The development and implementation of a biopsy safety strategy for oral medicine

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In brief

Enlightens the reader as to the potential risks associated with oral mucosal biopsies.

Demonstrate methods to mitigate the potential risks associated with oral mucosal biopsies.

Recommends review of biopsy safety.

The development and implementation of a biopsy safety strategy is described in this article. Analysis of previous adverse incidents relating to biopsies acted as a catalyst to review our biopsy pathway at Liverpool University Dental Hospital. Input from all staff involved enabled us to develop a biopsy safety strategy which was divided into five stages: preoperative assessment of patient and procedure, team briefings, biopsy surgical safety checklist, surgical removal and handling of biopsy specimens, and post-biopsy follow-up. It is hoped that other clinical teams will take the opportunity to review their own biopsy processes, in the light of our experience.

Introduction

Biopsies, involving the sampling of tissues taken from a patient for histopathological examination, are pivotal investigations for the diagnosis and subsequent management of many oral lesions and conditions. In oral medicine practice, the majority of biopsies are from oral soft tissues and are undertaken, not only in cases of suspected (pre)malignant lesions, but for the diagnosis of bullous, ulcerative and desquamative lesions in the mouth. The oral medicine department at Liverpool University Dental Hospital undertakes 700–800 oral mucosal biopsies per year with 3–5% resulting in a histopathological diagnosis of malignancy. The mandatory introduction of a surgical checklist for biopsies and review of untoward incidents acted as a catalyst for the team to consider the safety aspects of our entire biopsy process.

Patient safety relates to 'the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum'.[1] In 2009, the National Patient Safety Agency (NPSA) for England issued a list of 'never events', defined as 'serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented'.[2] In 2015, a revised never events policy and framework was issued including an updated definition of a never event (Box 1) and lists incidents to be included.[3] The authors acknowledge that the definition of a 'never-event' may differ in other parts of the UK. 'Wrong site surgery' meets the criteria for a never event; it is an avoidable clinical error which causes not only physical and emotional harm to the patient but also costs the NHS significant sums of money from negligence claims. In dental practice, the extraction of the wrong tooth is an avoidable clinical error and deemed wrong-site surgery according to the NPSA definition. Saksena *et al.*[4] described the development and implementation of an outpatient, 'correct site surgery' (CSS) checklist for dental extractions and oral surgical procedures. This was adapted from the World Health Organisation's (WHO) surgical safety checklist.[5] Liverpool University Dental Hospital (LUDH) subsequently introduced a similar CSS checklist and instigated a local requirement for this to be completed for all surgical procedures, including biopsies. This checklist was discussed by the oral medicine team and deemed to be unsuitable for biopsies. A decision was therefore made to review the safety of all stages of the biopsy pathway and not focus solely on the development of a bespoke, surgical checklist for biopsy.

This article outlines the development and implementation of a biopsy safety strategy for oral medicine. Similar safety issues, however, apply to all biopsies undertaken in the oral cavity by oral & maxillofacial surgeons and

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Box 1 Definition of a 'never event'

A 'never event' is a serious incident that meets all of the following criteria:[6]

- The event is wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented.
- The event has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened for the incident to be categorised as a never event.
- The category of never event has occurred in the past and a risk of recurrence remains.
- Occurrence of the never event is easily recognised and clearly defined.

other dental specialities. A detailed description of biopsy types and surgical techniques is outside the remit of this article and has been comprehensively reviewed by Oliver *et al.*[6]

Our approach to the development and implementation of a biopsy safety strategy for oral medicine

Oral medicine team meetings were initially held for all clinical members of staff involved in the biopsy pathway but subsequently included administrative, managerial and secretarial staff. This department has a close working relationship with our oral & maxillofacial pathologist thus facilitating histopathological correlation in diagnostically challenging cases. A review of current biopsy procedures already instigated as a result of previous patient safety incidents or 'near misses' enabled the team to identify existing areas of good practice, areas for improvement and potential risks. A patient safety incident is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient and can be a 'near miss', 'no harm incident', 'harmful incident' (adverse event) or 'reportable circumstance'; for example, a situation with potential for harm but without incident. 'Near misses' are incidents that do not involve or significantly compromise the outcome for the patient due to identification of the error and intervention. These incidents are used as learning tools to improve ongoing practice.[7] A review of our incident reporting (Datix) records identified patient safety incidents relating to oral biopsies. As part of our duty of candour, patients are informed about any incident involving them, as soon as it becomes apparent. Table 1 summarises these incidents and includes outcomes and actions implemented. The serious untoward incident (SUI) involving the failure to act on a clinical and histopathological diagnosis of oral malignancy, in a vulnerable patient, resulted in a root cause analysis (RCA) with important lessons being learnt and appropriate actions taken. This SUI provided a salutary lesson for all staff concerned and provided the initial impetus to review the safety aspects of all stages involved in the biopsy pathway.

The biopsy safety strategy

The biopsy safety strategy is based on established practice and the development and implementation of new measures to mitigate the possibility of patient safety incidents. This is divided into five stages:

1. Preoperative assessment of patient and procedure
2. Team briefings
3. Biopsy surgical safety checklist (BSSC)
4. Surgical removal and handling of biopsy specimens and
5. Post-biopsy follow-up.

The final strategy is summarised in Figure 1.

Stage 1 – Pre-operative assessment of patient & procedure

The safety and wellbeing of the patient must be considered at every stage of the biopsy journey and effective planning and communication is its key to success.

A comprehensive history and clinical examination is key to formulating a provisional or differential diagnosis which will indicate the type of biopsy to be undertaken. A medical history with a current list of medications will alert the clinician to any attendant risks of biopsy and precautions that may need to be undertaken; for example, patients on anticoagulation therapy. It is not within the remit of this article to discuss the impact of medical conditions on biopsy procedures. Problems can arise if a biopsy appointment is cancelled and administrative staff rearrange this without checking with the clinician. To reduce this type of potential risk, all changes to biopsy appointments are approved by a senior clinical member of staff following review of the patient case notes. This precautionary measure is important in cases where there is potential (pre)malignancy and the biopsy is necessary within a tight timeframe. Informed consent is a prerequisite to biopsy and it is crucial that the patient understands the reason for the procedure, what is involved and the potential for post-operative complications. Standard risks for a biopsy would include post-operative pain, bleeding, swelling and infection. Patients need to be made aware of the potential for a non-diagnostic or inconclusive result that may necessitate re-biopsy. For excisional biopsy, the risk of incomplete excision and recurrence with the need for repeat surgery should be discussed. A biopsy patient information leaflet is a useful aid in the consenting process, but is not a substitute for effective verbal communication with the patient.[8] Understating the procedure to minimise patient anxiety can result in patients being ill-prepared and paradoxically, can create more distress, especially if complications occur.

Table 1 Patient safety incidents related to biopsies

Incident	Description	Outcome	Actions Instigated
1	SUI: Failure to act on a diagnosis of oral malignancy. • Biopsy of suspicious lesion on tongue. • Follow-up appointment post biopsy was not made, patient lost to follow up. • Histopathology report did not reach consultant and was not actioned. • Clinical letter was not copied to patient's GP. • Patient presented 3 years later with advanced malignancy.	The patient was assessed as having a non-curative cancer and was scheduled for palliative care.	All biopsies are tracked on an electronic database. A follow-up appointment is now arranged for all patients who have undergone a biopsy. Non-attendance for review is noted and appropriate action instigated. The patient's GP is copied into all clinic letters. Patients are copied into all clinic letters.
2	Specimen pot received by pathology lab and deemed to have no specimen inside.	Clinically, a benign lesion had been excised and appropriate review arranged.	Additional patient label to be placed over specimen pot lid to 'seal' pot and make pot 'tamper-proof'.
3	Specimen pot delivered to pathology lab with ID stickers for two different patients.	Sample not processed; re-biopsy was undertaken.	All specimens are checked by two staff members, both immediately after the surgical procedure and prior to dispatch to laboratory.
4	Specimen was sent to laboratory but returned in the pathology transport bag unprocessed/overlooked.	Specimen re-sent for processing.	Pathology laboratory now fax a list of all received specimens, this is checked against the biopsy log to identify discrepancies.

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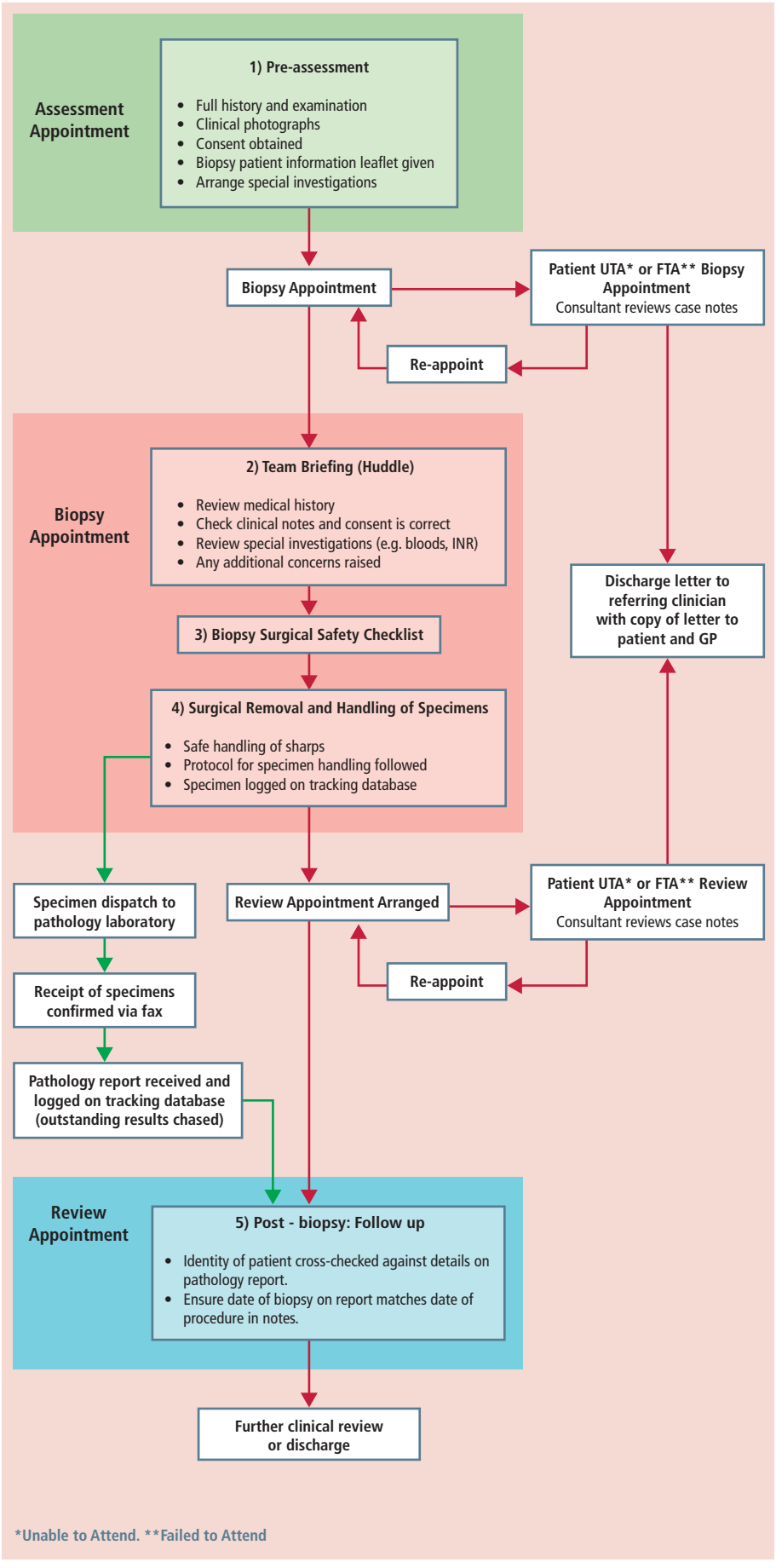
Training of all clinical staff involved in biopsies is essential. The preparation of surgical instruments and equipment for the procedure is generally the domain of an appropriately experienced, registered dental nurse. This aspect of planning is crucial to the smooth running of a biopsy procedure and will minimise any disruption that may predispose to clinical errors. In the authors' experience it is essential to have another clinical assistant available to supply any additional instruments or materials, and be available for emergencies. In secondary care, the clinician undertaking the biopsy is often not the same member of staff that initially assessed the patient. Effective communication is therefore essential within case note entries. Clinicians should clearly record the anatomical site of the lesion to be biopsied to ensure that a representative sample is taken. Any additional instructions, for example, the depth of sampling (important in suspected granulomatous conditions) or need for direct immunofluorescence, must be made clear. Clinical photography is invaluable, enabling colour images of the oral lesions to be printed and annotated to indicate the intended biopsy site(s). A copy of this can also be sent to the pathologist to aid clinico-pathological correlation. If this is not feasible, then a diagram (or topogram) can be appropriately marked in the case notes.

It is important that an appropriately trained and experienced clinician undertakes the biopsy procedure. A non-diagnostic biopsy may necessitate the patient having a repeat procedure which may result in physical and psychological morbidity.[6] A non-representative biopsy sample could result in failure to diagnose a (pre)malignant lesion with potentially serious consequences for the patient. The clinical presentation of the lesion under investigation may have changed at the biopsy appointment; this may necessitate re-evaluation of the biopsy site. In a few cases, the initial lesion may have resolved, thus obviating the need for biopsy. This requires confirmation by a senior clinician and should be clearly recorded in the patient record.

Stage 2 – Team briefings

Effective communication between members of the clinical staff before and during the biopsy is essential for a safe and effective biopsy. Prior to biopsy lists, team briefings (also referred to as 'huddles') can be an effective way of improving communication. However, these do need to have an agenda, structure, consistency and

Fig. 1 Biopsy safety strategy: Flow diagram



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time limit. Team briefings have recently been introduced into our oral medicine department and 15 minutes is allotted for these. The content of the team briefing includes the review of patient case notes, consent forms and clinical photographs, if available. While this process is generally led by the senior clinician involved, all members of the clinical team need to participate. Errors that have already been identified during team briefings include: issues with consent, the type of biopsy to be undertaken and additional equipment required.

Some members of the oral medicine team questioned the effectiveness of huddles in preventing errors and improving safety. Others feel that they impede the workflow process. In our department, biopsy sessions can have up to three separate lists running simultaneously and the team briefing has already proved helpful in planning which biopsies may be technically challenging, requiring a more senior clinician to be allocated such procedures. Team briefings, before biopsy, are used in addition to the BSSC and other established checks.

Stage 3 – Biopsy Surgical Safety Checklist (BSSC)

The rationale for the introduction of a BSSC was queried by some staff; they expressed the view that, a checklist might be of limited value, as 'wrong site surgery' for biopsies has not been a problem within the department. Wrong site excisional biopsies (for example, of a discrete lump) are easy to identify but wrong site incisional biopsies of an extensive oral condition (eg, oral lichen planus) are much more subjective, as the area of tissue to be sampled is not always clear. A decision was subsequently made that, as the use of a surgical safety checklist for all surgical procedures had been mandated by our Trust, the oral medicine team needed to develop a checklist they consider fit for purpose.

The development and implementation of a biopsy surgical safety checklist (BSSC) for oral biopsies

A preliminary BSSC for oral biopsies was piloted based on the format of the WHO Surgical Safety Checklist,[5] and the surgical safety checklist already in use elsewhere within LUDH; predominantly for exodontia. This consisted of three sections (Table 2), together with a topogram (schematic representation of the oral cavity) to mark the site of biopsy. In addition, the following information was displayed on the surgery whiteboard which can be seen by the clinical team: operator and assistant name, patient name, procedure site, as well as the local anaesthetic batch number and expiry date.

Oral medicine staff (n = 15) were informed of the pilot and how to undertake the checklist. Following the pilot, feedback was obtained from staff and patients. Staff provided responses on a Likert scale based on the domains in Box 2, and a free-text area was provided for other suggestions. Patients (n = 31) were given the opportunity to provide feedback (Box 3) via a Patient Related Experience Measure (PREM) questionnaire at the end of their biopsy appointment answering either 'yes, definitely', 'yes, to some extent' or 'no'.

Results

All staff felt the checklist was suitable for the process and also that they understood how to complete the checklist. There was a lack of agreement as to whether the checklist would reduce the risk of wrong site surgery for biopsies with 13% disagreeing with this and 38% feeling the checklist would have no effect. Staff members provided feedback on how the pilot BSSC could be improved (Box 4).

Overall patient feedback was positive towards the checklist and they were happy to be involved in the process, although some (17%) felt a degree of anxiety relating to this. Nearly all (97%) of patients felt that they should be involved in the checks for their biopsy.

Action plan

Following analysis of our findings and further staff discussion, an action plan was agreed and instigated to address the issues highlighted. The checklist was amended to include a larger section for denoting sample types and site, and additional sections for the clinician and assistant names. Printing the protocol for the handling of biopsy specimens on the reverse side of the checklist was agreed. The original topogram was replaced by a pictorial representation of the mouth as it was felt this was easier to accurately mark a site on this image. The BSSC currently in use is shown in Figure 2.

Table 2 Stages of the surgical safety checklist

Stage	Description
1) Time-out	Undertaken before commencing procedure. Ensure all checks are completed and that all staff members as well as the patient are happy to proceed.
2) Pause	Should there be any disruption to the procedure or change in operation/operator for any reason, staff should 'reaffirm' the procedure to be undertaken.
3) Post op debrief	Encourages analysis and comments from the team.

Box 2 Clinician questionnaire regarding pilot BSSC

1) I feel the form helps reduce the risk of wrong-site surgery for oral biopsy procedures.
2) I feel the content of the pilot checklist is suitable for oral biopsy procedures.
3) I feel I understand how to complete this form correctly.

Box 3 PREM questions regarding pilot BSSC

1) Would you feel more reassured knowing a checklist is used to make sure your procedure is undertaken correctly?
2) Are you more reassured that the surgeon discussed your procedure with the assistant?
3) Do you feel it is important to be involved in these checks?
4) Does being involved in these checks make you more apprehensive?

Box 4 Staff feedback to improve the pilot BSSC

- Provide a section to list each sample's site and type.
- Provide space for the name of the clinician and witness.
- Printing the checklist on the reverse of the existing protocol for handling biopsy specimens as the handling and labelling of specimen pots had also been highlighted as a potential area of risk.
- The additional use of a whiteboard as part of the checking process was questioned; as this could introduce another point of error.

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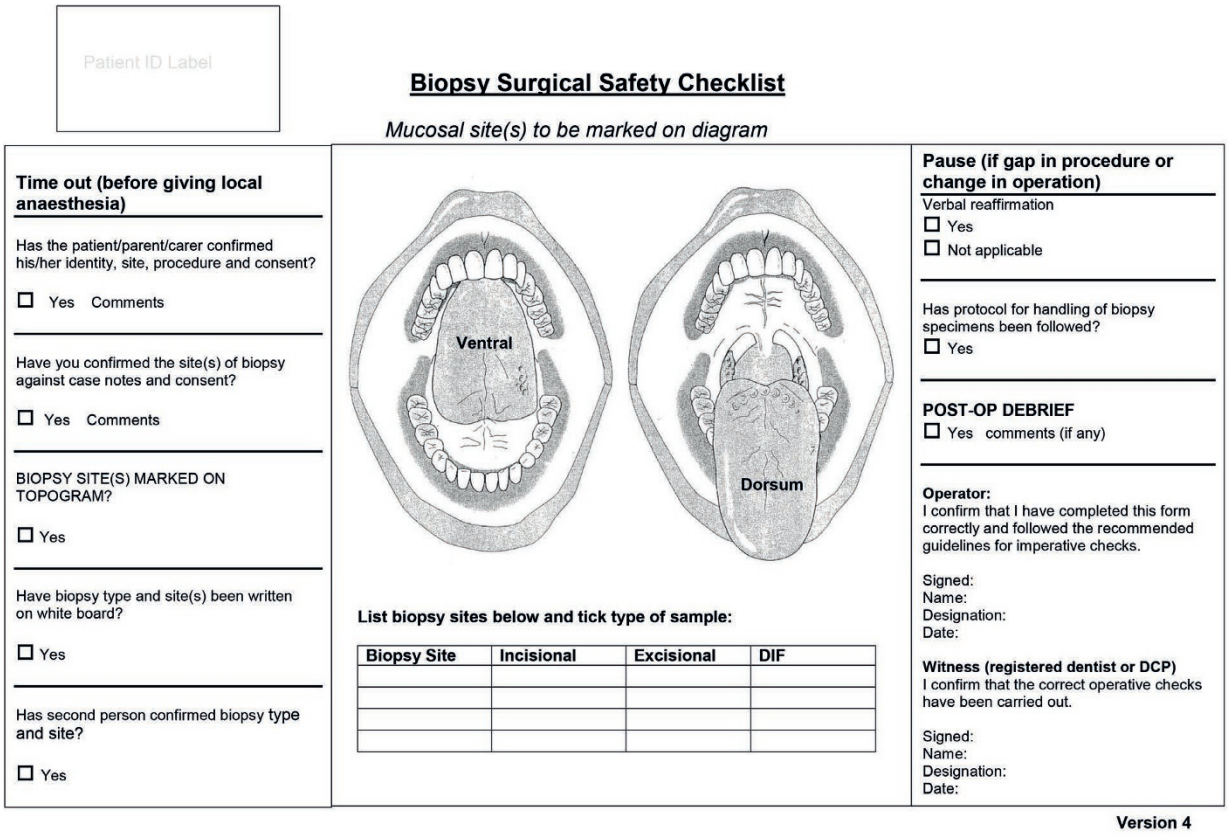

Fig. 2 Biopsy surgical safety checklist

Stage 4 – Surgical removal and handling of biopsy specimens

Some of the potential problems associated with biopsy techniques and how to overcome them have been reviewed by Oliver *et al.*[6] Poor tissue handling during the procedure can result in damage, potentially producing a crush artefact, thus rendering histopathological examination non-diagnostic. Similarly, an unrepresentative tissue sample has the potential to compromise patient safety, particularly if there is clinical suspicion of a (pre)malignant lesion. The safety of clinical staff involved in the procedure must also be considered, and steps taken to avoid needle stick and other sharps injuries. After the tissue sample has been removed, there are a number of potential errors that can occur regarding the handling of the specimen, recording of patient details and condition, and subsequent transfer from the clinic to the pathology laboratory. A potential area for error at this stage is the labelling of specimen pots. A protocol for the handling and labelling of biopsy specimens is shown in Box 5.

Currently, our pathology request forms are hand-written and there is the potential for the incorrect transfer of information from these onto the subsequent electronic histopathology report to occur. Other errors, arising during the handling and processing of biopsy specimens within the pathology laboratory are outside the scope of this article.

Timely and secure dispatch of the biopsy sample to the pathology laboratory for reporting is essential and following analysis of a SUI (Table 1), steps have been taken to track all specimens and histopathology reports. Firstly, the specimen is logged into a paper logbook before being placed into the specimen transport container. This paper logbook is transcribed onto an electronic spreadsheet daily by our medical secretarial staff. Information including patient details, date of dispatch and degree of urgency are recorded. This is reviewed on a daily basis and any reports not received within the expected time period can be followed up.

Box 5 Protocol for handling of biopsy specimens

Protocol for handling of biopsy specimens

- For routine histopathology, single samples should be placed in a patient labelled pot containing 10% neutral buffered formalin (volume at least ten times that of the specimen).
- For more than one sample from the same patient, each pot should be individually labelled and then sequentially numbered. The site and side of biopsy should be clearly written on the pot at the time each sample is placed into each individual pot.
- Normal or perilesional tissue for Direct Immunofluorescence (DIF) studies should be placed in Michel's medium or sent fresh to the histopathology laboratory.
- Once sampling is complete, a full detail patient label should be placed on top of the specimen lid as a "seal".
- The pathology form details should be cross checked with all individual samples – numbers and sites being checked with all appropriate clinical information. Samples that require transport to a different laboratory, such as for immunofluorescence should be separated from those going for routine histopathology and transported accordingly.
- Before dispatch of all specimens, a dental nurse should check that histopathology forms are completed and pots are correctly labelled.
- Urgent samples should be marked as such on the request form and immediately transported to the laboratory.
- The biopsy details for all patients should be transcribed onto the electronic biopsy tracking database to ensure patient and sample follow up.

Stage 5 – Post-biopsy: follow up

Tracking of histopathology reports mitigates potential errors in the follow-up of patients, particularly in cases where there is a suspicion of potential malignancy. Whenever possible, post biopsy review appointments are given to the patient, immediately after their biopsy procedure, as mailing these introduces an additional possibility of loss to follow up. At the completion of a biopsy or review clinic, the notes of all patients who fail or are unable to attend, are reviewed and appropriate measures taken. They are either contacted by telephone or sent a letter copied to both the referring clinician and patient; if the referring clinician is a dentist, the patient's GP is also sent a copy. If the diagnosis necessitates urgent review (eg. oral malignancy), the GP would be telephoned.

Discussion

The oral medicine team recognised that there were potential risks to patient safety throughout the biopsy pathway – from assessment of the patient, removal and transfer of the specimen to receipt of the histopathological report by the clinician. Although our focus was on the BSSC, we agreed to review our practices to develop and implement a biopsy strategy, covering all stages of the biopsy pathway.

Review of the literature indicates that there is little knowledge about the effectiveness of interventions to improve patient safety in dentistry.[9] A systematic review of patient safety interventions in dentistry found that the only interventions that reduce or minimise adverse events are surgical safety checklists. The development and introduction of a correct site surgery checklist in Central Manchester University Hospitals for outpatients undergoing dental extractions has resulted in 100% staff compliance with the checklist and no wrong site extractions have occurred since its instigation.[4] Similar checklists have been introduced by a team in Madrid for ambulatory oral surgical procedures but there is no indication as to whether this reduced the incidence of wrong site surgery.[10] It is important that any tools, including safety checklists, developed to improve patient safety, are customised for not only different healthcare settings but also different surgical procedures. A 'one size fits all' approach is likely to be unsuccessful; hence the rationale for our department adapting the surgical safety checklist used for exodontia within LUDH to make it bespoke for oral biopsies. The development of the BSSC within our oral medicine practice involved input and feedback from all members of the clinical and administrative team at every stage from an initial pilot to the current version. After the introduction of the pilot BSSC, 38% of staff felt that the checklist would have no effect on biopsy safety. This scepticism and resistance to the BSSC was understandable as 'wrong site' biopsies had not been recognised or reported as posing a patient safety threat. In addition, the necessity for notating the biopsy procedure on the whiteboards was questioned and some staff felt that this could introduce another potential point of error. Oral biopsy wrong site surgery is rarely reported which may lead to the assumption that these do not occur; however, it is likely that incidents are underreported. A summary of never events including wrong site soft tissue surgery indicated that 19 wrong skin lesions were removed in 2015/16; no wrong-site oral lesions had been reported during this time.[11]

Questioning the introduction of tools, such as surgical checklists to improve patient safety and scepticism about their effectiveness is not only understandable but has some validity. In a feature article, entitled '*The trouble with checklists*',[12] the author examined the reasons why the introduction of a pre-surgery check list heralded by the NHS as a simple, cheap way to improve patient safety, had not lived up to initial expectations. This article highlights the fact that a variety of factors can influence a checklist's success or failure, ranging from the attitudes of staff to the ways that administrators introduce the tool. The potential for 'ticking boxes', without paying attention to the safety precautions underpinning the checklist is explored. Operating-theatre staff at ten UK hospitals were interviewed about the barriers to implementing the WHO surgical checklist.[13] This highlighted the wide variation in how the checklist was implemented. Other issues raised included doubts regarding the design or the evidence base behind the checklist process as well as resistance from team members to its implementation.

Another reason that checklist initiatives may not be successful is failure of replication that is, adaption of one tool such as a surgical checklist, which has proved successful in one clinical environment, may not be effective in another; 'one size does *not* fit all'. This limitation underpinned our development of a bespoke checklist for biopsy. We also recognised that problems associated with surgical checklists may not be caused by the tool itself but how it is implemented. Staff engagement was pivotal to the development of our BSSC so that any issues limiting success could be identified early in the process and addressed.

Feedback from the patients undergoing biopsy within our department indicated the majority prefer the checklist to be used and feel safer as a result. In two large London teaching hospitals, a survey of patients concerning the checklist demonstrates strong support for the WHO surgical safety checklist.[14] The use of operating room team briefings has emerged as an effective form of communication with a proven track record of high reliability for reducing errors.[15]

Team briefings, colloquially referred to as 'huddles', now form part of our biopsy safety strategy and are gradually becoming accepted by those members of the clinical team, who initially expressed scepticism and doubts about their effectiveness.

Unless standardised protocols are followed, the removal and handling of biopsy specimens are other stages in the process where errors can occur, thereby compromising patient safety. Errors associated with incorrect labelling of specimen pots can have serious and wide-reaching consequences compromising patient safety. Immunofluorescence techniques for the diagnosis of suspected immunobullous disease cannot be undertaken if tissue specimens are placed in the wrong transport medium, thus delaying diagnosis and compromising patient management. Stratman *et al.*[16] described the 14 stages of a skin biopsy pathway which is akin to that of an oral mucosal biopsy. This highlights the multitude of stages where errors can occur. Makray *et al.*[17] investigated the incidence of identification errors in surgical pathology specimens. The incidence of error was 4.3 per 1,000 specimens with error types including unlabelled specimens, empty containers, incorrect laterality, incorrect site, incorrect patient, no patient name, and no site identified. We have developed and refined the protocols for the handling of biopsy specimens which has proved successful in reducing these types of errors and now forms part of our routine biopsy practice.

Review of our biopsy pathway has identified some areas in which improvement is required, particularly in the use of handwritten biopsy request forms. As part of the NHS *Five year forward view*[18] paper-free health records will soon be introduced and this will reduce the potential for errors during the transposing of handwritten to electronic notes.

The authors recognise that some of the measures developed and implemented as part of our biopsy safety strategy may not be relevant and/or applicable to the readers' own biopsy practice because local arrangements and clinical practice may differ. The local processes and interventions we developed and implemented for biopsy are undergoing continuous re-assessment and audit to ensure ongoing clinical governance.

In response to concerns about wrong site surgery, the NHS England Surgical Services Patient Safety Expert Group developed national standards of practice termed National Safety Standards for Invasive Procedures (NatSSIPs).[19] This document illustrates key steps required to ensure safe care for invasive procedures and promote standardisation of these as they are processed. The vision is that these are used by organisations to facilitate the development of local versions termed Local Safety Standards for Invasive Procedures (LocSSIPs); with this in mind our unit is in the process of developing such a document for invasive dental procedures within the hospital.

Conclusion

There is potential for errors throughout the biopsy pathway and these can impact on the safe and effective management of patients. The review of our biopsy pathway and patient safety incidents has enabled the development and implementation of additional safety measures. It is hoped that our approach to the implementation of a biopsy surgical safety strategy will encourage other clinical teams to re-assess their own local procedures and pathways.

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