Patient safety incidents in primary care dentistry in England and Wales: mixed methods study

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ABSTRACT

Background: In recent decades, there has been considerable international attention aimed at improving the safety of hospital care, and more recently this attention has broadened to include primary medical care. In contrast, the safety profile of primary care dentistry remains poorly characterized.

Objectives: We aimed to describe the types of primary care dental patient safety incidents reported within a national incident reporting database and understand their contributory factors and consequences.

Methods: We undertook a cross-sectional mixed-methods study, which involved analysis of a weighted randomized sample of the most severe incident reports from primary care dentistry submitted to England and Wales' National Reporting and Learning System. Drawing on a conceptual literature-derived model of patient safety threats that we previously developed, we developed coding frameworks to describe and conduct thematic analysis of free text incident reports and determine the relationship between incident types, contributory factors and outcomes.

Results: Out of 2,000 reports sampled, 1,456 were eligible for analysis. Sixty types of incidents were identified and organized across pre-operative (40.3%; n=587), intra-operative (56.1%; n=817) and post-operative (3.6%; n=52) stages. The main sources of unsafe care were *delays in treatment* (344/1,456; 23.6%), *procedural errors (excluding wrong-tooth extraction)* (227/1,456; 15.6%), *medication-related adverse incidents* (161/1,456; 11.1%), *equipment failure* (90/1,456; 6.2%) and *x-ray related errors* (87/1,1456; 6.0%). Of all incidents that resulted in a harmful outcome (n=77; 5.3%), over half were due to wrong tooth extractions (37/77; 48.1%) mainly resulting from distraction of the densist. As a result of this type of incident, 34 of the 37 patients (91.9%) examined required further unnecessary procedures.

Conclusions: Flaws in administrative processes need improvement since they are the main cause for patients experiencing delays in receiving treatment. Checklists and standardization of clinical procedures have the potential to reduce procedural errors and avoid over-utilization of services. Wrong-tooth extractions should be addressed through focused research initiatives and encouraging policy development to mandate learning from serious dental errors like never events.

Keywords: Ambulatory dentistry, community dentistry, patient safety, patient safety incidents, primary dental care.

Introduction

Healthcare-associated harm is estimated to occur in between 3% and 16% of hospital admissions.[1-3] In primary care, between two and three patient safety incidents occur per every 100 encounters;[4] with approximately 4% of these primary care incidents resulting in severe harm.[(4)] Over the past 20 years, healthcare organizations, researchers and policymakers around the world have begun to pay increasing attention to patient safety. Accumulated evidence about the extent of harm and underlying causes has been translated into interventions designed to improve the safety of the healthcare system,[5] such as incident reporting systems.[6, 7] The need to develop and introduce these systems was signalled within the reports *To Err is Human*[8] and *An Organisation with a Memory*.[9] Their fundamental role is "*to enhance patient safety by learning from failures of the health care system*".[10] The analysis of the retrieved data from these systems provide valuable insights about the trends and patterns of patient safety hazards at an organizational level[11] and can allow the identification of priorities for intervention.[12] This information further bring opportunities to develop evidence-based models for safe practices and support for education and learning.[11] Compared with other data sources,[13] incident reporting systems can provide continuous, near real-time insights about diverse patient safety incidents, including near misses.

Patient safety in primary care is a field that remains largely unexplored.[14, 15] In the United Kingdom (UK), initial mixed-methods studies analyzing general practice incident reports from the National Reporting and Learning System (NRLS) have shown their utility to categorize PSIs and identify patterns of contributory incidents and contributory factors.[16-20] However, patient safety research in dentistry is in its early development. A recent scoping review on PSIs and adverse events in dentistry shows that, over the past 20 years, this field has not employed standardized patient safety terminology and used varying study designs and methodologies to investigate unsafe care.[21] As a result, the current evidence cannot be generalised and provide reliable estimates of the frequency of incidents, their causes, or the outcomes of these errors. To standardize patient safety research in dentistry, recent studies have started to focus on the characterization of patient safety incidents,[22] including adverse events.[23, 24] Only two studies have explored primary dental care data from national incident reporting systems,[22, 25] from which one built an initial classification. [(22)] Although these classification systems provide a starting point, they should be further expanded/refined and include a clear distinction between incidents, their causes as well as the outcomes affecting the patient (adverse events) and healthcare system. Therefore, we aimed, firstly, to explore data from the NRLS to identify emerging themes and then develop categories and subcategories of incidents, their contributory factors, outcomes and degree of harm. Secondly, we aimed to describe incident patterns through identification of frequencies of the relationships between incidents and contributory factors. Thirdly, we aimed to describe the more frequent and harmful reported incidents.

Methods

We conducted a two-stage cross-sectional, mixed-methods study of the NRLS with a selected sample of reports from primary dental care for analysis. We combined qualitative methods and iterative generation of data summaries using descriptive statistical and thematic analysis methods.[26]

Data source

The NRLS is a national reporting system created in 2003 for the NHS in England and Wales by the former National Patient Safety Agency (NPSA). It is one of the most comprehensive reporting systems in the world.[27, 28] It consists of a database of incident reports submitted by National Health Service (NHS) healthcare organizations, however, patients and other members of the public can also submit online reports directly to the NHS. The NHS definition for the reported patient safety incidents refers to *"any injury or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare."*[29] Although reporting was initially voluntary, it has since 2010 been mandatory to report any incidents that resulted in severe patient harm or death. The reports contain categorical data (e.g. age, incident location and severity of harm) and three unstructured free-text fields to encourage reporters to provide a narrative description of the event, perceived causes and potential preventive measures.[26] Incident reports describing severe harm and death outcome are reviewed by healthcare staff and safety experts responsible for the NRLS to identify opportunities for the continuous improvement of care.

Sample selection

The complete data set consisted of 42,729 reports over a period of 8 years (between April 2005 and September 2013) from general practice in England and Wales. We applied the pre-coded NHS categories "Primary care setting" and "Dental surgery" to filter the dataset and obtain a sample of 11,836 records (see Figure 1). From these, we read the narrative descriptions and excluded the reports not related to dentistry. As a result, a revised sample of 4,247 reports was obtained. From this sample, all reports with a "moderate", "severe" and "death" (combined total, n=257) outcome were included. From the remaining "no harm" and "low harm" reports (n=3990), a random sample of 1,743 reports, weighted by year and the severity of harm, was generated to prioritize more recent (2012-2013) and harmful reports. As a result, a total of 2,000 reports were included for coding. The detailed sampling strategy is shown in Appendix 1.

Methodology

An overview of the methodology is shown in Figure 1. For the first stage, we explored 300 randomly-selected reports and deductively developed initial codes to structure the free-narrative descriptions of the reported incidents. This resulted in three coding frameworks to describe what happened, i.e. type of incident (Appendix 2), perceived reasons the incident occurred, i.e. contributory factors (Appendix 3) and incident outcomes (Appendix 4). These frameworks present a hierarchical arrangement of first- and second-level codes that were continuously refined throughout the study. The codes were constantly compared against categories from other patient safety classification systems. These included the World Health Organization's (WHO) International Classification for Patient Safety,[30] the LINNEAUS Patient Safety Classification for Primary Care,[31] the Primary Care Patient Safety (PISA) Classification System[18] and the results obtained from our previous scoping review.[21] The reports were coded by the first author (EEC). Moreover, a second coder (AS) was trained and provided the same sample of 300 randomly-selected reports and discussed with the main author, the challenges and additional improvements to the coding frameworks. For the second stage, we applied the coding frameworks on our weighted randomized sample of 2,000 reports. Following the method described by Rees et al.,[17] we applied the nine rules of the Recursive Model of Incident

Analysis[32] to structure the coding process (see Appendix 5). Following this approach, we applied between one to four codes in chronological order to describe primary incidents, contributory incidents and contributory factors. The main incident was labelled as a 'primary incident', which was the closest incident to the outcome experienced by the patient. Then, 'contributory incidents' were defined as those incidents preceding the primary incidents. Both primary incidents and contributory incidents were coded in accordance with the incident coding framework (see Appendix 2). A 'contributory factor' was defined as "*a circumstance, action or influence (such as poor rostering or task allocation) which is thought to have played a part in the origin or development of an incident, or to increase the risk of an incident*".[33] Contributory factors were coded in accordance with the contributory factors coding framework (see Appendix 3). Coding of the free-text narrative descriptions allowed the categorization of reports by incident type, potential contributory factors, outcome and severity of harm. This provided the basis for the subsequent data analysis. The severity of harm was assessed using the WHO's International Classification of Patient Safety definitions (see Table 1).[30] To assess the inter-coder reliability, 20% of the reports (n=400) were double coded (EEC and AS). Then, raw agreement and Cohen's K statistics[34] were calculated for the primary incident. A kappa of >0.7 was sought between the two coders. Disagreements in coding were arbitrated by a third person.

Data analysis

For the first stage, during the data coding, the reports were further thematically analyzed and re-read for familiarization. If needed, new codes were created to capture additional semantic (descriptive and in-depth) insights and latent (underlying or inferred) insights present in the narrative descriptions and the circumstances (context) in which the incidents occurred.[35, 36] All codes were grouped into themes and sub-themes to support our understanding of data and the underlying reasons for incidents that might not have been captured by the quantitative data.[35, 36] For the second stage, we undertook an exploratory, descriptive analysis[37] to generate descriptive summaries to identify priority areas based on: (i) the most frequent incidents; and (ii) the most harmful outcomes that resulted in moderate harm, severe harm or death. Following the method used by Rees et al.,[17] we employed pivot tables in Microsoft Excel[38] and cross-tabulated the most frequent incidents per clinical stage with available contributory incidents, contributory factor and their outcomes. We also cross-tabulated the degree of harm against the primary incident types to identify potential relationships in the data. Then, we identified additional patterns in the data by exploring all the frequencies of combinations of incidents and contributory factors (e.g. primary incident + secondary incident + contributory factor).

Ethics

Institutional Review Board approval was obtained from The University of Edinburgh's Centre for Population Health Sciences Research Ethnics Committee.

Results

Of the 2,000 randomized reports, 1,456 were included in the quantitative analysis. Reports were excluded if they did not describe a patient safety incident (n=311), were not related to dentistry (n=125), concerned patient falls (n=31), contained insufficient details (n=23), dentist harmed rather than the patient (n=18), or were about general non-specific complaints (n=6).

Raw agreement (86.5%) and Cohen's kappa (k) statistic for inter-rater coding reliability for primary incidents was high (k=0.860; p<0.01).

Incidents

Table 2 shows a description of the primary incidents we identified. These occurred in the pre-operative (40.3%; n=587), intra-operative (56.1%; n=817) and post-operative (3.6%; n=52) stages of dental care delivery. Main **pre-operative incidents** were delays in treatment (58.6%, n=344), innaccurate information on medical record (10.4%, n=61) and breaches of confidentiality (4.8%, n=28). In the **intra-operative stage,** these included procedural errors (27.8%, n=227), medication-related adverse incidents (161/817; 19.7%) and equipment failure (11.0%, n=90). The more frequent **post-operative incidents** were contraindicated medications prescribed/dispensed (n=15; 28.8%) and errors in the process of delivering a medication (n=12; 23.1%). Regardless of the clinical stage, the main five incident types were *delays in treatment* (23.6%; n=344), *procedural errors (excluding wrong-tooth extraction)* (15.6%; n=227), *medication-related adverse incidents* (11.1%; n=161), *equipment failure* (6.2%; n=90) and *x-ray related errors* (6.0%; n=87).

Contributory incidents and contributory factors

Of the 1,456 primary incidents, 34.8% (n=506) contained data about *contributory incidents*. From these 506, main *contributory incidents* were the dentist´s unavailability (20.2%), equipment failure (14.6%) and mismanagement of appointments (12.6%). Data about *contributory factors* were available in 42.8% (n=623) of the reports. From these 623, main *contributory factors* included distraction (25.5%), insufficient staff members (25.5%) and inadequate skills or knowledge (11.2%). All the possible combinations of primary incidents with contributory incidents and contributory factors organized by clinical stage are available in Appendices 6-8.

In the pre-operative period, frequent *contributory incidents* for **delays in treatment or procedure (n=344)** were the dentist´s unavailability (29.7%, n=102), mismanaging of appointments (16.9%, n=58), and ineffective transportation of patients (7.3%, n=25) (Examples 1 to 3 in Box 1). C*ontributory factors* included insufficient staff members (32.3%, n=111) (Example 4 in Box 1) and lack of equipment maintenance (4.4%, n=15). Secondly, for reports concerning **innaccurate information on records (n=61),** main *contributory incidents* were Information Technology (IT)-related errors (23.0%, n=14) (Example 5 in Box 1). Thirdly, for reports concerning **breaches of confidentiality (n=28),** frequent *contributory incidents* were the inefficient transfer of information between healthcare settings and wrong medical records (7.1%; n=2 each) (Example 6 in Box 1). Main *contributory factors* were failure to adhere to procedures or regulations (50.0%, n=14) (Example 7 in Box 1) and distraction (14.3%, n=4).

In the intra-operative period, *contributory incidents* for **procedural errors (n=227)** included equipment failure (9.3%, n=21) (Example 8 in Box 1) and insufficient clinical examination (2.2%, n=5). Main *contributory factors* were distraction (31.3%, n=71) (Example 9 in Box 1), unexpected movement from the patient (10.1%, n=23) (Example 10 in Box 1) and inadequate skills or knowledge (8.8%, n=20). Then, for **medication-related adverse incidents (n=161),** *contributory factors* included the patient's previous health-related conditions (13.7%, n=22) (Example 11 in Box 1) and non-compliance from the patient (5.6%, n=9) (Example 12 in Box 1). Lastly, for incidents concerning **equipment failure (n=90),** main *contributory factors* were lack

of equipment maintenance (44.4%, n=40) and poor equipment design (6.7%, n=6) (Example 13 in Box 1). In the post-operative period, *contributory incidents* for **contraindicated medications prescribed/dispensed (n=15)** were insufficient clinical examination (20.0%, n=3) (Example 14 in Box 1). C*ontributory factors* included the patient's previous history on allergies (46.7%, n=7) (Example 15 in Box 1) and staff distraction (20.0%, n=3) (Example 16 in Box 1). **Errors in the process of delivering a medications** (n=10) (Example 17 in Box 1) did not include *contributory incidents or factors.*

Outcomes

Table 3 shows the characterization of incident outcomes. Of the 1,456 incidents, 40.0% (n=583) did not describe an outcome. The more frequent outcomes were *increased documentation/follow-up* (12.4%; n=181), *vasovagal response* (8.2%; n=119), *laceration/bleeding* (6.9%; n=100), *delays in using the dental clinic* (5.8%; n=84), *unnecessary x-ray exposure* (5.1%; n=74) and *repeated procedures/additional treatment* (4.9%; n=72). Cross-tabulations of outcomes (n=1,456) with the degree of harm showed that 97.7% resulted in either no harm or low harm (n=1,379), and only 5.3% were harmful (n= 77). The main harmful ouctomes were unnecessary procedures (44.2%; n=34), anaphylaxis (9.1%; n=7) and vasovagal responses (7.8%; n=6). Cross-tabulations of these harmful outcomes with the primary incidents showed that all harmful reports that resulted in unnecessary procedures (n=34) were due to to *wrong-tooth extractions*. Then, harmful reports involving anaphylaxis (n=7) were mainly due to medication-related adverse incidents (42.9%; n=3) and contraindicated medications prescribed/dispensed (28.6%; n=2). Finally, harmful vasovagal responses (n=6) were mostly due to medication-related adverse incidents (83.3%; n=5).

For the main pre-operative incidents, frequent outcomes for **delays in treatment** (n=344) included increased documentation/follow-up (23.3%, n=80) and repeated procedures or additional treatment (5.8%, n=20) (Examples 18 and 19 in Box 1). **Incorrect or unavailable documentation** (n=61) mostly led to increased documentation/follow-up (14.8%, n=9) and delays in using the dental clinic (8.2%, n=5) (Examples 20 and 21 in Box 1). One **breach of confidentiality** resulted in legal implications (3.6%, 1/28;). Secondly, for the main intra-operative incindents, **procedural errors** (n=227) included laceration/bleeding (41.9%, n=95), chemical injuries (9.3%, n=21), repeated procedures/additional treatment (7.5%, n=17) and thermal injuries (6.2%, n=14) (Examples 23 to 26 in Box 1). **Medication-related adverse incidents** (n=161) mostly led to a vasovagal responses (64.0%, n=103) (Examples 27 and 28 in Box 1). **Equipment failure** (n=90) mostly led to delays in using the dental clinic (34.4%, n=31) (Example 29 in Box 1). Finally, for main post-operative incidents, **contraindicated medications prescribed/dispensed** (n=15) led to increased documentation/follow-up and anaphylaxis (20.0%, n=3 each) (Example 30 in Box 1). The majority of the reports concerning errors in the process of delivering a medication did not describe harmful outcomes (75.0%, 9/12).

Discussion

To our knowledge, this is the first mixed-methods study of incident reports from primary care dentistry, identifying the main incident types, their contributory factors and outcomes (clinical and non-clinical). At a conceptual level, our methodological approach aligns with the Swiss Cheese Model of System Accidents proposed by Reason.[39] Moreover, this mixed-methods approach seeks to identify the chronological sequence of events leading up to error by drawing

upon the Recursive Model for Incident Analysis. This approach has been used in general practice[16-18, 40, 41] and has received positive reviews.[42] We drew on a large national database of incidents and achieved very good agreement between two independent coders. Our coding frameworks enabled us to understand the relationships between incident types and contributory factors which highlight opportunities to improve patient safety.

However, we also acknowledge that the reports analyzed likely constitute the tip of the iceberg[43] as these only included events that were actually reported. Although the NRLS has collected over 15 million reports since 2003, less than 1% of these reports originate from primary care.[44] Whilst NHS healthcare professionals might be aware of the NRLS, their fear of punishment from reporting incidents, the time required to report, and the lack of belief that reporting will lead to change are all recognized barriers to reporting.[44] Also, our ability to extract detailed information surrounding context (e.g. demographics and disciplines involved) was limited as the reports were largely unstructured. Renton and Sabbah (2016) also reported this data quality issue.[25] In addition, the free narrative descriptions were often shorthanded and contained abbreviations or other jargon to describe clinical procedures. To bring sense to the data and avoid the risk of confirmation bias,[45] we assigned codes which represented what was explicitly described in the reports; inferences were avoided, in particular when no explicit description was available. Therefore, following the rules from the Recursive Model of Incident Analysis, we coded "primary incidents" as those closest to the outcome. Then, if available, we coded "contributory incidents" as those incidents that preceded the primary incident. We believe this work provides a starting point to systematically characterize future incident reports from primary care dentistry (Appendices 2 to 4).[22, 23, 25, 46-50]

Incidents

In our study, *delays in treatment* were the main pre-operative incidents and remained as the most frequent among all incident types. Although these incidents were not harmful in our study, their presence reveal flaws in the provision of efficient dental care. Nevertheless, delays in treatment can still contribute to diagnostic delays, which can result in the unnecessary clinical deterioration or complication of the patient´s condition or disease.[51] Therefore, we recommend improving administrative processes by understanding the demand for dental care services in the range of care contexts used for delivery. Guidance for the provision of safe, reliable and effective care is available from the Institute for Healthcare Improvement (IHI),[52] including a dentistry-focused IHI Open School course in partnership with the Dental Quality Alliance, established by the American Dental Association.[53]

Our findings also revealed that *procedural errors* were the main intra-operative incidents and the second most frequent among all incident types. Their frequency could be reduced by determining warranted and unwarranted variations in clinical practice. This might be achieved by reviewing compliance with evidence-based or best practice guidelines. However, an emerging threat to patient safety is the increasing complexity of clinical cases and multi-morbidities as the population gets older by living longer.[54] Therefore, as discussed by Hollnagel et al.,[55] clinicians should also have flexibility to adapt their procedures in accordance with the specific needs of the patient being treated. *Equipment failure* was the third most common intra-operative incident and the fourth most frequent among all incident types. This type of incident has been described previously by Perea-Perez et al.,[47] Hiivala et al.[48, 50] and an issue identified from the Food and Drug Administration (FDA) and the Manufacturer and User Facility

Device Experience (MAUDE) database.[56] Based on our findings, we believe equipment-failure incidents can be reduced by having all staff members familiarized with the maintenance processes and assign responsibility to team members to carry out this task on a periodical basis. In identifying patterns of incidents, we also identified *equipment failure* as a "contributory incident" for other "primary incidents" such as *procedural errors* and *errors in obtaining or processing x-rays*. This highlights the interaction of healthcare professionals with sophisticated tools and technologies could increase risk to patient safety,[54] and manufacturers should support practitioners and staff to safely use their equipment.

In our study, *wrong-tooth extractions* were the main source of harmful incidents. Although not frequent (2.7%), these have been studied previously[22, 25] and they meet the criteria of 'never events' due to their severity and degree of preventability.[25, 57] Prevention of these and other incidents can be achieved through the use available procedural checklists[58-61] to reduce reliance on memory and thus, limiting the impact of distraction or inattention in the occurrence of incidents.[62] A recent systematic review on patient safety interventions in dentistry revealed that surgical safety checklists, which covers tooth extractions, demonstrated efficacy to reduce or minimize AEs.[63] We also identified other less frequent intra-operative incidents, which have been also reported in the literature. These include the *inhalation and ingestion of foreign objects,* reported through the review of relatively small samples of adverse event case reports,[49] malpractice cases,[47] and dental patient records.[64] Although not frequent, inhalation of foreign objects alone has recently been proposed as a "never event" through international consensus.[65]

Perea-Perez et al.[47] and Hiivala et al.[48, 50] also previously reported similar post-operative incidents. However, incidents related to prescription of medications, or their dispensing, remain largely unreported.[21] Therefore, the evidence base about medication errors in dentistry needs further investigation. Medication errors involving antibiotics for example contribute to antimicrobial resistance worldwide[66] and antimicrobial resistance is an emerging threat to patient safety in the next 30 years.[54] Recently, the World Health Organization (WHO) launched the third Global Patient Safety Challenge to minimize medication related error[67] and dentistry should consider its contribution to this global agenda.

Contributory incidents and contributory factors

The majority of medical errors are due to faulty systems and processes.[8] Reason´s Swiss cheese model of system accidents[39] shows that human errors are often a consequence of latent organizational flaws, such as administrative or management issues. Our findings corroborate this and revealed issues of accessibility to services and mismanagement of appointments, insufficient staff members and lack of equipment maintenance. These issues were mainly related, as a contributory incident or a contributory factor, to patients experiencing delays in receiving treatment, which was the main incident reported to the NRLS. Although these incidents did not lead to harmful outcomes, they reveal the underutilization of primary dental care services. Underutilization of care is a prevalent issue in both high- and low-income economies.[68] Factors contributing to this issue broadly include: a) inaccessible healthcare services to the patient, b) the unavailability of effective services, for instance the result of a lack of resources, c) the clinician's failure to provide effective care, and d) the patients' (inadequate) compliance and adherence to effective healthcare interventions.[68] As the organizational structure of dental care is likely to differ between countries and clinical settings,

we believe quality improvement strategies should be developed and implemented locally. *Distraction* and *unexpected movement from the patient* were the most frequent "contributory factors" for procedural incidents and wrong-tooth extractions. This highlights any unexpected distraction can create conditions for unsafe care. Other reported contributory factors in the literature for wrong-extractions include: i) inadequate checks, ii) incorrect radiographs, and iii) wrong diagnoses have also been reported as causes for wrong-tooth extraction.[25]

Outcomes

Vasovagal responses and lacerations/bleeding were the most commonly described adverse outcomes. However, the majority of outcomes resulted in either no harm or low harm (94.7%; n=1,379) which frequently resulted in increased documentation/follow-up, delays in using the dental clinic, unnecessary x-ray exposure and repeated procedures/additional treatment. The identification of these outcomes showed the presence of flaws in the provision of efficient and effective primary dental care, which in addition to patient safety highlight two further compromised aims of quality improvement, as proposed by the former IOM.[51] Moreover, the over-utilization of healthcare services can: a) contribute to future unnecessary harm; b) result in additional financial demands for the patient; and c) cause waste of resources within the healthcare system.[69]

Our findings have helped to identify priority issues for improvement and are a starting point for setting patient safety research priorities in dentistry.[70] Patient safety in dentistry is still an emerging discipline which needs to be further developed in parallel with the quality of care. Health services researchers designing patient-safety-oriented interventions[51] should consider the more frequent and most harmful incidents reported in this study. Policy makers could take note of these emerging priorities and allocate resources accordingly. We believe this approach will contribute to reduce unintended harm and support appropriate utilization of primary dental care services. Our proposed priority issues can be pursued within research strategies that embrace robust primary research designs and methods with agreed working definitions.[30] Examples of these research designs include mixed methods studies of a mix of complimentary secondary data (e.g. medical records, malpractice cases). In doing so, priority areas and knowledge gaps should be corroborated in local contexts,[71] as well as furthering advances already made for data collection methods and taxonomies for patient safety in dentistry.[72] Natural Language Processing (NLP) could support the pace of progress and in terms of analysing large volumes of data about unsafe dentistry offers a set of informatics tools capable of transforming text into a structured format that can be used for research.[73] For example, data extraction systems based on NLP have been developed in the medical domain.[74] However, this innovation has yet to be explored in dentistry. Incident reporting systems, such as the NRLS in England and Wales, have generated many lessons to improve patient safety. The Council of European Dentists' has already recommended the development of reporting systems in dentistry,[75] and these should now be either developed exclusively for the profession or integrated into existing reporting systems, such as the NRLS, now the Patient Safety Information Management System led by NHS Improvement. Also, any further dentistry-focused initiative needs to be supported by clear regulations and policies that allow private and healthcare-funded dental practices to report incidents, preferably to a single system. Where multiple regulators have complimentary functions in countries, clear processes about incident reporting are needed for the dental profession to follow.[76]

Conclusions

Our study represents an important step forward into the characterization patient safety incidents and their contributory factors in primary care dentistry. Initiatives to improve quality, including patient safety, in dentistry should focus on improving the main sources of unsafe care identified in this work. However, our findings also reveal that over-utilization of dental care services is an issue that can be easily overlooked by researchers, policy makers and members of the dental profession. As more patient safety focused evidence continues to emerge, this needs to be integrated into evidence-based guidelines and compliance with these guidelines needs to be encouraged through fostering a patient safety culture. Patient safety is an emerging field in dentistry that offers a wide spectrum of opportunities for both research and improvement.

References

1. Jha AK, Prasopa-Plaizier N, Larizgoitia I, et al. Patient safety research: an overview of the global evidence. Qual Saf Health Care. 2010;19(1):42-7.
2. World Helath Organization. IBEAS: a pioneer study on patient safety in Latin America. Towards safer hospital care. Geneva, Switzerland: World Health Organization; 2011.
3. de Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care. 2008;17(3):216-23.
4. Panesar SS, Carson-Stevens A, Cresswell KM, et al. How safe is primary care? A systematic review. BMJ Qual Saf. 2015:bmjqs-2015-004178.
5. Wilson T, Sheikh A. Enhancing public safety in primary care. BMJ. 2002;324(7337):584-7.
6. Doupi P. National reporting systems for patient safety incidents: A review of the situation in Europe. 2009.
7. Department of Health. Building a Safer NHS for Patients: Implementing an Organisation with a Memory. Department of Health (UK) London; 2001.
8. Kohn LT, Corrigan JM, Donaldson MS. To Err Is Human: Building a Safer Health System: National Academies Press; 2000.
9. Department of Health. An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer: The Stationery Office London; 2000.
10. World Health Organization. WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. From Information to action. 2005.
11. Rooksby J, Gerry RM, Smith AF. Incident reporting schemes and the need for a good story. Int J Med Inform. 2007;76 Suppl 1:S205-11.
12. Brown C, Hofer T, Johal A, et al. An epistemology of patient safety research: a framework for study design and interpretation. Part 3. End points and measurement. Qual Saf Health Care. 2008;17(3):170-7.
13. Hogan H, Olsen S, Scobie S, et al. What can we learn about patient safety from information sources within an acute hospital: a step on the ladder of integrated risk management? Qual Saf Health Care. 2008;17(3):209-15.
14. Sheikh A, Panesar SS, Larizgoitia I, et al. Safer primary care for all: a global imperative. Lancet Glob Health. 2013;1(4):E182-E3.
15. Sheikh A, BatesMD DW. Iatrogenic harm in primary care. Harvard Health Policy Review. 2014;4(1):4-8.
16. Cooper A, Edwards A, Williams H, et al. Sources of unsafe primary care for older adults: a mixed-methods analysis of patient safety incident reports. Age Ageing. 2017;46(5):833-9.
17. Rees P, Edwards A, Powell C, et al. Patient Safety Incidents Involving Sick Children in Primary Care in England and Wales: A Mixed Methods Analysis. PLoS Med. 2017;14(1):e1002217.
18. Carson-Stevens A, Hibbert P, Williams H, et al. Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice. Health Services and Delivery Research. 2016;4(27):1-76.
19. Williams H, Edwards A, Hibbert P, et al. Harms from discharge to primary care: mixed methods analysis of incident reports. Br J Gen Pract. 2015;65(641):e829-37.
20. Rees P, Edwards A, Panesar S, et al. Safety incidents in the primary care office setting. Pediatrics. 2015;135(6):1027-35.
21. Ensaldo-Carrasco E, Suarez-Ortegon MF, Carson-Stevens A, et al. Patient Safety Incidents and Adverse Events in Ambulatory Dental Care: A Systematic Scoping Review. J Patient Saf. 2016;Publish Ahead of Print.

22. Thusu S, Panesar S, Bedi R. Patient safety in dentistry - state of play as revealed by a national database of errors. Br Dent J. 2012;213(3):E3.
23. Maramaldi P, Walji MF, White J, et al. How dental team members describe adverse events. J Am Dent Assoc. 2016;147(10):803-11.
24. Kalenderian E, Obadan-Udoh E, Maramaldi P, et al. Classifying Adverse Events in the Dental Office. J Patient Saf. 2017.
25. Renton T, Sabbah W. Review of never and serious events related to dentistry 2005-2014. Br Dent J. 2016;221(2):71-9.
26. Carson-Stevens A, Hibbert P, Avery A, et al. A cross-sectional mixed methods study protocol to generate learning from patient safety incidents reported from general practice. BMJ Open. 2015;5(12):e009079.
27. Lamont T, Scarpello J. National Patient Safety Agency: combining stories with statistics to minimise harm. BMJ. 2009;339:b4489.
28. National Patient Safety Agency. National Reporting and Learning Service 2003 [Available from: http://www.nrls.npsa.nhs.uk.
29. National Patient Safety Agency. What is a Patient Safety Incident? National Health Service; 2011 [Available from: http://www.npsa.nhs.uk/nrls/reporting/what-is-a-patient-safety-incident/.
30. World Alliance For Patient Safety Drafting Group, Sherman H, Castro G, et al. Towards an International Classification for Patient Safety: the conceptual framework. Int J Qual Health Care. 2009;21(1):2-8.
31. Klemp K, Dovey S, Valderas JM, et al. Developing a patient safety incident classification system for primary care. A literature review and Delphi-survey by the LINNEAUS collaboration on patient safety in primary care. Eur J Gen Pract. 2015;21 Suppl(sup1):35-8.
32. Hibbert P, Runciman W, Deakin A. A recursive model of incident analysis. Australian Patient Safety Foundation. 2007.
33. World Alliance For Patient Safety Drafting Group. The Conceptual Framework for the International Classification for Patient Safety. World Health Organization; 2009.
34. McHugh ML. Interrater reliability: the kappa statistic. Biochem Med (Zagreb). 2012;22(3):276-82.
35. Denzin NK, Lincoln YS. The Sage Handbook of Qualitative Research: Sage; 2011.
36. Creswell JW, Clark VLP. Designing and Conducting Mixed Methods Research: SAGE Publications; 2010.
37. Tukey JW. Exploratory data analysis. Addison-Wesley Series in Behavioral Science: Quantitative Methods, Reading, Mass: Addison-Wesley, 1977. 1977.
38. Excel Redmond, WA: Microsoft Corporations; 2011.
39. Reason J. Human error : models and management. 2000;320(March):4-6.
40. Rees P, Carson-Stevens A, Williams H, et al. Quality improvement informed by a reporting and learning system. Archives of disease in childhood. 2014;99(7):702-3.
41. Rees P, Edwards A, Powell C, et al. Pediatric immunization-related safety incidents in primary care: A mixed methods analysis of a national database. Vaccine. 2015;33(32):3873-80.
42. Schiff GD. Sick Children Crying for Help: Fostering Adverse Event Reports. PLoS Med. 2017;14(1):e1002216.
43. Boxwala AA, Dierks M, Keenan M, et al. Organization and representation of patient safety data: current status and issues around generalizability and scalability. J Am Med Inform Assoc. 2004;11(6):468-78.
44. Mayer E FK, Callahan R, Darzi A. National Reporting and Learning System Research and Development. England: NHIT Imperial Patient Safety Translational Research Centre; 2016.

45. Johnson CW. Reasons for the Failure of Incident Reporting in the Healthcare and Rail Industries. In: Redmill F, Anderson T, editors. Components of System Safety: Proceedings of the Tenth Safety-critical Systems Symposium, Southampton, UK 2002. London: Springer London; 2002. p. 31-57.
46. Perea-Perez B, Santiago-Saez A, Labajo-Gonzalez ME, et al. Professional liability in oral surgery: legal and medical study of 63 court sentences. Med Oral Patol Oral Cir Bucal. 2011;16(4):e526-31.
47. Perea-Perez B, Labajo-Gonzalez E, Santiago-Saez A, Albarran-Juan E, Villa-Vigil A. Analysis of 415 adverse events in dental practice in Spain from 2000 to 2010. Med Oral Patol Oral Cir Bucal. 2014;19(5):e500-5.
48. Hiivala N, Mussalo-Rauhamaa H, Tefke HL, et al. An analysis of dental patient safety incidents in a patient complaint and healthcare supervisory database in Finland. Acta Odontol Scand. 2016;74(2):81-9.
49. Obadan EM, Ramoni RB, Kalenderian E. Lessons learned from dental patient safety case reports. J Am Dent Assoc. 2015;146(5):318-26 e2.
50. Hiivala N, Mussalo-Rauhamaa H, Murtomaa H. Patient safety incidents reported by Finnish dentists; results from an internet-based survey. Acta Odontol Scand. 2013;71(6):1370-7.
51. Institute of Medicine, Committee on Quality of Health Care in America. Crossing the quality chasm: A new health system for the 21st century: National Academy Press; 2001.
52. Frankel A, Haraden C, Federico F, et al. A framework for safe, reliable, and effective care. White paper. Institute for Healthcare Improvement and Safe & Reliable Healthcare. Cambridge, MA 2017.
53. Institute for Healthcare Improvement. Open School Course from the Dental Quality Alliance (DQA) 2018 [Available from: http://www.ihi.org/education/IHIOpenSchool/Courses/Pages/Dental-Quality-Alliance-DQA.aspx.
54. Yu A, Flott K, Chainani N, et al. Patient safety 2030. London, UK: NIHR Imperial Patient Safety Translational Research Centre. 2016.
55. Hollnagel E. Safety-I and safety-II: the past and future of safety management: CRC Press; 2018.
56. Hebballi NB, Ramoni R, Kalenderian E, et al. The dangers of dental devices as reported in the Food and Drug Administration Manufacturer and User Facility Device Experience Database. J Am Dent Assoc. 2015;146(2):102-10
57. Department of Health. Provisional publication of Never Events reported as occurring between 1 April and 31 December 2016. London: NHS; 2017 31 January 2017.
58. Pinsky HM, Taichman RS, Sarment DP. Adaptation of airline crew resource management principles to dentistry. J Am Dent Assoc. 2010;141(8):1010-8.
59. Perea-Perez B, Santiago-Saez A, Garcia-Marin F, et al. Proposal for a 'surgical checklist' for ambulatory oral surgery. International journal of oral and maxillofacial surgery. 2011;40(9):949-54.
60. Christman A, Schrader S, John V, Zunt S, et al. Designing a safety checklist for dental implant placement: a Delphi study. J Am Dent Assoc. 2014;145(2):131-40.
61. Diaz-Flores-Garcia V, Perea-Perez B, Labajo-Gonzalez E, et al. Proposal of a "Checklist" for endodontic treatment. J Clin Exp Dent. 2014;6(2):e104-9.
62. Porto GG. Safety by design: ten lessons from human factors research. J Healthc Risk Manag. 2001;21(4):43-50.
63. Bailey E, Tickle M, Campbell S, et al. Systematic review of patient safety interventions in dentistry. BMC Oral Health. 2015;15(1):152.
64. Obinata K, Satoh T, Towfik AM, et al. An investigation of accidental ingestion during dental procedures. J Oral Sci. 2011;53(4):495-500.

564 65. Ensaldo-Carrasco E, Carson-Stevens A, Cresswell K, Bedi R, Sheikh A. Developing
565 agreement on never events in primary care dentistry: an international eDelphi study. Br
566 Dent J. 2018;224(9):733.
567 66. World Health Organization. Medication Errors: Technical Series on Safer Primary Care.
568 Geneva, 2016.
569 67. World Health Organization. Medication Without Harm - Global Patient Safety Challenge
570 on Medication Safety. Geneva, 2017.
571 68. Glasziou P, Straus S, Brownlee S, et al. Evidence for underuse of effective medical
572 services around the world. Lancet. 2017;390(10090):169-77.
573 69. Berwick DM. Avoiding overuse-the next quality frontier. Lancet. 2017;390(10090):102-4.
574 70. Lewis RQ, Fletcher M. Implementing a national strategy for patient safety: lessons from
575 the National Health Service in England. Qual Saf Health Care. 2005;14(2):135-9.
576 71. The Safer Care Primary Expert Working Group. Safer Primary Care: A Global Challenge.
577 Switzerland: World Health Organization; 2012.
578 72. Cresswell KM, Panesar SS, Salvilla SA, et al. Global research priorities to better
579 understand the burden of iatrogenic harm in primary care: an international Delphi
580 exercise. PLoS Med. 2013;10(11):e1001554.
581 73. Bates DW, Evans RS, Murff H, et al. Detecting adverse events using information
582 technology. J Am Med Inform Assoc. 2003;10(2):115-28.
583 74. Melton GB, Hripcsak G. Automated detection of adverse events using natural language
584 processing of discharge summaries. J Am Med Inform Assoc. 2005;12(4):448-57.
585 75. Commision of European Dentists. Resolution on Patient Safety. 2008.
586 76. Renton T, Master S. The complexity of patient safety reporting systems in UK dentistry.
587 Br Dent J. 2016;221(8):517-24.