, Cartos VM. Adverse drug and device reactions in the oral cavity: surveillance and reporting. *JADA*. 2013;144(9):1014-1021.
10. Lowe N, Scott W. Medical Device Reporting for User Facilities; 1996. Available at: <http://www.fda.gov/downloads/MedicalDevices/.../UCM095266.pdf>. Accessed December 9, 2014.
11. Perea-Peréz B, Santiago-Sáez A, García-Marin F, Labajo-González E, Villa-Vigil A. Patient safety in dentistry: dental care risk management plan. *Med Oral Patol Oral Cir Bucal*. 2011;16(6):e805-e809.

12. US Food and Drug Administration. Manufacturer and User Facility Device Experience Database—(MAUDE). Available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm>. Accessed January 28, 2013.
13. US Food and Drug Administration. Product classification. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&Submission_Type_ID=&DeviceName=&ProductCode=&DeviceClass=&ThirdParty=&Panel=DE&RegulationNumber=&PAGENUM=500&SortColumn=DeviceClass DESC. Accessed January 28, 2013.
14. US Food and Drug Administration. Device problem code disposition file. Available at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/EventProblemCodes/UCM134774.xls>. Accessed June 16, 2014.
15. Nations SP, Boyer PJ, Love LA, et al. Denture cream: an unusual source of excess zinc, leading to hypocupremia and neurologic disease. *Neurology*. 2008;71(9):639-643.
16. Hedera P, Peltier A, Fink JK, Wilcock S, London Z, Brewer GJ. Myelopolyneuropathy and pancytopenia due to copper deficiency and high zinc levels of unknown origin II. The denture cream is a primary source of excessive zinc. *Neurotoxicology*. 2009;30(6):996-999.
17. Tezvergil-Mutluay A, Carvalho RM, Pashley DH. Hyperzincemia from ingestion of denture adhesives. *J Prosthet Dent*. 2010;103(6):380-383.
18. Khimani F, Livengood R, Esan O, et al. Pancytopenia related to dental adhesive in a young patient. *Am J Stem Cells*. 2013;2(2):132-136.
19. Roylance F. Denture adhesives can cause zinc overdose, study says. Available at: <http://phys.org/news/2011-04-denture-adhesives-zinc-overdose.html>. Accessed December 9, 2014.
20. Battles JB, Lilford RJ. Organizing patient safety research to identify risks and hazards. *Qual Saf Health Care*. 2003;12(suppl 2):ii2-ii7.
21. Kaiser Family Foundation. State health facts: professionally active dentists; 2012. Available at: <http://www.statehealthfacts.org/comparabletable.jsp?ind=442&cat=8&sub=104&yr=279&typ=1&sort=a>. Accessed December 9, 2014.
22. Kalenderian E, Walji MF, Tavares A, Ramoni RB. An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office. *JADA*. 2013;144(7):808-814.
23. Code of the District of Columbia. §7-161. Mandatory adverse event reporting. Available at: <http://dccode.org/simple/sections/7-161.html>. Accessed December 9, 2014.
24. Title 17 District of Columbia Municipal Regulations. District of Columbia Municipal regulations for dentistry. Available at: http://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/Dentistry_DC_Municipal_Regulations_for_Dentistry.pdf. Accessed February 19, 2013.
25. Gurtcheff SE. Introduction to the MAUDE database. *Clin Obstet Gynecol*. 2008;51(1):120-123.
26. US Food and Drug Administration. FDA Adverse Event Reporting System (FAERS). Available at: <http://www.fda.gov/drugs/guidance/compliance/regulatoryinformation/surveillance/adversedrugged/default.htm>. Accessed December 9, 2014.
27. Malito A. Sedatives cited in toddler's dentist office death. Available at: <http://www.nbcnews.com/news/us-news/sedatives-cited-toddlers-dentist-office-death-n59156>. Accessed December 9, 2014.
28. Hawthorne J, Stein P, Aulisio M, Humphries L, Martin C. Opiate overdose in an adolescent after a dental procedure: a case report. *Gen Dent*. 2011;59(2):e46-e49.
29. Walji M. Developing a patient safety system for dentistry. Available at: http://projectreporter.nih.gov/project_info_description.cfm?aid=8588913&icde=19506063&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC. Accessed June 16, 2015.