The complexity of patient safety reporting systems in UK dentistry

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In brief

Provides an update on existing systems and procedures in relation to patient safety in dentistry in the UK.

Highlights the existence of conflicting advice which further complicates an overly burdensome process.

Suggests solutions to address the problems surrounding patient safety development in dentistry.

Since the *'Francis Report'*, UK regulation focusing on patient safety has significantly changed. Healthcare workers are increasingly involved in NHS England patient safety initiatives aimed at improving reporting and learning from patient safety incidents (PSIs). Unfortunately, dentistry remains 'isolated' from these main events and continues to have a poor record for reporting and learning from PSIs and other events, thus limiting improvement of patient safety in dentistry. The reasons for this situation are complex.This paper provides a review of the complexities of the existing systems and procedures in relation to patient safety in dentistry. It highlights the conflicting advice which is available and which further complicates an overly burdensome process. Recommendations are made to address these problems with systems and procedures supporting patient safety development in dentistry.

Introduction

Patients expect to be treated safely when seeking healthcare. 'Safe' means that patients are protected from abuse and avoidable harm. A patient safety incident (PSI) is defined as any unintended event caused by healthcare that either resulted in, or could have led to patient harm. PSIs have been shown to cause harm in 3% to 17% of hospital inpatients.[1,2]

When patient harm occurs in relation to healthcare it can be devastating, not just for the patient and their extended family and social network, but also for the treating clinician and their team. The CQC estimates that there are approximately 11,000 incidents of *severe* harm and up to 100,000 incidents of *serious* harm occurring each year within the NHS. Indeed, preventable adverse events could be costing 'approximately £1 billion' per year.[3] We now recognise that by embracing a systems approach and a supported open culture, prevention of future adverse events is possible, as already demonstrated within the aviation industry.

Significant changes in healthcare regulation in the UK have taken place over the last 10 years. While some have arisen due to the changes in political leadership, many regulatory changes have been in response to alarming adverse events within NHS patient care. The most recent response to the events in the Mid Staffordshire NHS Trust, the '*Francis Report*' (2012),[4] recommended significant changes in amending our culture (whistleblowing without consequences) in recognising potential weaknesses in our healthcare systems, and has resulted in the implementation of improved regulation and new systems to ensure patient safety is prioritised.

In the Government's initial response to the Francis Inquiry, published in March 2013, we accepted the need to introduce a statutory 'duty of candour' for health and care providers. This contractual duty of candour was 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. The Francis Inquiry also noted that observance of the duty should be policed by the Care Quality Commission (CQC).[5–7]

The Report[4] made a number of recommendations about the duty of candour that can be summarised as follows:

- Healthcare providers should be under a statutory duty of candour:
  - To inform the patient, or other duly authorised person
  - To inform their employer as soon as practicable, when they believe or suspect that treatment or care it provided has caused death or serious injury to that patient, and thereafter, provide such information and explanation as the patient reasonably may request
- It should be a criminal offence for any registered medical practitioner, or nurse or allied health professional or director of an authorised or registered healthcare organisation to knowingly obstruct another in the performance of these statutory duties, provide information to a patient or nearest relative with the intent to mislead them about such an incident or dishonestly make an untruthful statement to a commissioner or regulator, knowing or believing that they

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Box 1 The regulatory bodies to which dentists may have to report incidents

- **National Reporting and Learning System (NRLS) (NHS Bodies only)**
  The National Reporting and Learning System (NRLS) captures all patient safety incidents. When reporting patient safety incidents to the NRLS the actual (not potential) level of harm caused must be reported. (This does not apply to providers of adult social care, independent healthcare, primary dental care and private ambulance services)
- **Strategic Executive Information System (StEIS)**
  All serious events must be reported to both StEIS and NRLS. Clinicians in secondary care will report via DATIX (or similar incident reporting system)
  The Strategic Executive Information System (STEIS) captures all serious incidents. Serious incidents (as defined in the Serious Incident Framework) and this can include but are not limited to patient safety incidents.
- **Care Quality Commission (CQC)** (See later section on PSI reporting to the CQC)
- **RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013)**
  Serious incidents may need to be reported under the RIDDOR and the trigger point for RIDDOR reporting is over seven days' incapacitation (not counting the day on which the accident happened).
- **Medicines and Healthcare products Regulatory Authority (MHRA) and the Central Alerting System (CAS)**
  Any serious incident involving medication or medical devices (including implants) should be reported to the MHRA. The MHRA deals with ongoing reports from healthcare professionals, patients, and manufacturers, including:
  - Potential side effects of prescription and over the counter medicines and herbal remedies (Yellow Card Scheme)
  - Design faults / poor instructions or maintenance / incorrect use of devices (Adverse Incident Reporting Scheme)
  - Defective medicines
  - Serious side effects involving blood and blood components (SABRE).
- **Notifications of infectious diseases (NOIDs) and healthcare associated infection (HCAI)**
  Serious incidents must be reported to Public Health England (PHE - previously the Health Protection Agency).
- **The Health and Social Care Act 2008 code of practice for the prevention and control of infections** requires that NHS providers report cases and outbreaks of certain infections including *Clostridium difficile*, blood stream infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) and glycopeptide-resistant enterococci (GRE) and surgical site infections (SSI) following orthopaedic surgery.
- **Reporting to the police**
  The police are likely to investigate incidents where there is evidence, or suspicion of, a criminal offence having been committed, for example if an incident has arisen from or involves criminal intent, or gross negligence. In circumstances of unexpected death or serious harm requiring investigation by the police, the incident should be managed in accordance with the Memorandum of Understanding (currently under review). This protocol should be activated when an incident requires investigation by the police and the Health and Safety Executive (HSE) jointly. In the first instance the incident should be reported within the organisation in the normal way and to the commissioning body.
- **Safeguarding vulnerable adults/children**
  All concerns regarding significant risk of abuse should be reported to the local services responsible for safeguarding.
- **Mental health**
  Suicidal thoughts or behaviour. If any patient or member of staff reports suicidal thoughts or tendencies, they must be referred to their GMP for an urgent mental health team/ psychiatric assessment.
- **Regulations 1999 and Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER), Sharps regulations 2013, HTM 07-01 (healthcare waste)**
  Reporting relating to radiation, health waste and other industrial work related incidents are not covered in this paper.

are likely to rely on the statement in the performance of their duties.

It is recognised that patient safety incident reporting is particularly poor in dentistry compared with other healthcare settings.[8–12] Both NHS and independent providers are obliged to report serious events, and there are stipulated guidelines regarding these events (including 'Never Events') clarifying the responsibility for all healthcare providers in their duty to report. Absence of a centralised and open reporting culture in dentistry means that we will not benefit from a learning culture and repeated errors compromising patient safety will continue to persist. This situation must be addressed.

This paper is an attempt to unravel the complex and multiple regulations, systems, processes and online recommendations for reporting patient safety incidents relating to healthcare and more specifically to dentistry. Recommendations are made to challenge some of the complexities within the current systems and to provide potential solutions.

What is a patient safety incident?

Patient safety incidents (PSIs) include; Adverse events/incidents, clinical incidents, critical incidents, medical errors, clinical errors, medical mistakes and sentinel events. These events may result in high, moderate, low or no harm (near misses). It is often said that 'near misses' are the 'nuggets' in developing improvement in patient safety, as we learn about preventable risks without harming the patient. There are a variety of regulations applied by numerous regulatory bodies that make reporting certain patient safety (notifiable) incidents obligatory for healthcare providers, whether in independent or NHS practice (Box 1).

Permanent harm is defined as arising directly from the incident (medical or surgical) and not related to the natural course of the patient's underlying condition. It is defined as permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb, organ, tooth and brain damage.

What is a Never Event?

A 'Never Event' is defined as a serious incident, although not all Never Events necessarily result in severe harm or death.[13] A Never Event must:

- Be wholly preventable, where guidance or safety recommendations are available at a national level and that provide strong systemic protective barriers
- Have the potential to cause serious patient harm or death
- Have occurred in the past, for example through reports to (NRLS)
- Be easily recognised and clearly defined.

The 2015–2016 Never Event list published April 2015[13] includes 13 categories.

Here are some examples of Never Events of relevance to dentistry:

- **Wrong site surgery (WSS):** (includes permanent dentition only) refers to a surgical intervention performed on the wrong patient or wrong site. The incident is detected at any time after the start of the procedure
- **Wrong side block:** (includes permanent dentition only) refers to the use of local anaesthetic block on the wrong side and

also, initiation of surgery (ie an incomplete extraction and re-implantation of an inadvertently extracted wrong tooth is still a Never Event)

- **Wrong implant** refers to surgical placement of the wrong implant or prosthesis where the implant/prosthesis placed in the patient is other than that specified in the surgical plan either prior to or during the procedure and the incident is detected at any time after the implant/prosthesis is placed in the patient
- **Retained foreign object**: 'Foreign object' includes any items that should be subject to a formal counting/checking process at the commencement of the procedure and a counting/checking process before the procedure is completed (such as swabs, needles, instruments and guide wires). Other examples include; displaced teeth, fractured bur heads, bone screws, orthodontic appliances, dentures, implant and endodontic related equipment which may be inhaled, swallowed or displaced into the inferior dental canal or maxillary antrum.

In some instances, Never Events may be discovered some time after the incident occurred. While delayed discovery is not a factor in determining whether an incident is a Never Event, it may have a bearing on the 16 improvements deemed necessary following investigation (for example, where subsequent procedural changes mean that additional action may be unnecessary). Where a Never Event is discovered by one organisation but appears to be the responsibility of another, the 'discovering' organisation should inform the originating organisation, and is not required to report the incident as its own responsibility.

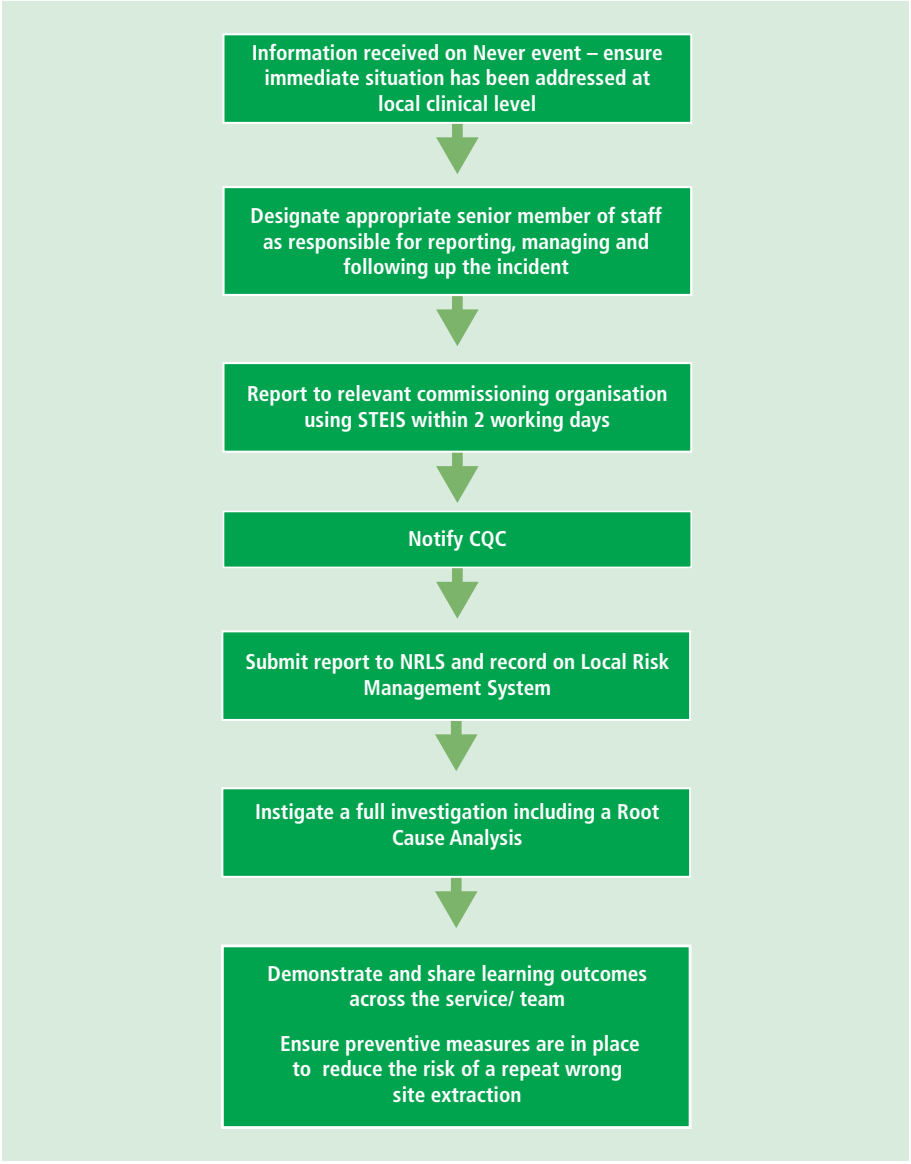
Systems and processes

The tripartite regulation of dentistry by the General Dental Council (GDC), Care Quality Commission (CQC) and NHS lacks clarity and is further complicated by the multiple regulations pertaining to patient safety in dental practice. As a result of these regulations the obligatory reporting is multiple and complex.

To whom should PSIs be reported?

The type of incident, relating to patient care, will dictate how, when and to whom you report the incident. There are many regulatory bodies (Box 1) to which dental providers may have to report incidents and some incidents have a stipulated timescale for reporting.

Fig. 1 Dental Never Events – wrong site extraction



Who should report the PSI?

All PSIs should be reported anonymously by a pre-designated registered provider (usually practice principal or service manager), whilst protecting the patient's privacy in line with Data Protection regulations 1998 (Fig. 1 provides an overview on reporting a PSI in dentistry in relation to wrong site extraction).

Reporting PSIs is simple for general medical practitioners as there is an electronic proforma available for NHS practices.[1] This simplifies PSI reporting to relevant bodies, most commonly the National Reporting and Learning System (NRLS). The CQC must also be informed of the PSIs in primary care NHS or independent practise. Within a trust or community dental service, the PSI would be reported through local risk management systems which are uploaded to the NRLS whilst directly informing local care commissioners. Serious events, including Never Events, must be reported within two days of their occurrence

Does reporting of PSIs only apply to NHS practice?

Both NHS and independent providers must report PSIs to the appropriate regulator. Recommendations for reporting of serious incidents occurring in independent sector healthcare or other provider outside the NHS include:

- Independent sector healthcare providers must report any serious incident involving a patient receiving NHS funded care to the commissioning organisation with responsibility for the contract
- Independent sector healthcare providers should report to the NRLS via the eForm[15] of the NRLS, although this is voluntary and

the CQC must be notified directly of abuse, serious injury and all deaths
- Independent sector healthcare providers are also responsible for reporting the incident directly to their appropriate regulator.

NHS Commissioning area teams can, if appropriate, provide access to STEIS for non-NHS providers for reporting purposes as long as those providers are on the NHS N3 network (which most dentists are not), although NHS emails can be used instead.

What should happen after reporting PSI?

Managing the response to Never Events is a critical component of corporate and clinical governance. Providers must establish effective governance mechanisms to ensure the following:

- The patient/family/carer must be informed as soon as possible when a Never Event occurs. Details of the conversation must be documented in the patient records; disclosure must not be delayed whilst the Never Event status is being determined. All staff should be familiar with related requirements of 'being open'[15] and the 'duty of candour'.[4] It is imperative that there is early, meaningful and sensitive engagement with the affected patients and/or their families/carers from the point that the Never Event is identified, throughout the investigation and action planning, to closure of the incident. Information should be shared in line with '*Being Open*' guidance and the duty of candour[15].
  - Investigations are undertaken by appropriately trained and resourced staff and/or teams that are sufficiently removed from the incident to be able to provide an objective view
  - An open and supportive culture is essential to facilitate and enable open reporting and learning from PSIs.

PSIs should be investigated via root cause analysis

Specifically dedicated trained staff should establish effective governance mechanisms to ensure the following:

- Timely reporting and liaison with their commissioning bodies
- Compliance with reporting and liaison requirements with agencies such as Monitor, the Trust Development Authority, the Care Quality Commission (CQC), Public Health England, the Health and Safety Executive, and coroners
- Investigations follow a systems-based methodology to ensure identification of all the possible contributory factors and root causes, with focused actions and learning outcomes
- Staff involved in the Never Event are supported and treated fairly, with reference to the NPSA Incident Decision Tree.[16] The primary focus of the investigation should be on identifying underlying factors that contributed to the Never Event occurring, including understanding why the relevant barriers were not properly in place to prevent the Never Event
- Commissioners are encouraged to publish information relating to all serious incidents, including Never Events, within annual reports and other public facing documents such as governing body reports, including data on the numbers and types of incidents, ensuring patient confidentiality is respected
- Incidence of Never Events must be identified in the commissioner's annual report and the provider's quality accounts (ensuring patient confidentiality). This should include, where possible:
  - Data on the type and number of Never Events, including historical context and related incidents
  - A summary of each Never Event
  - The learning derived from the incidents, with a particular focus on the system changes that have been made to reduce the probability of recurrence
  - How learning has been shared at all levels within the organisation, and also, externally

Box 2 The 5 Key Lines of Enquiry (KLOE) now replace the previously used outcomes

PSIs are mostly covered within the first and second KLOEs: 'Are services safe?' and 'Are services effective?'

Safe 1

This 'Key Line of Enquiry' questions what systems, processes and practices are in place to ensure that all treatment is carried out safely? (Regulations 12)

Safe 1 requires healthcare workers and organisations to record and report incidents and near misses. It recommends access to electronic reporting systems and a culture of shared learning.

Examples based on safety related regulations include:
- All members of the team being fully aware of RIDDOR and COSHH
- Staff having a clear understanding of how and when to raise concerns
- Staff understanding the importance of recording and reporting incidents and near misses (Regulation 18)
- Compliance with MHRA safety alerts.

Safe 2

This 'Key Line of Enquiry' questions how lessons are learnt and how improvements are made when things go wrong.

Examples based on safety regulations include:
- Recording and analysis of clinical errors, incidents and near misses
- Evidence of patients being informed when an error is made, with follow up and apology
- How lessons are learnt and what action has been taken to ensure it does not happen again
- How incidents and near misses are shared within the team
- Understanding and compliance with the duty of candour (Regulation 20).

Safe 3

This 'Key Line of Enquiry' questions what systems, processes and practices are in place to keep people safe and to safeguard them from abuse.

Examples based on safety related regulations include:
- Staff know how to identify suspected or actual abuse (Regulation 13)
- The team have a full understanding of the reporting systems for raising concerns
- Staff are trained appropriately and effectively
- Patient records are accurate, complete, legible, contemporaneous and are stored safely and in a confidential manner
- Appropriate and regular audits are carried out to ensure all requirements are met.

Effective 1

This 'Key Line of Enquiry' questions if people's needs have been assessed and care and treatment delivered in line with current legislation, standards and evidence based guidance.

Examples based on safety related regulations include:
- Evidence of comprehensive assessment to establish the needs and preferences of the individual – in relation to PSIs, this would relate to taking an accurate and full medical and dental history to ensure that any treatment provided is safe
- Any care provided and/or treatment planned is based on contemporaneous evidence based guidelines eg NICE, SIGN, RCS and Specialist Society guidelines.

- Never Events are clearly defined as serious incidents and therefore, must be reported to the CQC
- Failure to report a Never Event which subsequently comes to light through a third party route, (for example, a coroner's inquest, claim, media report, or patient complaint) is a serious failing on the part of staff involved and the organisation, and is likely to constitute a breach of CQC requirements[17] (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
- For any failure to report a Never Event where there is evidence that there were opportunities for the provider to identify and report the incident, commissioners should consider using the full range of powers afforded via the NHS Standard Contract, including the following remedial actions:
  - A detailed review and analysis of the circumstances leading to the failure to recognise and/or report the incident; relevant training (where indicated); and consideration of disciplinary action against individuals where there is evidence of deliberate non-disclosure
  - Requiring the provider's chief executive (or equivalent) to deliver full written and verbal explanations of the failure to report a known Never Event, the circumstances of the incident and the actions taken in response, in public to the CCG board and to the relevant patient (subject to their agreement)
  - Continued monitoring of agreed actions and use of powers to intervene (as per the NHS Standard Contract), where satisfactory progress is not made and patients remain at risk.

PSI reporting to the Care Quality Commission

In accordance with CQC's operating model, inspectors will ask if practices are safe, effective, caring, responsive and well-led, and will report their findings under the five key questions.

- Are they safe? By safe, they mean that people are protected from abuse and avoidable harm.
- Are they effective?
- Are they caring?
- Are they responsive to people's needs?
- Are they well led?

The CQC use Key Lines of Enquiry (KLOEs) (Box 2) and request examples which demonstrate that no regulations have been breached. Specific examples of good practice are highlighted, including;

- Having a clear understanding of and reporting as per RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013) and COSHH (Control of Substances Hazardous to Health)
- Staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and report them internally and externally where appropriate
- The provider complies with relevant patient safety alerts, recalls and rapid response reports issued from the Medicines and Healthcare products Regulatory Authority (MHRA) and through the Central Alerting System (CAS).

The CQC will also investigate 'How are lessons learned and improvements made when things go wrong?'

- Patients are told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result
- The provider identifies and analyses clinical errors, incidents, errors and near misses involving all relevant staff and patients where applicable
- Lessons are learned and communicated to make sure action is taken to improve safety.

What incidents should be reported to the CQC?

The incidents requiring obligatory reporting are as follows:

- Never Events, serious incidents to people who use the activity delivered by the service and sentinel events (Box 3)

Box 3 PSI previously defined as 'serious events' and 'sentinel events'

Serious incidents requiring investigation were defined by the NPSA's 2010 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation 2013 In summary, this definition describes a serious incident as an incident that occurred during NHS funded healthcare[1] (including in the community), which resulted in one or more of the following;
unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
A Never Event – all Never Events are defined as serious incidents although not all Never Events necessarily result in severe harm or death. (See Never Events Framework[1]);

- A scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- Allegations, or incidents, of physical abuse and sexual assault or abuse; and/or loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

PSIs previous named sentinel events

A sentinel event is defined by the Joint Commisssion (JTC) as any unanticipated event in a healthcare setting, resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural cause of the patient's illness.
The most commonly occurring examples are unintended retention of a foreign object, falls and performing procedures on the wrong patient.
Sentinel events include:

- Accident occurring in during attendance for NHS care
- Assault leading to permanent harm to patient or staff member
- Confidential information leak
- Communicable infectious diseases
- Failure to obtain consent where the procedure or treatment results in permanent harm to one or more patients or where the outcome requires lifesaving intervention or major surgical medical intervention or will shorten life expectancy
- Delayed diagnosis
- Drug incident wrong IV administration, anaphylaxis
- Hospital equipment failure
- Medical equipment failure
- Safeguarding vulnerable adult
- Unexpected patient death
- Allegation professional member of staff shows gross disrespect for dignity of a patient or deceased patient and are considered serious when;
  - verbal and or physical aggression
  - criminal acts involving patients
  - complains about a member of staff or primary care contractor where adverse media interest could occur
  - breach of confidentiality
  - Fraud

Box 4 Reporting to the regulator (CQC)

Dentists and their managers are reminded of the requirements to notify the Care Quality Commission of injuries to patient that last longer than 21 days.

- Most of the requirements for the CQC, as defined in current regulations guidance[17] are met by providing incident reports to the NRLS. The NRLS will forward relevant information to the CQC
- This exception does not apply to independent sector providers or primary care providers registered with CQC. They must report incidents directly to CQC
- NHS Foundation Trusts are also required to report relevant serious incidents requiring investigation to Monitor
- Incidents must be reported without delay as defined in legislation.

- Changes in; statement of purpose for an activity, new provider to carry out activity, cessation of provider contract, name changes, nomination changes
- Deaths of persons using the service
- Allegations of abuse
- Events that may stop the service from running safely and properly.

'Other incidents': The law says that you must notify the CQC without delay about a variety of 'other incidents' that take place while a regulated activity is being delivered or as a consequence of an activity being delivered.

Injuries: NHS providers notify relevant injuries to the NPSA using their local risk management system (LRMS) or the relevant eForm on the NPSA website.[16]

Deprivation of liberty applications and outcomes: There is a standard CQC form for notifying applications to deprive a person of their liberty under the Mental Capacity Act 2005, including the outcome of the applications. NHS providers can use this form to tell the CQC about applications by a hospital to a 'supervisory body', or to the Court of Protection for any other setting.

Abuse and allegations of abuse: It is important that providers tell relevant local safeguarding authorities about abuse and allegations of abuse in relation to their services appropriately, as described in the guidance about compliance.

Incidents reported to or investigated by the police: This notification requirement does not apply to NHS bodies.

Admission of a child or young person to an adult psychiatric ward or unit: Registered persons who provide psychiatric units for adults must notify CQC if they admit a child or young person aged under 18 years to such a location if that placement has lasted for a continuous period of more than 48 hours. All 'other incidents' notifications must be submitted without delay.

Medication adverse events: There is no requirement to notify CQC about medicine errors. However, a CQC notification would be required if the cause or effect of a medicine error met the criteria for one of the following to be notified:

- A death (must also be reported to NRLS)
- An injury (must also be reported to NRLS)
- Abuse or an allegation of abuse
- An incident reported to or investigated by the police.

Where relevant, it should be made clear that a medicine error was a known or possible cause or effect of these incidents or events being notified.

How to report these incidents to the CQC

All PSIs should be reported anonymously by a registered provider (usually practice principal or manager), whilst protecting the patient's privacy in line with the 1998 Data Protection Regulations, to the CQC or the NRLS and local primary care commissioners should be informed (see Box 4). Registered persons must use the forms supplied by CQC to submit notifications.

Discussion

Clinical practice is fraught with challenges and dentistry, in particular, is faced with increasing numbers of patient complaints and safety issues. Legislation for dental practice is predicated upon both patient and staff safety, however, the evolution of legislation into practice-based regulation and implementation has been slow with regards to patient safety. A recent systematic review of patient safety in primary care dentistry, reported that improving patient safety is a relatively new concept with a distinct lack of evidence base. In addition, reporting of adverse events in dentistry is significantly low.[8–12] A previous analysis of NRLS data relating to dentistry also highlighted poor practice in reporting adverse events in dentistry.[9]

Why is incident reporting so poor in dentistry?

There are several areas that contribute towards poor learning from PSIs in dentistry[9,11,12] including;

- Lack of a supportive and open culture
- Complex and obtuse systems and processes
- Lack of training and awareness of these systems and processes
- Lack of examples whereby reporting systems have benefited patients and practitioners in dentistry
- Poor communication and shared learning
- Poor understanding of what can be learnt from the reporting of near misses.

Improving patient safety is based upon learning from mistakes. Without an open, supportive and non-punitive culture, mistakes will not be reported and nor will healthcare workers learn from them. Currently, the dental 'system' is not supportive of open reporting and many dentists in both primary and secondary care are fearful and reticent about reporting difficulties and failures. There are examples of junior doctor intimidation in hospitals where they have caused WSS and as a result, have left their jobs. This needs to change.

The current reporting systems are complex and obscure. This paper highlights how complex and confusing the various systems are when applied to primary care and specifically, to dentistry. For example, it is clearly stated that Never Event PSIs are serious events and must be reported to the CQC from NHS or independent providers. However, the NRLS Revised Policy and framework for Never Events (2014)[18] clearly state that Never Events occurring in NHS care provision must be reported, with no reference to independent healthcare provision. It is no wonder that confusion arises with such conflicting information.

How can we improve reporting of PSIs in dentistry?

There is evidence that PSI reporting in a hospital environment may not be as effective as more labour intensive case note reviews.[19]

In 2004, the National Patient safety agency published Seven Steps to improving patient safety:[20]

- Build a safety culture
- Lead and support your practice team
- Integrate your risk management activity
- Promote reporting
- Involve and communicate with patients and the public

- Learn and share safety lessons
- Implement solutions to prevent harm.

The paper also identified barriers to reporting PSIs, including unclear benefits to regular reporting, fear of blame, sense of failure, concern regarding litigation, lack of resources, 'not my job', lack of definitions and obscure processes.

The NPSA (2004)[20] recommendations made to improve reporting of PSIs in primary care included:

- Improving awareness and understanding
- Adopting a common language for reporting
- Linking local reporting system with national MRLS reporting system
- Improving connectivity.

The British Government stated a commitment to making quality and safety the organising principle of NHS (2008).[3] Despite this high profile initiative, improvement in the UK has been slow. The simple objective of avoiding preventable harm would seem straight forward but it remains difficult to implement. The key challenges to improving patient safety were identified as visibility, ambiguity, complexity and autonomy. Standards published by the GDC fall short of requirements (General Dental Council [GDC] in 2013) and make little reference to patient safety:

- Principle 1 – put the patients' interest first
- Standard 1.5.4 – you must record all patient safety incidents and report them promptly to the appropriate national body
- Principle 8 – raise concerns if patients are at risk
- Standard 8.1 – always put patients' safety first.

Barriers to reporting PSIs in dentistry

The main issues with regard to under reporting in dental primary care appear to be complex[21] and most likely include a lack of understanding of:

- Definitions of PSIs
- Systems by which to report and learn
- The benefits of reporting PSIs
- A supportive open culture.[24]

Why should we bother reporting PSIs?

If the aviation operators continued to ignore safety incidents at work, many more deaths would have occurred. More importantly, there are missed opportunities for learning from each incident, which could potentially improve the quality of care/service provided and the environment in which the work is carried out.

Without an open and supportive culture, under reporting will continue. Unfortunately, there are still ongoing examples of intimidation and even junior staff that have been discharged following wrong site surgery (WSS) in dentistry, contravening the NPSA's '*Being Open*' Framework.[22]

It is recognised that patient safety incident reporting is particularly poor in dentistry compared with other healthcare settings.[8–12,14,21] Unless there is a centralised open reporting culture in dentistry, there will be no benefit from a learning culture and repeated errors compromising patient safety will persist. Urgent action is required to rectify this situation.

The duty of candour[15,23,24] summaries the key action 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
- The undertaking of relevant investigations and analyses
- The importance of keeping patients informed and about ensuring affected patients know that things are being done to prevent harm to others.

Recommendations

- Development of a supportive and non-punitive culture
- Mandatory team training in patient safety, including PSI reporting for the whole dental team with team leader (champions) development in all provider settings
- Development of a single, central, nationally funded PSI reporting process, supported by all the regulators, which has the responsibility of onward reporting of incidents to the regulatory bodies and dissemination of learning outcomes
- Encourage a culture change in dentistry, similar to primary care medicine, in order to improve reporting of, and learning from patient safety incidents. Dentistry should be more immersed in general healthcare directives and initiatives related to improving patient safety
- Clarify lines of communication for dissemination of patient safety information throughout dentistry (for example the recently published Nat SSIPPs or 'Sign up to Safety' campaign)
- Obtain national agreement for a more relevant data set for PSIs in dentistry (to improve learning outcomes)
- Promote the use of the eform[14] (as currently used by GPs) for reporting patient safety incidents in primary care dentistry.
- Improve the engagement with dental regulators GDC, CQC and NHS primary care dentistry, to align responsibility of promoting patient safety, and to address under reporting and mandatory training
- Promote alignment of dental commissioning with patient safety initiatives
- Advise amendment of the CQC Dental Provider Handbook to include sections on reporting (who/when/how) and a glossary of terms to define Never Events and other notifiable events.

This paper is an attempt to unravel the complex and multiple regulations, systems, processes and online recommendations for improving and reporting patient safety incidents relating to dentistry. A radical change is required to provide an open culture which encourages learning from and reporting incidents in dentistry. Standardisation, simplification and alignment between the regulators will significantly improve the processes and systems. The issues which have been raised are challenging, the concerns are well founded and the recommendations should be addressed as soon as possible, if the quality and safety of dental practice is to be improved.

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