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How Dental Team Members describe Adverse Events

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Abstract

Background—There is increased recognition that patients suffer adverse events (AEs) or harm caused by treatments in dentistry, and little is known about how dental providers describe these events. Understanding how providers view AEs is essential to building a safer environment in dental practice.

Methods—Dental providers and domain experts were interviewed through focus groups and in-depth interviews and asked to identify the types of AEs that may occur in dental settings.

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DISCLOSURE

None of the authors reported any disclosures.

None of the authors declare any conflict of interest, financial or other.

Statement of Responsibility

The manuscript has been read and approved by all authors and represents honest work. Below, please find the contribution of each of the authors to this manuscript:

RR conceptualized the project with EK and MW and developed the scientific grant proposal; PM and MW developed the scripts for the domain expert interviews and focus groups; PM facilitated the focus groups; JW conducted the domain expert interviews; PM conducted the analysis of the verbatim transcriptions and field notes from the domain expert interviews and the focus groups; JE and MK assisted with the focus groups and initial data preparation; EK developed the AE classification and the revised Eindhoven classification for causes. PM and EK adjudicated the incidents into causes and adverse events and adjudicated the causes and AEs further into separate classifications. JW, RV, MK, JK, VD, NH, DS and KK further refined the AE classification. AY performed all statistical analyses; EK and PM drafted the manuscript that was reviewed and edited by all authors.

Results—The first order listing of the interview and focus group findings yielded 1,514 items that included both causes and AEs. 632 causes were coded into one of the eight categories of the Eindhoven classification. 882 AEs were coded into 12 categories of a newly developed dental AE classification. Inter-rater reliability was moderate among coders. The list was reanalyzed and duplicate items were removed leaving a total of 747 unique AEs and 540 causes. The most frequently identified AE types were “Aspiration/ingestion” at 14% (n=142), “Wrong-site, wrong-procedure, wrong-patient errors” at 13%, “Hard tissue damage” at 13%, and “Soft tissue damage” at 12%.

Conclusions—Dental providers identified a large and diverse list of AEs. These events ranged from “death due to cardiac arrest” to “jaw fatigue from lengthy procedures”.

Practical Implications—Identifying threats to patient safety is a key element of improving dental patient safety. An inventory of dental AEs underpins efforts to track, prevent, and mitigate these events.

Keywords

Adverse event; Dentistry; Never event; Cause; Classification

INTRODUCTION

Medical adverse events are one of the leading causes of death in the US, and those that originate in the hospital setting have enjoyed significant attention.¹ There are multiple definitions of adverse events (AE) in medicine.^{2, 3} In this study, we define AEs as “harm caused to the patient by dental care, regardless of whether it is associated with an error or is considered preventable.” Dentists perform highly technical procedures in complex environments, work in teams, and use a multitude of devices and tools.⁴⁻⁹ However, less is known about the safety of dental care and this gap is troubling because a large proportion (65.5%)⁷ of the U.S. population goes to the dentist at least once a year. Evidence from case reports in the literature⁶ as well as a recent analysis of data from the FDA MAUDE database⁵, which tracks device related issues, confirmed that AEs do happen in the dental office. Examples of reported dental AEs include aspirated crowns⁸ and lacerations due to the use of high speed handpieces.⁴

The formal study of patient safety in medicine emerged in the 1990s propelled by the Institute of Medicine (IOM) report “To Err is Human”. The report challenged the US to build a safer healthcare system for the 21st century and great progress has been made in medicine, especially in hospital settings.¹⁰ The IOM suggested that safety improvements should encompass three activities: preventing AEs, making AEs visible, and mitigating the effects of AEs.¹⁰ However, the dental patient safety literature has mainly focused on managing risk,¹¹ exploring different approaches to improving specific surgical procedures,¹² or selection of dental products/materials.¹³ In our previous work¹⁴⁻¹⁶ we have proposed the adoption of The Agency for Healthcare Research and Quality Patient Safety Initiative which incorporates four major elements to address patient safety: (1) Identifying threats to patient safety; (2) Identifying and evaluating effective patient safety practices; (3) Educate, disseminate, implement, and raise awareness; and (4) Monitor threats to patient safety to

ensure that a positive safety culture is maintained and a safe environment continues. In order to benchmark the safety culture in dentistry, we previously adapted the extensively validated Medical Office Survey on Patient Safety Culture^{17, 18} and surveyed providers at 3 academic dental institutions.¹⁵ The results showed that the patient safety culture in these settings was sub-optimal across many measures compared with results from outpatient medical offices.

Building on previous research in dental patient safety,^{19–27} our goal for this study was to contribute to Element 1 of the patient safety initiative by developing an inventory of AEs generated by interviewing dental team members.

METHODS

The research was reviewed and approved by the Human Subject Committees of both participating institutions. We used individual domain expert (DE) and focus groups (FG) interviews to develop a list of adverse events (AE) that may occur in practice. One single investigator conducted all ten of the DE interviews, and a different single investigator conducted each of the six FGs. Calibration occurred during weekly team meetings during the 6-month period leading to the actual interviews.

Individual telephone interviews with domain experts

Individual interviews are effective means of collecting data to describe providers' perceptions of complex phenomena in health care research.²⁸ Based upon established and emerging specializations in dentistry, we identified ten practice domains: orthodontics, periodontics, endodontics, implant dentistry, oral surgery, prosthodontics, general restorative, radiology, oral pathology and oral medicine. A purposive sample of one DE from each of these domains (total n = 10) was interviewed by telephone for one hour to ensure the inclusion of domain-specific AEs. DEs were identified as associate or full professors who have practiced for more than 10 years in the specific field and published extensively. We employed a qualitative descriptive approach²⁹ used in medical research aimed at describing phenomena.³⁰ Interviews were designed to encourage specialists to reach deep into their personal or vicarious clinical experiences. A standardized interview (Appendix 1) ensured the fidelity of the interview questions posed to each expert (See table 1). Deliberative methods³¹ were used in both the DE and FG interviews by providing the participants with both the definition of AEs: "harm caused to the patient by dental care, regardless of whether it is associated with an error or is considered preventable", and a handout of exemplar AEs in dentistry such as "extraction of the wrong tooth".

Focus Groups

Focus group methods are an established and efficacious means of observing the experience, opinions and perspectives of a large number of study participants during a relatively brief amount of time. Focus group interviews are widely used in health research to gain insights into people's perspectives³² and are increasingly used in dental studies seeking a depth of understanding not captured in quantitative approaches with forced choice responses.^{33–37} The rationale for using a broad spectrum of academic dental providers in the academic setting was that they would be more likely to have direct or vicarious experience with a

broad range of AEs than the majority of dental providers such as those in community or private practices. Three mutually exclusive dental constituencies were stratified for the study sample: 1. faculty dentists, 2. dental students and residents, and 3. dental staff who were not dentists. Purposive sampling was used to recruit participants at each of two university-based dental clinics. We used a free listing method²⁵ based upon previous studies aimed at developing inventories of medical issues.^{26, 27} The FG interview guide (Appendix 1) ensured the fidelity of the interview structure between the six groups. The literature indicates that free Listing methods are designed to capture a saturated list of responses to a single question.^{38, 39}

Data classification approach

Figure 1 shows the eight steps of the analysis starting with analysis of the verbatim transcriptions and field notes from each interview. Telephone interviews with DE were recorded using a password protected WebEx platform; FGs were recorded using a digital audio recorder. Two research assistants took notes while the facilitator conducted the DE interview. Two research assistants also attended the FGs, one took notes, the other wrote the name of each AE on a flipchart. A research assistant transcribed each of the DE interview and FG recordings. A co-investigator checked every third transcription for accuracy by listening the audio recording while reading the transcription. All notes and flipcharts were transcribed; a qualitative descriptive approach³⁰ allowed only literal documentation of what participants identified as AEs.

To organize the data, each item listed as an AE from the FGs and DE interviews was classified. We discovered that many of the items reported as AEs were actually causes (defined as factors that may lead to harm and not the harm itself)⁴⁰⁻⁴² and not AEs (instances of actual harm that reach the patient). For example: “surgical site infection post operatively” was classified as an AE as it involves harm (infection) to the patient. While, “jumping from chair to chair with the same gloves” was classified as a cause. Two reviewers independently separated AEs from causes.

Items labeled as causes were then further classified. Semantic relationships among items emerged, which led a review of the literature on classifications, and the eventual development of eight categories of causes that we based upon the medical version of the Eindhoven Classification Model.^{43, 44, 45, 46} See Table 2.

We next classified AEs. As no AE classification exists for dentistry, we used a retrospective literature review of case reports on dental patient safety and analysis of dental device related AEs of the FDA MAUDE database to develop an initial classification of AEs. Initially, 23 AE categories were identified, which were further collapsed into 12 categories (Table 3). We included quality of care to capture items that were not causes, yet could not be considered an AE. E.g. loss of a temporary crown or bridge once or twice during treatment of a permanent crown or bridge; patient’s lips getting dry and cracked during prolonged procedure; or poor aesthetics.

Two members of the research team with complementary expertise, one oral surgeon and one behavioral scientist, acted as independent coders to test the utility of the categories for both

the causes and AEs. The first researcher had considerable experience studying dental patient safety related issues. The second researcher conducted the FGs and had substantial expertise in qualitative data synthesis necessary for AE classification. They independently coded every reported cause into one of the eight categories. The same procedure was followed for each of the reported AEs using the 12 AE categories. Tests for inter rater reliability using Kappa statistical tests were conducted to assess the reliability of the classifications.

A consensus process was used to determine the final classification category in cases of disagreement. We follow Katzenbach's⁴⁷ principles of high functioning teams. Reaching consensus was by making sure that all perspectives were heard and understood.

We then combined data from FG and DE interviews to generate an inventory of dental AEs and causes.

RESULTS

A total of 76 informants were asked to list AEs in dentistry; DE (n=10), and FG participants (n=66) during three focus groups in each of the university-based dental schools for a total of six groups that included dental faculty (n=16) dental residents and students (n= 26) and non-dentist clinical staff members (n=24).

The first order listing of the DE and FG interviews yielded a total 1,514 items reported as AEs. Analysis indicated that respondents confused causes with AEs. The DEs initially identified 524 events as AEs. Of these reported events, we identified that 36% (n=189) were causes rather than AEs. Among the 990 AEs identified by the FGs, 45% (n= 443) were causes. Figure 2 presents the confusion between causes and AEs. In total 747 unique AEs and 540 unique causes were identified (see Appendix 2 and 3).

An exemplar of the confusion is an item reported as an AE by a FG participant, "Poor home care instructions." While this might cause an AE, it is not itself an AE. As a cause, however, we coded it as a rule based error (Table 2). Another such example from a DE was, "Failure to have adequate staffing in the room given the level of sedation." While this cause might lead to disastrous consequences; poor staffing levels by themselves are not AEs. This example was coded as a latent organizational error.

Examples of human failures reported by FG and DE participants, include "practicing beyond the scope of training" (rule based error); "obstructing the airway when making an impression" (skill based error); and "failure to recognize decay" or "failure to diagnose" (knowledge based errors). For other examples see Table 2.

After the adjudication of the discrepant cases, the two independent raters agreed upon the final cause classifications. See Figure 3. Classifications for DE and FG combined show that rule based errors accounted for 43% (n=234) of the reported causes, skill based errors for 22% (n=120), and knowledge based errors for 13% (n=72) of the causes classified as provider related. By contrast, 11% (n=58) of the reported causes were classified as latent-organizational and only 5% (n=24) as latent-technical.

Of the 747 unique AEs included in the final analysis, the most frequently identified AE types in descending order of frequency were “Wrong-site, wrong-procedure, and wrong-patient errors” at 16% (n=116), “Hard tissue damage” at 15% (n=112), “Soft tissue injury” at 13% (n=101), and “Other Harm” at 12% (n=89). And although quality of care issues are not considered AEs, we included those in the analysis as they accounted for 10% (n=75). (Figure 4.)

Table 4 indicates that the inter-rater reliability between the two independent coders was moderate⁴⁸ in all instances (DE causes, DE AEs, FG causes, and FG AEs).

DISCUSSION

Our results demonstrate that dental team members listed a wide range of harms that might result from dental treatment. After further organizing these events we found that aspiration/ingestion was cited the most, while pain was cited the least. Aspiration or ingestion has been reported to occur infrequently, and of the two, ingestion occurs more often.⁴⁹ After food, objects of dental origin are second most likely to be aspirated.⁵⁰ However, these adverse events are difficult to ignore as they require extensive and invasive medical care, are costly and create a potential liability.⁵¹ By contrast, providers mentioned mild and manageable pain less frequently, despite the fact that pain follows a range of dental procedures. The quantification of the frequency of pain might increase dental teams’ awareness of a full range of potential AEs in daily practice.

Our study is the first known attempt to interview dental teams and identify an inventory of dental adverse events. We developed a classification system to organize these events in to one category and found that AEs and causes may be classified in multiple categories. As this research is a work in progress we make no claim that the inventory of AEs and causes is complete and their classification is subject to amendment based on additional information and context. The focus groups produced more items than the individual interviews, while the domain experts, identified more direct or vicarious experience with rare, unusual, or never events (i.e. motor loss after TMJ surgery; or unintended displacement of tooth into the infra-temporal fossa). As a result, we collected content rich data that included unlikely, common, and previously overlooked AEs (e.g., extracting the wrong tooth; gingival trauma due to restorative procedure; and sinus perforation). The free listing approach, similar to brainstorming, allowed only for naming AEs, rather than further in depth discussion.

While we did not anticipate the confusion with causes being identified as AEs, these items have provided a rich perspective on how dental providers perceive harm in the dental office and can be used in the future to minimize or prevent AEs from occurring.

An unanticipated finding was the number identified AEs that we classified as quality of care issues. It was based upon the consultation of this project’s Advisory Committee, composed of experts and pioneers in medical adverse events, that we developed the general rule for deciding on what constitutes an AE rather than a quality of care issue; 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 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 under fill of an endodontic treated canal.

There are clear advantages for the implementation of a standardized categorization of dental AEs. It allows for the development of registries, and thus the ability to identify threats to patient safety; raises awareness and monitors threats to patient safety; and allows for future identification and evaluation of patient safety practices.

Some limitations exist in our research. Our study involved two academic dental institutions so we hope to expand the work to a broader range of dental practices in the future. Single DEs in each of the ten practice domains are not a representative sample but this approach allowed us to capture domain specific AEs. For the purpose of clarity, we distributed a working definition of AEs and a short list of AE examples to the DE and FG participants prior to commencing the interviews. Items on the list were not included in the data that we reported unless the participants restated them. While this may have compromised the free listing, it provided a clear message what constituted an AE.

It is possible that a future study population might identify additional items. The purposive sample of ten DEs may reflect only individuals’ perspective of dental AEs. We expect that this type of non-probability sampling does in fact introduce some degree of bias.⁵²⁵³ While the non-probability sample in the DE interviews and FGs is a potential source of bias, we used the purposive sampling technique in order to reach participants who would be more likely to have greater knowledge of AEs than other dental providers. Further, despite extensive calibration efforts, two reviewers coding AE data into the twelve classifications (See Table 3) were only able to reach moderate agreement, indicating ambiguity inherent to classifying events. In future work we look forward to further applying and expanding this initial list of AEs; determining how frequently these AEs occur in practice and how we can efficiently detect them.

CONCLUSION

Dental providers identified a large and diverse array of dental incidents that were divided into causes of harm, adverse events that produce patient harm and quality of care issues. Our results demonstrate that a classification system such as the one developed in this study may be a viable approach to increase dental providers awareness, and to think proactively, about the full range of harm that patients may experience as a result of dental treatment. This study contributes to an emerging culture of patient safety in dental medicine.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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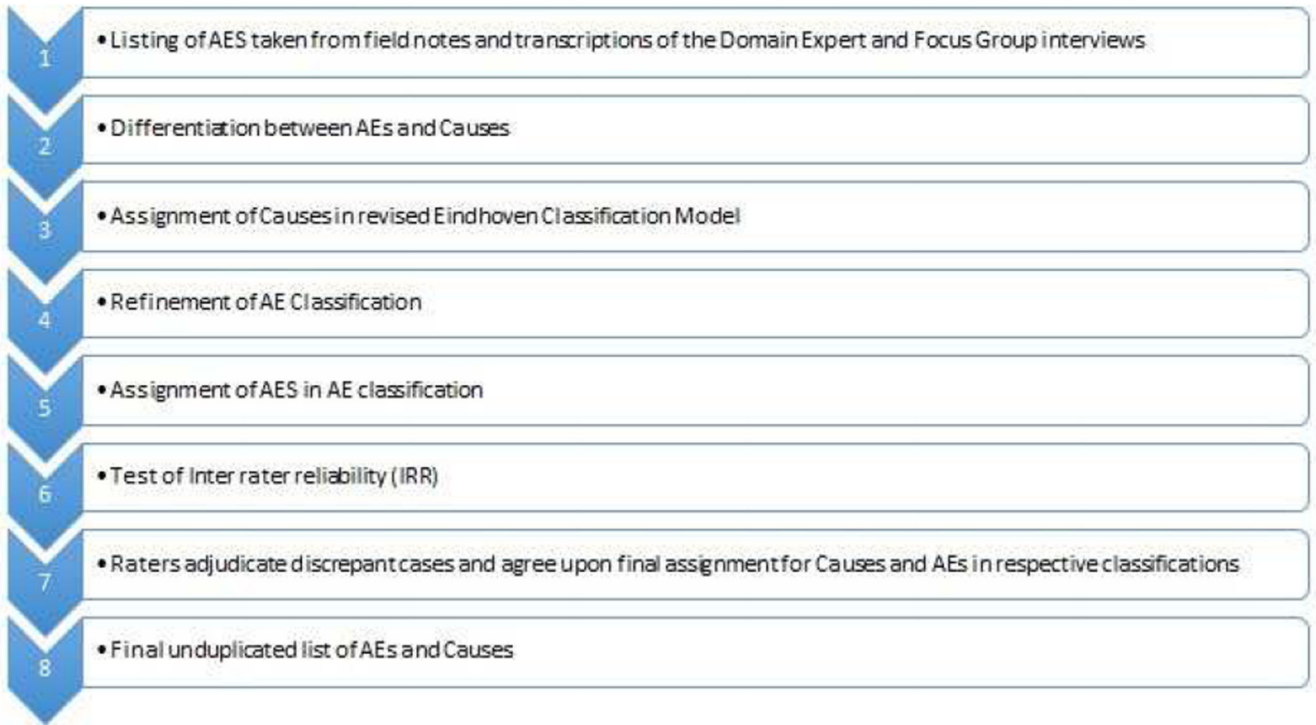


Figure 1.
Eight Phases of Analysis for domain expert and focus group findings

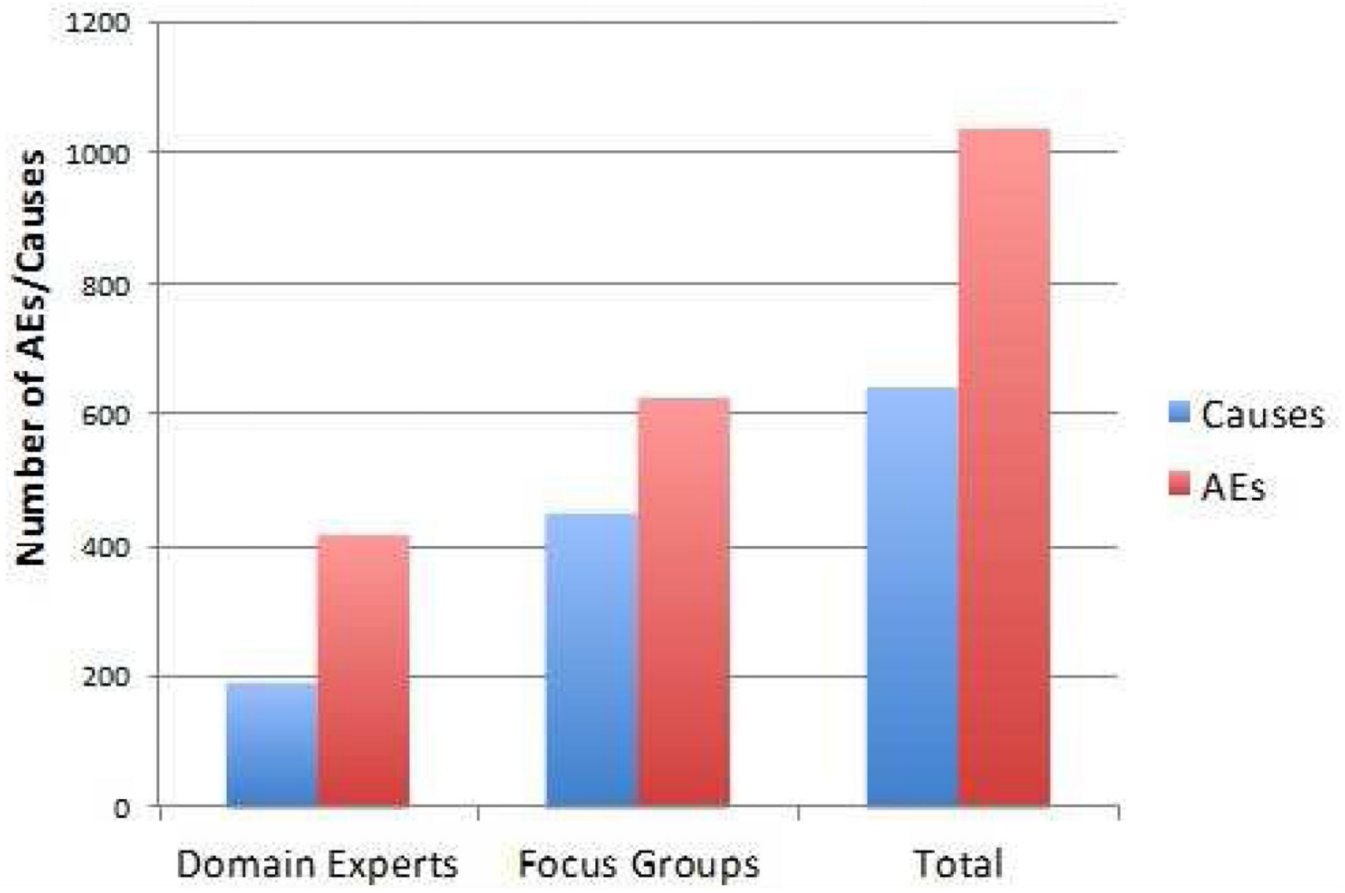


Figure 2. Frequency of responses by domain experts and focus groups participants that were classified as Causes and AEs.

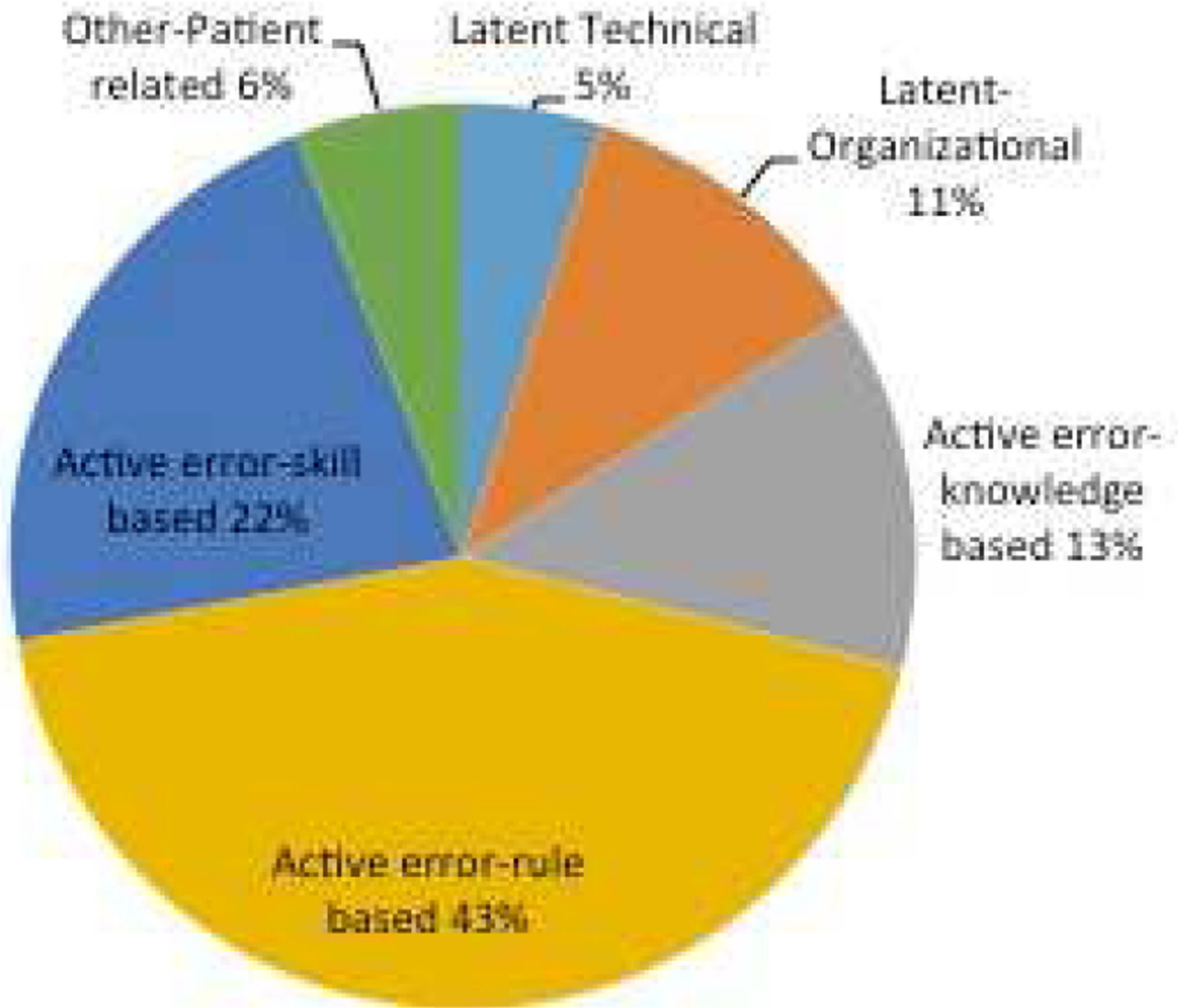


Figure 3.
Based on: TW van der Schaaf, Eindhoven Classification Model for Medical Domain

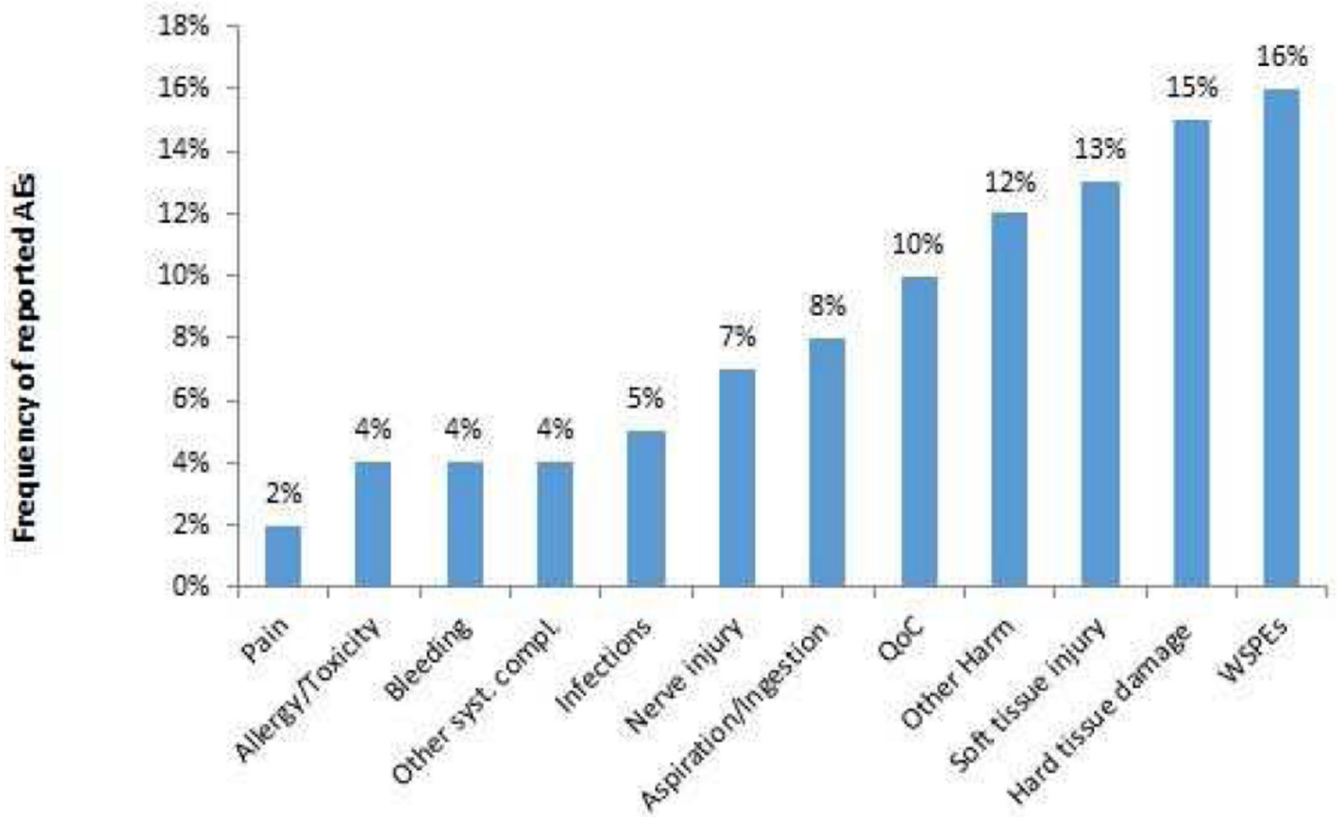


Figure 4.

Items coded by the Dental AE Classification* (N=747)

*Note that we do not consider Quality of Care (QoC) issues adverse events; those events were included in the analysis as they made up 10% of the overall reported events. WSPes: Wrong site, wrong patient errors.

Table 1

Focus Group and Domain Expert Core Interview Questions

Following personal introductions, a review of the purpose of the study, and the ground rules for the focus group, the facilitator reviewed the working definition of adverse events adopted from the literature. At that point, the facilitator asked the five questions listed below. The co-facilitators took notes on the phone calls with Domain experts, and wrote responses on flip charts that were hung in sight of the participants. The questions focused exclusively on listing adverse events. The facilitators were trained keep the focus on naming adverse events.

- 1 What are some common AEs?
- 2 What are some less common AEs?
- 3 In your (expert) opinion, which AEs should never happen?
- 4 Are there any other AEs, like those outside of your area of expertise/knowledge that come to mind?
- 5 Do you have any additional comments or questions?

Table 2

Classifications of Causes Based on Eindhoven Classification Model: Medical Version (Battles et al. 1998)¹ of Adverse Events in Dentistry with Exemplars

Classification	Responses from respondents (unweighted)
Latent Technical	<ul style="list-style-type: none"> • Failure to ensure sterilization equipment is working properly • Improper calibration of x-ray equipment • Inability to access patient records across electronic health record platforms • Incompatibility in digital format of x-ray images between providers during emergencies
Latent Organization	<ul style="list-style-type: none"> • Failure to have a code cart • Lack of proper staff training • Failure to do comprehensive oral exams due to workflow pressures • Inadequate staff training regarding sterile techniques
External-based active error	None reported
Knowledge-based active error	<ul style="list-style-type: none"> • Failure to use proper technique in administering local anesthesia • Failure to diagnose TMJ • Missed open margins • Failure to address root pathologies
Rule-based active error	<ul style="list-style-type: none"> • Poor home care instructions • Jumping from chair to chair with bloody gloves • Failure to screen for coagulopathy problem or a bleeding problem before biopsy • Failure to have three people in the room during deep sedation general anesthesia
Skill-based active error	<ul style="list-style-type: none"> • Leaving cement in the sulcus • Improper extraction technique damaging floor of mouth • Biopsy samples distorted due to laser exposure preventing pathologic diagnosis • Hitting an adjacent tooth in osteotomy
Patient-related other	<ul style="list-style-type: none"> • Financial barriers interrupting sequence of treatment • Failure to perform final restoration due to patient noncompliance • Patient contributions (behaviors) to soft tissue damage during procedures • Lost healing abutments
Unclassifiable other	<ul style="list-style-type: none"> • Anxiety transferred to the clinician • Tripping over hoses • Physical abuse by provider to child • Broken hand pieces during treatment

Table 3

Dental Adverse Event Classifications * based upon AHRQ classifications for medical errors: <http://psnet.ahrq.gov/primer.aspx?primerID=18>) with Exemplars

AE Classification	Responses from respondents (unweighted)
Allergy/Toxicity/Foreign	<ul style="list-style-type: none"> Nitrous oxide toxicity
Body Response	<ul style="list-style-type: none"> Allergic reaction to dental materials Drug-drug interactions Upper vascular epinephrine injections resulting in rare allergic reactions
Aspiration/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 post-surgery Medication induced candidiasis Development of a deep space infection warranting additional treatment
WSPEs Procedure on wrong site Procedure on wrong patient Wrong treatment due to misdiagnosis Other wrong treatment	<ul style="list-style-type: none"> Failed crowns due to wrong material selection Treating the wrong tooth Endodontic treatment of non-restorable teeth Performing surgical procedure in wrong area
Bleeding	<ul style="list-style-type: none"> Perforation of arteries during surgical procedure Post-surgical 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 following dental surgery Inadequate anesthesia resulting in pain Excessive pain following oral surgery Inaccurate crown adjustment leading to tooth pain, discomfort and TMD
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 wisdom tooth extraction
Soft tissue injury/ 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 following osseous surgery
Nerve injury	<ul style="list-style-type: none"> Mandibular nerve injury

AE Classification	Responses from respondents (unweighted)
	<ul style="list-style-type: none"> • 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 GI 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 • Poorly fitting crowns • Aesthetic failure, crowns are completely different color than patient's teeth

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Table 4

Inter-rater reliability (IRR)

	κ	CI	z-score	p-value
DE Causes (n = 189)	0.41	95% (0.32, 0.5)	11.8	<0.0001
DE AEs (n=336)	0.47	95% (0.42, 0.53)	28.1	<0.0001
FG Causes (n = 443)	0.41	95% (0.35, 0.46)	16.1	<0.0001
FG AEs (n=547)	0.48	95% (0.44, 0.53)	34.5	<0.0001

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