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## Developing agreement on never events in primary care dentistry: an international eDelphi study

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## **ABSTRACT**

Never events (NEs) are a subset of serious patient safety incidents that should not occur if appropriate preventive measures are implemented. Although there is a consensus in medicine, there is no agreement on NEs in dentistry.

We undertook an electronic Delphi exercise to develop an international agreement on NEs for primary care dentistry. We initially identified candidate NEs through a systematic review of the literature and then analysed dentistry-related reports in a national incident reporting system. Next, we invited an international panel of 41 experts to complete two rounds of questionnaires; 32 agreed to participate (78%) and completed the first round and 29/41 (71%) members completed the second round. We provided anonymised controlled feedback between rounds and used a cut-off of 80% agreement to define consensus.

Consensus was achieved for 23 out of 42 candidate NEs. These related to routine assessment, and pre-operative, intra-operative and post-operative stages of dental procedures.

To our knowledge, this is the first international expert consensus-based approach that has identified NEs for primary care dentistry. We suggest that dental regulators consider these to support quality assessment and governance activities.

## Introduction

Patient safety incidents occur in all healthcare settings worldwide.<sup>(1-4)</sup> The resulting harm from unsafe healthcare patient safety incidents is estimated to occur in one every 10 inpatient hospital admissions,<sup>(2, 5-8)</sup> and <1% of encounters in primary care.<sup>(9)</sup> Seminal publications such as the Harvard Malpractice Study<sup>(10)</sup> and the Institute of Medicine's (now the National Academy of Medicine) "To Err is Human"<sup>(11)</sup> encouraged healthcare organisations, researchers and policymakers around the world to pay attention to patient safety. Since 2002, as issued in Resolution 55.18, the World Health Assembly recognised patient safety incidents in healthcare as a significant public health concern.<sup>(12)</sup>

Over the past 20 years, standard definitions relating to patient safety<sup>(13, 14)</sup> have become available (Table 1), and the accumulated evidence about the extent of harm and underlying causes has been translated into interventions designed to reduce harm.<sup>(15)</sup> An example of this is the implementation of policies in countries like the United States (US),<sup>(16)</sup> the United Kingdom (UK),<sup>(17, 18)</sup> Canada<sup>(19)</sup> and Australia<sup>(20)</sup> for the reduction of "never events" (NEs). In the UK, NEs are a subtype of 'serious incidents'<sup>(21)</sup> within the Revised Serious Incident Framework<sup>(21)</sup> and are defined "as serious, largely preventable PSIs that should not occur if the available preventive measures are implemented".<sup>(13)</sup> A list of NEs for hospital settings was developed in England by the National Patient Safety Agency (NPSA) in 2009 and was later revised by the Department of Health in 2015 (Table 2).<sup>(13)</sup> Due to their clear potential for severe harm,<sup>(17, 18)</sup> national guidance and national safety recommendations encourage reporting of NEs.<sup>(17, 18)</sup> In England, such policies enable Clinical Commissioning Groups (CCGs) to recover healthcare costs when a procedure or treatment results in a NE.<sup>(22)</sup> NEs are collected and monitored in patient safety incident reporting systems overseen by the NHS Improvement's Patient Safety Domain.<sup>(23)</sup>

The World Health Organization's (WHO) emerging agenda for "Safer Primary Care"<sup>(3)</sup> has advocated for a better understanding of patient safety in primary care as this field remains largely unexplored.<sup>(24, 25)</sup> This includes the epidemiology of patient safety incidents in primary care dentistry.<sup>(26-29)</sup> A recent scoping review of the literature showed patient safety research in dentistry over the past 20 years is poorly conceptualised and described with important methodological limitations.<sup>(30)</sup> As a result, an estimate of the burden of patient safety incidents remains unknown. One of the largest cross-sectional studies was conducted by Thusu et al.<sup>(31)</sup> They analysed 2,2012 patient incidents reports from which they reported injuries, medical emergencies, inhalation and ingestion of foreign objects, adverse reactions and wrong-tooth extractions as main areas of concern. They also suggested wrong-tooth extractions as a potential NE. This incident is currently the only clearly defined NE related to dentistry that has been included in the NE list used in the English NHS<sup>(13)</sup> and accounts for around 120 reported cases per year.<sup>(23, 32)</sup>

Although wrong-tooth extractions are clearly defined NEs, little is known about other potential NEs for dentistry. Established surgical NEs such as wrong-site surgery, wrong implant and retained foreign objects may be applicable to dentistry. However, these surgical NEs also overlap with other NEs from other disciplines in secondary care. Examples include a wrong kidney biopsy, wrong knee implant and retained part of an umbilical venous catheter. As a result, no formal list has been developed for primary care dentistry, and no systematic attempts have been made to identify and propose NEs for international use. Black and Bowie took an initial step in proposing a list of NEs for primary care

dentistry.<sup>(33)</sup> However, the authors also recommended a more systematic approach to review the literature and identify other potential NEs existing within primary care dentistry. The authors also suggested the need to address a more diverse composition of participants to be more representative of primary dental care settings. Therefore, we aimed to develop and achieve consensus on a list of NEs with experts from around the world, and identify NEs with the greatest need and opportunity for future intervention strategies to improve patient safety in primary care dentistry.

## Methods

We undertook an electronic Delphi exercise based on the method developed by the US Research and Development Corporation (RAND).<sup>(34, 35)</sup> This involved a formal, structured process for generating consensus among a group of experts based on feedback obtained from their anonymous responses.<sup>(36-38)</sup> This approach is favoured in cases where little to no empirical or historical data exist.<sup>(37, 39, 40)</sup> There were three stages to the study (see Figure 1): (i) the identification of candidate NEs and questionnaire development; (ii) the selection of experts; and, (iii) the iterative completion of a sequence of questionnaires by this panel of experts. The use of electronic questionnaires instead of paper-based questionnaires represented a modification to the originally described Delphi process. This electronic approach has been previously used in other studies.<sup>(41, 42)</sup>

Ethical approval was obtained from The University of Edinburgh's Centre for Population Health Sciences Research Ethics Committee. (Ethics Application number 1624)

### Stage 1: Identification of candidate never events and questionnaire development

As the Delphi method aims to make effective use of informed expert judgement,<sup>(40)</sup> the experts needed a baseline of available empirical evidence.<sup>(34)</sup> Therefore, in accordance with the definition provided by the former NPSA (see Table 1),<sup>(13)</sup> we used three approaches to identify the candidate NEs that we included in our initial questionnaire.

First, we conducted a systematic scoping review of the primary care dentistry literature from January 1994 to January 2015.<sup>(30)</sup> Then, additional candidate NEs were identified through the examination of 12,000 patient safety incident reports related to dentistry submitted to the National Reporting and Learning System (NRLS) from 2005 to 2013. These were manually cleaned and we identified 4,249 relevant reports. Each incident was reviewed by the study team to make a judgment about whether they could meet the NE criteria according to the original NPSA definition (see Table 1). Finally, the third approach constituted the revision of existing lists of NEs in hospital care developed by the NPSA<sup>(13)</sup> and NEs for general practice.<sup>(43)</sup> Table 2 shows the NEs we believed, based on our clinical experience, were transferable to dentistry.

Based on these approaches, we developed an initial list of candidate NEs. As shown in Table 3, these were grouped into four stages. These were conceptualised as the period that comprises any routine assessment or check-up, the period before clinical treatments were carried out (pre-operative stage), the period of clinical treatment (intra-operative stage), and the period after the clinical treatment (post-operative stage).

### Stage 2: Selection of experts

We identified participants from different countries, levels of experience, academic backgrounds and specialties disciplines (e.g. general dentistry, paediatric dentistry, endodontics, oral surgery and public health) within primary dental care. Table 4 shows the criteria used for the identification and selection of experts. All eligible experts received an invitation to participate by e-mail that included an

information sheet and a consent form. Participants were asked to read these documents and provide their voluntary signed consent before their participation.

### Stage 3: Iterative completion of a sequence of questionnaires

In the first round, we distributed e-mails containing the questionnaire including the definition of NEs and the instructions for answering each item. Each item corresponded to a candidate NE and included three criteria which participants were asked to score. These were based on the criteria of “preventability”, “severity” and the criterion “should be classified as never event” outlined by the Never Events Policy and Framework of the NHS (Table 4).<sup>(13)</sup> We removed the criterion surrounding “the past and future risk” as our systematic scoping review identified evidence of 14 of our initial list of candidate NEs being reported over a period of 20 years.<sup>(30)</sup>

Participants were asked to assign a number between 1 to 5 as a relative score<sup>(44)</sup> in which the number five represented the closest proximity of each candidate NE to meet the NE criteria displayed in Table 3. Also, they were asked to provide reasons for their assigned scores and recommendations for any modification, addition or elimination of NEs on the list. The responses were collected, anonymised and summarised. Moreover, participants were asked to suggest any potential NE not included. A period of three weeks was given to complete and return the questionnaire. We started the study on September 11th, 2016. To maintain high response rates, three reminders were sent on the 7<sup>th</sup>, 12<sup>th</sup> and 19<sup>th</sup> day. Non-responders were given an additional reminder on the 21<sup>st</sup> day.

For the second round, NEs were rephrased or discarded in line with the scores, comments and suggestions received in the first round. Participants were provided with the group’s median score for each item along with their responses (expressed in medians) and an anonymous summary of the comments received. Then, they were asked to read this feedback and decide if their original scores should be changed. If they decided to modify them, they were asked to score the items on the same scale and provide a reason for changing their original score. Again, they were asked to provide reasons for their assigned scores and recommendations for modification of items, additions or elimination of NEs on the list.

### Analysis

After each round, all the responses were collected and anonymised. Then, all scores and comments were transcribed into a data collection tool in Microsoft Excel software.<sup>(45)</sup> According to the Delphi method, after each round, median scores were estimated per item.<sup>(35, 44)</sup> To summarise the overall score for each NE, overall median scores of the three criteria for every candidate NE were calculated. The median of these final responses represented the group response.<sup>(44)</sup> Any unanswered field was considered as “no opinion.” The retrieved comments were also summarised and were envisaged for the refinement of the list of NEs, and that was included in the second round. Contrasting comments were grouped and compared to assess the possible inclusion of additional items.

Percentages of agreement were assessed by grouping the overall median proportions of ‘agree’ and ‘totally agree’. Proportions greater or equal to 80% were interpreted as a satisfactory agreement. This procedure was repeated after each round until consensus greater or equal to 80% was achieved. Participants also received feedback from the final stage.

### Data availability

All raw data generated during questionnaire completion during the first and second rounds are not

made publicly available to assure the anonymity of the participants. Summary data are available from the corresponding author on reasonable request and after anonymising the requested data.

## Results

A total of 41 experts were invited to participate in the study. Out of these, 32 (78%) agreed to participate and provided their informed consent and completed the first round questionnaire. No potential participant explicitly refused to take part in the study. Of these, 29/41 (71%) went on to finish the second round. Reasons for not completing the second questionnaire included no replies after the third reminder was sent (n=2) and no response after further clarification was asked about the answers provided. The detailed demographics and professional features of the expert panel are shown in the supplementary section (see Table S1).

In brief, out of the 32 the participants, the majority were from UK (n=7), followed by Mexico and Sudan (n=5 each). Then, two participants each from Cambodia, Colombia and Spain, and one participant each from the following countries: Argentina, Australia, Brazil, Chile, China, Indonesia, Kenya, South Africa and the US. Public Health and Community Dentistry were the main disciplines (n=9) represented, followed by General Dentistry (n=6), Paediatric Dentistry (n=4) Periodontics (n=3), Sedation and Special Care Dentistry (n=3), and orthodontics (n=2). See supplementary Table 1 for a full breakdown of disciplines represented. Concerning the professional roles, 16 participants had both academic and clinical roles whereas eight had professional roles in academia and public health. Only three participants had academic, clinical and public health roles.

### First and second rounds

We formulated 24 candidate NEs, which were incorporated into the first questionnaire. No agreement was reached for any of the first 24 candidate NEs in the first round. The scores, comments and feedback we received provided the basis for refining and expanding the initial list into 43 candidate NEs. After the second round, consensus was achieved in 23 out of the 43 candidates NEs (See Table 6). These related to routine assessment (n=3), pre-operative (n=3), intra-operative (n=13) and post-operative (n=4) stages of dental procedures. Examples of these include e.g. 'failure to register patient's history of allergies to medication' (routine assessment), 'failure to sterilise re-usable instruments' (pre-operative), 'wrong-tooth extractions' (intra-operative) and 'prescription of teratogenic drug to patients known to be pregnant'.

## Discussion

In our study, we achieved international expert consensus in 23 out of 43 candidate NEs (See Table 6). Our list compares well with 10 of the 27 NEs proposed by Black and Bowie (published after the completion of our study).<sup>(33)</sup> Although not identical, we identified similar domains for NEs (e.g. drug prescription, wrong-tooth extractions, infection control practices, aspiration of foreign objects and treating the wrong patient). However, we also identified additional priorities as 13 of our proposed NEs did not match those proposed by Black and Bowie.<sup>(33)</sup> Of the 17 remaining NEs, five of these were similar to candidate NEs used during the first and second rounds of our study. These were mistaken patient identity, wrong-tooth treated (excluding extraction), tooth extraction in patients treated with bisphosphonates, use of outdated material and ingestion of foreign objects. However, these were not included in our list as we did not achieve consensus equal or greater than 80%. Probable reasons for discrepancies (for the rest of the 12 NEs that did not match our list) are the process for identification of candidate NEs and the composition of experts. Black and Bowie<sup>(33)</sup> initially conducted a rapid

literature review and then held workshops with dental practitioners. Our list, however, was developed and structured in accordance to the conceptualized stages in our systematic scoping review.<sup>(30)</sup> On the other hand, Black and Bowie<sup>(33)</sup> identified a sample of experts in Scotland whereas our sample of experts had a more heterogeneous and international composition. Moreover, the feedback we received from our experts during the first and second round highlighted that recommendations, guidelines and availability of clinical/environmental resources were likely to be different between countries.

### Implications for policy and practice

Our list of NEs can inform further interventions and policies.<sup>(46, 47)</sup> National and international patient-safety-focused agendas should now be developed for primary care dentistry **considering the variability of regulatory frameworks between countries**. Berger et al.<sup>(48)</sup> enlisted three recommendations to reduce the incidence of NEs.

First, their inclusion into incidents reporting systems is needed<sup>(48)</sup> to ensure clinical governance to monitor and learn from NEs. Although dentistry-focused national incident reporting systems have been already recommended,<sup>(49)</sup> such systems have not been introduced yet. **We believe our proposed list of NEs should inform efforts to interrogate patient safety data, like incident reports, as well as electronic medical records and repositories of malpractice claims.** Policies like the Framework for the Identification and Management of Never Events<sup>(17, 18)</sup> from the NHS should be either developed or adapted for dentistry and supported by education and training efforts, as well as clear policies for ‘just culture’<sup>(50)</sup> reporting or disciplinary actions.<sup>(51)</sup>

The concept of ‘never event’ was first introduced by Kizer in 2001 to describe the ‘*most egregious health care errors*’ that should never occur.<sup>(52)</sup> However, this concept is not globally used and, when available, definitions for NEs vary between countries,<sup>(53)</sup> **can make comparisons between countries challenging.**<sup>(54)</sup> **Even when regulatory frameworks are available, the presence of multiple regulations by, for example, the General Dental Council (GDC),<sup>(55)</sup> the Care Quality Commission<sup>(56)</sup> and NHS England<sup>(18, 21)</sup> towards incident reporting by dentists in the UK, create complexity and unclear processes for dentists to follow.**<sup>(57)</sup> The consequences of this complexity have been discussed by Renton et al.<sup>(32)</sup> after they reviewed serious events and NE reports relevant to dentistry in the NRLS and Strategic Executive Information System databases. Analysed reports were incorrectly coded, missing information and, in some cases, were duplicated within the same database.<sup>(32)</sup> **The need to integrate existing incident reporting systems has been already highlighted<sup>(58)</sup> followed by the development of the Patient Safety Incident Management System, as the successor of the existing NRLS.<sup>(59)</sup> This integrated approach for reporting incidents should also include those occurring in dentistry.<sup>(57)</sup> Within an international context, countries need to collaborate and share information about common patient safety issues.<sup>(4)</sup> If needed, guidance towards the introduction of incident reporting systems can be provided and this is currently being developed by WHO. In doing so, patient safety organisations, policymakers and dentistry should establish standards for the accuracy of NEs derived from administrative data and agree on a standard definition of a NE.**<sup>(53)</sup>

Secondly, communication between healthcare personnel needs improvement and standardization of procedures are necessary.<sup>(48)</sup> Failures in communication and teamwork are one of the main issues in primary care delivery.<sup>(60)</sup> From a systems-based perspective, policies should be developed to create an infrastructure at a national level to build and maintain professional networks and services to enable professionals to communicate and learn from each other.<sup>(61)</sup> On the other hand, many treatments or procedures in dentistry do not follow established evidence-based guidelines.<sup>(62)</sup> The guidelines should now be developed with a robust evidence base for further implementation and evaluation by national regulatory bodies supported by the law and agreed on standards of performance.<sup>(63)</sup> Examples within

the UK include the Professionals Standards Authority<sup>(64)</sup> which oversees independent regulatory bodies such as the General Medical Council<sup>(65)</sup> and the GDC.<sup>(66)</sup> These regulatory agencies, in their areas of interest, set the standards of competence and conduct that healthcare professionals must meet to obtain and maintain their registration and fitness to practice. Additional functions include to review the content and quality of education and training courses. Pre-service and in-service education on patient safety needs to be discipline-oriented in accordance with a system-based perspective to facilitate its sustainable improvement.<sup>(61)</sup> Other measures to tackle patient safety include the investigations undertaken by the Care Quality Commission<sup>(67)</sup> and the National Clinical Assessment Service for poorly performing healthcare professional.<sup>(68)</sup> Another strategy learned from the human factors research undertaken in hospital-based studies is to reduce the reliance on memory, attention or perception.<sup>(69)</sup> Examples of this include patient safety checklists for oral surgery,<sup>(70)</sup> endodontic procedures,<sup>(71)</sup> wrong-tooth extractions<sup>(72)</sup> and dental implant placement.<sup>(73)</sup> However, their effectiveness have not been adequately tested.<sup>(27)</sup> Although the analysis of patient safety incidents, including NEs, bring a valuable opportunity for learning and to implement strategies for quality improvement, a possible difficulty exists around how to most effectively foster an environment receptive to change.<sup>(74)</sup> Facilitators for a patient safety culture include the recognition of the risks of dental care delivery through all health sectors and dental associations, including the support of dental schools by integrating patient safety into their curricula and the organisational structure of dentistry.<sup>(75)</sup> The WHO's patient safety curriculum guides have outlined the core learning requirements for healthcare professionals.<sup>(76, 77)</sup> Patient safety guidance to maximise opportunities to learn from incidents in general practice are available,<sup>(78)</sup> and these should also be developed for dentistry.

Finally, the third recommendation concerns the implementation of more effective systems to help minimise elements of human fallibility.<sup>(48)</sup> As we reported in our systematic scoping review,<sup>(30)</sup> patient safety incidents are not limited to human error. Therefore, we should also understand the conditions, environment and the influence of policies in which primary dental care is delivered. These factors can be identified through the analysis of incident reports which include all types of patient safety incidents, including 'near misses', 'no harm incidents' and NEs. Incidents which did not reach the patient are referred as 'near misses', whereas a 'no harm incident' is one in which an event reached a patient, but no discernible harm resulted.<sup>(14)</sup> Both incidents are considered during the initial steps for patient safety management since high detection rates are needed for the identification of unintended risk and hazards.<sup>(79)</sup> Moreover, for NEs, serious harm and/or death are not required to have happened for a NE to be reported.<sup>(18)</sup> Therefore, as the concept of NEs can overlap with 'near misses' and 'no harm incidents', these should also be identified and analysed as the root causes of these incidents might be similar.<sup>(80)</sup> In doing so, learning points can be identified which can then be implemented for both quality and safety improvement. Effective primary care teams, health information technology, effective transitions of care, effective diagnostic services and patient engagement are also opportunities for patient safety improvement in primary care<sup>(81)</sup> which should be disseminated across the profession. Existing patient safety frameworks should be used. Examples of this include the framework for risk and safety by Vincent et al.<sup>(82)</sup> (1998), Reason's Swiss cheese model of system accidents (2000)<sup>(83)</sup> and the Primary Care Patient Safety (PISA) Classification System.<sup>(84)</sup>

### Strengths and limitations

Our study has addressed the methodological concerns highlighted in the study by Black and Bowie.<sup>(33)</sup> Firstly by developing an initial NE-list supported by a comprehensive and systematic scoping review,<sup>(30)</sup> complemented by a mixed methods review of patient safety reports from primary dental care in a national patient safety incident reporting system, and the review of established NEs in general practice<sup>(43)</sup> and secondary care.<sup>(13)</sup> Secondly, we followed a structured and rigorous approach

appropriately modified from processes developed by the RAND Corporation.<sup>(34, 35)</sup> Finally, we recruited an international sample of professionals with clinical and academic backgrounds, as well as experience in public health who provided different insights of NEs. As a result, we obtained a consensus from a diverse composition of participants with adequate response rates to both rounds (i.e. 78% and 71%, respectively).

Patient safety research is poorly organised in primary dental care; it is mostly descriptive, with a variety of approaches to the terminology, the study designs and different patient populations with little evidence to identify priorities which can be translated into action.<sup>(30)</sup> Therefore, as the experts' feedback is a reflection of their current knowledge, experience and/or perceptions around incidents that matched our criteria for NEs, patient-safety expertise across participants was likely to be variable but overall low. In our study, although we were able to include experts from a diverse range of relevant backgrounds. As more evidence accumulates and training and education in patient safety training increases, the number of patient-safety focused experts are likely to increase. Therefore, we believe our proposed list should be further developed based on the consensus of future patient-safety-experts' opinions and the evidence emerging from primary care dentistry. As each country has different regulatory frameworks, our list or any future update should also consider international regulatory frameworks.

### Recommendations for further research

Research priorities must now be set so NEs can be translated into action,<sup>(74)</sup> particularly into possible preventive measures, policy-making and resource allocation for interventions. We believe a systematic approach to research priority setting based on the method proposed by the Child Health and Nutrition Research Initiative (CHNRI) with the Global Forum for Health Research<sup>(85)</sup> can be used. Also, as the field of patient safety develops more in dentistry, our NE list should be further improved as more evidence accumulates and more professionals are trained in patient safety.

### Conclusions

We have achieved an international expert consensus-based list of NEs for primary care dentistry. This list can be considered to support quality assessment and governance activities. This list should be further improved as more evidence on patient safety incidents accumulates in primary dental care. We believe a future step should be to use this list for setting global research priorities on NEs that can be translated into prevention strategies based on a robust evidence base. We encourage dental regulators, professional and academic communities in dentistry to foster patient safety through evidence-based initiatives that can be translated into action.

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### Author contributions statement

All authors reviewed and/or reviewed the manuscript before submission. E.E.C conducted the study and wrote the article. E.E.C. and K.C. developed the protocol and submitted it for ethical approval. R.B. provided the professional networks for the identification and participation of the experts. A.C.S., K.C., R.B., and A.S. provided a substantial contribution to the discussion of content.

## Competing financial interests

The author(s) declare no competing financial interests.

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**Table 1. Key concepts developed for medicine**

Concept	Definition
Patient safety	“The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum...” <sup>(14)</sup>
Patient safety incident	An event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. <sup>(14)</sup>
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering and death. <sup>(14)</sup>
Serious incidents	Events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response <sup>(13, 21)</sup>
Never events	Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. <sup>(13)</sup>

**Table 2. Revised list of never events list from the Department of Health<sup>(13)</sup>**

	Potential for transferrable to dentistry?
Wrong site surgery	Yes
Wrong implant/prosthesis	Yes
Retained object post-procedure	Yes
Mis-selection of a strong potassium-containing solution	No
Wrong route administration of medication	No
Overdose of insulin due to abbreviation or incorrect device	No
Overdose of methotrexate for non-cancer treatment	No
Mis-selection of high strength midazolam during conscious sedation	No
Failure to install functional collapsible shower or curtain rails	No
Falls from poorly restricted windows	No
Chest or neck entrapment in bedrails	No
Transfusion or transplantation of ABO-incompatible blood components or organs	No
Mis-placed naso- or oro-gastric tubes	No
Scalding of patients	No

**Table 3. Never event criteria by the National Patient Safety Agency<sup>(13)</sup>**

<ul style="list-style-type: none"> <li>• It is wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers (preventability)</li> <li>• It has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorized as a never event (seriousness)</li> <li>• There is evidence of its occurrence in the past, and a risk of recurrence remains (past and future risk)</li> <li>• It is easily recognized and can be clearly defined (recognizable)</li> </ul>
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**Table 4. Criteria for the identification of experts**

Criteria	Justification
More than three years of active clinical experience	Minimum time we assumed was required for experts to experience their own PSIs and ascertain which ones should be considered never events
More than three years of active academic experience	Minimum time we assumed was required for experts to observe patient safety incidents committed by students and ascertain which ones should be considered never events
Any experience in leadership roles within institutions or national dental associations	Potential advocates for patient safety in primary care dentistry
Any experience in patient safety at a clinical or organizational level	To assure that participants were familiar with patient safety as a discipline and their concepts

**Table 5. Example of the rating approach for candidate never events**

Preventability of wrong tooth extractions
1. Strongly disagree
2. Disagree
3. No opinion
4. Agree
5. Strongly agree

Table 6. Consensus on candidate never events after the second and final round

Candidate never events during...	Group median response	% of agreement*
<b>... routine assessment</b>		
Failure to register patient's history of allergies to medication	5	96.6
Failure to refer for oral cancer assessment after patient's lesion do not heal after two weeks of receiving treatment	5	93.1
Failure to implement oral cancer screening as part of the routine assessments	5	89.7
<b>... preoperative stage</b>		
Treatment provided to the wrong patient	5	96.6
Failure to check patient's identity before implementing a procedure	5	93.1
Failure to sterilize re-usable instruments	5	89.7
<b>... intraoperative stage</b>		
Wrong tooth extracted	5	96.6
Use of non-sterilized re-useable instruments	5	89.7
Patient's eye injured due to the omission of using appropriate eye protection	5	89.7
Administration of unlabelled cartridge of local anaesthetics	5	89.7
Jaw fracture during implant placement due to poor treatment plan	5	89.7
Jaw fracture during implant placement due to its incorrect placement	5	89.7
Injection of sodium hypochlorite into surrounding structures during root canal treatment/irrigation	5	89.7
Use of dental material in a patient with known history of allergy to the dental material used	5	89.7
Re-use of disposable items	5	86.2
Aspiration (inhalation) of foreign objects	5	86.2
Use of non-disinfected equipment	5	82.8
Re-use of damaged endodontic files	5	86.2
Injection of wrong aesthetic solution	5	86.2
<b>... post-operative stage</b>		
Prescription of a drug to a patient with a known allergy to the drug	5	93.1
Prescription of teratogenic drug to patients known to be pregnant	5	93.1
Retained foreign objects after surgical procedures (excluding root canal procedures)	5	89.7
Incorrect medication prescribed to paediatric patients	5	89.7

\*(agree + strongly agree)



## Supplementary information

Supplementary table S1. Demographic and professional features of the Delphi expert panel

Expert No.	Gender	Country	Main Discipline	Academic	Clinical practitioner	Public health practitioner
1	Male	Argentina	Prosthodontics	✓	✓	✓
2	Male	Australia	Public health and community	✓		✓
3	Female	Brazil	Public health and community	✓		✓
4	Male	Cambodia	Paediatric dentistry	✓		
5	Female	Cambodia	Public health and community	✓		✓
6	Female	Chile	General dentistry	✓	✓	
7	Male	China	Public health and community	✓	✓	✓
8	Female	Colombia	Geriatric Dentistry	✓	✓	
9	Male	Colombia	Public health and community	✓		✓
10	Female	Indonesia	Public health and community	✓		✓
11	Male	Kenya	Orthodontics	✓	✓	
12	Male	Mexico	Periodontics	✓	✓	
13	Female	Mexico	Paediatric dentistry	✓	✓	
14	Female	Mexico	General dentistry	✓	✓	
15	Female	Mexico	Periodontics	✓	✓	
16	Female	Mexico	Paediatric dentistry	✓	✓	
17	Male	South Africa	Public health and community	✓	✓	✓
18	Female	Spain	General dentistry	✓		✓
19	Male	Spain	General dentistry	✓		✓
20	Female	Sudan	Public health and community	✓		✓
21	Male	Sudan	Paediatric dentistry		✓	
22	Female	Sudan	Oral and Maxillofacial surgery	✓	✓	
23	Female	Sudan	General dentistry	✓	✓	
24	Female	Sudan	Periodontics	✓	✓	
25	Female	UK	Sedation and Special Care Dentistry	✓		
26	Male	UK	Orthodontics	✓	✓	
27	Female	UK	Government Policy and Strategy Advisor			✓
28	Male	UK	General dentistry	✓	✓	
29	Female	UK	Sedation and Special Care Dentistry	✓	✓	
30	Male	UK	Sedation and Special Care Dentistry	✓	✓	
31	Female	UK	Prosthodontics	✓	✓	
32	Female	USA	Public health and community		✓	✓

Supplementary table S2. List of candidate never events that did not reach consensus

Candidate never events during...	Group median response	% of agreement*
... preoperative stage		
Failure to prescribe antibiotic prophylaxis before treating patients at risk of developing endocarditis	4	79.3
Surgical or complex procedure carried out without the voluntary and signed informed consent	4	79.3
Failure to take pre-operative radiographs prior invasive or surgical procedures	4	69.0
... intraoperative stage		
Extraction in a patient with a non-medically controlled bleeding disorder	5	79.3
Severe apical tooth resorption due to applying heavy forces during orthodontic treatment	4	79.3
Nerve damage due to errors in treatment plan	4	79.3
Treatment performed to a patient with a previously known untreated medical condition that can potentially be exacerbated by the dental treatment	5	75.9
Wrong tooth treated (excluding extraction)	4	75.9
Thermal injury to the pulp for not using irrigation during cavity/crown preparation	4	75.9
Overdose of sedatives	5	75.9
Needle stick injuries	4	75.9
Thermal injury to the soft tissues during root canal obturation with guttapercha	4	69.0
Ingestion (swallowing) of foreign objects	4	65.5
Tooth extraction in a patient that received radiotherapy in the jaw or maxilla	4	65.5
Chemical injury by dental materials	4	65.5
Tooth extraction in a patient treated with bisphosphonates	4	62.1
Perforation of the maxillary sinus	4	62.1
Intravascular injection of local anaesthetic	4	62.1
Perforation of the tooth during root canal treatment	4	58.6
Acrylic set inside the mouth	3	48.3

\*(agree + strongly agree)