

Review of never and serious events related to dentistry 2005–2014

T. Renton¹ and W. Sabbah^{*2}

In brief

Identifies where, when and why patient safety is compromised.

Identifies limitations of the reporting system of iatrogenic incidents.

Provides recommendations to avoid limitations of incident reporting system.

Provides recommendations to avoid patients compromising incidents.

Aims To review never and serious events related to dentistry between 2005–2014 in England. **Methods** Data from the National Reporting and Learning System (NRLS), with agreed data protection and intelligence governance, was used – snapshot view using the timeframe January 2005 to May 2014. The Strategic Executive Information System (STEIS) database was reported separately for 2012–2013 and 2013–2014. The free text elements from the database were analysed thematically and reclassified according to the nature of the patient safety incident (PSI). **Results** From the NRLS dataset, 32,263 patient safety events were reported between 1 January 2005 and 30 May 2014. Never events (NEs) from STEIS files were all wrong site extractions (WSS), reported separately for 2012–2013 and 2013–2014. The total number was 43.36 of the 43 PSIs were WSS involving: multiple extractions and bimodal age distribution (very young or over 60 years). Forty-seven percent of never events resulted in no harm, 20% low harm, 7% moderate harm, less than 1% severe harm and 23 deaths over this period (five of which were not related to dentistry). Serious harm and death risk factors included: care in an acute trust ward, peri oncological, reconstructive surgery (OMFS), patient age over 67 years with concurrent medical complexity (Ischaemic heart disease). Sixty percent of PSIs occurred in OS/OMFS in acute trust inpatients and 20% in primary care. From STEIS 2012–2013, 21 WSS were reported of which 50% occurred in oral surgery (OS) or oral and maxillofacial surgery (OMFS). The reported sites were 45% in operating theatre and 42% in dental surgery. **Conclusion** Incidences of iatrogenic harm to dental patients do occur but their reporting is not widely carried out. Improved awareness and training, simplifying the reporting systems improved non-punitive support by regulators would allow the improvement of patient safety in dental practise.

Introduction

Preventable patient safety events (PSIs) can and do occur, sometimes with severe consequences for patients and to the distress of the health-care professionals involved.¹ For example, the perception of error, stress and teamwork in the healthcare field is rather worrying in that 79% of surgeons and 49% of anaesthetists do not seem to have the perception of fatigue while working.² Other studies also showed (perhaps

without surprise) that 50% of medical staff find it difficult to discuss mistakes and 33% do not even think that they are capable of making mistakes.³

In order to try to identify where, when and why patient safety is compromised and to learn from these events, two major NHS safety databases were established ten years ago to which practitioners and managers report patient safety incidents (PSIs). Some of which are never events listed on the STEIS database, which records never events irrespective of the degree of harm caused to the patients (many have no harm related to the event but fulfil the criteria for never events). The second database is the NRLS which records all reported incident for (DATIX or other systems) recording adverse events. Some of these may be never events but most are not. The level of

harm (none, low, moderate, severe and death) are recorded alongside these events with related data including speciality, site, hospital trust and free text. Uptake of reporting and learning from near misses and never events has been encouraged within NHS trusts by use of mandatory training, mandatory use of checklists and financial incentives for evidence for improving patient safety.

The concept of a near miss is taken from a corporate model – Heinrich's 'Safety Triangle', which places near-miss events at the base of the triangle, accidents in the middle and finally fatalities at the top, with the assumption that by eliminating near-miss events, accidents and fatalities will eventually disappear. James Reason developed the 'Swiss Cheese' model of system failure in business whereby holes in the cheese slices line up to allow significant system failure to

¹Professor, Department of Oral Surgery; ²Senior Lecturer, Department Dental Public Health, Kings College London
*Correspondence to: W. Sabbah
Email: wael.sabbah@kcl.ac.uk

Refereed Paper. Accepted 8 June 2016

DOI: 10.1038/sj.bdj.2016.526

©British Dental Journal 2016; 221: 71–79

arise, similar to yellow flags and red flags in the aviation industry. Early adopters of learning from near misses and recognition of potential system failures were the aviation, oil and construction industries. Medical studies have reported that the near-miss experiences are a wake-up call for systematic risk reducing efforts and the use of checklists in surgery.² However, evaluation of this model, applied in pharmacology, disputed that attempts in avoiding near misses would obviate fatalities or serious incidents.⁴

Prof Don Berwick, who led a system-wide review of safety in the NHS⁵ said:

‘No one who works in any hospital wants to see patients come to any harm at all. When serious errors occur, it is a tragedy for both patients and staff, so the courage and commitment shown by the NHS in publishing this data are admirable.’ He goes on to state that:

‘There is a need for a transparent culture within the NHS where mistakes are reported and learning is shared to improve patient safety. Patients who have suffered harm because of any medical error should rightly expect that what happened to them has been the subject of a thorough investigation to determine what happened, why and what lessons have to be learned.

‘One way to help improve safety is by openly and honestly recognising, discussing and examining mistakes in care. That helps us create continually better systems and procedures.

‘Blame and punishment have no productive role in the scientifically proper pursuit of safety.’

In order to minimise risks and harm to patients, Monitor and the Care Quality Commission (CQC) analyse over 150 data sets to assess quality of care in acute hospital trusts (Table 1).⁶ Two of those data sets are serious events, including never events, and complaints. Serious incident reporting criteria (STEIS) include never events and can be incidents resulting in severe harm or death to patients while under NHS care. Examples include; lack of consent (otherwise assault and battery), acquisition of infections (*C. difficile*, MRSA etc), notifiable diseases and accidents.

The term ‘never event’ was first introduced in 2001 by Ken Kizer, former chief executive of the National Quality Forum in the United States, in reference to avoidable patient harm. The term has been expanded to identify adverse events that are clearly identifiable and measurable (resulting in death or significant disability). This encourages healthcare providers to implement preventable measures to improve patient safety. In the UK the term was introduced in April 2009, following Lord Darzi’s proposal in *High quality care for all*.⁷ Never events may highlight potential weaknesses in how an organisation manages fundamental safety processes and so this policy and framework provides the NHS with an essential lever for improving patient safety. Regardless of the outcome of an individual never event, they are always considered serious incidents as described in the Serious Incident Framework.⁸

The revised never events framework of March 2015 reassessed a subset of serious incidents and therefore, this policy should always be read in conjunction with the Serious Incident Framework.⁸ The updated criteria for never events are that they are particular type of serious incidents that meet the following criteria:

- They are wholly preventable where guidance or safety recommendations provide strong systematic barriers
- They are available at a national level
- They implanted by healthcare workers
- Each never event has the potential to cause serious patient harm or death (however serious harm or death is not required)
- There is evidence that it has occurred in the past (ie, it is a known source of risk)
- It can be easily defined, identified and continually measured. This requirement helps minimise disputes around classification and

ensures focus on learning and improved patient safety

- It is anticipated that never event list will be reviewed annually.

What are never events?

The Foundation Trust network response to the never events framework consultation⁹ supported revision of the serious events framework. The Revised Never Events Policy Framework¹⁰ proposed standardising operating theatre procedure, education and training of the workforce. The recent never events list 2015/16 is shortened¹¹ and those relevant to dentistry are:

- Never events in dentistry¹¹ include; wrong site block
- Wrong tooth extraction (including initiation of extraction on wrong tooth, wrong side LA block and or incision). Applies to permanent dentition only
- Wrong implant/incorrect placement of dental implant
- Retained foreign body
- Misplaced nasal or oro-gastric tubes.

There are incidents in which patients are harmed that fall outside the never event classification including for example, a patient experiencing a drug reaction or experiencing anaphylactic shock and even death. These drug-related events have to be reported on the yellow MHRA form. These preventable errors must be treated as seriously as a never event, but there is a risk they may not get the same attention.

Reported serious events (including never events) are assessed and categorised as grade 1 or 2, depending on the seriousness of the event. They should all be reported to:

- A primary or secondary care trust (or clinical commissioning group)
- The Care Quality Commission (CQC) Monitor through the NRLS, with never events being specified in the free text field (Monitor for foundation trusts and the NHS Trust Development Authority for non-foundation trusts)
- The Strategic Executive Information System (STEIS).

Within hospital trusts the serious incident should be reported on the providers’ local risk management system (DATIX) and on STEIS within 48 hours. The grading of the incident (1-3) using DATIX will dictate further action and requirement for root cause analysis and proof of learning from the incident.

Table 1 Never events¹¹

Wrong site surgery
Wrong implant/prosthesis
Retained foreign object post-operation
Mis-selection of strong potassium-containing solutions
Wrong route administration of medication
Overdose of insulin
Overdose of methotrexate for non-cancer treatment
Overdose (mis-selection of high strength) of midazolam during conscious sedation
Failure to install functional collapsible shower or curtain rails
Falls from poorly restricted windows
Chest or neck entrapment in bedrails
Transfusion or transplantation of ABO-incompatible blood components
Misplaced naso- or oro-gastric tubes
Scalding of patients.

In primary care never events must be reported to both STEIS and to the NRLS until a single system has been developed. Serious events are investigated and shared with the commissioners and an action plan shared widely to improve the service. The CQC may use information on never events to inform regulatory processes, alongside other indicators, and may take enforcement action.

This review of NRLS and STEIS data for dentistry for the last 10 years aims to assess;

- Areas of significant risk for patient safety related to dentistry based upon reported NEs and STEIS data
- The accuracy of the reported data and if the current data set is fit for purpose in facilitating learning and patient safety development in dentistry
- The rate of reporting of serious events (SEs—examples include; patient collapse, anaphylaxis, wrong medication administration) and NEs in dentistry.

With the purpose to analyse reported patient safety incidents in dentistry over the last decade and assess lessons learnt from the data set.

Methods

A review of never and serious events related to dentistry between 2005–2014 was conducted using data provided by NRLS with agreed data protection and intelligence governance. A snapshot view using the timeframe January 2005 to May 2014 was used. A review was also undertaken of the STEIS database which records never events irrespective of the degree of harm caused to the patients (many have no harm related to the event but fulfil the criteria for never events). Data was reported separately for 2012–2013 and 2013–2014. A keyword text search of the description of the cases was carried out to identify severe and death incidents in the NRLS file. The free text elements from the database were analysed thematically and reclassified according to the nature of the patient safety incident (PSI). Descriptive statistics were provided.

A subset analysis of events related to death or serious harm

First we examined the distribution of all never events as reported in the NRLS. Second, we examined the occurrence of severe events and death from 2005 to 2014 within different dental specialities, namely periodontics,

orthodontics, maxillofacial/ oral surgery, endodontics, and dental surgery and within location of care (general/acute hospitals, community hospitals, primary care settings, residence and public places). The distribution of specific events, and events related to death were also reported.

We used binary logistic regression to assess the association between the occurrence of severe events and death with three factors, namely speciality (general dentistry, maxillofacial/ oral surgery and other dental specialities), setting (general practice, nursing, medical and community clinics, and acute/ general hospital) and patient's age (>12, 12–17, 18–35, 36–55 and >55 years). This analysis was only conducted for those with complete data in all variables included. Hence, 162 cases where the speciality was not reported were dropped from the regression analysis.

Finally, we assessed the STEIS reported wrong site extraction occurrence in 2012–2014 by reporting organisation, and within location of operation and clinical department.

Results

There were 32,263 patient safety events, including never events, reported in total, between 1 January 2005 and 30 May 2014, in relation to the search criteria and relating to dentistry. The harm related to the never events reported was 47% no harm, 20% low harm, 7% moderate harm, less than 1% severe harm and 23 deaths over this period (Table 2).

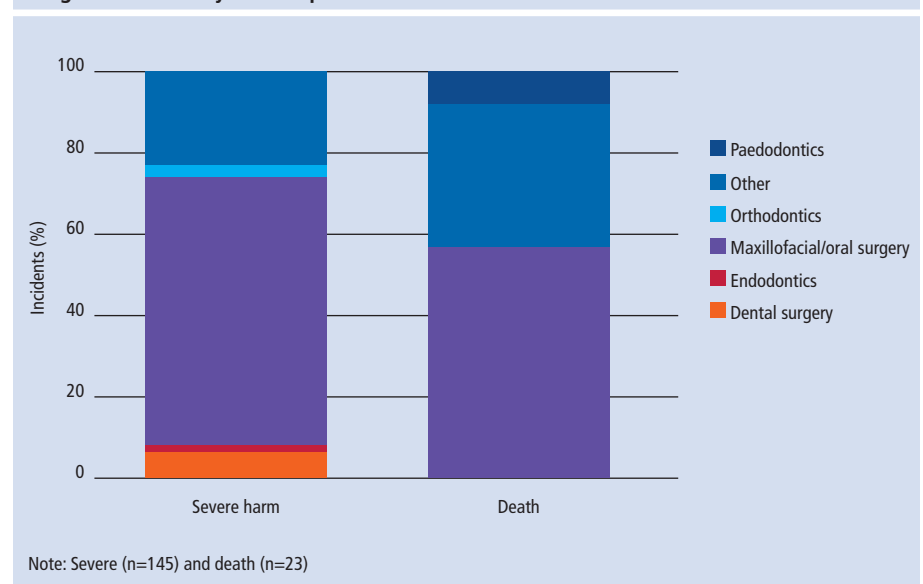
What is the association between serious events and never events to: death, speciality, location and age of patient? Where is the highest risk?

Based upon NRLS data, 60% of serious harm and death events occurred in relation to OMFS in acute trust wards (Fig. 1). On exploring free text, 93/168 cases occurred in relation to OMFS), 20% of serious harm and death events occurred primary in care (Fig. 2). Most patients with reported serious harm or death related to dentistry were treated in an acute trust setting (Fig. 2). The causes related to serious harm or death related to dentistry varied and on text

Table 2 NRLS incident reported as occurring between 1 January 2005 and 30 May 2014. Incidents from dental surgery specialities not identified as Never Events (N = 32263)

Event? Incident?	Total
Death	23
Severe harm	145
Moderate harm	1237
Low harm	6,335
No harm	24,523

Fig. 1 Incidents by dental specialities



analyses were predominantly related to patient collapse, delayed cancer diagnosis, wrong site surgery (WSS) and administrative errors (Table 3).

The most common serious event reported was WSS in 36 cases. Delay in identifying or treating

cancer was the second most common reported serious event (26 cases). Deaths related to dental care were 23 cases. On text analysis there were 28 reports of death but only 23 were related to dentistry. Five deaths were not related to dental treatment and should not have been included

in the NRLS data set relating to dentistry, for example death of a builder on scaffolding outside a clinic. Most of the 23 deaths related to dental or maxillofacial surgery occurred peri-surgically and included patient collapse on the ward, airway tracheostomy difficulties and complications related to pre-existing medical problems (mainly cardio thoracic). Those patients undergoing surgery for cancer with a mean age over 70 years were most commonly at risk of death related to dental intervention and most likely predominantly maxillofacial surgery related. The most common cause of death was myocardial infarction (Table 4).

Accuracy of data

Overall the data was incomplete with missing demographics, details of outcome, investigation or learning points and recommendations taken forward.

There appeared to be duplicate reporting in the serious harm events. Seven events seemed inappropriately reported and included in the NRLS data, (patient reported suicidal thoughts at consultation, patient panicking, change of anaesthesia from sedation to LA, patient collapse due to dry socket 10 days after routine dental surgery, 2 needle stick injuries, intraoperative arterial bleed) none of which resulted in patient harm.

Eleven events occurred outside the dental speciality (physio [1], obstetrics [3], general medical practice [1], care home [1], paediatrics [2] and outside healthcare buildings including a builder on scaffolding and falls in car parks [2]). Hence, the accuracy of many of these cases may be questionable. NE from STEIS files were all wrong site extraction, reported separately for 2012-2013 and 2013-2014, total number is 43. Twenty-one WSS were reported in the STEIS in 2012-2013 of which 50% occurred in oral surgery (OS) or oral and maxillofacial surgery (OMFS). The reported sites were 45% in operating theatre and 42% dental surgery and 13% in other sites (wards, clinics). Based upon the existing reporting system it often remains unclear to identify the exact location of where the patient safety events occur (that is, primary or secondary care). Most of the reports arose from secondary care trusts. The most common clinical departments reporting WSS events were from the operating theatre (47%) which by definition must be in secondary care as GAs are prohibited in primary care and dental surgery (38%) which we presume is primary care (including community dental services), but the data is not definitive and could have taken place in secondary care (Fig. 3).

Fig. 2 Severe and death incidents by location of care

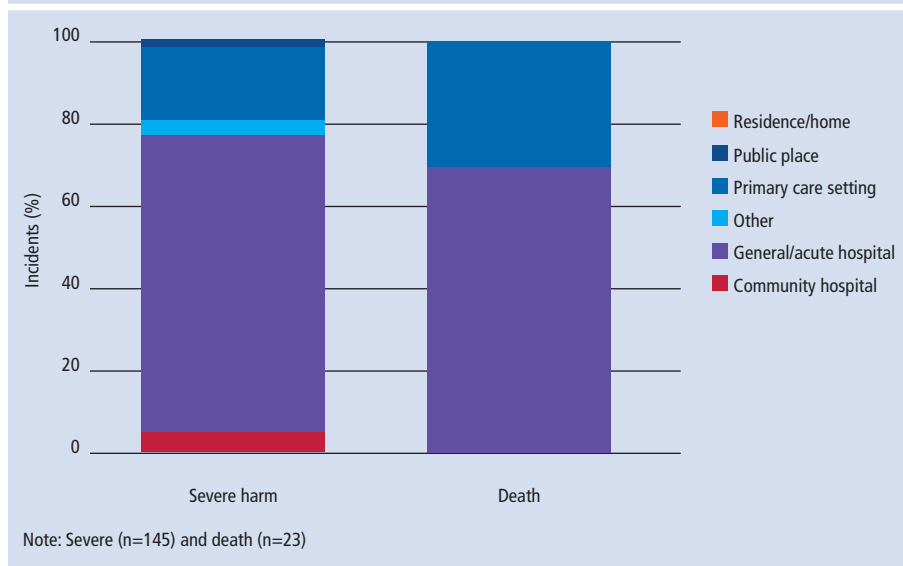


Table 3 Reported causes for 168 serious harm and death events

Serious harm or death event cause	Number	Analysis
Collapse or death	25	10 cardiac, 3 faints, 5 collapse no diagnosis, 4 DVT PE, 3 acute sepsis,
Delayed cancer or wrong diagnosis affecting treatment	26	20 carcinoma, 1 dislocated TMJ, 2 fatal sepsis repeated E&D presentation, 2 lost free vascularised flaps 1 respiratory obstruction
WSS	36	31 inadequate checks, 2 radiographs incorrect, 2 special need patients, one wrong diagnosis
Medical	9	6 anaphylaxis, 1 flumazeil, 1 wrong IV fluids, 1 morphine overdose
Haemorrhage	4	2 anticoagulants, 2 no contributory factors
Administrative	20	6 missing notes, 4 unavailable results, 4 cancellation from operation list, 1 consultant not available, 2 wrong consent sheet, 1 consultant not covering on call, 2 lack of bed availability
Non dental	11	1 Physio, 3 obstetrics, 1 general medical practice, 1 care home, 2 paediatric, 3 outside healthcare buildings including a builder on scaffolding and falls in car parks
Fall slip	8	6 falls slips in OMFS wards, 1 in corridor and 1 in shower
NG tube Trachy management	10	Airway, NG tube, PEG mismanagement
Tissue damage	6	4 lip burns, ear (towel clip) 1 bed sore, 1 swollen eye
Previous trauma contributing to Serious outcome not treatment	3	Significant prior trauma causing problem not treatment or mismanagement
Acquired infection	4	1 MRSA, 1 Clostridium difficile, 1 infective endocarditis and 1 sepsis
Retained items	2	Swab in maxillary antrum and retained denture
Other	4	Needle stick injuries

Wrong site surgery (WSS)

WSS was the most common event to be reported in relation to dentistry (37%) (Table 3). Reports of WSS based upon NRLS are 33 WSS, however, 36 on text analysis. Analysis of STEIS for 2012-13 and 2013-14 reveals 21 and 22 reported WSS. This displays a significant discrepancy in WSS between NRLS and STEIS data sets. Information on speciality, location and other details are not provided on STEIS 2012 data set provided. In 2012-14, 12 of these events (where age was reported) occurred in patients under 16 years of age. One event appeared to be a duplicate event. WSS events were only reported from 19 (total events 21) out of 220 NHS Trusts, again reflecting a poor level of compliance with reporting WSS events over the year.

Death and severe incidents were significantly more likely to occur in maxillofacial and oral surgery than with general dentists with an odds ratio of 1.98 (95% CI: 1.30, 3.04) (Table 5). Death and severe incidents were significantly less likely to happen in acute/general hospitals than in general practice with odds ratios 0.53 (95% CI: 0.32, 0.87) (Table 5). Patient age was not related to reported incidents even though nearly 50 of STEIS events were reported in patients under 16 years of age over one year.

The data presented confirms that 32,263 reported patient safety events were reported between 1 January 2005 and 30 May 2014, 47% of which were no harm, 20% low harm, 7% moderate harm, less than 1% severe harm and 23 deaths over this period. Serious reported PSIs were significantly related to WSS events, reported from maxillofacial or oral surgery specialties in acute trusts, taking place in operating theatres and dental surgeries. Only 20% of PSIs were reported from primary care and only 19 of 220 NHS trusts reported any event over this period. This confirms the low reporting of PSIs within the dental specialities; incidences of iatrogenic harm to dental patients do occur but their reporting is not widely used. Several data errors were identified and the analysis confirms that there is a limited capacity to learn from the data set as many relevant points both generic and speciality specific are missing.

Discussion

Dental extractions are the most common surgical intervention undertaken worldwide. Specific challenges for prevention of WSS in dentistry include: four possible quadrants,

Table 4 Events related to death of the patient

Event	Number	Age
Unrelated to dental care	5	
MI	9	Mean age 88
Sepsis	2	Mean age 65
Haemorrhage	2	Mean age 65 end stage liver disease, changing tracheostomy block excision
Anaphylaxis	2	Aged 15 and 46
Respiratory obstruction	2	Aged 81 and 57 (tracheostomy change)
Pulmonary embolism	2	Aged 66 post cancer treatment
Deep vein thrombosis	1	Aged 60 cancer surgery
Diabetic crisis	1	Age not stated
C-diff infection	1	Age 82
Existing medical AML presents bleeding gums	1	Age not stated

Fig. 3 Wrong site extraction reported to StEITS by clinical department, 2012-2013

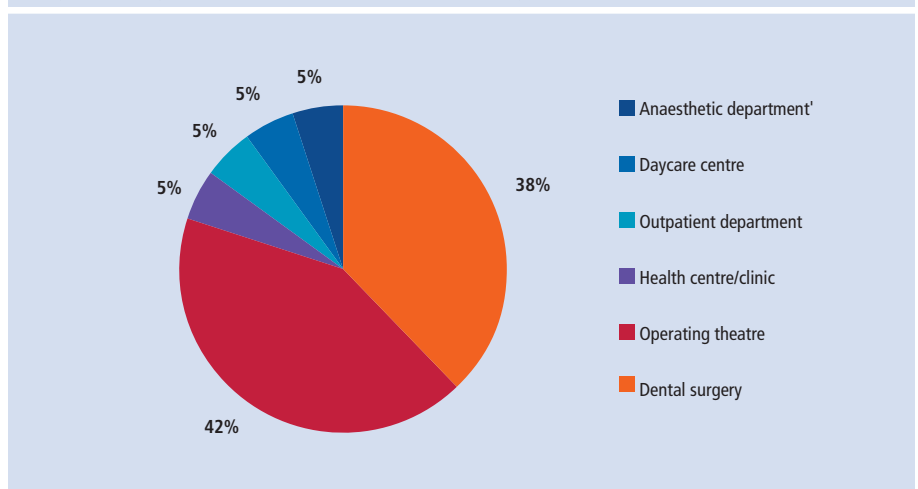


Table 5 Factors associated with unreported death or severe incidents 2005-2014 (N = 32,101)

		Odds ratio	Significance	[95% confidence interval]
Speciality	General dentist	Reference		
	Other speciality	0.5	0.06	0.24, 1.03
	Maxillofacial and oral surgery	1.98	0.002	1.30, 3.04
Setting	General practice	Reference		
	Nursing, medical and community clinics	1.07	0.83	0.60, 1.89
	Acute/general hospitals	0.53	0.01	0.32, 0.87
Age	Up to 11	Reference		
	12-17	0.643	0.36	0.25, 1.66
	18-35	0.52	0.11	0.24, 1.15
	36-55	0.97	0.94	0.48, 1.96
	More than 55	0.72	0.32	0.38, 1.36

primary and secondary dentitions, supernumerary teeth and additional stress of most procedures being undertaken on anxious awake patients under local anaesthesia meaning there is a massive potential for wrong site surgery. In addition, most procedures are undertaken in primary care where, until now, the governance structures and preventative processes pertaining to never events have not reached. The only previous analysis of NRLS data, specifically assessing dental related incidents was undertaken on data from January to December 2009. It was concluded that iatrogenic harm to dental patients occur but their reporting is not widely used.¹² Several other reports assessing different data sets relating to patient safety in dentistry have similarly reported deficiencies in reporting PSIs related to dentistry.¹³⁻¹⁵

The only previous analysis of NRLS data, specifically assessing dental related incidents was undertaken on data from January to December 2009.¹² Two thousand and twelve incident reports were analysed and organised into ten categories. The commonest was due to clerical errors – 36%. Five areas of patient safety incidents (PSIs) were further analysed: injury (10%), medical emergency (6%), inhalation/ingestion (4%), adverse reaction (4%) and wrong site extraction (2%). It was concluded that iatrogenic harm to dental patients occur but their reporting is not widely used.¹²⁻¹⁵ More recently a group at Manchester Dental School have explored various strategies to improve patient safety in relation to dentistry including WSS. Human factors are discussed in addition to related risks alongside lack of awareness and under reporting in primary care.²⁰

Under reporting of PSIs may be considered in this data activity as only 19 of a possible 155 acute NHS trusts reported dentally related PSIs. In addition, there were only eight reports from community dental body, of which there are currently 78. There were only three reports from general dental practices, of which there are 10300 registered provider practices in the UK. However, the data from our study may not reflect that there is a good safety culture in dentistry, but the supportive open culture and ease of reporting mechanisms do not exist. It is likely that incidents are discussed and that learning is facilitated as a result of patient safety incidents, but not reported and standardised in line with NRLS and NHS Institute for Innovation and Improvement standards for patient safety.

The field of patient safety in primary care dentistry is largely unknown. We cannot

assume that a vast number of patient safety incidents are happening in primary care dentistry just because we don't have the data to prove that they are not. GDPs may be less likely to carry out wrong site surgery as they have generally seen the patient several times over a number of years, whereas hospital visits are usually with different practitioners/trainees at every visit, thus increasing the chances of errors.

There may be several issues relating to this poor PSI reporting in dentistry including:

- Lack of open and supportive culture
- Duty of candour
- Dentists understanding of the need for learning from reported events
- Prevention of never events in dentistry
- Rate of under reporting and improving patient safety in dentistry by improving reporting and learning from PSIs
- Dataset accuracy and relevance of the current data set. Can we learn from this dataset and modify practice to improve patient safety in dentistry?
- Lack of open and supportive culture.

The Francis Report¹⁷ has recommended significant changes related to opening the UK healthcare culture (whistle-blowing without consequences) in recognising potential weaknesses in our healthcare systems, and has resulted in the implementation of improved regulations and new systems to ensure patient safety is prioritised, with poor care recognised early and prevented for the future.

It is recognised that patient safety incident reporting is particularly poor in dentistry compared with other healthcare settings.^{6,18} Reporting of adverse events in dentistry remains poor and explanations for inadequate compliance are many and discussed later. Both NHS and independent providers are obliged to report serious events. There are stipulated guidelines regarding these events (including 'never events') clarifying the responsibility for all health care providers in reporting these events. Without a centralised open reporting culture in dentistry, we will not benefit from a learning culture and repeated errors compromising patient safety will persist. We must not allow this to continue.

As yet NHS patient safety standards do not reach dentistry and they are not yet embedded in GDC or CQC dental specific standards. UK dentistry is experiencing higher complaints and litigation rate than any other healthcare sector resulting in the dental teams becoming

fearful and defensive. A change in culture supported by GDC and CQC is required to establish an open and supportive culture for the dental teams to feel at ease in reporting near misses and PSEs so that the profession in general can continue to improve patient safety.

Duty of candour

The duty of candour,³ introduced in April 2015, is the duty imposed on a public authority 'not to seek to win litigation at all costs but to assist the court in reaching the correct result and thereby to improve standards in public administration'.¹⁶ Duty of candour emphasises the following points:

- The importance of learning from mistakes by reporting incidents and near misses
- Ensuring management/regulators and commissioners provide organisational support to do this, as well as their responsibility to act on this information
- Undertaking relevant investigations and analysis
- Keeping patients informed and ensuring affected patients know that things are being done to prevent harm to others.

There is also a contractual duty of candour imposed on all NHS and non-NHS providers of services to NHS patients in the UK to 'provide to the service user and any other relevant person all necessary support and all relevant information' in the event that a 'reportable patient safety incident' occurs. A 'reportable patient safety incident' is one which could have or did result in moderate or severe harm or death.¹⁶

The Francis Report made a number of specific recommendations about the Duty of Candour.¹⁷

Should dental extractions wrong site surgery be a never event?

Many suggest that due to the inability to mark the surgical site and the four quadrants, with deciduous and permanent dentitions, dental extractions correct site surgery is more complex and challenging than other surgeries. So does dental WSS fit the criteria for a never event?

- Are they are wholly preventable where guidance or safety recommendations provide strong systematic barriers and are available at a national level? Yes (The relevant national guidelines and systems to prevent dental WSS have been discussed in this article).
- Are they implanted by healthcare workers? Yes.

- Is there is evidence that it has occurred in the past (that is, it is a known source of risk)? Yes
- Each never event has the potential to cause serious patient harm or death (however serious harm or death is not required) The second issue is whether a wrong dental extraction causes serious harm to the patient? Wrong site surgery by definition is 'assault and battery' as it does not conform to the acquired consent, and is by definition, patient harm. In addition WSS involving teenagers and other age groups may result in loss of teeth that may necessitate prolonged and expensive corrective treatment (orthodontics, implants etc)
- Can it can be easily defined, identified and continually measured? Yes. (This requirement helps minimise disputes around classification and ensures focus on learning and improved patient safety)
- It is anticipated that the never event list will be reviewed annually.

Thus healthcare providers are beholden to report and learn from PSIs. There are many frequently asked questions regarding which events are indeed never events related to dental extractions and these are clarified in Table 5.

How can we prevent WSS?

Never events can lead to serious adverse outcomes and they damage patients' confidence and trust in the NHS. They can almost always be avoided when existing best practice is implemented. They may also highlight problems in an organisation's safety culture and its processes for learning and improvement. All high risk activities, variation in processes, protocols, technical language, training and team member status lead to uncertainty and increase the likelihood of error. Reliable and robust systems are built by reducing variation, promoting the development of safe behaviours and supporting the exercise of responsibility. Implementation of the following guidance can help providers to prevent wrong site surgery: this system of profession-led national and local standards will reduce variation and promote best practice, while still providing scope for local innovation and reinforcing responsibility at provider level

The take home message defaults to the findings of the 2014 review⁹ that there is no single cause underlying the occurrence of the never events which are almost always the result of multiple sources of error.

Following publication of the never events policy framework in October 2012 the NHS commissioning Board set up a task force to look at surgical safety, resulting in the publication '*Standardise, educate, harmonise: Commissioning the conditions for safer surgery*'.¹² It is the final report of NHS England's surgical never events task force, a literature review and survey of 600 practitioners, which was requested to examine the three most common never events including:

- Wrong site surgery (which includes operating on the wrong site, carrying out the wrong procedure, and operating on the wrong patient)
- Wrong prosthesis (for example, the wrong size components in a replacement hip or inappropriately placed dental implant)
- Retained foreign object (the most frequently retained foreign objects are surgical swabs, dental implants, drill heads, endodontic instruments, unplanned retained or displaced tooth roots or instruments, but this also includes surgical instruments).

Also to:

- Analyse the reasons for the persistence of three never events in surgery
- Consider whether the World Health Organization checklist was helping to reduce them
- Make recommendations about what NHS England, with its responsibilities for commissioning, could do to reduce them further.

A consistent and compelling message emerged: there is no single cause underlying the occurrence of the never events we reviewed. Never events are almost always the result of multiple sources of error.

Many sources of error consistently recognised in the research literature range from human factors, working environment and practise, systems and supportive structures, training in learning from PSIs, poor professional behaviour and team building.

To address these issues the NHS surgical safety taskforce chose to propose a three-pronged strategy, aware that the success of this strategy will rest on each prong having equal status. Many of the recommendations are those of the Francis Report.¹⁷

The three prongs are standardisation, education and harmonisation.

The National Standards should be incorporated into the NHS standard contract, meaning

that they apply to all NHS funded care, whether carried out by NHS trusts or private providers.

Standardisation

The national guidelines and systems recommended include, the patient safety alert system and the WHO checklist.⁷

The NPSA, in collaboration with a multi-professional expert reference group, adapted the WHO Surgical Safety Checklist for use in England and Wales and incorporated previous best practice identified by the NPSA and the Royal College of Surgeons on making surgery safer in its patient safety alert. One of the best examples of standardising is use of the WHO checklist:

- The checklist is changing culture. There is now the increasingly widespread view that 'this is the way things should be done'. By 2011 91% of theatre staff surveyed would have wanted the checklist used for their own surgery
- If the checklist is treated as a tick box exercise it is of limited use.
- The checklist has promoted systemic change and prompted safer behaviour
- The checklist alone is not sufficient. We must lower the prevalence of harm using a broader approach.

The second element is systemic education and training, including for those managing operating environments. Surgical safety must be addressed at all levels; in undergraduate level qualifications for doctors, nurses, and operating department practitioners; in postgraduate training, including the NHS Management training programme; and in trust provision for continuing professional development. Addressing surgical safety means, among other things, teaching practitioners about human factors, and how human-human and human-technology interactions affect safety. Further recommendations address the responsibilities of Higher Education England, the General Medical Council, Deaneries and medical Royal Colleges for ensuring that curricula and training programmes incorporate appropriate safety training; and of the CQC for reviewing the adequacy of provider training.

The final element is harmonising activity to support patient safety in hospitals. Examples of our recommendations under the theme of harmonisation include: NHS England and Clinical Commissioning Groups to impose penalties only where provider response to

a never event, including patient support, is assessed as ineffective (thus avoiding creating a deterrent to reporting); Responsible Officers to ensure that appraisal for revalidation includes evidence of activity concordant with local standards; and the NHS Litigation Authority to make clear how national standards and local standards contribute to defining the required legal standard of care.

The Surgical Never Events Taskforce report¹⁰ was to develop a set of high-level national standards of operating department practice that will support all providers of NHS-funded care to develop and maintain their own more detailed standardised local procedures.¹⁹

Looking after patients and professionals following adverse events

Importantly, we argue in our report that never events are not over when a patient leaves the operating theatre. The task force looked carefully at the support that patients and their loved ones need when patient safety incidents happen. Professional-ethical duties and the contractual duty of candour mandate that patients are told promptly and honestly when something has gone wrong.

Applying these generic principles of patient safety in dentistry may prevent WSS and other PSIs. Only a few studies have reported on possible strategies to minimise WSS or to improve patient safety in dentistry.^{18,20-25} The common conclusions are that most cases of wrong-site tooth extractions are preventable and can be minimised by the development of an educational programme, an informative, unambiguous referral form, a pre-operative check list, and incorporation of the Universal Protocol for dental notation.^{18,20-25} The main finding from the systematic review²⁵ was that checklists are the only reliable way to avoid PSIs in dentistry.

More recently, a group at Manchester Dental School have explored various strategies to improve patient safety in relation to dentistry, including WSS. Human factors are discussed in addition to related risks alongside lack of awareness and under reporting in primary care.²⁰ They suggested that by refining a surgical safety checklist for outpatient oral surgery along with the key strategic actions needed to ensure effective cultural change and optimum patient safety in the outpatient setting, WSS could be prevented.²¹ They also highlight how patient safety incidents can be better analysed and audited by monitoring the

use of an outpatient checklist.^{18,20-22} Mandatory training in communication and teamwork explicitly around patient safety can ensure safe management of patients.²² Introduction of a patient safety dashboard assessing: WSS; use of benzodiazepine antagonist; compliance (NICE; Trust Policies; and consent procedures; surgical checklist; mandatory training) was introduced for the dental institute.²¹ Additional patient safety dashboard incidents included: TMD patients presenting with trismus; incorrect placement of dental implants; nerve injuries; accuracy of letters requesting extraction for orthodontics; and failure of biopsy management. Each metric is a potential learning opportunity to improve performance.²¹

Supporting teams after PSIs

We cannot assume that there is significant under reporting of PSIs in dentistry until we have the actual evidence. However, failure to report a never event, which subsequently comes to light through a third party route (for example, coroner's inquest, claim, complaint or media report), is likely to constitute a breach of CQC requirements (Regulation 16 and 18 of the CQC [registration] Regulations 2009) and Service Condition 33 of the 2014/15 NHS Standard Contract which sets out provider responsibilities for reporting incidents.⁶

The reporting of PSIs in healthcare is complex, requiring understanding of various recommendations of processes and systems to various different regulators of healthcare. Dentistry is regulated by three regulators: NHS England; the Care Quality Commission (CQC); and the GDC. This tripartite arrangement causes a degree of ambiguity and complexity. It is already stated⁷ within the general dental 'Standards for the Dental Team'²⁶ that a principle of care is 'put the patient first', and that 'you must record all patient safety incidents and report them promptly to the appropriate national body'. However, global uptake of NHS governance and patient safety mechanisms are not yet embraced in primary care or indeed dentistry. There is ongoing NIHR funded research to improve awareness, of patient safety reporting systems and address under-utilisation and improve compliance in dental primary care,^{24,25} but there is a lot to achieve.

Lastly, and most importantly, is the current lack of a supportive and open culture in learning from reported PSIs in dentistry, and many dentists remain fearful due to the current high levels of complaints and litigation related to UK dentistry. Patient safety involves

many aspects of care. A recent review²⁴ identifies key themes including: medical history (polypharmacy and co-morbidities); competence and skill level; the use of safeguards and tools to ensure safety; the importance of effective communication (including working with a chaperone); and the role of reflective practice. Suggestions for improvement included: effective sharing of information with other healthcare professionals; easy access to guidelines and educational tools; adoption of practice protocols; team working; and the use of universal charting systems to limit ambiguity.

Can we modify practise to improve patient safety in dentistry?

This review of STEIS and NRLS data sets related to dentistry not only highlights low reporting but also inaccuracies and difficulty in learning from the data provided. There is a current review of the NRLS dataset, and dental professionals must be part of the conversation to ensure dental PSIs reflect dental procedures and include human factors (not yet included) in a systematic manner, not just in free text, that is meaningful to the clinicians to facilitate learning and change in practice where necessary.

Conclusions

This report highlights the need for improving the reporting of patient safety incidents relating to dentistry. National directives and standards are set but fail to 'reach' dentistry. Our dental regulators need to develop a more proactive and aligned role in promoting mandatory training in PS. A cultural and systematic change in dentistry is required, as has happened with primary care medicine, to improve patient safety incident reporting with resultant visible improvement in patient safety. There are several issues, including:

- Developing a better understanding of PSIs related to dentistry, including; what they are; their importance in reporting them; and using them to learn how to improve our practice
- Promote and understand the benefits of the reporting systems
- Develop a simplified reporting system supported by the regulators with standardised tools and mandatory training. This will be addressed by the recent National Surgical Safety in Interventional Procedures (NatSSIPs)²⁷ directive, which recommends

the development of local SSIPs. A generic LocSSIP form has been developed for dental extractions which will be available on the NatSSIPs' site in due course

- Develop a supportive and not punitive culture for reporting and learning. NatSSIPs directive²⁷ will also promote regulator support in learning from PSIs
 - Agree on a more relevant data set for PSIs in dentistry to improve learning from them and, as a result, improve dental care
 - Provision of clarification of a line of communication to disseminate patient safety information throughout dentistry (for example the recently published NatSSIPs or 'Sig up to safety' campaign)
 - Promotion of the use of the eform for reporting patient safety incidents in primary care dentistry. This eform is used by general medical practitioners to report PSIs
 - Improve the engagement from dental regulators GDC, CQC and NHS primary care dentistry to align responsibility of promoting patient safety, and address under reporting and mandatory training
 - Promote alignment of dental commissioning with PS initiatives.
1. World Health Organisation, 2008. World Alliance for Patient Safety Progress Report 2006-2007.
 2. Patient Safety Domain. Standardise, educate, harmonise: Commissioning the conditions for safer surgery. NHS England. 2014. Available online at <https://www.england.nhs.uk/wp-content/uploads/2014/02/sur-nev-ev-tf-rep.pdf>. (accessed July 2016)
 3. Lewis K. *Now What? 'Success is the journey, not the destination'*. 2014. Available online at <http://www.devon-ippg.org/kevin-lewis-nowl>. (accessed December 2015).
 4. Wharton N. *The relationship between minor and serious injuries 2011*; Available at: <http://www.jomc.co.uk/the-relationship-between-minor-and-serious-injuries/>. (accessed December 2015).
 5. Department of Health. *Berwick review into patient safety. Recommendations to improve patient safety in the NHS in England*. 2013; Available at: <https://www.gov.uk/government/publications/berwick-review-into-patient-safety> (accessed December 2015).
 6. Care Quality Commission. *Monitoring NHS acute hospitals*. 2015. Available online at: <http://www.cqc.org.uk/content/monitoring-nhs-acute-hospitals> (accessed December 2015).
 7. NHS. *WHO Surgical Safety Checklist (adapted for England and Wales) and Supporting Information*. 2009. Available at: <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59860> (accessed December 2015).
 8. NHS England. *Serious Incident Framework*. 2013; Available at: <http://www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf> March 2013 (accessed December 2015).
 9. NHS England. *Never Events Policy Framework Review*. 2014; Available at: <https://www.engage.england.nhs.uk/consultation/never-events-policy-framework-review> (accessed December 2015).
 10. NHS England. *Revised Never Events Policy and Framework- NHS England*. 2015; Available at: <https://www.england.nhs.uk/wp-content/uploads/2015/03/never-events-list-15-16.pdf> (accessed December 2015).
 11. NHS England. *Never Events List 2015-16*. 2014; Available at <https://www.england.nhs.uk/wp-content/uploads/2015/03/never-events-list-15-16.pdf> (accessed December 2015).
 12. 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**: E3-E3.
 13. Rattan R, Wilson N H, Tiernan J. *Risk management in general dental practice*. Quintessence; 2004.
 14. 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**: 1370–1377.
 15. Perea-Pérez B, Santiago-Sáez A, García-Marín F, Labajo-González E, Villa-Vigil A. Patient safety in dentistry: dental care risk management plan. *Med Oral Patol Oral Cir Bucal* 2011; **16**: e805–e809.
 16. Treasury Solicitor's Department. *Guidance on Discharging the Duty of Candour and Disclosure in Judicial Review Proceedings*. 2010; Available online at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/285368/Tsol_discharging_1_.pdf (accessed December 2015).
 17. Mid Staffordshire NHS Foundation Trust. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*. 2013; Available online at <http://webarchive.nationalarchives.gov.uk/20150407084003/http://www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf> (accessed December 2015).
 18. Bailey E, Tickle M, Campbell S. Patient safety in primary care dentistry: where are we now? *Br Dent J* 2014; **217**: 339–344.
 19. NHS. *National Safety Standards for Invasive Procedures*. 2015. Available at: <https://www.england.nhs.uk/wp-content/uploads/2015/09/natssips-safety-standards.pdf>. (accessed December 2015).
 20. Saksena A, Pemberton M, Shaw A, Dickson S, Ashley M. Preventing wrong tooth extraction: experience in development and implementation of an outpatient safety checklist. *Br Dent J* 2014; **217**: 357–362.
 21. Pemberton M, Ashley M, Shaw A, Dickson S, Saksena A. Measuring patient safety in a UK dental hospital: development of a dental clinical effectiveness dashboard. *Br Dent J* 2014; **217**: 375–378.
 22. Ashley M, Pemberton M, Saksena A, Shaw A, Dickson S. Improving patient safety in a UK dental hospital: long-term use of clinical audit. *Br Dent J* 2014; **217**: 369–373.
 23. Pemberton M. Developing patient safety in dentistry. *Br Dent J* 2014; **217**: 335–337.
 24. Bailey E. Contemporary views of dental practitioners' on patient safety. *Br Dent J* 2015; **219**: 535–540.
 25. Bailey E, Tickle M, Campbell S, O'Malley L. Systematic review of patient safety interventions in dentistry. *BMC Oral Health* 2015; **15**: 152.
 26. Council GD. *Standards for the dental team*. London: GDC, 2013.
 27. NHS England. *Supporting the introduction of the National Safety Standards for Invasive Procedures*. 2015. Available online at <https://www.england.nhs.uk/wp-content/uploads/2015/09/psa-natssips.pdf>.