

Title	Lead Author	Journal	Year	AMA/APA Citation	Notes
An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office	Kalendarian	Journal of the American Dental Association	2013	Kalendarian E, Walji M, Tavares A, Ramoni R. An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office. <i>Journal Of The American Dental Association (1939)</i> [serial online]. July 2013;144(7):808-814. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.	<p>AE definition: “Harm caused by medical treatment, regardless [of] whether it is associated with error or considered preventable. ...It is from the point of view of a patient that harm can sometimes be easily ascertained: ‘If I were the patient, would I be happy if this happened to me?’” – a very broad umbrella definition.</p> <p>Describes a “trigger” or, search tool with trigger words, for inclusion of a chart for review for Adverse Events. Three triggers framed to gain insight into AEs – Incision and Drainage Trigger (CDT C7510 and D7520), Implant Failure Trigger (CDT D6100 EZCode 563101), Multiple-Visits Trigger (>6 visits)</p> <p>Calculated positive predictive values for each trigger, showing the likelihood of a trigger presenting a record with a true AE.</p> <p>“In [the] study population, more than one-third of the randomly selected patients had experienced and AE.” – This is of a random selection, i.e. not those “triggered” records.</p> <p>“Our study results show that the trigger tool approach is capable of identifying AEs more efficiently: 50 percent of records that were positive for any of the three dental triggers contained an AE, whereas 34 percent of randomly selected patient records indicated an AE.”</p> <p>It is their recommendation that “all dental care teams should initiate regular assessments of AEs that occur within their practices, including conducting records reviews.”</p> <p>“In the context of the trigger tool, an AE involves harm to the patient, regardless of whether the AE is associated with error... Focusing on errors shifts the discussion toward individual blame, whereas concentrating on events experienced by patients helps to keep the focus on systemic improvement to reduce patients’ suffering.”</p>
				Kalendarian, E., Walji, M. F., Tavares, A., & Ramoni, R. B. (2013). An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office. <i>Journal Of The American Dental Association (1939)</i> , 144(7), 808-814.	
An analysis of dental patient safety incidents in a patient complaint and healthcare supervisory database in Finland	Hiivala	Acta Odontologica Scandinavica	2016	Hiivala N, Mussalo-Rauhamaa H, Tefke H, Murtomaa H. An analysis of dental patient safety incidents in a patient complaint and healthcare supervisory database in Finland. <i>Acta Odontologica Scandinavica</i> [serial online]. 2016;74(2):81-89. Available from: MEDLINE, Ipswich, MA. Accessed July 26, 2017.	<p>Each incident was assigned to one of eight types of PSI (Patient Safety Incident) – diagnostics, dental treatment, equipment and supplies, medications or prescription drugs, hygiene or infection control, communication, physical environment related and other.</p> <p>Patient safety: The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.</p> <p>Patient safety incident: An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. An incident can be reportable circumstance, a near miss, a no harm incident or a harmful incident (adverse event)</p> <p>Harmful incident (adverse event): An incident which resulted in harm to the patient</p> <p>“In primary care other than dentistry, diagnostic errors account for the majority of malpractice claims followed by medication errors... Most dental patient allegations concern treatment and diagnostics, while PSIs are most often related to treatment, diagnostics, communication, dental equipment and medications.”</p>
				Hiivala, N., Mussalo-Rauhamaa, H., Tefke, H., & Murtomaa, H. (2016). An analysis of dental patient safety incidents in a patient complaint and healthcare supervisory database in Finland. <i>Acta Odontologica Scandinavica</i> , 74(2), 81-89. doi:10.3109/00016357.2015.1042040	
Attitudes toward patient safety standards in U.S.	Leong	Journal of Dental Education	2008	Leong P, Afrow J, Weber H, Howell H. Attitudes toward patient safety standards in U.S. dental schools: a pilot study. <i>Journal Of Dental Education</i> [serial	“The purpose of this study was to test the hypothesis that the patient safety culture in US dental school clinics is less developed than in hospitals by utilizing a survey instrument developed to measure patient safety culture in US hospitals.” – They found that “there are areas of perceived weakness in the patient safety culture of the dental schools visited.”

dental schools: a pilot study			online]. April 2008;72(4):431-437. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.	<p>AHRQ Hospital Survey on Patient Safety Culture.</p> <p>“All three dental groups (faculty, staff, and students) surveyed gave less positive responses to the three questions on the reporting of problems than the medical benchmark. There could be several reasons for the less positive responses including the lack of a user-friendly reporting system in dental school clinics and the lack of feedback to all three dental groups about the usefulness of incident reports and changes made to reduce errors as a result of timely reporting.”</p> <p>“The dental school survey respondents rated dental schools lower than the medical benchmark in the area of proactive activities toward patient safety. Few of the sites visited had a process in place to summarize and trend patient safety incident data that would allow them to focus on preventive rather than reactive activities.”</p>																																																																																																																																																																
BigMouth: A multi-institutional dental data repository	Walji	Journal of the American Dental Association	<p>2014</p> <p>Walji M, Kalenderian E, Ramoni R, et al. BigMouth: a multi-institutional dental data repository. <i>Journal Of The American Medical Informatics Association: JAMIA</i> [serial online]. November 2014;21(6):1136-1140. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Walji, M. F., Kalenderian, E., Stark, P. C., White, J. M., Kookal, K. K., Phan, D., & ... Ramoni, R. (2014). BigMouth: a multi-institutional dental data repository. <i>Journal Of The American Medical Informatics Association: JAMIA</i>, 21(6), 1136-1140. doi:10.1136/amiajnl-2013-002230</p>	<p>Work to develop a data repository of EHRs.</p> <p>“Secondary uses of data already stored in dental EHRs have great potential to improve the data-driven knowledge base in dentistry and answer basic questions such as ‘how long do tooth-colored fillings last?’ and ‘how often do patients with diabetes receive the recommended periodontal screenings?’ Linking data from dental EHRs with medical EHRs may also clarify the relationship between oral and general health.”</p> <p>BigMouth is a limited dataset – patients are de-identified with the exception of dates and zip codes.</p>	<p>Table 2 Demographic characteristics, oral health status, and selected procedures of patients in the clinics of four dental schools in the BigMouth Dental Data Repository database between January 1, 2010 and December 31, 2011</p> <table border="1"> <thead> <tr> <th rowspan="2"></th> <th colspan="4">School of dentistry</th> </tr> <tr> <th>School 1</th> <th>School 2</th> <th>School 3</th> <th>School 4</th> </tr> </thead> <tbody> <tr> <td>Demographics</td> <td>N=15 219</td> <td>N=34 126</td> <td>N=34 318</td> <td>N=13 927</td> </tr> <tr> <td>Mean age (SD)</td> <td>48 (17.0)</td> <td>47 (17.8)</td> <td>50 (23.2)</td> <td>45 (17.5)</td> </tr> <tr> <td>Sex (%)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td> Male</td> <td>42.4</td> <td>46.1</td> <td>45.3</td> <td>39.2</td> </tr> <tr> <td> Female</td> <td>55.7</td> <td>53.9</td> <td>53.3</td> <td>55.9</td> </tr> <tr> <td> Others/don't know</td> <td>1.9</td> <td>0.0</td> <td>1.4</td> <td>4.9</td> </tr> <tr> <td>Diagnosis</td> <td>N=6227</td> <td>N/A</td> <td>N=10 451</td> <td>N=3775</td> </tr> <tr> <td>Defective restoration (%)</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td> Open margin</td> <td>4.6</td> <td></td> <td>5.6</td> <td>1.7</td> </tr> <tr> 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Classifying Adverse Events in the Dental Office	Kalenderian	Journal of Patient Safety	<p>2017</p> <p>Kalenderian E, Obadan-Udoh E, Walji M, et al. Classifying Adverse Events in the Dental Office. <i>Journal Of Patient Safety</i> [serial online]. June 30, 2017; Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Kalenderian, E., Obadan-Udoh, E., Maramaldi, P., Etolue, J., Yansane, A., Stewart, D., & ... Walji, M. F. (2017). Classifying Adverse Events in the Dental</p>	<p>TABLE 1. Dental AE Type Classification</p> <table border="1"> <thead> <tr> <th>AE Category</th> <th>AE Count</th> </tr> </thead> <tbody> <tr> <td>Pain</td> <td>56</td> </tr> <tr> <td>Infection</td> <td>17</td> </tr> <tr> <td>Hard tissue damage</td> <td>12</td> </tr> <tr> <td>Nerve injury</td> <td>6</td> </tr> <tr> <td>Soft tissue damage/inflammation</td> <td>5</td> </tr> <tr> <td>Other orofacial harm</td> <td>2</td> </tr> <tr> <td>Allergy, toxicity, or foreign body response</td> <td>1</td> </tr> <tr> <td>Aspiration or ingestion of foreign body</td> <td>1</td> </tr> <tr> <td>Wrong site, wrong patient, or wrong procedure</td> <td>0</td> </tr> <tr> <td>Bleeding</td> <td>0</td> </tr> <tr> <td>Other systemic harm</td> <td>1</td> </tr> <tr> <td>Other harm</td> <td>0</td> </tr> <tr> <td>Total</td> <td>101</td> </tr> </tbody> </table>	AE Category	AE Count	Pain	56	Infection	17	Hard tissue damage	12	Nerve injury	6	Soft tissue damage/inflammation	5	Other orofacial harm	2	Allergy, toxicity, or foreign body response	1	Aspiration or ingestion of foreign body	1	Wrong site, wrong patient, or wrong procedure	0	Bleeding	0	Other systemic harm	1	Other harm	0	Total	101	<p>“Harm refers to any ‘impairment of structure or function of the body and/or any deleterious effect arising there from.’” However, “dental AEs do not neatly fit into the categories developed in the medical realm.”</p> <p>Developed a Dental AE Type Classification – handpicked by consensus with input from an advisory committee, which was then pilot tested via a chart review process.</p> <p>They used the same dental triggers as described previously, with the caveat that “a ‘trigger’ is an opportunity or clue used to identify AEs in a patient’s dental record but do not represent AEs themselves.” When reviewing these records, “it is important to realize the difference between harm and contributing factors that may lead to harm”</p>																																																																																																																																			
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				<p>Office. <i>Journal Of Patient Safety</i>, doi:10.1097/PTS.0000000000000407</p> <p>“The patient safety revolution can be traced to the seminal Institute of Medicine seminal report, ‘To Err is Human.’ It states that quality consist[s] of the following three domains: (1) safety, defined as “freedom from accidental injury”; (2) practice consistent with current medical knowledge and best practice; and (3) responsiveness to customer-specific values, expectations and preferences.”</p> <ul style="list-style-type: none"> - This could be expanded for the use in pilot projects: monitoring for patient safety and quality includes the imperative to make sure the patients are (1) free from accidental injury, (2) receive care equivalent to the quality found in existent dental best practice and (3) receiving care according to their expectations and needs. (Note: work on this concept a bit more). <p>The authors also posit a Dental AE Severity Tree in Figure 1 for classifying AEs into several categories. These categories can help delineate reporting requirements and timelines for AEs as well as help guide root cause analysis in chart reviews.</p>	
Clinical documentation of dental care in an era of electronic health record use	Tokede	The Journal of Evidence-Based Dental Practice	2016	<p>Tokede O, Ramoni R, Patton M, Da Silva J, Kalenderian E. Clinical documentation of dental care in an era of electronic health record use. <i>The Journal Of Evidence-Based Dental Practice</i> [serial online]. September 2016;16(3):154-160. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Tokede, O., Ramoni, R. B., Patton, M., Da Silva, J. D., & Kalenderian, E. (2016). Clinical documentation of dental care in an era of electronic health record use. <i>The Journal Of Evidence-Based Dental Practice</i>, 16(3), 154-160. doi:10.1016/j.jebdp.2016.07.001</p>	<p>“Regardless of any true consensus on the ideal content of a ‘good’ dental record, patient care is clearly not served if practitioners and allied health professionals do a suboptimal job of documenting and maintaining records.”</p> <p>Provider feedback sought through a Delphi process on “what a typical dental clinical record should contain and the frequency of update of each entry.”</p> <p>“Although the ADA and the AAPD provide a list of what should be included in a dental record, they do not at this time provide guidance as to how often those should be updated.”</p> <p>“health care providers resent forces that decrease the amount of time available for patient care or for other needs.”</p> <p>“Dental providers agree that complete and accurate record keeping is essential to patient care and those items such as histories, examination findings, diagnosis, radiographs, treatment plans, consents, and clinic notes should be recorded. There, however, does not seem to be universal agreement on how frequently such items should be recorded in the dental record.”</p>
From good to better: toward a patient safety initiative in dentistry	Ramoni	Journal of the American Dental Association	2012	<p>Ramoni R, Walji M, Kalenderian E, et al. From good to better: toward a patient safety initiative in dentistry. <i>Journal Of The American Dental Association</i> (1939) [serial online]. September</p>	<p>Four element patient safety initiative from AHRQ to minimize patient safety hazards:</p> <p>Element 1: Identifying threats to patient safety. “Two approaches that have proven successful in medicine are adverse event reporting systems (AERSs) and focused chart reviews.” Another important part would be a list of “never-events” such as wrong site surgery that should never happen.</p>

				<p>2012;143(9):956-960. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Ramoni, R. B., Walji, M. F., White, J., Stewart, D., Vaderhobli, R., Simmons, D., & Kalenderian, E. (2012). From good to better: toward a patient safety initiative in dentistry. <i>Journal Of The American Dental Association (1939)</i>, 143(9), 956-960.</p>	<p>Element 2: Identifying and evaluating effective patient safety practices. Root cause analyses and health care failure mode and effect analyses (HFMEA) are two approaches that have been refined in the medical field. Root cause analysis is retrospective; the objective is to find the root, or underlying, cause of the event or near miss. HFMEA is prospective; the intention is to evaluate a health care process to identify potential vulnerabilities. "The focus of the HFMEA is defined on the basis of information regarding the prevalence and severity of adverse events or patient risk factors."</p> <p>Element 3: Educate, disseminate, implement and raise awareness. Within dentistry, the Organization for Safety, Asepsis and Prevention distributes best-practice information in the area of infection control, including a checklist for dental offices.</p> <p>Element 4: Continually monitor and evaluate threats to patient safety to ensure that a positive safety culture is maintained and a safe environment continues.</p>
Fundamentals of a patient safety program	Frush	Pediatric Radiology	2008	<p>Frush K. Fundamentals of a patient safety program. <i>Pediatric Radiology</i> [serial online]. November 2008;38 Suppl 4:S685-S689. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Frush, K. S. (2008). Fundamentals of a patient safety program. <i>Pediatric Radiology</i>, 38 Suppl 4S685-S689. doi:10.1007/s00247-008-0882-1</p>	
How dental team members describe adverse events	Maramaldi	Journal of the American Dental Association	2016	<p>Maramaldi P, Walji M, Kalenderian E, et al. How dental team members describe adverse events. <i>Journal Of The American Dental Association (JADA)</i> [serial online]. October 2016;147(10):803. Available from: MasterFILE Premier, Ipswich, MA. Accessed July 26, 2017.</p>	

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Defined AEs as “harm caused to the patient by dental care, regardless of whether it is associated with an error or is considered preventable.”
 “Our work includes proposing the adoption of the Agency for Healthcare Research and Quality’s patient safety initiative which incorporates 4 major elements to address patient safety: identifying threats to patient safety; identifying and evaluating effective patient safety practices; educating, disseminating, implementing, and raising awareness; and monitoring threats to patient safety to ensure that a positive safety culture is maintained and a safe environment continues.”
 Goal of this study was to develop an inventory of AEs generated by interviewing dental team members.
 “Examples of reported dental AEs include aspirated crowns and lacerations due to the use of high-speed handpieces.” Analyses indicated that respondents confused causes with AEs. “Aspiration or ingestion was cited the most, whereas pain was cited the least.”
 “An unanticipated finding was the number of identified AEs that we classified as quality-of-care issues.”... “an incident would have to ‘stand the test of our peers,’ meaning that our colleagues would most likely agree that the event could indeed be considered an AE. Examples included most often were those for which the actual harm was not easily identifiable or ‘defensible to our peers,’ such as esthetic issues after treatment, a failed provisional crown, or an underfill of an endodontically treated canal.”
 – Think more about this.

TABLE 2
Dental adverse event classifications based on Agency for Healthcare Research and Quality classifications for medical errors with examples.⁴⁷

ADVERSE EVENT CLASSIFICATION	RESPONSES FROM RESPONDENTS (UNWEIGHTED)
Allergy, Toxicity, or Foreign Body Response	<ul style="list-style-type: none"> Nitrous oxide toxicity Allergic reaction to dental materials Drug-drug interactions Upper vascular epinephrine injections resulting in rare allergic reactions
Aspiration or Ingestion of Foreign Body	<ul style="list-style-type: none"> Tracheostomy resulting from aspiration of foreign body Swallowed components Aspiration of teeth Swallowing of orthodontic brackets
Infection	<ul style="list-style-type: none"> Sinusitis due to unintended sinus lift Infection postsurgery Medication-induced candidiasis Development of a deep space infection warranting additional treatment
Procedure on Wrong Site or Wrong Side, Procedure on Wrong Patient, Wrong Treatment Due to Misdiagnosis, or Other Wrong Treatment Errors	<ul style="list-style-type: none"> Failed crowns due to wrong material selection Treating the wrong tooth Endodontic treatment of nonrestorable teeth Performing surgical procedure in the wrong area
Bleeding	<ul style="list-style-type: none"> Perforation of arteries during surgical procedure Postsurgical complications: hematoma Anesthetic complication resulting in bleeding Excessive bleeding of the donor site after soft-tissue grafting
Pain	<ul style="list-style-type: none"> Root sensitivity after dental surgery Inadequate anesthesia resulting in pain Excessive pain after oral surgery Inaccurate crown adjustment leading to tooth pain, discomfort, and temporomandibular disorder
Hard-Tissue Damage	<ul style="list-style-type: none"> Bone fracture during extraction Bur injury to adjacent tooth Root fractures in the process of placing posts Mandible fracture during third-molar extraction
Soft-Tissue Injury or Inflammation	<ul style="list-style-type: none"> Lip laceration Improper elevator use resulting in damage to floor of the mouth Injuries to soft tissue during debonding in orthodontics Swelling after osseous surgery
Nerve Injury	<ul style="list-style-type: none"> Mandibular nerve injury Improper location of injection to parotid gland causing temporary paralysis of facial nerve Surgical damage to the posterior, superior alveolar nerve Nerve damage during placement of the implant
Other Systemic Complications	<ul style="list-style-type: none"> Seizure induced by dental treatment Cardiac depression due to anesthesia overdose Ingestion of fluoride resulting in irritation to gastrointestinal lining Development of degenerative joint disease after orthognathic surgery
Other Harm	<ul style="list-style-type: none"> Damage to the patient’s dental appliances Unintentional laser burns causing vision damage Provider communication resulting in patient anxiety Unintended harm to adjacent anatomic structures when using any instrumentation
Quality-of-Care Issue	<ul style="list-style-type: none"> Delivering poor-fitting dentures Impression material lodged in mouth Poor-fitting crowns Esthetic failure, crowns are completely different color than patient’s teeth

⁴⁷ Source: Agency for Healthcare Research and Quality.

Lessons learned from dental patient safety case reports

Obadan

Journal of the American Dental Association

2015

Obadan E, Ramoni R, Kalenderian E. Lessons learned from dental patient safety case reports. *Journal Of The American Dental Association (JADA)* [serial online]. May 2015;146(5):318. Available from: MasterFILE Premier, Ipswich, MA. Accessed July 26, 2017.

Obadan, E. M., Ramoni, R. B., & Kalenderian, E. (2015). Lessons learned from dental patient safety case reports. *Journal Of The American Dental Association (JADA)*, 146(5), 318. doi:10.1016/j.adaj.2015.01.003

Overview of Dental Adverse Events by Type of Harm.

Type of Harm [†]	Example of Patient Harm	Frequency (n)	Percent (%) [*]
		<i>n</i> =270	100
Delayed appropriate treatment/ disease progression and/ or unnecessary treatment associated with misdiagnosis	Melkersson-Rosenthal syndrome misdiagnosed as angioedema and dental abscess resulting in multiple tooth extractions	62	23.0
Other systemic complications including adverse reactions to dental device/material/procedure	Intracerebral hematoma after tooth extraction	57	21.1
Allergy/ Hypersensitivity reactions	Latex allergy (bitewing radiograph pack, rubber dam, prophylaxis cup)	29	10.7
Systemic infection	Cerebral abscess after dental procedure	28	10.4
Soft tissue injury/ inflammation	Accidental injection of formalin into soft tissues instead of local anesthetic	23	8.5
Aspiration of foreign body	Aspiration of rubber mouth prop	11	4.1
Nerve damage or injury	Paresthesia of infraorbital region	11	4.1
Hard-tissue damage	Root perforation during endodontic treatment	8	3.0
Psychological distress/ disorder	Anorexia nervosa induced by painful orthodontic treatment	7	2.6
Toxicity/ drug overdose	Injection of 1:1000 adrenaline versus 1:100,000	7	2.6
Orofacial infection	Necrotizing fasciitis of infraorbital region	6	2.2
Poor hemostasis/ prolonged bleeding	After traumatic tooth extraction in hemophilic patient	6	2.2
Ingestion of foreign body	Ingestion of endodontic file	5	1.9
Other orofacial complications	Tear of suspensory ligaments in temporomandibular after excessive digital manipulation of chin by dentist	5	1.9
Retention of foreign object(s) with sequela(e)	Breakage of surgical bur and retention within bone	3	1.1
Poor aesthetic results postdental treatment	Malpositioned implants	2	0.7

* p-value: <0.001

[†]Arranged in descending order of frequency.

adverse events occur to foster better understanding of contributors to dental adverse events; developing checklists, protocols and computerized decision aids to reduce reliance on memory;...standardizing operating procedures to minimize variability based on dentists' training or practice styles..."

Used a Dental Adverse Event Severity Scale to group cases according to the degree of harm that the patient experienced. The largest category was "delayed appropriate treatment/disease progression and/or unnecessary treatment associated with misdiagnosis." *****

"Categorizing the adverse events we identified in the case reports proved very challenging due to the absence of an established dental patient safety taxonomy as well as the tremendous variability in scope and content of the published case reports."

** "The path has been illuminated by safety science in other domains... e.g., establishing nonpunitive incident reporting systems and conducting thorough root cause analyses when

Degree of Harm^{*}

Degree of Harm	Frequency (n)	Percent (%)
	<i>n</i> =270	100
E1 (Temporary minimal harm w/ minimal intervention)	18	6.7
E2 (Temporary minimal harm w/ significant intervention)	12	4.4
E3 (Temporary significant harm w/ minimal intervention)	23	8.5
E4 (Temporary significant harm w/ significant intervention)	38	14.1
F (Temporary harm w/ emergency room transfer/hospitalization)	65	24.1
G1 (Permanent minimal harm w/ minimal intervention)	3	1.1
G2 (Permanent minimal harm w/ significant intervention)	6	2.2
G3 (Permanent significant harm w/ minimal intervention)	16	5.9
G4 (Permanent significant harm w/ significant intervention)	41	15.2
H (Intervention required to sustain life)	18	6.7
I (Patient death)	30	11.1

* See appendix 2 for details of the Dental Adverse Event Severity Scale

Measuring up: Implementing a dental quality measure in the electronic health record context

Bhardwaj

Journal of the American Dental Association

2016

Bhardwaj A, Ramoni R, Walji M, et al. Measuring up: Implementing a dental quality measure in the electronic health record context. *Journal Of The American Dental Association (1939)* [serial online]. January 2016;147(1):35-40. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.

				Bhardwaj, A., Ramoni, R., Kalenderian, E., Neumann, A., Hebballi, N. B., White, J. M., & ... Walji, M. F. (2016). Measuring up: Implementing a dental quality measure in the electronic health record context. <i>Journal Of The American Dental Association (1939)</i> , 147(1), 35-40. doi:10.1016/j.adaj.2015.06.023	
Open wide: looking into the safety culture of dental school clinics	Ramoni	Journal of the American Dental Association	2014	Ramoni R, Walji M, Kalenderian E, et al. Open wide: looking into the safety culture of dental school clinics. <i>Journal Of Dental Education</i> [serial online]. May 2014;78(5):745-756. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.	
				Ramoni, R., Walji, M. F., Tavares, A., White, J., Tokede, O., Vaderhobli, R., & Kalenderian, E. (2014). Open wide: looking into the safety culture of dental school clinics. <i>Journal Of Dental Education</i> , 78(5), 745-756.	
Patient safety and dentistry: what do we need to know? Fundamentals of patient safety, the safety culture and implementation of patient safety measures in dental practice	Yamalik	International Dental Journal	2012	Yamalik N, Perea Pérez B. Patient safety and dentistry: what do we need to know? Fundamentals of patient safety, the safety culture and implementation of patient safety measures in dental practice. <i>International Dental Journal</i> [serial online]. August 2012;62(4):189-196. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.	<p>Definition of patient safety: “The reduction (or elimination as far as possible) of damage to patients resulting from health care processes or accidents associated with them.”</p> <p>Adverse event: “Unexpected result of medical treatment that causes the prolongation of treatment, any type of morbidity, mortality or any other damage to which the patient should not have been exposed. This is a broad concept that includes errors, accidents, delays in care, negligence, complications associated with treatment, etc. It does not include the symptoms of the patient’s presenting illness. The definition of ‘adverse event’ as it is commonly used across the health care sector is difficult to apply to dental care. Adverse events may be avoidable or unavoidable. An example of a preventable adverse event is the prescription of a drug to which a patient is allergic as a result of failing to consult clinical records. An example of a non-preventable adverse event is and adverse reaction to the administration of a local anesthetic in a patient without clinical pathology or allergic history. However the fact that an adverse event is not preventable does not meant that we should be unprepared to act quickly and appropriately if it occurs.”</p> <p>An “important feature of patient safety is its ‘non-punitive’ character.”</p> <p>“Firstly, and as the primary consideration, the promotion of patient safety is an ethical obligation in any health care profession.” “Patient safety is closely linked to the concept of quality care. Any dental care in which all possible risk factors can be controlled represents the highest-quality dental care, and there is a clear relationship between the quality of treatment and the success of outcomes.”</p>
				Yamalik, N., & Perea Pérez, B. (2012). Patient safety and dentistry: what do we need to know? Fundamentals of patient safety, the safety culture and implementation of patient safety measures in dental practice. <i>International Dental Journal</i> , 62(4), 189-196. doi:10.1111/j.1875-595X.2012.00119.x	

Patient safety in dentistry - state of play as revealed by a national database of errors	Thusu	British Dental Journal		<p>Thusu S, Panesar S, Bedi R. Patient safety in dentistry - state of play as revealed by a national database of errors. <i>British Dental Journal</i> [serial online]. August 2012;213(3):E3. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Thusu, S., Panesar, S., & Bedi, R. (2012). Patient safety in dentistry - state of play as revealed by a national database of errors. <i>British Dental Journal</i>, 213(3), E3. doi:10.1038/sj.bdj.2012.669</p>	<p>Study to investigate the types of patient safety incidents that occur in dentistry and the accuracy of the National Patient Safety Agency database in for the NHS in England.</p> <table border="1" data-bbox="1338 168 2005 760"> <thead> <tr> <th colspan="2">Table 2 Classifications of patient safety incidents</th> </tr> </thead> <tbody> <tr> <td>Adverse reaction</td> <td>Patient experienced an adverse reaction due to procedure</td> </tr> <tr> <td>Clerical</td> <td>PSI due to wrong notes/cancellations/delayed procedures/wrong name tags but no harm</td> </tr> <tr> <td>Communication</td> <td>PSI due to poor/lack of communication between healthcare professionals + poor/lack of communication with patient</td> </tr> <tr> <td>Equipment failure</td> <td>Use of medical/dental equipment that failed to work leading to potential of patient harm but not resulting in actual harm</td> </tr> <tr> <td>Fall</td> <td>Injury due to patient's fault or external environment not related to treatment or clinical environment</td> </tr> <tr> <td>Infection control</td> <td>Harm or potential of harm due to poor infection control</td> </tr> <tr> <td>Inhalation</td> <td>Procedure or treatment leading to patient inhaling foreign objects</td> </tr> <tr> <td>Injury</td> <td>Treatment/procedure leading to direct injury to patient</td> </tr> <tr> <td>Management</td> <td>PSI due to poor clinical management</td> </tr> <tr> <td>Medical</td> <td>Incident due to underlying medical condition not exacerbated by procedure or treatment</td> </tr> <tr> <td>Operator injury</td> <td>Accidental injury to the dentist or member of the dental team eg needlestick injury to dentist</td> </tr> <tr> <td>Radiographs</td> <td>Avoidable repeated exposure to radiation due (very relevant to dentists as they take their own radiographs and report on them, similar to radiologists and radiographers)</td> </tr> <tr> <td>Wrong site extraction</td> <td>Wrong site extraction (NB not extractions resulting in new injury)</td> </tr> </tbody> </table>	Table 2 Classifications of patient safety incidents		Adverse reaction	Patient experienced an adverse reaction due to procedure	Clerical	PSI due to wrong notes/cancellations/delayed procedures/wrong name tags but no harm	Communication	PSI due to poor/lack of communication between healthcare professionals + poor/lack of communication with patient	Equipment failure	Use of medical/dental equipment that failed to work leading to potential of patient harm but not resulting in actual harm	Fall	Injury due to patient's fault or external environment not related to treatment or clinical environment	Infection control	Harm or potential of harm due to poor infection control	Inhalation	Procedure or treatment leading to patient inhaling foreign objects	Injury	Treatment/procedure leading to direct injury to patient	Management	PSI due to poor clinical management	Medical	Incident due to underlying medical condition not exacerbated by procedure or treatment	Operator injury	Accidental injury to the dentist or member of the dental team eg needlestick injury to dentist	Radiographs	Avoidable repeated exposure to radiation due (very relevant to dentists as they take their own radiographs and report on them, similar to radiologists and radiographers)	Wrong site extraction	Wrong site extraction (NB not extractions resulting in new injury)
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Patient safety in primary care dentistry: where are we now?	Bailey	British Dental Journal	2014	<p>Bailey E, Tickle M, Campbell S. Patient safety in primary care dentistry: where are we now?. <i>British Dental Journal</i> [serial online]. October 2014;217(7):339-344. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p> <p>Bailey, E., Tickle, M., & Campbell, S. (2014). Patient safety in primary care dentistry: where are we now?. <i>British Dental Journal</i>, 217(7), 339-344. doi:10.1038/sj.bdj.2014.857</p>	<table border="1" data-bbox="1338 771 2341 1112"> <thead> <tr> <th colspan="2">Table 1 Definitions of patient safety</th> </tr> </thead> <tbody> <tr> <td>The Institute of Medicine, 2000</td> <td>The prevention of harm to patients</td> </tr> <tr> <td>Vincent, 2006</td> <td>The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare</td> </tr> <tr> <td>The World Health Organisation, 2011</td> <td>The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum</td> </tr> <tr> <td>The National Advisory Group on the Safety of Patients in England, 2013</td> <td>Avoiding harm from the care that is intended to help</td> </tr> </tbody> </table> <p>departments. Due to this, the dental practitioner may not be aware that an adverse event has occurred.”</p> <p>“...a peculiarity to dentistry is that the manifestation of a complication caused by dental treatment is frequently treated by other healthcare providers such as paramedics and hospital emergency</p>	Table 1 Definitions of patient safety		The Institute of Medicine, 2000	The prevention of harm to patients	Vincent, 2006	The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare	The World Health Organisation, 2011	The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum	The National Advisory Group on the Safety of Patients in England, 2013	Avoiding harm from the care that is intended to help																		
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Systematic review of patient safety interventions in dentistry	Bailey	BMC Oral Health	2015	<p>Bailey E, Tickle M, Campbell S, O'Malley L. Systematic review of patient safety interventions in dentistry. <i>BMC Oral Health</i> [serial online]. November 28, 2015;15:152. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p>																													

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The reporting of race and ethnicity information in the dental public health literature	Susarla	Journal of Public Health Dentistry	2014	<p>Susarla H, Dentino K, Kalenderian E, Ramoni R. The reporting of race and ethnicity information in the dental public health literature. <i>Journal Of Public Health Dentistry</i> [serial online]. 2014;74(1):21-27. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p>	
				<p>Susarla, H. K., Dentino, K. M., Kalenderian, E., & Ramoni, R. B. (2014). The reporting of race and ethnicity information in the dental public health literature. <i>Journal Of Public Health Dentistry</i>, 74(1), 21-27. doi:10.1111/j.1752-7325.2012.00358.x</p>	
What Exactly is Patient Safety	Emanuel		2008	<p>Emanuel L, Berwick D, Walton M, et al. What Exactly Is Patient Safety?. [serial online]. August 2008;Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.</p>	
				<p>Emanuel, L., Berwick, D., Conway, J., Combes, J., Hatlie, M., Leape, L., & ... Walton, M. (2008). What Exactly Is Patient Safety?.</p>	
Unanticipated Problems Involving Risks & Adverse Events Guidance		HHS Office of Human Research Protections	2007	<p>https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html</p>	<p>Definitions: Unanticipated problems involving risks to subjects or others include any incident, experience, or outcome that meets all of the following criteria:</p> <ol style="list-style-type: none"> 1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described and (b) the characteristics of the subject population being studied. 2. Related or possibly related to participation in the research, and; 3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. <p>Adverse Event : Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.</p>

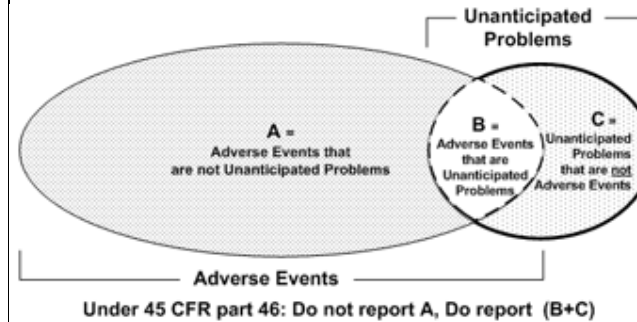
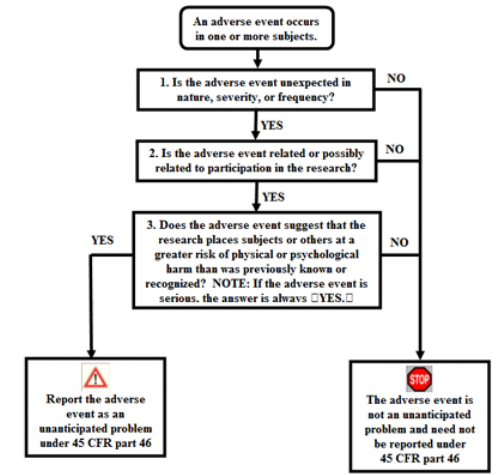
Serious Adverse Event: Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria:

1. Results in death;
2. Is life-threatening;
3. Requires inpatient hospitalization or prolongation of existing hospitalization;
4. Results in a congenital anomaly/birth defect; or
5. Any other adverse event that, based upon appropriate medical judgement may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Unexpected adverse event: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:

1. The known or foreseeable risk of adverse events associated with the procedures involved in the research; or
2. The expected natural progression of any underlying disease, disorder or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

"...an incident, experience, or outcome that meets the three criteria above [for unanticipated problems] generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others."



The diagram illustrates three key points:
 The vast majority of adverse events occurring in human subjects are not unanticipated problems (area A).
 A small proportion of adverse events are unanticipated problems (area B).
 Unanticipated problems include other incidents, experiences, and outcomes that are not adverse events (area C).