

Tool kit for ‘Local Safety Standards for Invasive Procedures’ (LocSSIPs) for wrong site extraction in Dentistry

This toolkit is aimed at all clinical dental teams involved in dental extractions. It gathers together recommendations regarding the development of safety standards in the NHS to minimise the risk of wrong site surgery in all dental settings, focusing on the issue of wrong tooth extraction.

Dentistry provides one of the NHS’s highest activity of surgical interventions. Uniquely the vast majority of these surgical interventions occur under local anaesthesia on conscious, anxious patients. This high volume, often complex work, creates opportunity for mistakes to happen that can be devastating for both the patient and the clinician. Wrong site surgery in dentistry may not always cause significant physical harm to the patient such as the loss of a limb, but it is nonetheless potentially symptomatic of problems in the clinical systems and processes of the environment in which it occurs. By utilising simple routine good practice, it should be possible to minimise the incidence of wrong site surgery in dentistry.

What is a LocSSIP and how is it developed?

A key initiative by NHS Improvements in 2015 was The National Safety Standards for Invasive Procedures (NatSSIPs) bringing together national and local learning from the analysis of Never Events, Serious Incidents and near misses through a set of recommendations that will help provide safer care for patients undergoing invasive procedures. This does not in any way replace the existing [WHO Surgical Checklist](#), but rather enhances it by looking at additional factors such as the need for education and training. The principle behind the NatSSIPs is that organisations will review their current local processes for invasive procedures and ensure that they are compliant with the new national standards. This will be done by organisations working in collaboration with staff to develop their own set of ‘Local Safety Standards for Invasive Procedures’ (LocSSIPs) see Appendix 1.

Why are LocSSIPs important?

In 2009, the NHS in England identified several clinical incidents that were serious and largely preventable and designated each of these incidents as a Never Event (NE).⁵ The NE list has been modified several times since, with the most recent guidance being released in March 2015. In this guidance, NHS England identified 14 NEs. Three of the NEs are particularly relevant to dentistry, namely:

- ‘Wrong site surgery’,
- ‘Wrong implant/prosthesis’
- ‘Retained foreign object post-procedure’

They are relevant to all patients receiving NHS funded care. The existing Framework suggests that Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes.⁵ Never Events are different to other Serious Incidents as the fundamental principle of having the Never Event list is that even a single Never Event should be avoidable if available preventive measures have been implemented. Near misses and Never Events offer a significant opportunity to learn lessons. To quote the framework “NHS England are committed to ensure that learning from Never Events is the primary purpose of reporting and investigating them.”

How are LocSSIPs connected to Never Events in dentistry?

For all invasive procedures, a Local Safety Standard for Invasive Procedure (LocSIPP) should be implemented, based on the principles outlined in the NatSSIPs document and summarised in Appendix 1.

What is an ‘invasive procedure’ and how does it affect dentistry?

The FAQ section of the NatSSIPs document answers this point as follows: ‘If it is still not clear whether one of the procedures you perform comes under the NatSSIPs, you should ask yourself whether the procedure has the potential to lead to a Never Event if it is not handled well – if the answer is “yes”, this would bring it into the remit of the NatSSIPs.’ Wrong tooth extraction is a Never Event and hence there is a need for developing a template LocSIPP that can be used or adapted for use in clinical dental practice in all settings where NHS patients are treated. The template ‘Dental extraction LocSSIPs individual patient pathway’ (figure 1) provides a simple example. Other more complex LocSSIPs for dental extractions have been developed and links to some of these other examples are given below.

How are LocSSIPs applied?

The example Dental extraction LocSSIPs individual patient pathway (Figure 1) provides an outline of good practice for the dental team when undertaking dental extractions and related procedures. By ‘PAUSING’ (for confirmation) with a minimum of two persons and routinely rechecking mid procedure, errors can be minimised. Errors are more likely to happen with interruptions, which can be commonplace in the dental surgery, so if distractions do occur, recheck the treatment plan (using displayed surgical plan and radiograph) and reaffirm with your assisting member of staff before continuing. The ultimate responsibility for wrong tooth extraction remains with the dentist. Identification of teeth is outside the GDC core Scope of Practice for dental nurses. However, by utilising an empowered dental nurse as an assisting member of staff in all stages of the pathway where necessary, it will engender the correct team mind-set and approach to improving patient safety. The LocSSIPs will be available on the website: <https://improvement.nhs.uk/resources/examples-local-safety-standards-invasive-procedures/> and on other stakeholder websites including FDS RCS, FGDP and BDA.

What happens when things go wrong?

When errors occur, the team should investigate and analyse why these may have happened and learn from the experience to minimise future problems. Reporting such errors, with or without patient harm is recommended by using established pathways, facilitating a national perspective to provide support where there are issues and to improve patient safety. An example of how to manage a never event is provided in the form of an Exemplar, see Appendix 2.

If a patient safety incident occurs, this can be reported to the National Reporting and Learning System which provides the opportunity for potential national learning. In secondary care this will normally be done via the organisation’s local risk management system and in primary care by use of the e-form available on the NRLS website <https://report.nrls.nhs.uk/> or via the commissioner if the practice doesn’t have access to a local risk management system. If an incident meets the definition of a Serious Incident, see <https://www.england.nhs.uk/patientsafety/serious-incident/> (which includes Never Events), this should be reported to the Strategic Executive Information System (StEIS), which can be undertaken by informing the appropriate commissioner.

In secondary care, failure to report a Never Event which subsequently comes to light through a third party route, (e.g. 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 (*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.

How do I learn from near misses and never events?

Learning from near misses (mistakes resulting in no harm) and Never Events is the key objective. Using these patient safety incidents is a useful way to identify any potential learning needs of the Practitioner or team and the ease of access to these educational needs. This may help direct postgraduate, undergraduate or team learning for educational establishments and future Continuing Professional Development.

Investigations of safety incidents should follow a systems-based methodology to ensure contributory factors, root causes and focused actions, and learning are all identified. Learning from patient safety incidents including never events requires appropriately trained and resourced staff removed from the incident or specific dedicated and trained staff. Currently, this is a role which does not exist in General Dental Practice and would require a level of training and resource which is not available and requires development. Appendix 3 provides an outline about learning from near misses and never events and a reflective log that could be used for appraisal or portfolio. Access to other examples of good practice of patient safety checklists for dental extractions are available via the FDS RCS, FGDP, and BDA website links.

What else do I need to know?

Frequently asked questions about never events in dentistry are provided in Appendix 4 and there is a list of examples of good practice in Appendix 5.

In summary, the promotion of patient safety underpins good clinical practice.

Implementation of LocSSIPs will involve all regulators. The NHS in England, the General Dental Council and the Care Quality Commission are signed up to supporting NatSSIPs. In Dental Practice, the dental team will need to develop and promote a patient safety culture led by the senior clinician and /or Practice manager who provide a supportive environment where learning is encouraged after safety incidents.

NHS England dental commissioners recognise the importance of a supportive, learning culture in dental practices. Learning from incidents and near misses is a key part of practice and team development, to ensure a safe service for patients. The timely reporting of a Never Event will be considered in this light as a positive indicator of a learning culture within the practice.

Health Education England will ensure that mandatory training will be developed in accordance with these standards.

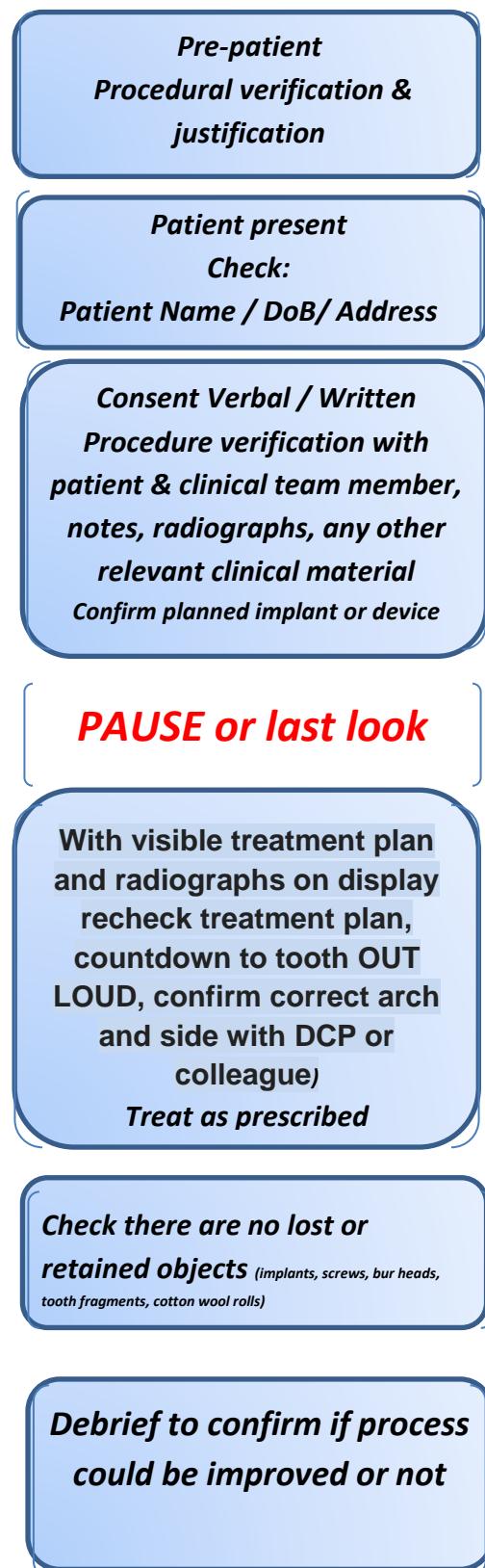
The GDC supports the introduction of LocSSIPs in dentistry to minimise the potential for patient harm. The GDC also encourages incident reporting when events do occur, to encourage an open and honest learning environment for dental professionals to work within, where mistakes and isolated incidents are treated distinctly from allegations of fitness to practise. If a Never Event occurs we would want to see that the dental professional had been open and honest following the incident, in accordance with the guidance on Duty of Candour and the reporting requirements set out in the Standards for the Dental Team.

The CQC welcomes the introduction of the LocSSIP for wrong tooth extraction in dentistry. This represents an opportunity to learn from such incidents and improve the overall standard of care.

This toolkit is part of patient safety culture which involves many aspects including team and human factor training, maintenance of a log book detailing near misses, patient safety incidents including Never Events and evidence of learning from these events and resultant modification of systems and processes. The tool kit will evolve with local development according to local needs and examples of locally developed LocSSIPs will be available on the NatSSIPs website. (<https://www.england.nhs.uk/patientsafety/never-events/natssips/>).

FIGURE 1 Example Dental extraction LocSSIPs Individual patient pathway

If at ANYTIME there is an interruption, ensure you repeat the “three Rs”: Reposition; Recheck; Reaffirm with your assistant.



Appendix 1

The Local Safety Standards for Invasive Procedures (LocSSIPS) process for Wrong Site Extraction

The National Safety Standards for Invasive Procedures (NatSSIPs) bring together national and local learning from the analysis of Never Events, Serious Incidents and near misses through a set of recommendations that will help provide safer care for patients undergoing invasive procedures. This does not in any way replace the existing [WHO Surgical Checklist](#), but rather enhances it by considering additional factors such as the need for education and training. The principle behind the NatSSIPs is that organisations will review their current local processes for invasive procedures and ensure that they are compliant with the new national standards. This will be achieved by organisations working in collaboration with staff to develop their own set of ‘Local Safety Standards for Invasive Procedures’ (LocSSIPs), for example; a LocSSIP for an Exodontia procedure.

The LocSSIPs process

The development of LocSSIPs (Local Safety Standards for Invasive Procedures) is based upon the high level safety principles identified in the National Safety Standards for Invasive Procedures (NatSSIPs).¹

There are a number of steps which are critical to patient safety. These are outlined below.

Pre patient verification & justification

This takes place when the patient attends for their Exodontia appointment:

- Setting may be primary or secondary care.
- Procedure may be undertaken under Local anaesthetic (LA), LA+/- sedation or general anaesthetic.
- First stage consent should ideally be undertaken prior to the procedure appointment and confirmed on the day of operation (tailored consent forms for dentoalveolar surgery are currently being assessed for improved patient safety).
- Treatment plan must be stipulated clearly using Palmer notation and with the teeth for exodontia written in full, plus a description where clarification is necessary.

The safety briefing should consider each patient on the procedural list in order, from both an operator and assistant perspective. The content of the safety briefing should be modified locally, and must be relevant to the patient and exodontia procedure.

- Team members should understand their roles, names should be known and all members of the team should be encouraged to speak up, if they have concerns.
- For each patient, the discussion should include, when relevant, but not limited to:
 - Diagnosis and planned procedure
 - Availability of prosthesis, if required
 - Site and side of procedure
 - Infection risk, e.g. MRSA status
 - Allergies

- Relevant comorbidities or complications
 - Need for antibiotic prophylaxis
 - Equipment requirements and availability, including special equipment or ‘extras’
- The expected duration of each procedure, to include anaesthetic procedures, should be identified. This should promote a discussion about agreed plans if it appears that the duration of the planned exodontia procedures will exceed the time allocated.
- Any additional concerns from an operator or assistant perspective must be discussed, and contingency plans made.
- Every team member should be encouraged to ask questions, seek clarification or raise concerns about any aspect of patient care or the planned exodontia procedure.

Patient checks which must be undertaken once the patient is present

Participation of the patient (and/or parent, guardian or carer) in the ‘time out’, should be encouraged when possible.

- It should include when relevant, but is not limited to, checks and confirmation of:
 - Patient identity (Name, date of birth and address)
 - The procedure to be performed (Exodontia)
 - Verification of surgical site (=/- marking) (teeth to be extracted)

Consent and documentation checks

Check for consistent documentation (referral, consultation, consent and treatment plans). To minimise the risk of a surgical site error, the correct teeth for extraction must be verified by a full review to ensure consistency of the clinical record, diagnosis, treatment plan, investigation results, written consent, intraoral surgical site check and confirmation by the patient.

- Confirm consent
- Confirm investigation results are available (radiographs on display, haematology results or other)
- Reliable marking of surgical sites such as teeth which may be small, broken down, filled or buried; may not be possible. Some clinicians may indicate side of unilateral surgery by marking the face externally
- Tooth notation must be standardised such that only the Palmer notation, with ‘written in full’ description, where clarification is necessary. This must be clearly documented on the consent form, checklist and whiteboard (or patients bib, or on visible computer screen electronic record of patient) and must be visible by the surgeon and team during surgery, for verification by the team
- Reference to radiological imaging may be useful/ essential. Any relevant radiographs must be on display (hard copy or electronic), visible by surgeon and team for verification during surgery

Pause or ‘Time Out’

All patients undergoing any invasive procedures, including Exodontia, under general, regional or local anaesthesia, or under sedation, must undergo safety checks immediately before the start of the procedure.

- The ‘time out’ should not be performed until any omissions, discrepancies or uncertainties identified in the ‘sign in’ have been fully resolved. On rare occasions, the immediate urgency of a procedure may mean that it may have to be performed without full resolution of any omissions, discrepancies or uncertainties. Such occurrences should be reported as safety incidents.
- Any member of the procedure team may lead the ‘time out’. All team members involved in the procedure should be present at the ‘time out’. The team member leading the ‘time out’ should verify that all team members are participating. This will usually require that they stop all other tasks and face the ‘time out’ lead.
- A ‘time out’ must be conducted immediately before skin incision or the start of the procedure to again confirm:
 - correct patient
 - correct treatment plan
 - correct site
- Immediately before the insertion of a regional anaesthetic, the dentist and assistant must simultaneously check the surgical site marking and the site and side of the block for intended surgery. Using the displayed treatment plan (Palmer notation) on white board or computer screen, verification of site is possible with full text if required. Examples of this practice e.g. Stop Before You Block/ Pause before you Pull are available in the Toolkit and on the NatSSIPs website
- In addition, verbal counting of the dentition from midline, whilst pointing with an instrument to each tooth to confirm surgical site (tooth to be extracted) with confirmation from your assistant (of side and countdown), will provide clarification and verification

Prevention of retained objects.

This standard supports safe and consistent practice in accounting for all items used during invasive procedures and in minimising the risk of them being retained unintentionally. The processes outlined in LocSSIPs should ensure that all items are accounted for and that no item is unintentionally retained at the surgical site, in a body cavity, on the surface of the body, or in the patient’s clothing or bedding. LocSSIPs should cover all potentially retainable items used in procedures, as well as those used as part of anaesthesia and sedation, e.g. throat packs placed by the anaesthetist during oral surgery. Issues to consider prior to Debrief:

- Confirmation that instruments, sharps and swab counts are complete (or not applicable).
- Confirmation that any specimens have been labelled correctly, to include the patient’s name and site or side when relevant.
- Discussion of post-procedural care, to include any patient-specific concerns.
- Equipment problems for inclusion in the debriefing.

Debrief

Procedural team debriefing is a key element of practice in the delivery of safe patient care during invasive procedures, and forms part of both the WHO Surgical Safety Checklist and the Five Steps to Safer Surgery. The debriefing should be seen as being an important part of the safe performance of an invasive procedure.

- The content of the team debriefing should be modified locally and must be relevant to the patient and the Exodontia procedure. For each patient, the discussion should include, but is not limited to:
 - Things that went well
 - Any problems with equipment or other issues that occurred
 - Any areas for improvement
- Records of debriefings should include an action log that can be used to communicate examples of good practice and any problems or errors that occurred. Each procedural team should have an identified member who is responsible for feeding this information into local governance processes.
- If a significant issue about the care of a patient arises during the debriefing, a clear and contemporaneous note of this should be made in the patient's records. Local governance processes must ensure that issues identified in debriefing action logs are communicated at an appropriate level within the organisation, and that there is a mechanism to capture and promote learning.

<p>Appendix 2 Exemplar Scenario</p> <p>A 13 year old boy is referred back to his own GDP for Orthodontic extractions. The Specialist Orthodontist requests extraction of maxillary first premolars and mandibular second premolars as part of the Orthodontic treatment plan.</p>	<p>History:</p> <ul style="list-style-type: none"> a) Medical History: Nil relevant b) Dental History: Phobic – previous experience of difficult deciduous extractions c) Social History: Attends with Mother who is also dental phobic 	<p>Risk Factors:</p> <ul style="list-style-type: none"> a) Dentist had already carried out Orthodontic extractions that same day, for another teenage boy, where the treatment plan had requested extraction of maxillary and mandibular first premolars. b) Dentist is working with a bank nurse who is unfamiliar with the clinic and team and regular processes and systems for the practice. c) It has been a busy day and they are running late. d) There is only a printed DPT available. e) Dentist double checks with the child and mother with regard to their understanding of the teeth to be extracted, and they are unsure. However, they agree that today, the teeth on the right side will be extracted. f) The child is nervous and requires reassurance and extra time. He becomes upset following the administration of the local anaesthetic and extraction of maxillary right first premolar. The Dentist offers referral for conscious sedation as an alternative treatment plan, but Mother has taken time off work and is keen to get as many extractions completed today as possible. She is unhappy that all 4 extractions will not be completed today. g) The dentist feels under pressure to remove the mandibular premolar as swiftly and atraumatically as possible. The mandibular right first premolar is extracted instead of the second right premolar. h) The practice does not routinely use a WHO surgical check list.
<p>Dentist immediately realises the error which has been made.</p>		<p>Immediate steps in relation to patient: Explanation to Parent and Child:</p> <ul style="list-style-type: none"> a) Dentist gives a complete and honest explanation of the error in accordance with 'Being Open' and 'Duty of Candour'. b) Dentist gives a full apology. c) Dentist explains next clinical steps and that the Orthodontist will be informed and that they will need to consider possible treatment options. d) Dentist explains next steps with regards to reporting and investigation.

		<p><u>Immediate steps in relation to administrative Process:</u></p> <ul style="list-style-type: none"> a) Dentist ensures that there is a full and contemporaneous record made within the clinical notes. b) Dentist ensures that the nurse also writes a full and contemporaneous record. c) Dentist ensures that the nurse feels supported and is given the opportunity to debrief. d) Dentist informs appropriate person (senior member of staff) within the practice e.g. Partner, Associate, Manager. They should in turn ensure that the dentist is supported throughout the investigation. (This should include all members of the team involved e.g. dental nurse). e) Dentist or Manager (as appropriate), advises the Commissioning Body of the wrong site extraction. f) The Commissioning Body report the wrong site extraction within 2 working days, via STEIS. g) The Registered CQC Manager for the practice, notifies the CQC. h) A report is submitted to NRLS and the wrong site extraction is recorded on the Local Risk Management System e.g. DATIX. i) An appropriate senior manager is designated to carry out an investigation. <p><u>Investigation:</u></p> <ul style="list-style-type: none"> a) A full investigation is instigated including a Root Cause Analysis b) All processes/systems and protocols within the practice, are reviewed. c) All Contributory Risks factors are considered as part of the investigation. d) An Action Plan is developed. e) Preventive measures are put in place to reduce the risk of a repeat occurrence, including use of WHO surgical checklist, and Pause before Pulling. f) Learning outcomes are shared across the practice. g) Any training needs within the practice are identified and implemented. h) A culture of safety is promoted within the practice. i) The patient and parent are informed of outcomes of the investigation.
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Appendix 3

Learning from Never Events – A Wrong Site Extraction (WSE), including Reflective Learning Log for Appraisal

How does the team learn from a WSE?

Investigation and analysis of a WSE, should collect information regarding not only the technical aspects of what went wrong but also the human factors that may have contributed to the WSE . Managing the response to Never Events is a critical component of corporate and clinical governance.

An open and supportive culture is essential to facilitate and enable open reporting and learning from Never Events.

Providers must establish effective governance mechanisms to ensure that:

- There is early, meaningful and sensitive engagement with the affected patients and/or their families/carers from the point that the WSE is identified, throughout the investigation and action planning, to closure of the incident. Details of the conversation must be documented in the patient records, and disclosure must not be delayed whilst the Never Event status is being determined. All staff should be familiar with related requirements of Being Open² and the Duty of Candour³ and information should be shared in line with this Guidance;
- 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;
- Never Events are investigated via root cause analysis by specific dedicated and trained staff. Investigations should follow a systems-based methodology to ensure identification of all the possible contributory factors and root causes;
- The investigation will also identify focused actions, including those which relate directly to the patient and their family/carer, plus clear learning outcomes.

Effective governance mechanisms should be established to ensure:

- timely reporting and liaison with their commissioning bodies.
- the incident is reported to the CQC.
- compliance with reporting and liaison requirements with agencies such as: NHS Improvement ; the Care Quality Commission (CQC); Public Health England and the Health and Safety Executive.
- 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, again 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 incident(s), 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.
- A strong and supportive culture, which supports the team involved in a Never Event, will enable the required learning from the incident and facilitate improvements in the quality of practice. The support provided is critical if we are to avoid ‘second victims’ amongst those members of staff involved in a Never Event such as wrong site extraction.
- At an individual level, the practitioner should be logging the incident and providing a reflection with learning outcomes for their Appraisal documents.
- **N.B. It is acknowledged that there is a need for a simplified reporting system and therefore, work will commence on developing a revised reporting system in early 2017.**

REFLECTIVE LEARNING LOG - for APPRAISAL

Patient Identifier:
Age & sex of patient:
Medical/Dental and relevant Social History:
Brief summary of Never Event, including: <ul style="list-style-type: none">● Risk Factors
Effect of never event on patient: <ul style="list-style-type: none">● How will the outcome be managed?
How did the clinical team manage the never event? <ul style="list-style-type: none">● What went well?● What did not go well?
What has been learnt from the never event? <ul style="list-style-type: none">● Root causes● Mitigation of risk factors● What will be done differently next time?● How will it influence your future approach to similar cases?
<ul style="list-style-type: none">● How has the learning been shared amongst the team/service?● Has the learning been reflected in updated operational procedures/training?● Have the members of the team who were involved in the never event, received adequate and appropriate support?

Appendix 4

Frequently Asked Questions (FAQs) related to Dental Wrong Site Surgery

Open reporting of dental wrong site surgery (WSS) is routine in secondary care as part of a drive to improve patient safety. However, global uptake of NHS governance and patient safety mechanisms have not yet been wholly embraced within primary care and more specifically dentistry. Within the General Dental Council ‘Standards for the Dental Team’, a core principle of care is to ‘put the patient first’, and ‘you must record all patient safety incidents and report them promptly to the appropriate National body’.⁴

What is a Never Event in dentistry?

The Revised Never Events Policy and Framework 2015 from NHS England⁵ modified the list of Never Events related to dentistry to the following 3 incidents;

- **Wrong site surgery**
 - A surgical intervention performed on the wrong patient or the wrong site, including wrong tooth extraction of a permanent (adult) tooth, even if re-implanted
 - Interventions that are considered surgical but may be done outside of a surgical environment e.g. wrong site block, and biopsy
- **Wrong implant /wrong site placement of dental implant**
- **Retained foreign body**

The ‘Revised Never Events Policy and Framework – Frequently asked Questions’ provides some guidance on interpretation of the Never Events Policy specifically with respect to **wrong tooth extraction**. These are as follows:

Does the wrong tooth extraction apply to deciduous teeth?

No - although strong systemic protective barriers exist to prevent this incident from occurring, there is no known risk of serious harm or death.

Does the wrong tooth extraction apply to inadvertent removal of teeth (with dental caries) which would have been removed at a future appointment?

Yes, as the strong systemic protective barriers exist to prevent this incident from occurring, even though it may be planned to remove the tooth in the future.

Should the immediate re-implantation of a tooth removed in error, be reported as a Never Event?

Yes - as the strong systemic protective barriers exist to prevent this incident from occurring and it is not known if the re-implantation will be successful.

Does wrong site surgery apply to extraction undertaken under local anaesthetic as well as general anaesthetic?

Yes - all wrong site surgical interventional procedures in adults are included in WSS.

Does wrong site surgery apply to giving a block on the incorrect site?

Yes, if it is undertaken as part of a planned dental procedure *as 'they are a particular type of serious incident that meet all the following criteria: They are 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'*.

What counts as the start of surgery for wrong site surgery?

The start of surgery should be considered the point at which the patient's physiology begins to be permanently altered. This includes the beginning of a mucosal incision or tooth extraction as this will result in scarring and requires time for healing and recovery. Dental restorations and orthograde root canal therapy are not currently regarded as surgical interventions for the purpose of Never Event reporting.

Do these standards replace the WHO Surgical Safety Checklist and Five Steps to Safer Surgery?

No – the NatSSIPs are in large part based on the WHO checklist and the Five Steps, and we hope that the NatSSIPs will strengthen and enhance them in all hospitals. All of the five steps are included as standards within the NatSSIPs: **Safety Briefing, Sign In, Time Out, Sign Out and Debriefing**.

When should the 'Time Out' be performed?

The NatSSIPs are clear that a '**Time Out**' "must be conducted immediately before skin incision or the start of the procedure".

Some procedures performed in the Emergency Department are so urgent that there is no time to perform steps like the 'Briefing' and the 'Time Out'. What should we do?

The patient's safety must always come first, and there will occasionally be patients that need immediate, life-saving procedures performed. However, these are rare, and even if the procedure is urgent, there is often time to perform a brief version of a 'Time Out' that makes sure that the correct procedure is being performed on the correct patient, and that everyone involved knows what the clinical plan is for the patient.

Who must you inform?

Timely reporting and liaison with 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. Never Events are clearly defined as serious incidents and therefore, must be reported to the CQC (NHS England Never Event Policy).

You must inform your commissioner and NRLS in accordance with Never Event Policy framework. If a student is involved, the head of school must also be notified. You can report Never Events directly to the National Reporting and Learning System (NRLS) <https://report.nrls.nhs.uk/nrlsreporting/> (see Appendix 2).

N.B. It is acknowledged that there is a need for a simplified reporting system and therefore, work will commence on developing a revised reporting system in early 2017.

Who must you report to if the Never Event involves a dental trainee (e.g. Dental Foundation DF, Dental Core Trainee DCT or Dental Specialty DS)?

In addition to following the agreed for any clinician:

- For DF: their designated trainer should be made aware who will escalate to both their programme training director / lead and Postgraduate Dental Dean at HEE.
- For DCT & DS: their Educational Supervisor should be informed who will escalate to both the Specialty Training Programme Director and Postgraduate Dental Dean.
- This allows appropriate support and guidance to be given to the trainee at a very difficult and vulnerable time of their career. It will also ensure that HEE is in a position to react quickly to issues that may compromise patient safety.

Exemplar - How to manage a wrong site extraction (See Appendix 2)

How do you learn from a never event and demonstrate learning? (See Appendix 3)

Will the CQC, GDC and NHS England be alerted?

You must inform CQC and dental commissioners (NHS England) but CQC and NHS England dental commissioners recognise the importance of a supportive, learning culture in dental practices. Learning from incidents and near misses is a key part of practice and team development, to ensure a safe service for patients. The timely reporting of a Never Event will be considered in this light as a positive indicator of a learning culture within the practice.

You do not need to inform the GDC.

What about site marking in dentistry?

NatSSIPs England State on Page 34, Section 4.6, Procedural verification of site marking, Point 4:

'Reliable marking of surgical sites such as teeth, which may be small, broken down, filled or buried, may not be possible. Tooth notation must be standardised such that only the Palmer notation is used, and this must be clearly documented on the consent form, checklist and whiteboard for verification by the team. To minimise the risk of a surgical site error, the correct procedure must be verified by full review to ensure consistency of the clinical record, diagnosis, treatment plan, investigation results, written consent, intraoral surgical site check and confirmation by the patient. Reference to radiological imaging may be useful'.

NatSSIPs England <https://www.england.nhs.uk/wp-content/uploads/2015/09/natssips-safety-standards.pdf>

There is recognition that various numerical international dental notation formats may add to confusion in confirming treatment planning. Alpha numerical systems (for example; UL4 or LR8) may be preferred option for text communication in referral letters and operating lists.

If stages of the LocSSIPs are omitted because of the urgency of the procedure, this should be noted in the patient records and reviewed afterwards to see if local standards can be modified to include as many safety checks as possible before very urgent procedures.

Is the creation of Local Safety Standards for Invasive Procedures (LocSSIPs) based on the NatSSIPs mandatory?

The Patient Safety Alert published in September 2015 supports the introduction of the NatSSIPs, which represent current best practice and were created by a number of key organisations with expertise and experience in delivering patient care and setting safety standards. Supported by bodies such as NHS Improvement, Health Education England, the CQC, GDC, GMC and NMC, we are helping providers to build these safety standards into their working practice by creating LocSSIPs based on them. Although the Patient Safety Alert in itself cannot mandate the introduction of these standards, the widespread professional and regulatory support for them, and the likelihood that the CQC will assess providers' compliance with them in the future, means that all organisations providing NHS funded care in England should introduce LocSSIPs in line with the Patient Safety Alert.

What does the September 2016 deadline mean that is referred to in the Patient Safety Alert 'Supporting the introduction of the National Safety Standards for Invasive Procedures' ?

The fourth action of the Patient Safety Alert asks organisations to 'Commence implementation of procedures and practice compliant with LocSSIPs within cycles of continuous improvement including consideration of teamwork and training, human factors and cultural aspects of compliance'. This does not mean that organisations were expected to have all their identified LocSSIPs developed and in place by September 2016, but must be able to demonstrate progress that they have made with implementation.

What are invasive procedures?

The National Institute for Health and Care Excellence (NICE) defines an "invasive procedure" as a procedure used for diagnosis or for treatment that involves

- Making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel, or
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body - for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth, or
- Using electromagnetic radiation (which includes X-rays, lasers, gamma rays and ultraviolet light) - for example, using a laser to treat eye problems.

If it is still not clear whether one of the procedures you perform comes under the NatSSIPs, you should ask yourself whether the procedure has the potential to lead to a Never Event if it is not handled well – if the answer is “yes”, this would bring it into the remit of the NatSSIPs. Even if it is not an ‘invasive procedure’ as defined above, we hope that the NatSSIPs will still be useful to you when developing your standard operating procedures for these outpatient procedures. There are many important principles in the NatSSIPs that can be applied to most invasive and non-invasive procedures and can help minimise accidental harm to patients.

We have implemented our LocSSIPs but have had a Never Event in spite of the standards being followed. What should we do?

First of all please ensure that this is reported and investigated in accordance with the Revised Never Events Policy and Framework 2015. As part of the investigation, please check carefully that your LocSSIPs are fully compliant with the relevant NatSSIPs, and whether the LocSSIPs were properly followed for the patient who suffered the Never Event. We would appreciate it if you would share an anonymised summary of the investigation report with us, highlighting key learning and actions points, so that we can share the learning from it and if appropriate, develop the NatSSIPs further to make sure that this does not happen to another patient. Please email us on patientsafety.enquiries@nhs.net.

The standards say that we MUST do something but this is not relevant to the procedures for which we are developing the LocSSIPs. What should we do?

The healthcare professionals, human factors experts and lay representatives who developed the NatSSIPs were really careful only to use the word “must” when they thought that the action described needed to be taken for all invasive procedures. If you feel unable to take the action that the NatSSIPs require you to, then this should be discussed with your local governance or safety lead and, if appropriate, your commissioner. If it is agreed that the action is inappropriate, then this should be documented. Please also let us know through patientsafety.enquiries@nhs.net to inform future revisions to the NatSSIPs.

I work in a private hospital. Can I use the NatSSIPs to create local standards?

The NatSSIPs must be used to create LocSSIPs in all organisations that provide NHS funded care in England. If your private hospital does not provide NHS-funded care, you can still create LocSSIPs that are compliant with the NatSSIPs, and we hope that you will review your standard operating procedures to see if they are compliant. We think that the NatSSIPs will help improve the safety of patient care wherever patients are treated.

Why are these standards not more detailed when it comes to specific workforce requirements?

The range of invasive procedures performed across the NHS is so large that it would have been impossible to define exact workforce provisions for each procedure. Furthermore, local circumstances differ, and the LocSSIPs must be based on local experience as well as the NatSSIPs. The multidisciplinary team performing the procedures should work with managers and patients to agree the number and skill-mix of the staff, and this should be written into the LocSSIP, along with the actions that will need to be taken if the workforce does not match these standards. Examples of workforce standards are amongst the guidance referenced in Appendix A of the NatSSIPs document.

What if I do procedures in a Primary Care setting?

This applies to procedures whether they are performed within a Primary or Secondary setting.

The definition of an ‘invasive procedure’ is above. We hope that the NatSSIPs will be useful to you when developing your standard operating procedures for relevant procedures that are undertaken in a primary care setting. As we learn about the creation of LocSSIPs, and the implementation of new ways of working in response, we will consider any specific requirement for general practice and share examples of LocSSIPs as appropriate.

Is the expectation that we develop a LocSSIP for each NatSSIP that is relevant to our clinical practice?

We expect organisations to base their LocSSIPs on the structure of the NatSSIPs, but we understand that local circumstances will mean that some steps and standards are combined, and that there may not necessarily be a LocSSIP for each NatSSIP. The important thing is that all steps are considered when creating LocSSIPs.

Do we need to rewrite our current standard operating procedures (SOPs)?

You need to review your current procedures to ensure that they are compliant with the NatSSIPs. It may well be that some SOPs will need very little modification to make them LocSSIPs that are compatible with the NatSSIPs. However, some SOPs will need more changes to make them fully compliant.

Should there be a LocSSIP for every procedure?

Action two of the Patient Safety Alert asks organisations to ‘Identify all procedures undertaken across clinical settings in your organisation that the NatSSIPs are applicable to’. This does not mean that every procedure should have its own LocSSIP, as it may be appropriate for a LocSSIP to cover a number of procedures, e.g. speciality-specific minor procedure lists.

Further FAQs about NatSSIPs can be found at <https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2016/05/NatSSIPs-faqs-updated.pdf>

For further information

<https://www.england.nhs.uk/patientsafety/never-events/>

<https://improvement.nhs.uk/resources/never-events-data/>

<http://www.nrls.npsa.nhs.uk/resources/collections/never-events/core-list/>

<https://www.england.nhs.uk/patientsafety/never-events/natssips/>

<https://www.england.nhs.uk/wp-content/uploads/2015/09/natssips-safety-standards.pdf>

<https://www.england.nhs.uk/2015/09/natssips/>

<http://www.ahsn-nenc.org.uk/wp-content/uploads/2016/05/Joan-Russell.pdf>

<https://improvement.nhs.uk/resources/create-local-safety-standards-invasive-procedures/>

REFERENCES:

1. National Safety Standards for Invasive Procedures, NHS England 2015
<https://www.england.nhs.uk/patientsafety/never-events/natssips/>

2. Being Open: communicating patient safety incidents with patients, their families and carers , National Patient Safety Agency 2009.

3. Building a Culture of Candour: a review of the threshold for the duty of candour and of the incentives for care organisations to be candid, March 2014 -

<http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf> 9 The Duty of Candour

4. General Dental Council Standards for the Dental Team, 2013.

5. Revised never events policy and framework 2015 <http://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/never-evnts-pol-framwrk-apr2.pdf>.

Appendix 5

List of examples of good practice in prevention of Wrong Site Extraction

Roles and Responsibilities extractions under LA Birmingham Dental Hospital

Roles and Responsibilities for the GA Paediatric Chair Case List Birmingham Dental Hospital

Stop_before_you_block_NHS Eng Newcastle Dental School

Time_out_before_you_take_out_NHSEng Newcastle Dental School

Outpatient Surgical Safety Checklist, University Dental Hospital Manchester, CMFT, Author A Saksena

BDJ Preventing wrong tooth extraction Saksena et al

LocSSIPs WSE working group

SPEC/ORG	NAME
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SCD	Vanita Brookes
Paed	Stephen Fayle
FDS (Chair)	Tara Renton & Selina Master
Dental Hospitals	Mike Pemberton
DMFR	Jane Luker (email only)
Manchester Patient Safety Group	Alka Saksena
NHS England, Office of CDO	Janet Clarke
ADH Clinical Directors	Avril MacPherson
Dental Deans	Callum Youngson
Manchester Patient Safety Group	Edmund Bailey
ABAOMS	Justin Durham
National Examining Board for Dental Nurses	Pam Daley
BSHDT (Dental Therapists and Hygienists)	Invited
NHS Lead for NatSSIPs	Fran Watts
Nurse Manager and Governance Lead for Dental Hospital	Lesley Davies (email only)
CQC	John Milne & Claire Robbie
Lay Member	Sue Parroy (First meeting)
OMFS, Deputy Lead BAOMS Dental Alveolar Specialist Interest Group	Max Chauhan
Dental Indemnity	Bryan Harvey (MDU) Stephen Henderson (MPS)
BAOS	Mike Murphy
NHS Improvement	Joan Russell
GDC	Jessica Rothnie, GDC Standards Policy Manager
BDA	David Cottam, Deputy Chair of the BDA's General Dental Practice Committee
HEE	Peter Briggs
PHE	John Morris
Administrative support	Stephen Brown