## Cellular pathology audit template

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| Date of completion | (To be inserted when completed) |
| Name of lead author/ participants | (To be inserted) |
| Specialty | Cellular pathology/Oral, maxillofacial and head & neck pathology |
| Title | An audit of quality of reporting of intraoral mucosal biopsies taken for the diagnosis and assessment of potentially malignant lesions |
| Background | Histopathological examination is considered an essential part of assessment of patients with white/red lesions of the oral mucosa, primarily but not exclusively for the assessment of malignant potential. Notwithstanding the difficulties surrounding the effects of sampling error, subjectivity in grading and an uncertain natural history, the presence of dysplasia is considered to be one of the most useful predictive markers in the future development of invasive malignancy.1 |
| Aim & objectives | To determine compliance with recommendations and standards relevant to the various steps involved in processing intraoral mucosal biopsies taken for the diagnosis and assessment of white/red lesions of the oral mucosa, including:  adequacy of clinical information  appropriateness of sampling  adequacy of macroscopic description and processing  quality of microscopic description, report and interpretation. |
| Standards & criteria | **Criteria range:**  Some items (e.g. Item 3 ‘Exposure to risk factors’ and Item 5 ‘Adequacy of sampling’) are not necessary to permit interpretation of the histological findings and do not require compliance as such. They are regarded as examples of good clinical practice, reflecting the quality of the patient management pathway.  Item 9 (Number of levels): Compliance is set arbitrarily at 95%, on the basis that a confident assessment of the mucosal abnormality could be determined with fewer sections in no more than 5% of samples.  Item 12: Definitive statement on the presence or absence of invasive malignancy is not necessary on all samples (e.g. a simple frictional keratosis).  Item 20 (turnaround time): 90% of reports authorised and available within 7 days of the biopsy date as recommended by the RCPath.  Other items: 100%, or, if not achieved, the existence of documentation that explains the variance.  **Clinical**  The clinical indication for biopsy should be stated (e.g. new diagnosis of a white/red patch, known dysplasia under follow-up). A description of the site(s), extent and appearances of the abnormality (e.g. homogeneous or non-homogeneous) and knowledge of the exposure to suspected risk factors (e.g. tobacco) aid interpretation.  **Site of origin**  Biopsies from different parts of the oral cavity should be submitted and processed in such a way that their site of origin is identifiable. If the site of a biopsy is not identifiable, the audit response is ‘no’, but discretion is advised.  **Macroscopic description**  Small and/or fragmented biopsy specimens can be difficult to orientate and interpret. Recording such findings may provide partial explanation of equivocal reports.  **Slide preparation**  All fragments should be embedded in their entirety and examined through 3 levels. It is often possible to identify candidal hyphae without the use of histochemical stains but such stains are useful in affirming the absence of fungal infection.  **Microscopic report**  The report should describe the changes in the oral mucosa, bearing in mind the normal histological differences between subsites: hyperkeratosis; epithelial hyperplasia/atrophy; cytological and architectural atypia; inflammatory cell infiltrates; fibrosis; the presence or absence of candida. The differential diagnosis of oral mucosal white/red lesions includes conditions that have specific histopathological features, offering the opportunity to redress clinical uncertainty and provide definitive diagnosis.  If there is definite or probable epithelial dysplasia, it should be graded. WHO grades of mild, moderate and severe or the 2-tier system of high grade versus low grade can be employed. If no grading is possible, this should be stated.  The term ‘leukoplakia’ should not appear as an unqualified diagnosis. Its use in biopsy reporting is inappropriate except when supporting certain specific clinical diagnoses (e.g. proliferative verrucous leukoplakia, oral hairy leukoplakia).  **Turnaround time**  Compliance with the agreement between the laboratory and users of the laboratory services regarding the proportion of cases compliant with turnaround times for this specific patient pathway.2 |
| Method | **Sample selection:**  At least 25 cases from local archives, ideally sequential and from the past 2 years.  **Data to be collected on proforma (see below).** |
| Results | (To be completed by the author)  The results of this audit show the following compliance with the standards.   |  |  | | --- | --- | |  | % compliance | | **Clinical details** | | | 1. Indication for biopsy is stated clearly |  | | 1. Clinical description of the lesion is recorded: | | | 1. Site or sites of lesion |  | | 1. Appearances of lesion |  | | 1. History of exposure to risk factors is recorded |  | | 1. Clinical diagnosis is recorded |  | | 1. Sampling is adequate |  | | 1. Anatomical site of origin is clearly identifiable for all biopsies |  | | **Macroscopic description/slide preparation** | | | 1. Number of fragments is recorded |  | | 1. Size of the largest fragment is recorded |  | | 1. At least 3 levels are available for each biopsy |  | | 1. Histochemical stains to demonstrate candida are available (if report states that fungal infection is not identified) |  | | **Microscopic report** | | | 1. Biopsies from separate sites are described separately or biopsies from different sites which have the same features are described together |  | | 1. Definitive statement is made as to whether or not there is invasive malignancy |  | | 1. Definitive statement is made as to whether or not there is dysplasia |  | | 1. If the mucosa shows dysplasia, a grade is provided (mild/moderate/severe or high grade/low grade) |  | | 1. Definitive statement on the presence or absence of candida |  | | 1. Description of changes in mucosal morphology is clear enough to be ascertained by the auditor |  | | **Summary and conclusions** | | | 1. Summary of microscopic changes is given |  | | 1. Preference for a diagnosis, or the inability to distinguish between diagnoses, is recorded |  | | 1. The term ‘leukoplakia’ (as an unqualified diagnosis) is absent |  | | 1. The report is authorised within the agreed period from the date on which the biopsy was taken |  |   **Commentary:** |
| Conclusion | (To be completed by the author) |
| Recommend- ations for improvement | Present the result with recommendations, actions and responsibilities for action and a timescale for implementation. Assign a person(s) responsible to do the work within a timeframe.  **Some suggestions:**  highlight non-compliance with recommendations  present findings to colleagues in histopathology or clinical services. |
| Action plan | (To be completed by the author – see attached action plan proforma) |
| Re-audit date | (To be completed by the author) |
| References | 1. El-Naggar AK, Chan JK, Grandis JR, Takata T, Slootweg PJ. *WHO Classification of Head and Neck Tumours. WHO/IARC Classification of Tumours (4th ed, vol 9).* Lyon, France: International Agency for Research on Cancer press, 2017. 2. The Royal College of Pathologists. *Key Assurance Indicators for Pathology Services. Recommendations from the Royal College of Pathologists.* London, UK: The Royal College of Pathologists, 2019. Available at: <https://www.rcpath.org/uploads/assets/24572f2b-b65f-4a4b-b9e4d0f526dbac55/G181-Key-assurance-indicators-for-pathology-services.pdf> |

## Data collection proforma for reporting of intraoral mucosal biopsies taken for the diagnosis and assessment of potentially malignant lesions

## Audit reviewing turnaround times

Patient name:

Hospital number:

Date of birth:

Sample no.:

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|  | **1**  **Yes** | **2**  **No** | **3**  If no, was there documentation to explain the variance? **Yes/No** plus free-text comment | **4**  Compliant with guideline based on ‘Yes’ from column 1 or an appropriate explanation from column 3. **Yes/No** |
| **Clinical details** | | | | |
| Indication for biopsy is stated clearly |  |  |  |  |
| Clinical description of the lesion is recorded:   1. Site or sites of lesion 2. Appearances of lesion |  | | | |
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| History of exposure to risk factors is recorded |  |  |  |  |
| Clinical diagnosis is recorded |  |  |  |  |
| Sampling is adequate |  |  |  |  |
| Anatomical site of origin is clearly identifiable for all biopsies |  |  |  |  |
| **Macroscopic description/slide preparation** | | | | |
| Number of fragments is recorded |  |  |  |  |
| Size of the largest fragment is recorded |  |  |  |  |
| At least three levels are available for each biopsy |  |  |  |  |
| Histochemical stains to demonstrate Candida are available (if report states that fungal infection is not identified) |  |  |  |  |
| **Microscopic report** | | | | |
| Biopsies from separate sites are described separately or biopsies from different sites which have the same features are described together |  |  |  |  |
| Definitive statement is made as to whether or not there is invasive malignancy |  |  |  |  |
| Definitive statement is made as to whether or not there is dysplasia |  |  |  |  |
| If the mucosa shows dysplasia, a grade is provided (mild/moderate/severe or high grade/low grade) |  |  |  |  |
| Definitive statement on the presence or absence of candida |  |  |  |  |
| Description of changes in mucosal morphology is clear enough to be ascertained by the auditor |  |  |  |  |
| **Summary and conclusion** | | | | |
| Summary of microscopic changes is given |  |  |  |  |
| Preference for a diagnosis, or the inability to distinguish between diagnoses, is recorded |  |  |  |  |
| The term ‘leukoplakia’ (as an unqualified diagnosis) is absent |  |  |  |  |
| If invasive malignancy is detected, the report is authorised within 7 days of the date on which the biopsy was taken |  |  |  |  |

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| **Audit action plan**  An audit of quality of reporting of intraoral mucosal biopsies taken for the diagnosis and assessment of potentially malignant lesions | | | | | | |
| Audit recommendation | Objective | Action | Timescale | Barriers and constraints | Outcome | Monitoring |
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