Development of an Inventory of Dental Harms: Methods and Rationale

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ABSTRACT

Objectives: While adverse events (AEs) are all too prevalent, their underlying causes are difficult to assess because they are often multifactorial. Standardizing the language of dental AEs is an important first step toward increasing patient safety for the dental patient.

Methods: We followed a multimodal approach building a dental AE inventory, which included a literature review; review of the MAUDE database; a cross-sectional, self-administered patient survey; focus groups; interviews with providers and domain experts; and chart reviews.

Results : One hundred eight unique allergy/toxicity/foreign body response, 70 aspiration/ingestion of foreign body, 70 infection, 52 wrong site/wrong patient/wrong procedure, 23 bleeding, 48 pain, 149 hard tissue injury, 127 soft tissue injury, 91 nerve injury, 171 other systemic complication, and 177 other orofacial complication were identified. Subtype AEs within the categories revealed that allergic reaction, aspiration, pain, and wrong procedure were the most common AEs identified among known (i.e., chart reviews) and hypothetical (i.e., interviews) sources.

Conclusions: Using a multimodal approach, a broad list of dental AEs was developed, in which the AEs were classed into 12 categories. Hard tissue injury was noted frequently during interviews and in actuality. Pain was the unexpected AE that was consistently identified with every modality used.

Practical Implications: Most AEs result in temporary harm with hard tissue injury being a common AE identified through interviews and in actuality through chart reviews. Acknowledging that AEs happen is an important step toward mitigating them and assuring quality of care for our patients.

Keywords: adverse events; dentistry; pain; patient safety; multimodal

Fifteen years ago, the Agency for Healthcare Research and Quality (AHRQ) defined 4 elements as part of its patient safety initiative: element 1: identifying threats to patient safety; element 2: identifying and evaluating effective patient safety practices; element 3: educating, disseminating, implementing, and raising awareness; and element 4: continually monitoring and evaluating threats to patient safety to ensure that a positive safety culture is maintained and a safe environment continues.[1] Almost a decade ago, recognizing that patient safety and quality improvement need to be part of the dental culture, we challenged the dental profession to "commit to change."[2] Under the guidance of our advisory committee, we pursued this goal by exploring our own patient safety initiative (PSI) element 1: the development of an inventory of all harms (i.e., adverse events [AEs]) that may happen to a patient during dental treatment.[2]

Within the medical field, efforts to develop an inventory of AEs that could occur during inpatient and/or outpatient care are in the infancy stage. Mandatory reporting of AEs would facilitate the establishment of such an inventory, but this is not a requirement at the national level in the United States. A number of states require some types of AEs to be reported, but it is widely recognized that underreporting is the norm.[3] In 2002, the National Qualify Forum developed, through a consensus process, a standardized list of 27 preventable, serious AEs in health care that would facilitate reporting, and some states enacted legislation or took

administrative action to require reporting of these "never events."[3] Other efforts to develop some sort of listing of AEs include the Value of Safety Information Data Sources Initiative, which endeavors to document "single high value valid cases," and the development of a method for "aggregating lower value cases" with respect to biopharmaceutical AEs (i.e., the number of AEs collected by biopharmaceutical companies and reported to regulatory authorities).[4] The Food and Drug Administration (FDA) proposed the development of a list of serious adverse reactions for clinical trials; however, nonserious events are not included.[5] Garrouste-Orgeas et al[6] have also provided an overview of the AEs in the intensive care unit setting. The focus in medicine has in general been on listing never events, which are serious AEs, in the hope of better understanding and mitigating the underlying system issues. The VAERS, the Vaccine Adverse Event Reporting System developed in 1990, is the U.S. national early warning system to detect possible safety problems with licensed vaccines. It is a passive reporting system, meaning that providers and patients self-report into the system. As such, it is useful for the detection of unusual or unexpected patterns of AEs that might indicate a possible safety problem with a vaccine.[7] It has been credited with identifying the extremely rare chance of a blood clot after the Johnson & Johnson vaccine for COVID-19.[8]

The AHRQ developed its PSI in response to a federal mandate to develop patient safety improvement activities, mainly based on the Institute of Medicine report, *To Err is Human: Building a Safer Health System*. A 4-year evaluation by RAND of AHRQ's PSI showed that specifically in Element 1: Identifying Threats, progress was slow, primarily because of the failure to establish regional or national reporting systems.[9] In addition, there is a strong need to develop a standardized list of all AEs, not just never events. The impact of AEs and their underlying causes (i.e., errors) are difficult to assess because they are often multifactorial, including differences in case mix, confounding disease factors, and the occurrence of multiple events in the same patient. Indeed, comparing the rates of AEs and their underlying causes across studies, institutions, or populations is difficult without a standardized language and set of definitions for each potential harm.[6] Hence, with funding from the National Institutes of Health (i.e., National Institute of Dental and Craniofacial Research), we set out to develop a standardized list of all AEs in the dental domain, using a multimodal approach.

METHODS

Permission to carry out the study was obtained from each participating institution's institutional review board. We followed a multimodal approach to building our dental AE inventory (Fig. 1).

FIGURE 1: Multimodal approach to the development of the dental AE Inventory.

Literature Review

We searched electronic bibliographic databases (e.g., PubMed, Embase, Web of Science, and CINAHL) using the following key words: patient safety, medical errors, adverse effects, dental care, dental procedures, dental treatment, and facility. The final search date was June 30, 2013. One hundred eighty-two published case reports/series containing 270 cases were included in the final review. Background characteristics were collected on authors, publication year, country, citation, and the accession number (i.e., PubMed ID). Each case was further characterized according to the incident description, case characteristics (i.e., age, sex), clinic setting where AE originated, phase of patient care during which the AE was detected, proximal cause, type of patient harm, degree of harm, and recovery actions.[10]

Food and Drug Administration MAUDE Database

The MAUDE database is a mandatory reporting mechanism for device manufacturers. Both dentists and patients can register their complaints using this database. We mined the database for dental AEs between 1996 and 2012.[11]

Patient Self-reporting

A cross-sectional, self-administered paper-based survey was provided to 440 South African dental patients at the end of their patient visit. Patients were asked about their past experiences with unsafe events as well as about the quality of service they had received in the past 1 year at any clinic in South Africa. Patients were given an opt-out option, and their consent was implied by participating in the survey.[10]

Focused Chart Reviews

Based on the Institute for Healthcare Improvement's global and outpatient trigger tools, which identify records with characteristics ("triggers") that are associated with AEs, a dental clinic trigger tool was created.[12] A pilot project was developed, and, based on its favorable results, a second study was completed that further refined the triggers and identified additional dental AEs.[13]

Chart Reviews

The Dental Practice Study determined the frequency and types of AEs that occur in dentistry on the basis of retrospective chart audit, without the use of triggers, and as such explored the likelihood that a patient sitting in a dentist chair might experience harm (Figs. 2, 3).[14]

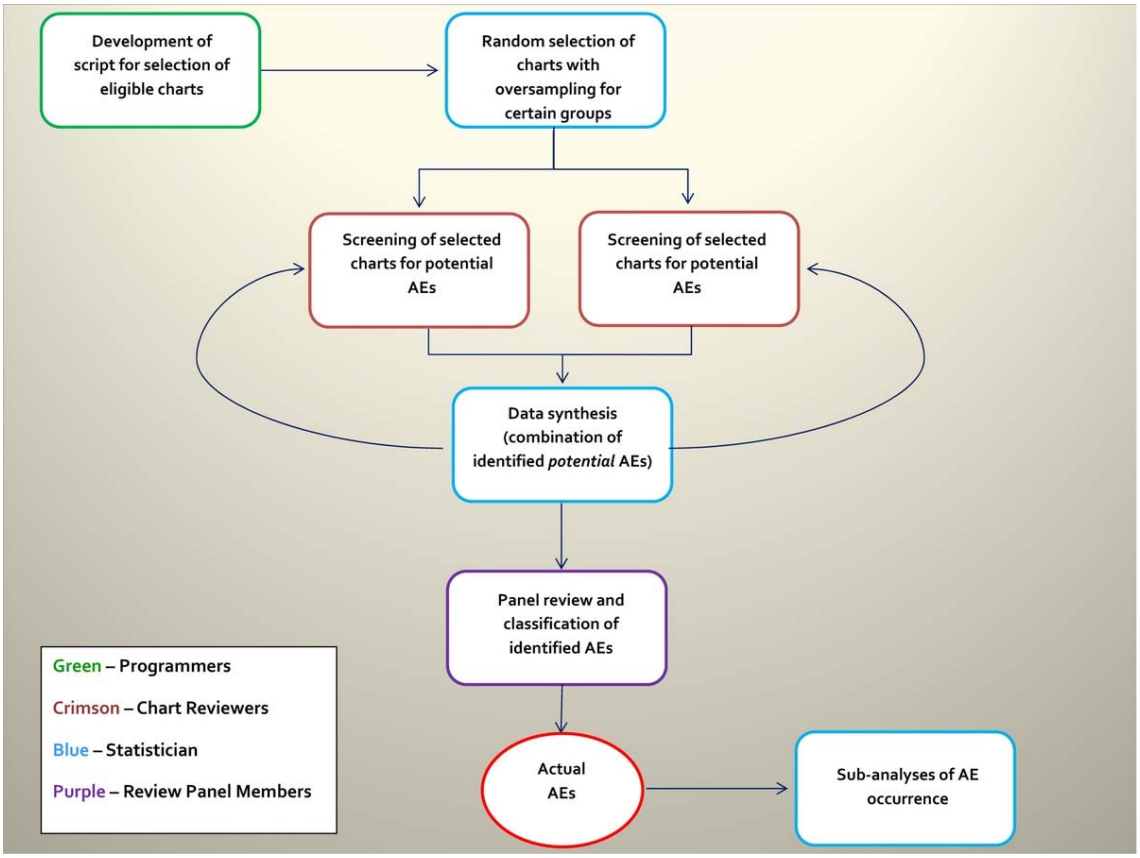

FIGURE 2: Dental practice study random chart review: process to identify dental AEs.

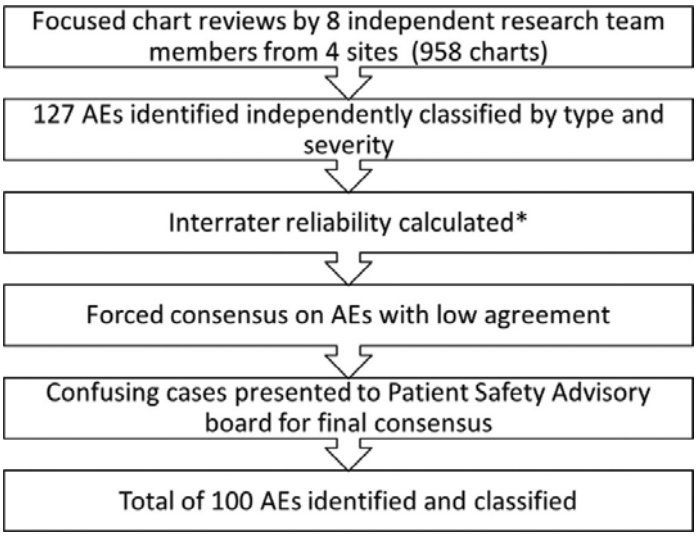

FIGURE 3: Chart review project using triggers: process to identify dental AEs.

Focus Groups and Domain Expert Interviews

Through focus groups and in-depth interviews, dental providers and domain experts were asked to identify the types of AEs that may occur in dental settings. The identified AEs were

categorized according to a novel dental AE category (Table 1).[15] A previously developed severity scale[15] was assigned to each AE (Fig. 4).

TABLE 1 - Dental AE Classification

Allergy/Toxicity/FB Response	Hard Tissue Injury
Aspiration/ingestion of an FB	Soft tissue injury
Infections	Nerve injury
Wrong site, wrong patient, wrong procedure	Other systemic complications
Bleeding	Other orofacial complications
Pain	Other harm

FB, foreign body.

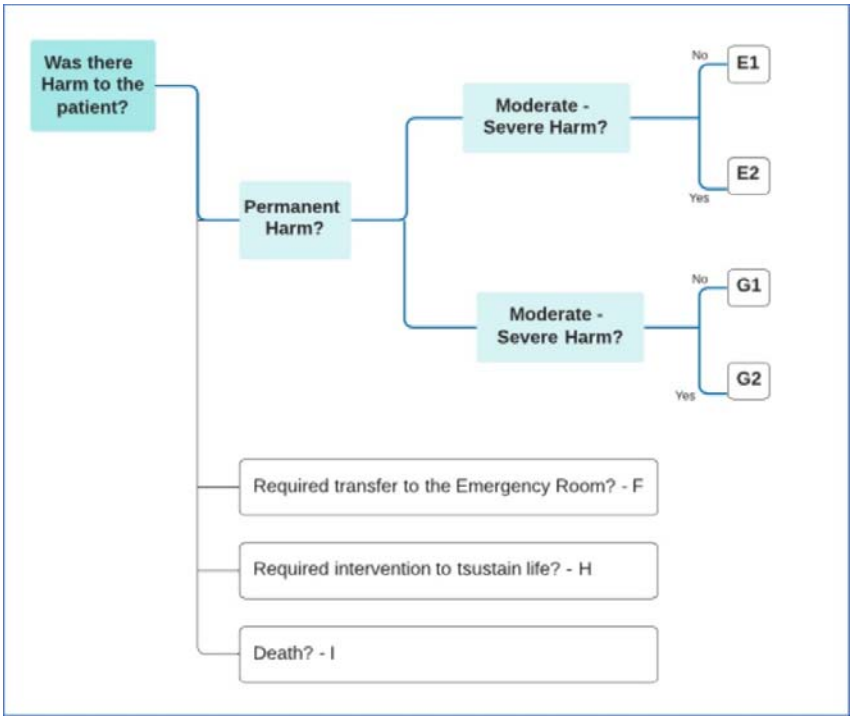

FIGURE 4: Severity scale for dental AEs.

RESULTS

A total of 1086 total AEs were classified. After removing duplicates, 108 unique allergy/toxicity/foreign body response, 70 aspiration/ingestion of foreign body, 70 infection, 52 wrong site/wrong patient/wrong procedure, 23 bleeding, 48 pain, 149 hard tissue injury, 127 soft tissue injury, 91 nerve injury, 171 other systemic complication, and 177 other orofacial complication were found. Both "known" (i.e., MAUDE database, chart reviews, literature review) and "hypothetical" (focus group, domain expert interview) sources were successful at identifying AEs across all AE types. Specifically, exploring the known sources identified about one-third of the AEs, while interviews and focus groups with providers identified almost all of the AEs. "Known" sources most frequently identified other systemic complications AEs (5% of all AEs), while "hypothetical" sources most often noted other orofacial complications AE types (12% of all AEs). Among the AEs identified by "known" sources, wrong site/wrong

TABLE 2 - Adverse Events Noted by All Sources, With Most and Least Common Subtypes

AE Type	n	% of All AEs	Known Source (% of All AEs)	Hypothetical Source (% of All AEs)	Most Common Subtype	Least Common Subtype
Allergy/toxicity/fb response	108	10%	6%	6%	Allergic reaction	FB response
Aspiration/ingestion FB	70	6%	1%	5%	Aspiration	Ingestion
Infection	70	6%	2%	4%	Unspecified	Acute infection
Wrong site, wrong patient, wrong procedure	52	5%	1%	4%	Wrong procedure	Wrong patient
Bleeding	23	2%	1%	1%	Other bleeding	Hematoma
Pain	48	4%	3%	2%	Pain	Sensitivity
Hard tissue injury	149	14%	4%	9%	Other	Evulsion
Soft tissue injury	127	12%	3%	9%	Lacerations, cysts	Abrasion
Nerve injury	91	8%	4%	5%	Motor loss	Palsy/paralysis
Other systemic complication	171	16%	5%	11%	Unspecified	Digestive issues
Other orofacial complication	177	16%	3%	12%	Unspecified	Neck-related issues
Total	1086	100%	31%	69%		

FB, foreign body.

patient/wrong procedure, aspiration/ingestion, and bleeding AEs were least common (1% each). Among AEs noted by "hypothetical" sources, bleeding AEs was also the least common (1%). See Table 2.

Within each AE type, the AEs were broken down into subtypes. The allergic/toxicity/foreign body response AEs were mostly (61%) identified as allergic reactions and rarely (1.8%) identified as a foreign body response. Approximately half (54%) of all aspiration/ingestion AEs were aspirations. Seventy-five percent of wrong site/wrong patient/wrong procedure AEs consisted of wrong procedures; wrong patient was the least common wrong site/wrong patient/wrong procedure AE (1.9%). A total of 85.4% of pain AES were directly related to pain, as opposed to sensitivity (14.6%). A total of 14.2% of soft tissue injury AEs were identified as lacerations, while cysts and abrasions were both the least common soft tissue injury AEs (2.4% each). Twenty-two percent of the nerve injury AEs were identified as motor loss with only 4.4% as palsy/paralysis. The most common subtype for the remaining AE types (e.g., infection, bleeding, hard tissue injury, other systemic complication, and other orofacial complication) fell into the "other/unspecified" subcategory, indicating perhaps more specific subtypes are needed to subcategorize these dental AEs. Digestive issues (2%) were least common among other systemic complication AEs; neck-related AEs (1.1%) were least common among other orofacial complication AEs; hematomas were least common (26%) among bleeding AEs; and extraction/evulsion AEs were the least common (2.5%) among hard tissue injury AEs. See Table 2.

DISCUSSION

Our inventory was compiled using known and hypothetical sources. Known sources are areas of information that convey real AEs. Hence, they include the actual patient record, databases that capture actual AEs, case reports that document actual events, chart reviews, and patient reports. The most prevalent AEs reported in the literature are delayed appropriate treatments and wrong or unnecessary treatments, often associated with misdiagnosis.[10] These published case reports provide an excellent window into understanding the nature and extent of dental AEs. However, they must be seen as siloed and incomplete contributions to dentistry's understanding of AEs. The one database that includes dental AEs, the FDA MAUDE database, showed that the top 6 devices involved with dental AEs were related to implant placement. The failure to osseointegrate was the most common complaint noted in the MAUDE database.[11] Patients have proven to be reliable AE reporters: in one study, almost half of the patients reported that they had experienced a dental-related safety event and approximately 15% said that it had lasted for several months to years.[10] Focused chart reviews, using specific triggers (scripts), have been proven to be a better source of AEs than random chart review (Table 3). Specifically, the triggers to find AEs related to failed implant AEs and soft tissue injury seem promising.

Hypothetical sources are the areas of information where AEs are theorized about by experts as a probable event. The hypothetical sources, thus, include the information received through domain expert interviews and focus groups. Collectively, they most often identified other systemic complications and other orofacial complications as probable AEs.[15] It is notable that the AEs most frequently mentioned (e.g., systemic events, death) by these individuals were far less often identified by the known sources, that is, in the actual dental setting. It is possible that the dental professionals who participated in these interviews and focus groups frequently mentioned and/or extensively discussed the AEs they are most worried about occurring, even if those events occur rarely and good systems are in place to prevent them. Furthermore, while

TABLE 3 - Trigger Performance Comparison

	Pilot (2015)				**Actual (2017)**			
Trigger Name	**Total Charts Reviewed**	**Charts With AEs**	**Total AEs Found**	**Charts With Trigger AE (PPV, 95% CI)**	**Total Charts Reviewed**	**Charts With AEs**	**Total AEs Found**	**Charts With Trigger AE (PPV, 95% CI)**
Extraction following RCT/crown/filling	99	9	**9**	9 (0.09) (0.05–0.17)	173	20	**23**	7 (0.04, 0.018–0.085)
Failed implant	34	7	**7**	7 (0.21, 0.09–0.38)	196	46	**47**	41 (0.21, 0.16–0.27)
Post–surgical extraction or post–period treatment complications	100	16	**16**	16 (0.16, 0.09–0.25)	—	—	—	—
Nerve injury	36	7	**7**	7 (0.19, 0.09–0.37)	477	70	**75**	35 (0.07, 0.05–0.10)
Infections	100	29	**33**	28 (0.28, 0.19–0.38)	363	83	**88**	73 (0.20, 0.16–0.25)
Soft tissue injury	100	7	**9**	7 (0.07, 0.031–0.14)	285	50	**52**	36 (0.13, 0.09–0.17)
Allergy/toxicity/FB response	35	8	**8**	8 (0.23, 0.11–0.40)	215	20	**20**	14 (0.07, 0.04–0.11)
Aspiration/ingestion FB	68	1	**1**	1 (0.015, 0.0007–0.09)	176	16	**16**	7 (0.04, 0.02–0.08)

Bold type indicates the number of AEs found in the charts that had an AE. Some charts had more than one AE.
CI, confidence interval; FB, foreign body; PPV, positive predictive value; RCT, root canal treatment.

pain was mentioned infrequently compared with other AEs, it was prominently found as an AE or second AE despite having no specific triggers explicitly looking for it. In the authors' ongoing work in this area, they are finding increasing evidence of pain as an AE (Table 4).

TABLE 4 - The Percent Distribution of Dental AE and the Perceived Distribution

Dental AE Categories	**Observed Dental AE Distribution, %***	**Provider Perceived Dental AE Distribution, %†**
Quality of care	—	10
Allergy/toxicity/FB response	0	4
Aspiration/ingestion of FB	0	8
Wrong site/wrong patient/wrong procedure	0	16
Bleeding	3	4
Nerve injury	4	7
Other systemic complications	4	4
Other orofacial complications/other	11	12
Soft tissue injury	14	13
Infection	14	5
Hard tissue injury	21	15
Pain	28	2

*There were 71 observed dental AEs.
†There were 747 unique reviewed dental AEs.
FB, foreign body.

As we compiled this first-ever dental AEs inventory, we were struck by the lack of standardization among dental professionals regarding AEs as well as methods to capture them. To date, the FDA MAUDE database is the only mechanism people can use to report dental AEs, while other medical fields have a variety of reporting databases, although these tend to be fragmented and focus mainly on never events. In addition, any other current existing state databases are not accessible to patients or employers and, as such, do not provide a medium for learning opportunities. As we work to develop a comprehensive dental database for AEs, we should consider how to make it available to patients and particularly consider using layman's terms as synonyms to make it easily accessible.

The establishment of a standardized dental AE database has tremendous implications for future use. For comparison, developed in 2003, the National Reporting and Learning System (NRLS) collects data from all National Health Service organizations to its central database of patient safety incident reports in England and Wales.[16] It reported 2,246,622 incidents from April 2019 to March 2020, a 10.3% increase from the previous year, continuing its upward trend. Incidents are categorized by type, setting, and degree of harm. The NRLS was developed as a system to support learning and develop a culture of safety. Its ongoing increase in incidence reporting reflects "a constantly improving reporting culture, providing more opportunities to learn and reduce the risk of harm to patients."[17] This database allows for the identification of hazards and offers opportunities to improve safety in patient care. Specifically, the NRLS provides patient safety alerts, patient safety guides, regular feedback based on the collected data, and safety information on specific topics.[16] In all, this provides tremendous learning opportunities and allows for the development of systems to continuously improve patient care.

One of the challenges of developing an active AE database is that the organization will likely have to undergo the process of registering as a patient safety organization (PSO). Congress developed the federal Patient Safety and Quality Improvement Act of 2005 and the final patient safety rule, which is overseen by the AHRQ,[18] became effective in January 2009. The act extends confidentiality and privilege protections to (1) eligible information developed by providers for reporting to a PSO, (2) analyses conducted by the PSO, and (3) development of information by the PSO for the conduct of patient safety activities. Patient safety organizations must collect and analyze data in a standardized manner. The AHRQ has created forms that use common definitions and reporting formats to facilitate the collection and reporting of patient safety events. There are a total of 82 PSOs listed by AHRQ, with just one, the recently formed Dental Patient Safety Foundation (DPSF), related to dentistry.[19] The DPSF's focus mainly covers AEs related to anesthesia, infection control, medical emergency preparedness, environmental and clinical issues, and provider/staff health.[20]

LIMITATIONS

The dental AE compilation presented here is not meant to be an exhaustive list. Rather, we consider it a living document that should be updated as new technology and new diseases come into play and more sources of input become available. We urge patients, providers, vendors, and family members to add to the inventory of dental AEs by going to the DPSF Web site (https://www.dentalpatientsafety.org).

CONCLUSIONS

Standardizing the language of dental AEs is an important first step toward patient safety for the dental patient. Using a multimodal approach, a broad list of dental AEs was developed, in which the AEs were grouped in 12 major categories. Many of the AEs in these categories were also divided by subtype. The most frequent AEs identified through interviews (other orofacial and other systemic complications) occur far less often in actuality. Hard tissue injury was noted frequently during interviews and was in fact one of the most frequent AEs identified in actuality. Pain was the unexpectedly AE that was consistently identified with every modality used.

REFERENCES

1. Agency for Healthcare Research and Quality. *AHRQ's Patient Safety Initiative: Building Foundations, Reducing Risk: Interim Report to the Senate Committee on Appropriations*. MD: Rockville; 2003.
2. Ramoni RB, Walji MF, White J, et al. From good to better: toward a patient safety initiative in dentistry. *J Am Dent Assoc*. 2012;143:956–960.
3. Kizer KW, Stegun MB. Serious reportable adverse events in health care. In: Henriksen KBJ, Marks ES, et al., eds. *Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools, and Products)*. Rockville, MD: Agency for Healthcare Research and Quality; 2005.
4. TransCelerate BioPharma Inc. Value of safety information data sources. TransCelerate BioPharma, Inc. 2012–2021. Available at: http://www.transceleratebiopharmainc.com/initiatives/value-of-safety-information-data-sources/. Accessed April 27, 2021.
5. Food and Drug Administration Guidance for Industry. E2F Development Safety. Update Report Rockville, MD: U.S. Department of Health and Human Services.

2011. Available at: https://www.fda.gov/downloads/drugs/guidances/ucm073109.pdf. Accessed April 27, 2021.
6. Garrouste-Orgeas M, Philippart F, Bruel C, et al. Overview of medical errors and adverse events. *Ann Intensive Care*. 2012;2.
7. U.S. Department of Health and Human Services About VAERS. Rockville, MD: U.S. Department of Health and Human Services. Available at: https://vaers.hhs.gov/about.html. Accessed April 27, 2021.
8. Centers for Disease Control and Prevention selected adverse events reported after COVID-19 vaccination. 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html. Accessed April 27, 2021.
9. Farley DO, Damberg CL. Evaluation of the AHRQ patient safety initiative: synthesis of findings. *Health Serv Res*. 2009;44:756–776.
10. Obadan EM, Ramoni RB, Kalenderian E. Lessons learned from dental patient safety case reports. *J Am Dent Assoc*. 2015;146:318–26.e2.
11. Hebballi NB, Ramoni R, Kalenderian E, et al. The dangers of dental devices as reported in the Food and Drug Administration Manufacturer and User Facility Device Experience Database. *J Am Dent Assoc*. 2015;146:102–110.
12. Kalenderian E, Walji MF, Tavares A, et al. An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office. *J Am Dent Assoc*. 2013;144:808–814.
13. Walji MF, Yansane A, Hebballi NB, et al. Finding dental harm to patients through electronic health record–based triggers. *JDR Clin Trans Res*. 2020;5:271–277.
14. Tokede O, Walji M, Ramoni R, et al. Quantifying dental office-originating adverse events: the Dental Practice Study Methods. *J Patient Saf*. 2017.
15. Maramaldi P, Walji MF, White J, et al. How dental team members describe adverse events. *J Am Dent Assoc*. 147:803–811.
16. NHS England Welcome to NRLS Reporting. London, England: 2021. Availablet at: https://report.nrls.nhs.uk/nrlsreporting/. Accessed April 27, 2021.
17. NHS England and NHS Improvement NRLS national patient safety incident reports: commentary. London, England: 2020. Available at: https://www.england.nhs.uk/wp-content/uploads/2020/03/NAPSIR-commentary-Sept-2020-FINAL.pdf. Accessed April 27, 2021.
18. Center for Patient Safety What Is a Patient Safety Organization (PSO). Chesterfield, MO: Center for Patient Safety. 2020. Available at: http://www.centerforpatientsafety.org/pso/what-is-a-patient-safety-organization-pso/. Accessed April 27, 2021.
19. Agency for Healthcare Research and Quality Patient Safety Organization (PSO) Program. Rockville, MD. Available at: https://www.pso.ahrq.gov/listed. Accessed April 27, 2021.
20. Dental Patient Safety Foundation Dental Patient Safety Foundation. Orland Park, IL. 2018. Available at: https://www.dentalpatientsafety.org. Accessed April 27, 2021.