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Classifying Adverse Events in the Dental Office

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Abstract

Background—Dentists strive to provide safe and effective oral healthcare. However, some patients may encounter an adverse event (AE) defined as “unnecessary harm due to dental treatment”. In this research we propose and evaluate two systems for categorizing the type and severity of AEs encountered at the dental office.

Methods—Several existing medical AE type and severity classification systems were reviewed and adapted for dentistry. Using data collected in prior work, two initial dental AE type and severity classification systems were developed. Eight independent reviewers performed focused chart reviews and AEs identified were used to evaluate and modify these newly developed classifications.

Results—958 charts were independently reviewed. Among the reviewed charts, 118 prospective AE’s were found and 101 (85.6%) were verified as AEs through a consensus process. At the end of the study, a final AE Type classification comprising 12 categories, and an AE severity classification comprising 7 categories emerged. Pain and infection were the most common AE types representing 75% of the cases reviewed (55% and 17% respectively) and 88% were found to cause temporary, moderate to severe harm to the patient.

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Conclusions—AEs found during the chart review process were successfully classified using the novel dental AE type and severity classifications. Understanding the type of AEs and their severity are important steps if we are to learn from and prevent patient harm in the dental office.

Keywords

Adverse Event; Dentistry; Classification; Severity; Harm; Quality; Learning Organization

INTRODUCTION

Dentists, as doctors of oral health, oversee clinical teams to ensure the delivery of "safe and effective oral care".[1] Emerging scientific literature[2–11] however, suggest that dental patients experience a significant number of adverse events (AEs) or unnecessary harm while receiving dental care, such as, tooth crown ingestion or aspiration, wrong tooth extraction, or unexpected severe and prolonged pain after molar extractions. Providing safe oral care implies reducing the risk of inflicting unnecessary harm to the dental patient to an acceptable minimum.[7] Harm refers to any "impairment of structure or function of the body and/or any deleterious effect arising there from".[12] The patient safety paradigm[13] starts with the proper identification and assessment of AEs in a professional culture open to learning from mistakes.[14] The Agency for Healthcare Research and Quality (AHRQ) developed a detailed patient safety initiative with a goal to "have a positive impact on patient safety by providing knowledge and tools to understand medical errors and to create solutions that mitigate or eliminate harm to patients suffered as a result of health care."[13] To the best of our knowledge, specific dental-related patient safety metrics are yet to be developed. In order to fill this gap, the authors obtained grant funding (NIDCR 1R01DE022628-01A1) to develop a patient safety initiative for dentistry.

In addition, other healthcare industries such as the pharmaceutical and medical device research industries have mandatory reporting requirements for clinical research. When AEs occur, they systematically document the seriousness of the AE (level of harm), its impact on enrolled participants, and its association with a study related device, drug, or procedure. This enables the identification of the various contributing factors and allows for the creation and dissemination of recommendations for systems changes.[15] By contrast, clinical dentistry does not have any such mandatory reporting requirements for AEs, and if we did, there would be no standardized format for reporting these events. A dental AE classification system would help to better organize and communicate about the types of harm in the dental office. It would provide insights into their prevention, elimination and/or the mitigation of their effects. The impact of AEs is also not equal, some cause greater harm than others, therefore, a standardized severity rating is needed to understand the extent of damage caused by AEs. In the absence of any precursory dental-specific metrics and tools, we turned to systems developed by the medical profession for classifying, assessing severity and reporting AEs.

The National Cancer Institute's (NCI) Common Terminology Criteria for Adverse Events v4.0 (CTCAE) is a comprehensive categorization system of AEs in cancer treatment that includes a severity grading scale for AEs.[16] It uses terms taken from the clinically

validated Medical Dictionary of Regulatory Activities (MedDRA's), and is organized across 24 primary System Organ Classes.[16] Another notable classification system was used in the Harvard Medical Practice Study (HMPS), which categorized hospital adverse events according to the type of injury and incorporated a six-point disability scale on which "serious" disability was defined as disability persisting for more than six months[17]. Adverse events were classified in operative and non-operative, each containing five and ten sub-categories respectively[18]. The World Health Organization (WHO's) International Classification for Patient Safety (ICPS) is a conceptual framework that consists of ten high-level classes, each further hierarchically subdivided into categories and sub-categories.[12] Forty-eight concepts have been identified with agreed upon definitions and preferred terms.[12] The degree of harm is defined along five levels from none to death.[12, 19] The ICPS is not considered a classification, but rather a framework with a set of concepts that are linked by semantic relationships.[12, 19]

Similarly, the Medicare Hospital-Acquired Conditions classification[20] contains ten categories that are mainly surgical and post-surgical management related, however, it does not have a severity rating scheme. The United States (US) National Quality Forum (NQF) captures the level of harm in serious reportable events (SREs).[21] As part of the Outpatient Adverse Event Trigger Tool developed by the Institute for Healthcare Improvement (IHI)[22], a severity classification methodology was proposed using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Errors.[23] In sum, medical classification and severity rating systems demonstrate the viability of monitoring patient safety; important steps in moving towards a patient safety initiative.[4] As expected, our evaluation of these systems quickly revealed that dental AEs do not neatly fit into the categories developed in the medical realm. Similarly, the level of severity of dental AEs did not easily fit within the existing medical severity scales. The focus of this paper is to report on the methodology for developing and refining a usable dental AE classification and severity rating system, and the results of a pilot study to evaluate its usefulness in classifying AEs found through chart reviews.

METHODS

The research was reviewed and approved by the Human Subject Committees of all participating academic institutions.

Development And Refinement Of The Dental AE Type Classification

The following five medical classifications were analyzed for their overlap in categories: (1) NCI's CTCAE[16] twenty-four System Organ Classes, (2) HMPS[24] eleven categories, (3) WHO's ICPS[12, 19] thirteen categories within the "Incident Type" class (4) IHI outpatient trigger tool's[22] eleven categories, and (5) Medicare's Hospital-Acquired Conditions'[20] ten categories.

NCI's CTCAE lists a total of 679 AEs, from which we identified 86 items that were potentially related to oral health (Appendix 1). We studied the HMPS classification scheme[18], and its operative and non-operative categories that include the following sub-categories of AEs: Wound infection, Technical complication, Late complication, Non-

technical complication, Surgical failure, Drug-related, Diagnostic mishap, Therapeutic mishap, Procedure-related, Fall, Fracture, Postpartum, Anesthesia-related, Neonatal, and System/other. A condensed version of the HMPS categorization was introduced by Nuckols et al[24] with 10 broad categories:1. Medications, 2. Operations, 3. Therapeutics, 4. Diagnostics, 5. Miscellaneous, 6. Procedures, 7. Anesthesia, 8. Peripartum, 9. Neonatal, and 10. Falls. The WHO's ICPS[12, 19] also has ten high-level classes: the first class, "Incident Type," contains thirteen major categories: Clinical Administration, Clinical Process/Procedure, Documentation, Healthcare Associated Infection, Medication/IV Fluids, Blood/Blood Products, Nutrition, Medical Device/Equipment, Behavior, Patient Accidents, Infrastructure/Building/Fixtures, and Resources/Organizational Management. The IHI's outpatient trigger tool[22] includes medically-oriented items that indicate an AE may have occurred. Items include new diagnosis of cancer; nursing home placement, admission and discharge from the hospital, two or more consults in one year, surgical procedure, emergency room visit, greater than five medications, physician change, complaint letter, greater than three nursing calls in one week, and abnormal lab value. The final medical AE classification system analyzed was Medicare Hospital-Acquired Conditions.[20] It included foreign object retained after surgery, air embolism, blood incompatibility, pressure ulcers, falls, manifestations of poor glycemic control, catheter-associated urinary tract infection, vascular catheter-associated infection, deep vein thrombosis/pulmonary embolism, and surgical site infection.

The initial dental AE type classification (comprising 23 categories) was developed by analyzing dental AEs reported to the FDA MAUDE database,[2] and documented in the scientific literature.[25] This work produced a dental AE list that was expanded after collecting a list of commonly encountered AEs from dental providers.[26] The initial dental AE type classification and the aggregated findings from our comprehensive analysis of medical AE classification systems were reviewed by the research group's Advisory Committee, comprising experts in medical AEs (see acknowledgments). The findings from each preceding stage of this process led to the creation of a working system for classifying dental AEs. This classification was then pilot tested by independent reviewers across the 4 sites using a focused chart review process. This led to the further refinement of the AE classification and Severity systems. For example, during the calibration process for the chart reviews, we discovered that sinus perforation (a frequently reported AE in our previous study[26] could be classified as either a soft tissue injury, or a hard tissue injury. As a result, we created an additional classification for AEs that did not fit into a single existing category; Other Oro-facial Harm. We also dropped the use of the word "complication" and replaced it with "harm." The last three of the twelve AE classification categories in table 1 are now "other oro-facial harm", "other systemic harm,' and "other harm." Finally, all prospective AE cases were verified collectively using a consensus process during conferences calls and a full-day in-person working meeting.

Development And Refinement Of The Dental AE Severity Classification

To our knowledge, there is no standardized measure for assessing the severity of dental AEs. In order to develop a severity scale for the AE classifications, we systematically reviewed

the severity ratings of AEs used in the IHI outpatient trigger tool, NCI CTCAE, WHO ICPS, and NQF.

The Institute of Healthcare Improvement's (IHI) outpatient trigger tool[22] has five categories of harm. From least to most severe they are: Temporary harm to the patient and required intervention, Temporary harm to the patient and required initial or prolonged hospitalization, Permanent patient harm, Intervention required to sustain life, and Patient death. The CTCAE[16] assesses the severity of an AE through five gradients of harm. From least to most severe they are graded: 1. Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated, 2. Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADLs (activities of daily living), 3. Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADLs, 4. Life-threatening consequences; urgent intervention indicated, and 5. Death related to AE. The WHO ICPS used a five-point gradient for assessing the degree of harm: None, Mild, Moderate, Severe, and Death. Finally, we reviewed the NQF list of serious reportable events (SREs).[21] SREs included: Surgical or invasive procedure events, Product or device events, Patient protection, Care management events, Environmental, Radiological events and Potential criminal events.

Using the findings from our review of the medical AE severity ratings, and feedback from our advisory committee, we created an initial AE severity rating scale which was used to assess the severity of AEs in our prior work[25] and modified in subsequent work[3]. Based on our observations in these studies and through an iterative process, we further refined the severity scale and created a severity tree to simplify its use in the chart review process (Figure 1).

Pilot Test (Chart Review Process)

Eight independent research team members representing four US academic dental institutions (two per site) performed focused chart reviews[22] using eight newly constructed or previously developed triggers[3] of active electronic health records (EHRs). A 'trigger' is an opportunity or clue used to identify AEs in a patient's dental record but do not represent AEs themselves. The eight reviewers were tasked with determining whether the case fit the definition of an AE. The outcome of interest was AE type, which was measured as a binary variable based on the dental AE classification, as well as, the severity. A standardized log sheet was developed to extract the AEs from the charts. The reviewers were trained and calibrated using a uniform AE definition, classification (AE Type), and level of harm (AE Severity). Inter-rater reliability was calculated using the prevalence and bias-adjusted kappa to address the kappa paradox. The average percent agreement for AE determination was 82.2%. Further, the average, pairwise prevalence and bias adjusted kappa (PABAK) was 57.5% (κ=0.575) for determining AE presence. The average percent agreement for categorization of the AE type 78.5% while the PABAK was 48.8%. Lastly, the average percent agreement for categorization of AE severity was 82.2% and the corresponding PABAK was 71.7%. According to the standards for inter-rater reliability, a kappa ranging

from 0.40 to 0.60 constitutes moderate agreement.[27, 28] All statistical calculations were performed in R v3.1.1© using the "irr" and "epiR" packages.

RESULTS

Dental AE Type Classification

A comparison of the five medical AE classifications showed an overlap of concepts in the surgical/medical procedure, general disorders and infection categories (Appendix 2). Specifically, the CTCAE had more items that overlapped with the other classification systems than did any of the others. We also observed that similar concepts were presented with different wording across classifications. Although the CTCAE exemplified a comprehensive listing of potential AEs for cancer patients (n=679), only 87 of its items appeared to have potential relevance to oral health or dentistry. We concluded that using the system organ classes in the CTCAE was not effective for documenting oral health AEs. Similarly, the HMPS categories, Medicare's Hospital-Acquired Conditions, and the ICPS also appear well suited to categorize medical and hospital AEs, but not oral health events. For example, categories to indicate damage to hard oral tissues, e.g. teeth were difficult to categorize using the existing schemes.

Suggestions that came from the medical AE experts on the Advisory committee were critical. Based on their early experiences developing medical classification systems, they suggested testing the clinical validity of any given AE with the "give me a break" test. That is, in order to label an event an AE, it must stand up to the rigor of peer review by professional colleagues. For example, would the failure of a provisional crown constitute an AE? Initially, we thought yes, but while it would be undesirable to have a provisional crown fail, a singular failure did not pass this test. On the other hand, if the provisional crown failed time and again, was aspirated or led to an abutment tooth fracture, it would be considered an AE. A similar example in medicine would be vomiting after chemotherapy, which the Advisory Committee explained was not considered an AE in itself, unless ongoing violent vomiting resulted in an inability to absorb nutrients and requiring parental nutrition/rehydration.

Putting together our findings from the analysis of these five medical AE classifications, the dental AEs found through the FDA MAUDE database[2], our literature review,[25] our empirical interviews with providers[26], our consultation with the Advisory Committee on this project, and our focused chart reviews, we made revisions to the initial dental AE classification system[26] and arrived at 12 final categories for the Dental AE Type Classification System.

Dental AE Severity Classification

In reviewing the four medical severity ratings, we found that while they effectively reflected increasing degrees of severity based upon the temporal impact of harm and what was needed to mitigate the effects of the AE, it was not fully applicable to outpatient dentistry. AEs in dentistry appear to be less catastrophic, and as such, we felt it necessary to be able to

differentiate not only between temporary and permanent harm but indicate if the harm was mild or severe.

Specifically, we noted that the CTCAE severity grades, ICPS and the IHI scales had some similarities (death, intervention required). They also had relevance for oral health. The NQF SREs focused on causes rather than AEs. While the SREs may be of importance to root cause analysis for sentinel events, they did not fit for severity ratings for dental AEs. By contrast, the IHI scale had utility for dentistry. It assessed harm based upon the short and long term impact of the AE upon the patient. The more severe the immediate impact, or more extensive the long-term mitigation required, the higher the severity rating. We used this approach in developing our own severity scale for dental AEs.

Items from the IHI trigger tool, ICPS and the CTCAE were integrated into more granular elements specific to oral health. With the support of the Advisory Board, we developed an initial AE severity scale for oral health comprising 15 items. This scale was pilot tested in our prior work analyzing the scientific literature.[25] Based on feedback from the reviewers, and through an iterative process, it was further condensed, simplified and adapted into a severity tree (Figure 1). The first four items on the scale (A–D) were dropped, the "magnitude of the intervention" was also dropped from each step, and the "moderate" and "severe" categories were combined. The final step was the application of the severity scale to AEs identified through EHR chart reviews by independent reviewers across several sites.

Overall Evaluation Of The Dental AE Type and Severity Classifications

The following shows an example of a case that a reviewer would be asked to classify:

> "While a gold onlay for #30 was being tried in prior to cementation, the onlay inadvertently became dislodged and lost in the oropharyngeal space. KUB revealed a radiopaque foreign object in the area of the duodenum, measuring approximately 1cm. Patient informed that her airways were clear and that she will pass the foreign body."

Reviewers would classify the above as adverse event type: "Aspiration/Ingestion of Foreign Body" with severity of Temporary (reversible or transient) moderate to severe harm to the patient (E2).

There were 3283 (not including random charts) triggered charts. Of these, 958 charts were independently reviewed representing 29% of the triggered population. Among the reviewed charts, 118 prospective AE's were found and 101 (85.6%) were verified as AEs during the consensus process. Pain and infection were the most common AE types representing 75% of the cases reviewed (55% and 17% respectively). In the remaining reviews, hard tissue damage was assessed in 12%, soft tissue damage/inflammation in 6%, nerve injury in 5%, and other oro-facial harm in 2% of cases. Examples of AEs found during the chart reviews include: dry socket, failure of implant to osseo-integrate two months after placement with loss of bone and requiring removal; pulp exposure during caries removal due to sudden movement of pediatric child; pain; and excessive swelling. Results of the classification after consensus was reached are documented in Table 1. Overwhelmingly,

the most recorded adverse event severity was “temporary, moderate to severe harm to the patient” (E2) representing 88% of the cases (Table 2).

DISCUSSION

The medical profession has made considerable strides understanding patient safety. It is now time for dentistry to embrace patient safety and move towards a better safety initiative.[4, 29] In order to create, monitor and maintain what AHRQ describes as a patient safety initiative,[13] the identification and assessment of AEs are important first steps. The AE classifications and severity ratings provide unique opportunities to the dental profession to explore how to provide safe and effective high quality oral care to patients. The nature of adverse events that have been reported in the medical literature are different from those that occur in dentistry. Significant AEs in the dental office are rare and seldom life threatening. Additionally, with 32 teeth as a starting point and our ability to function well with significantly fewer teeth as well as our ability to replace lost teeth, the attitude towards accidently injuring a tooth has been quite different from doing so with any other body part. Our results suggest the feasibility of the use of a classification system in helping to organize the different types of AEs that patients may encounter through dental treatment. It is important to realize the difference between harm and contributing factors that may lead to harm, e.g., aspiration of a gold onlay is the actual harm, whereas not using a rubber dam, or unexpected movement of the patient would be contributing factors.

There were challenges in classifying some of the AE cases we encountered in our chart review. In our study the reviewers were asked to pick the single best category to describe the AE. However, we discovered that some AEs could be classified into multiple categories, e.g, a patient presenting with swelling and significant pain two days after periodontal flap surgery could be classified under “Pain” as well as “Infection”. While restricting the classification to only one category is useful for reporting purposes, this approach may not fully capture the nature of the harm, which is a limitation of our approach. In some cases our chart reviewers reported that there was insufficient information to classify an AE, e.g., radiographs could be helpful to determine if a peri-apical abscess is new or pre-dated restorative treatment. This speaks to the importance of having adequate clinical documentation that can be used to assess the quality and safety of dental care.[30]

Our severity scale was adapted from one developed by NCC-MERP to classify medication-related adverse events.[23] The severity of harm in dentistry is qualitatively different from that in medicine. While medicine is focused on cases of severe harm (such as death or requiring hospitalization), the most harm that occurs in dentistry is less life altering. Hence, we not only elected to capture harm that is either permanent (extraction of the wrong tooth) or temporary (sinus perforation) but also further divided the harm into slight or moderate/severe in an effort to better distill the most severe cases. We did not explore cases indicated as slight or minimal harm as we believe that in this first effort focusing on more severe harm will help us ultimately undercover underlying systems that can be improved to prevent these more extreme forms of harm from happening again.

The patient safety revolution can be traced to the seminal Institute of Medicine (IOM) seminal report, “To Err is Human.” It states that quality consist of 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.[31] We have visually presented these concepts contextualized for the dental profession in Figure 2. All of these elements must be met in order to achieve quality. Assessing adherence to best practices such as percentages of patients having annual dental visits is an important marker, but not a substitute for assessing safety. There must be markers to assess patient safety so that trends can be observed, reported, and used to improve quality.

Reporting of AEs is a crucial step for any organization or profession to learn from its mistakes and move toward the establishment of a learning organization[32] or profession. Reporting of AEs, however, does not improve safety in and of itself. An AE must be much more than a report. It should lead to exploring underlying systems failures, ultimately leading to change.[15] Individuals as well as organizations will gain more from reporting AEs when their information is aggregated and compared to others so that learning can occur across settings to prevent or minimize the probability of recurrences of the same or similar AEs.[15]

Our extensive study of adverse events in both dentistry and medicine underscores that safety and quality cannot be separated. The absence of quality benchmarking in dentistry that is made available to the public is remarkable when compared to medicine. Meaningful use data is an exemplar. When the US Government committed $27 billion to incentivize the adoption of meaningful use data through the 2009 Health Information Technology for Economic and Clinical Health Act, dentists were included with physicians as eligible participants. Of the 141,910 providers enrolled in the Medicaid portion of meaningful use (MU) that was relevant for outpatient dentistry[33], 15,213 (21%) were dentists. These dentists have received $333,557,837 (9%) in MU incentive pay, however, it appears that the majority of them have participated only for the first year of MU, but not for the following years that will require reporting of nine Clinical Quality Measures (CQMs)[34] and twenty Objectives. By contrast,[35] 73 percent of physicians are participating in the portions of MU that require CQM and Objective reporting.”[36] In addition, 95,170 medical providers make up 67% of Medicaid MU enrollees. They received $2,598,954,521 or 69% of the Medicaid portion of the program, with the remainder being paid out to midwives, optometrists, physician assistants and nurse practitioners.[35] Myriad reasons might explain why relatively few dentists are participating in the subsequent years of MU. Our concern is that the adoption of a patient safety must not mirror the MU example wherein providers’ participation was short-term. The patient safety paradigm in dentistry must be a long-term commitment by individual providers and the professional at large.

Classifying AEs, categorizing their severity, and eventually standardizing how AEs are captured in databases for query, are key factors to the development of a learning profession. Medicine has accomplished many of these tasks. While dentistry has only begun embracing a patient safety paradigm, it does not have to take the long road that our medical colleagues have traveled. We can learn from their triumphs and strive towards the creation of a learning

profession by not only agreeing that patient safety is the first element of quality, but also adopt a standardized classification of adverse events and level of harm as a crucial ingredient in the development of this endeavor.

CONCLUSION

Patient safety is a critical component of quality, and classifying adverse events (AEs) and their severity is an important step towards the ability to analyze patient safety data in a meaningful way. The use of dental AE type and severity classifications facilitate the categorization of and communication about dental AEs during routine chart reviews.

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Appendices: Classifying Adverse Events in the Dental Setting

Appendix 1: Oral Health Related Terms (86 Terms) Taken From National Cancer Institute’s CTCAE Terminology (679 Terms)

	Level of Harm; Grade 1 = least and 5 = most				
Adverse Event	**1**	**2**	**3**	**4**	**5**
Ear pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Cheilitis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL; intervention indicated	-	-
Dental caries	One or more dental caries, not involving the root	Dental caries involving the root	Dental caries resulting in pulpitis or periapical abscess or resulting in tooth loss	-	-
Dry mouth	Symptomatic (e.g., dry or thick saliva) without significant dietary alteration; unstimulated saliva flow >0.2 ml/min	Moderate symptoms; oral intake alterations (e.g., copious water, other lubricants, diet limited to purees and/or soft, moist foods); unstimulated saliva 0.1 to 0.2 ml/min	Inability to adequately aliment orally; tube feeding or TPN indicated; unstimulated saliva <0.1 ml/min	-	-
Gingival pain	Mild pain	Moderate pain interfering with oral intake	Severe pain; inability to aliment orally	-	-
Lip pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Mucositis oral	Asymptomatic or mild symptoms; intervention not indicated	Moderate pain; not interfering with oral intake; modified diet indicated	Severe pain; interfering with oral intake	Life-threatening consequences; urgent intervention indicated	Death
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	-	-
Oral cavity fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function	Severely altered GI function; TPN or hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Oral dysesthesia	Mild discomfort; not interfering with oral intake	Moderate pain; interfering with oral intake	Disabling pain; tube feeding or TPN indicated	-	-
Oral hemorrhage	Mild; intervention not indicated	Moderate symptoms; medical intervention	Transfusion, radiologic, endoscopic, or elective	Life-threatening consequences;	Death

	Level of Harm; Grade 1 = least and 5 = most				
Adverse Event	**1**	**2**	**3**	**4**	**5**
		or minor cauterization indicated	operative intervention indicated	urgent intervention indicated	
Oral pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Periodontal disease	Gingival recession or gingivitis; limited bleeding on probing; mild local bone loss	Moderate gingival recession or gingivitis; multiple sites of bleeding on probing; moderate bone loss	Spontaneous bleeding; severe bone loss with or without tooth loss; osteonecrosis of maxilla or mandible	-	-
Salivary duct inflammation	Slightly thickened saliva; slightly altered taste (e.g., metallic)	Thick, ropy, sticky saliva; markedly altered taste; alteration in diet indicated; secretion-induced symptoms; limiting instrumental ADL	Acute salivary gland necrosis; severe secretion-induced symptoms (e.g., thick saliva/oral secretions or gagging); tube feeding or TPN indicated; limiting self care ADL; disabling	Life-threatening consequences; urgent intervention indicated	Death
Salivary gland fistula	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; altered GI function; tube feeding indicated	Severely altered GI function; hospitalization indicated; elective operative intervention indicated	Life-threatening consequences; urgent operative intervention indicated	Death
Tooth development disorder	Asymptomatic; hypoplasia of tooth or enamel	Impairment correctable with oral surgery	Maldevelopment with impairment not surgically correctable; disabling	-	-
Tooth discoloration	Surface stains	-	-	-	-
Toothache	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Vomiting	1 – 2 episodes (separated by 5 minutes) in 24 hrs	3 – 5 episodes (separated by 5 minutes) in 24 hrs	>=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated	Death
Edema face	Localized facial edema	Moderate localized facial edema; limiting instrumental ADL	Severe swelling; limiting self care ADL	-	-
Facial pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Fatigue	Fatigue relieved by rest	Fatigue not relieved by rest; limiting instrumental ADL	Fatigue not relieved by rest, limiting self care ADL	-	-
Fever	38.0 – 39.0 degrees C (100.4– 102.2 degrees F)	>39.0 – 40.0 degrees C (102.3– 104.0 degrees F)	>40.0 degrees C (>104.0 degrees F) for <=24 hrs	>40.0 degrees C (>104.0 degrees F) for >24 hrs	Death
Injection site reaction	Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)	Pain; lipodystrophy; edema; phlebitis	Ulceration or necrosis; severe tissue damage; operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Localized edema	Localized to dependent areas, no disability or functional impairment	Moderate localized edema and intervention indicated; limiting instrumental ADL	Severe localized edema and intervention indicated; limiting self care ADL	-	-
Neck edema	Asymptomatic localized neck edema	Moderate neck edema; slight obliteration of anatomic landmarks; limiting instrumental ADL	Generalized neck edema (e.g., difficulty in turning neck); limiting self care ADL	-	-
Pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Allergic reaction	Transient flushing or rash, drug fever <38 degrees C (<100.4 degrees F); intervention not indicated	Intervention or infusion interruption indicated; responds promptly to symptomatic treatment (e.g., antihistamines, NSAIDS, narcotics); prophylactic medications indicated for <=24 hrs	Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates)	Life-threatening consequences; urgent intervention indicated	Death

	Level of Harm; Grade 1 = least and 5 = most				
Adverse Event	**1**	**2**	**3**	**4**	**5**
Anaphylaxis	-	-	Symptomatic bronchospasm, with or without urticaria; parenteral intervention indicated; allergy-related edema/angioedema; hypotension	Life-threatening consequences; urgent intervention indicated	Death
Autoimmune disorder	Asymptomatic; serologic or other evidence of autoimmune reaction, with normal organ function; intervention not indicated	Evidence of autoimmune reaction involving a non-essential organ or function (e.g., hypothyroidism)	Autoimmune reactions involving major organ (e.g., colitis, anemia, myocarditis, kidney)	Life-threatening consequences; urgent intervention indicated	Death
Cranial nerve infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Device related infection	-	-	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Gum infection	Local therapy indicated (swish and swallow)	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Infective myositis	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Joint infection	-	Localized; local intervention indicated; oral intervention indicated (e.g., antibiotic, antifungal, antiviral); needle aspiration indicated (single or multiple)	Arthroscopic intervention indicated (e.g., drainage) or arthrotomy (e.g., open surgical drainage)	Life-threatening consequences; urgent intervention indicated	Death
Lymph gland infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Mucosal infection	Localized, local intervention indicated	Oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Otitis media	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Periorbital infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Pharyngitis	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Salivary gland infection	-	Moderate symptoms; oral intervention indicated (e.g., antibiotic, antifungal, antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Sinusitis	-	Localized; local intervention indicated	IV antibiotic, antifungal, or antiviral intervention	Life-threatening consequences;	Death

	Level of Harm; Grade 1 = least and 5 = most				
Adverse Event	**1**	**2**	**3**	**4**	**5**
		(e.g., topical antibiotic, antifungal, or antiviral)	indicated; radiologic, endoscopic, or operative intervention indicated	urgent intervention indicated	
Soft tissue infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Tooth infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Wound infection	-	Localized; local intervention indicated (e.g., topical antibiotic, antifungal, or antiviral)	IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Infections and infestations - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Bruising	Localized or in a dependent area	Generalized	-	-	-
Burn	Minimal symptoms; intervention not indicated	Medical intervention; minimal debridement indicated	Moderate to major debridement or reconstruction indicated	Life-threatening consequences	Death
Fracture	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic but non-displaced; immobilization indicated	Severe symptoms; displaced or open wound with bone exposure; disabling; operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Intraoperative head and neck injury	Primary repair of injured organ/ structure indicated	Partial resection of injured organ/structure indicated	Complete resection or reconstruction of injured organ/structure indicated; disabling	Life-threatening consequences; urgent intervention indicated	Death
Wound complication	Incisional separation of <=25% of wound, no deeper than superficial fascia	Incisional separation >25% of wound; local care indicated	Hernia without evidence of strangulation; fascial disruption/dehiscence; primary wound closure or revision by operative intervention indicated	Hernia with evidence of strangulation; major reconstruction flap, grafting, resection, or amputation indicated	Death
Wound dehiscence	Incisional separation of <=25% of wound, no deeper than superficial fascia	Incisional separation >25% of wound with local care; asymptomatic hernia or symptomatic hernia without evidence of strangulation	Fascial disruption or dehiscence without evisceration; primary wound closure or revision by operative intervention indicated	Life-threatening consequences; symptomatic hernia with evidence of strangulation; fascial disruption with evisceration; major reconstruction flap, grafting, resection, or amputation indicated	Death
INR increased	>1 – 1.5 × ULN; >1 – 1.5 times above baseline if on anticoagulation	INR increased	>1 – 1.5 × ULN; >1 – 1.5 times above baseline if on anticoagulation	INR increased	>1 – 1.5 × ULN; >1 – 1.5 times above baseline if on anticoagulation
Anorexia	Loss of appetite without alteration in eating habits	Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated	Associated with significant weight loss or malnutrition (e.g., inadequate oral caloric and/or fluid intake); tube feeding or TPN indicated	Life-threatening consequences; urgent intervention indicated	Death
Arthralgia	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Arthritis	Mild pain with inflammation,	Moderate pain associated with signs of inflammation,	Severe pain associated with signs of inflammation, erythema,	-	-

	Level of Harm; Grade 1 = least and 5 = most				
Adverse Event	**1**	**2**	**3**	**4**	**5**
	erythema, or joint swelling	erythema, or joint swelling; limiting instrumental ADL	or joint swelling; irreversible joint damage; disabling; limiting self care ADL		
Avascular necrosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; limiting instrumental ADL	Severe symptoms; limiting self care ADL; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Exostosis	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; limiting instrumental ADL	Severe symptoms; limiting self care ADL; elective operative intervention indicated	-	-
Fibrosis deep connective tissue	Mild induration, able to move skin parallel to plane (sliding) and perpendicular to skin (pinching up)	Moderate induration, able to slide skin, unable to pinch skin; limiting instrumental ADL	Severe induration; unable to slide or pinch skin; limiting joint or orifice movement (e.g. mouth, anus); limiting self care ADL	Generalized; associated with signs or symptoms of impaired breathing or feeding	Death
Head soft tissue necrosis	-	Local wound care; medical intervention indicated (e.g., dressings or topical medications)	Operative debridement or other invasive intervention indicated (e.g., tissue reconstruction, flap or grafting)	Life-threatening consequences; urgent intervention indicated	Death
Myalgia	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Myositis	Mild pain	Moderate pain associated with weakness; pain limiting instrumental ADL	Pain associated with severe weakness; limiting self care ADL	-	-
Osteonecrosis of jaw	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated (e.g., topical agents); limiting instrumental ADL	Severe symptoms; limiting self care ADL; elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Trismus	Decreased ROM (range of motion) without impaired eating	Decreased ROM requiring small bites, soft foods or purees	Decreased ROM with inability to adequately aliment or hydrate orally	-	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Dysgeusia	Altered taste but no change in diet	Altered taste with change in diet (e.g., oral supplements); noxious or unpleasant taste; loss of taste	-	-	-
Facial muscle weakness	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Facial nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Glossopharyngeal nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	Life-threatening consequences; urgent intervention indicated	Death
Headache	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-

	Level of Harm; Grade 1 = least and 5 = most				
Adverse Event	**1**	**2**	**3**	**4**	**5**
Hypoglossal nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Paresthesia	Mild symptoms	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Sinus pain	Mild pain	Moderate pain; limiting instrumental ADL	Severe pain; limiting self care ADL	-	-
Syncope	-	-	Fainting; orthostatic collapse	-	-
Trigeminal nerve disorder	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Moderate symptoms; limiting instrumental ADL	Severe symptoms; limiting self care ADL	-	-
Epistaxis	Mild symptoms; intervention not indicated	Moderate symptoms; medical intervention indicated (e.g., nasal packing, cauterization; topical vasoconstrictors)	Transfusion, radiologic, endoscopic, or operative intervention indicated (e.g., hemostasis of bleeding site)	Life-threatening consequences; urgent intervention indicated	Death
Sleep apnea	Snoring and nocturnal sleep arousal without apneic periods	Moderate apnea and oxygen desaturation; excessive daytime sleepiness; medical evaluation indicated; limiting instrumental ADL	Oxygen desaturation; associated with hypertension; medical intervention indicated; limiting self care ADL	Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated	Death
Erythema multiforme	Target lesions covering <10% BSA and not associated with skin tenderness	Target lesions covering 10 – 30% BSA and associated with skin tenderness	Target lesions covering >30% BSA and associated with oral or genital erosions	Target lesions covering >30% BSA; associated with fluid or electrolyte abnormalities; ICU care or burn unit indicated	Death
Bullous dermatitis	Asymptomatic; blisters covering <10% BSA	Blisters covering 10 – 30% BSA; painful blisters; limiting instrumental ADL	Blisters covering >30% BSA; limiting self care ADL	Blisters covering >30% BSA; associated with fluid or electrolyte abnormalities; ICU care or burn unit indicated	Death
Periorbital edema	Soft or non-pitting	Indurated or pitting edema; topical intervention indicated	Edema associated with visual disturbance; increased intraocular pressure, glaucoma or retinal hemorrhage; optic neuritis; diuretics indicated; operative intervention indicated	-	-
Stevens-Johnson syndrome	-	-	Skin sloughing covering <10% BSA with associated signs (e.g., erythema, purpura, epidermal detachment and mucous membrane detachment)	Skin sloughing covering 10 – 30% BSA with associated signs (e.g., erythema, purpura, epidermal detachment and mucous membrane detachment)	Death
Hematoma	Mild symptoms; intervention not indicated	Minimally invasive evacuation or aspiration indicated	Transfusion, radiologic, endoscopic, or elective operative intervention indicated	Life-threatening consequences; urgent intervention indicated	Death
Hypertension	Prehypertension (systolic BP 120 – 139 mm Hg or diastolic BP 80 – 89 mm Hg)	Stage 1 hypertension (systolic BP 140 – 159 mm Hg or diastolic BP 90 – 99 mm Hg); medical intervention indicated; recurrent or persistent (>=24 hrs); symptomatic increase by >20 mm Hg (diastolic) or to >140/90 mm Hg	Stage 2 hypertension (systolic BP >=160 mm Hg or diastolic BP >=100 mm Hg); medical intervention indicated; more than one drug or more intensive therapy than previously used indicated Pediatric: Same as adult	Life-threatening consequences (e.g., malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated Pediatric: Same as adult	Death

	Level of Harm; Grade 1 = least and 5 = most				
Adverse Event	**1**	**2**	**3**	**4**	**5**
		if previously WNL; monotherapy indicated Pediatric: recurrent or persistent (>=24 hrs) BP >ULN; monotherapy indicated			
Hypotension	Asymptomatic, intervention not indicated	Non-urgent medical intervention indicated	Medical intervention or hospitalization indicated	Life-threatening and urgent intervention indicated	Death
Phlebitis	-	Present	-	-	-

Appendix 2: Overlap Of Five Medical Approaches To Observing Adverse Events

National Cancer Institute's Common Terminology Criteria for Adverse Events v 4.0 (CTCAE)	**Harvard Medical Practice Study**	**IHI Outpatient Trigger Tool**	**WHO International Classification for Patient Safety (ICPS)**	**Medicare Hospital-Acquired Conditions**
Blood and lymphatic system disorders			• Blood/Blood Products	• Blood incompatibility
Cardiac disorders				
Congenital, familial and genetic disorders				
Ear and labyrinth disorders				
Endocrine disorders				• Manifestations of poor glycemic control
Eye disorders				
Gastrointestinal disorders				
General disorders and administration site conditions	Diagnostics Medications Miscellaneous	• 2 or more consults/ year • Physician change • >5 medications • Complaint letter • >3 nursing calls	• Clinical Administration • Documentation • Medical Device/ Equipment • Infrastructure/Building/ Fixtures • Resources/Organizational Management	
Hepatobiliary disorders				
Immune system disorders				
Infections and infestations			• Healthcare Associated Infection	• Surgical site infection • Vascular catheter-associated infection • Catheter associated urinary tract infection
Injury, poisoning and procedural complications	Procedures	• ER visit		
Investigations	Therapeutics	• Abnormal lab value		
Metabolism and nutrition disorders			• Nutrition	
Musculoskeletal and connective tissue disorders				• Pressure ulcers
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)		• New Diagnosis of cancer		
Nervous system disorders				
Pregnancy, puerperium and perinatal conditions	Nepnatal Peripartum			
Psychiatric disorders			• Behavior	
Renal and urinary disorders				

National Cancer Institute's Common Terminology Criteria for Adverse Events v 4.0 (CTCAE)	Harvard Medical Practice Study	IHI Outpatient Trigger Tool	WHO International Classification for Patient Safety (ICPS)	Medicare Hospital-Acquired Conditions
Reproductive system and breast disorders				
Respiratory, thoracic and mediastinal disorders	Anesthesia			
Skin and subcutaneous tissue disorders				
Social circumstances	Falls	• NH placement • Admission/discharge of hospital		
Surgical and medical procedures	Operations	• Surgical procedure	• Clinical Process/ Procedure • Medication/IV Fluids • Patient Accidents	• Foreign object retained • Falls
Vascular disorders				• Air embolism • Deep vain thrombosis/ pulmonary embolism

Box 1

Dental Triggers Examples

Trigger name	Trigger description	AEs detected
Allergy or Toxicity or Foreign body response	Patients who had "*foreign body*" text in their notes and had received at least one treatment in the given calendar year	Allergic reaction to orthodontic brackets, or medication
Aspiration or Ingestion of foreign body	Patients who had *terms like "aspiration", "aspirated"* in their notes and had received at least one treatment in the given calendar year.	Ingestion or Aspiration of crown or screw during placement of restoration
Failed implant	Patients who had a failed implant diagnosis or implant removal procedure code on any tooth in the given calendar year.	Peri-implantitis, lack of implant integration

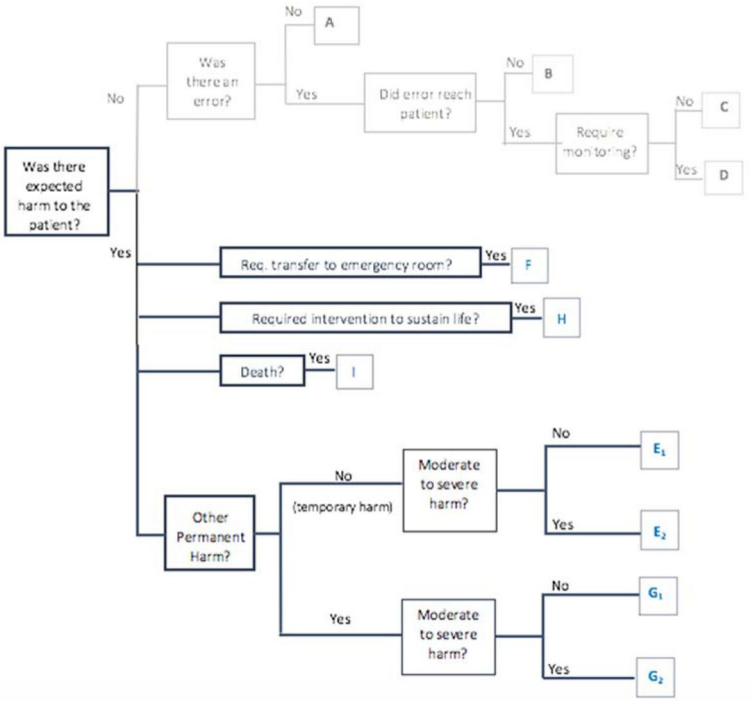

Figure 1.

Dental AE Severity Tree

Description of Dental AE Severity Categories:

Category E1: Temporary (reversible or transient) minimal/mild harm to the patient

Category E2: Temporary (reversible or transient) moderate to severe harm to the patient

Category F: Harm to the patient that required transfer to emergency room and/or prolonged hospitalization

Category G1: Permanent minimal/mild patient harm

Category G2: Permanent moderate to severe patient harm

Category H: Intervention required to sustain life

Category I: Patient death

Severity tree showing the chart review process for assigning severity categories to an adverse event. The reviewer begins on the left side and follows the branches of the tree to the right by answering each question.

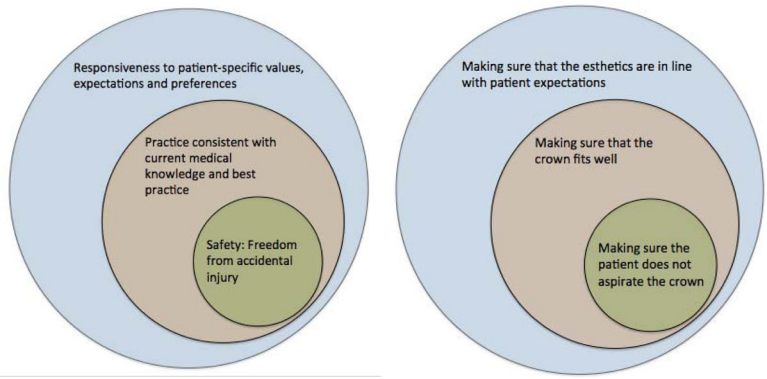

Figure 2.

Patient safety is a core component of quality of care. (Institute of Medicine (2000) To Err Is Human[37])

A hypothetical illustration of safety as a component of quality dental care delivery using tooth crowns. The smallest circle represents the attempt to keep the patient free from accidental injury by ensuring the patient does not aspirate the crown. This fits into the bigger circle of quality by ensuring the crown is functional. The last piece of quality is to ensure that it meets the patient's preference and aesthetic expectations.

Table 1

Dental AE Type Classification

AE Category	AE Count
Pain	56
Infection	17
Hard tissue damage	12
Nerve injury	6
Soft tissue damage/inflammation	5
Other oro-facial 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**

Table 2

Dental AE Severity Classification

AE Severity	Count
E2 (Temporary Moderate to Severe Harm)	89
G2 (Permanent Moderate to Severe Harm)	10
E1	0
G1	1
Total	**101**

Table 3

Dental Triggers Showing Reviewed Charts (3283 charts were triggered with specific triggers and 91,936 with a random sample of charts)

Triggers	**# Triggered Charts**	**#Reviewed Charts**
T1:Extraction Following RCT/Crown/Filling	110	99
T2: Untreated Periodontitis	224	100
T3: Failed Implant	34	34
T4 : Post-surgical extraction complications or Post Perio TX complications	377	100
T5: Repeated Fillings	391	129
T6: Multiple Visits	60	58
T7:Random Charts	91936	99
T8 : Nerve Injury	36	36
T9: Infections	430	100
T10: Soft tissue injury/inflammation	1449	100
T11: Allergy/Toxicity/Foreign Body response	36	35
T12: Aspiration/Ingestion of Foreign Body	136	68
Total	**3283 (+91936)**	**958**