# Head & Neck MDT Snapshot Audit 2023:

# MDT Audit of the Management of Head & Neck Squamous Cell Carcinoma

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| **Protocol version:** | 1.0 |
| **Date:** | 10th October 2023 |
| **Funding:** | None |
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# 1 Version History

| Protocol version no. | Date | Version |
|---|---|---|
| **1.0** | 17/10/2023 | First draft as prepared by the Project Management Team for Executive Committee review. |

# 2 Table of acronyms

| Acronym | Meaning |
|---|---|
| **CT** | Computed tomography |
| **EBV** | Epstein-Barr Virus |
| **FNAC** | Fine needle aspiration cytology |
| **HN/H&N** | Head and Neck |
| **HNSCC** | Head and neck squamous cell carcinoma |
| **HPV** | Human papillomavirus |
| **HRA** | Health Research Authority |
| **MDT** | Multidisciplinary team |
| **MRI** | Magnetic resonance imaging |
| **MRN** | Medical record number |
| **PET-CT** | Positron emission tomography and computed tomography |
| **PMT** | Project management team |
| **SCC** | Squamous cell carcinoma |

# 3 Project summary

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|---|---|
| **Study Title** | Head & Neck MDT Snapshot Audit 2023:<br>MDT Audit of the Management of Head & Neck Squamous Cell Carcinoma |
| **Short Title** | HNSCC Audit 2023 |
| **Study Leads** | INTEGRATE Head & Neck Subspecialty Committee |
| **Study Design** | Multi-centre retrospective national audit |
| **Study Participants** | Patients >18 year old with confirmed mucosal squamous cell carcinoma of the head and neck |
| **Planned Sample Size** | No *a priori* calculation |
| **Follow-up duration** | 2 years |
| **Planned study period** | 1st September to 30th November 2021 |
| **Aim** | To assess current real-world management of HNSCC in the UK |
| **Primary Objectives** | 1. To gain a large-scale understanding of the management decisions of patients with HNSCC discussed at MDT in the UK<br>a. by collecting patient demographics and HNSCC disease data<br>b. by collecting MDT recommendations<br>2. To assess this management for adherence to national guidelines |
| **Secondary Objectives** | 1. To gain an understanding of the variation in HN MDT recommendations<br>2. To evaluate the 2-year overall, disease-specific and disease-free survival outcomes, and recurrence rates of head and neck cancers<br>3. To audit UK-wide HNSCC pathways and their compliance with cancer waiting targets, including identifying delays and potential areas for improvement<br>a. 28 days 'Faster Diagnosis Standard' (FDS) for primary HNSCC<br>b. 31 days from the referral to decision-to-treat<br>c. 62 days from referral to the commencement of treatment (31 days for recurrent HNSCC)<br>4. To examine the use of local anaesthetic biopsy for histological diagnosis and its impact on pathway timings<br>5. To assess the HN MDT workforce against national guidelines |
| **Methods** | Identify patients with HNSCC discussed at HN MDT within the study period.<br>Central submission of anonymised cases for pooled analysis. |

# 4 Background

Head and Neck cancers are the seventh most common cancer globally, with a prevalence of 4.1 million cases reported in 2016 (1). The term encompasses a diverse, heterogeneous group of pathologies that can affect multiple anatomical regions and interact with several important physiological systems. In addition, 60-70% of HN cancer patients present with locally or regionally advanced disease, making multimodal management a necessity (2). As such, managing HN cancers can be complex and well-suited for a MDT approach (2). This involves collaboration and discussion between multiple different medical specialities to improve patient care, including Ear, Nose and Throat (ENT), Oral and Maxillofacial Surgeons (OMFS), Plastic Surgeons, Oncologists, Radiologists, Pathologists, Oncology Nurses, Dietitians and Speech and Language Therapists.

The MDT concept emerged in the 1980s when it was found surgery with post-operative chemotherapy or radiotherapy improved outcomes in patients diagnosed with cancer (3). In the 1990s and early 2000s, several retrospective studies demonstrated that MDT approaches improved survival rates for cancer patients and positively affected treatment decisions (4–6). For HN cancers, a meta-analysis conducted by Shang et al demonstrated that patients managed via an MDT approach had a higher survival rate (HR = 0.84, 95% CI (0.76-0.92), P = 0.0004) (7). MDTs were also found to improve adherence to evidence-based guidelines and to improve efficiency in care (8,9). A retrospective audit conducted by Kelly et al (10) found that MDT discussion improved rates of pre-operative nutritional assessments (57% vs. 39%), PET-CT staging (41% vs. 2%) and reduced the interval between surgery and radiotherapy for patients with head and neck cancer. These clear benefits have resulted in the MDT being widely adopted throughout the world in cancer management.

In the United Kingdom, the guidelines for decision-making in the management and preoperative workup of HN Cancers are provided by the National Institute for Health and Care Excellence (NICE) (11). Outside these guidelines, general recommendations for running an effective MDT include strong leadership to help guide decision-making (2,12–14), the importance of good record-keeping (12,14) the inclusion of allied healthcare professionals such as Speech and Language Therapy to help with supportive interventions (3) and the importance of a specialist oncology nurse to act as a point of contact between the team and the patient (2,3,12).

The British Association of Head and Neck Oncologists (BAHNO) produced their first guideline on the management of HN cancers in 2002. In 2020 it published its most recent guideline “British Association of Head and Neck Oncologists (BAHNO) standards 2020” (15), which set out to establish standards for HN MDTs UK-wide, as well as encourage sharing of knowledge between different MDTs. Anecdotally there is variation in practice amongst MDTs throughout the country, with some more oncologically-orientated and others more surgically-orientated. Standardising HN MDTs is difficult due to regional variation in resources and demographic characteristics. As such, this protocol outlines a national retrospective audit to understand the decision-making process for patients with HN cancer across the United Kingdom, focusing specifically on HNSCC that comprises the majority of diagnoses.

# 5 Aim and objectives

## 5.1 Aim

1. To define the current management of primary and recurrent mucosal HNSCC in the UK.

## 5.2 Primary Objectives

1. To gain a large-scale understanding of the management decisions of patients with HNSCC discussed at MDT in the UK
    a. by collecting patient demographics and HNSCC disease data
    b. by collecting MDT recommendations
2. To assess this management for adherence to national guidelines

## 5.3 Secondary Objectives

1. To gain an understanding of the variation in HN MDT recommendations
2. To evaluate the 2-year overall, disease-specific and disease-free survival outcomes, and recurrence rates of head and neck cancers
3. To audit UK-wide HNSCC pathways and their compliance with cancer waiting targets, including identifying delays and potential areas for improvement
    a. 28 days 'Faster Diagnosis Standard' (FDS) for primary HNSCC
    b. 31 days from the referral to decision-to-treat
    c. 62 days from referral to the commencement of treatment (31 days for recurrent HNSCC)
4. To examine the use of local anaesthetic biopsy for histological diagnosis and its impact on pathway timings
5. To assess the HN MDT workforce against national guidelines

# 6 Study design and setting

## 6.1 Study design

Retrospective multi-centre observational audit of practice.

## 6.2 Study setting

UK secondary or tertiary centres investigating and treating HNSCC.

# 7 Patient eligibility criteria

## 7.1 Inclusion criteria

- 18 years and older
- Patients with a new or recurrent histologically diagnosed primary mucosal HNSCC (non-cutaneous) of one of the following subsites:
    - Oral cavity
    - Oropharynx
    - Nasopharynx
    - Sinonasal cavity
    - Hypopharynx
    - Larynx
- Patients who underwent discussion at a HN MDT, with a complete and final MDT treatment recommendation made between 1st September 2021 and 30th November 2021

## 7.2 Exclusion criteria

- Patients under 18 years old
- Patients with a primary HN cancer of thyroid, cutaneous, salivary gland, lateral skull base, or non-squamous cell origin
- Patients with an HNSCC of unknown primary
- Patients with a diagnosis of dysplasia, or carcinoma-in-situ

# 8 Study procedures and methodology

## 8.1 Project registration

This is a local investigator-led, non-commercial, non-interventional national audit of clinical practice. No patient identifiable information will be collected by the PMT and data analysis will not identify hospitals individually. As such, the anticipated risks to patient confidentiality are extremely low.

The project must be registered with local Clinical Governance Departments responsible for the conduct of local audit prior to submission of any data to the PMT.

## 8.2 Patient identification

Local investigators will obtain a list of consecutive patients from their centres for inclusion into the study.

These patients will:

- have had a diagnosis of primary or recurrent HNSCC

  AND

- have been discussed at MDT

  AND

- have had a definitive 'decision to treat' for their primary or recurrent HNSCC documented via their MDT outcome between 1st September 2021 and 30th November 2021.

Local investigators are advised to acquire patient lists via their H&N MDT co-ordinators. Where a patient list is obtained via an MDT coordinator, it is recommended that the list is limited to the most recent discussion date for each patient, so that final MDT outcomes can be retrieved following investigations. 2-year follow-ups for these patients will then be retrieved by local investigators where available.

Where necessary, the PMT will be able to further guide local investigators upon request: **hnmdtaudit@entintegrate.co.uk**

The MDT notes and 2-year outcomes for all patients will be reviewed by the local team and full eligibility criteria applied. All eligible patients will be recorded onto an Excel Data Tool. All screened patients and any reasons for exclusions will be recorded.

## 8.3 Sampling time frame

### *8.3.1 Data collection window*

#### *8.3.1.1 Start date*

The study launches on 1st December 2023

#### *8.3.1.2 End date*

Final submission of data will be at the discretion of the PMT, with a provisional deadline of 1st March 2024, with scope to extend to promote data completeness.

## 8.4 Consent

This audit will report the treatment recommendations and outcomes of management that have already taken place. There will be no impact on the management of patients as a result of inclusion in the study. All data will be anonymised, and no patients will be identifiable in subsequent reports, presentations or publications. As such, consent from individual patients will not be required.

## 8.5 Anonymisation of patients

The PMT will neither request nor be provided names, addresses, date of birth, race, NHS numbers, medical record numbers (MRN) or identifiable information for any patients.

Reporting and analysis will not identify individual cases in any subsequent reports, presentations or publications.

Data flow will be one-way, from the Data Disclosure to the Data Receiver (PMT). There will be no traceability from the PMT's database to local records.

If any identifiable data is received, the files will be deleted and the site will be informed.

## 8.6 Dataset

The full dataset is delineated in the study Excel Data Tool. This tool will collect data in the following areas:

- **Demographics and referral details:** demographics; smoking status; alcohol status; ECOG performance status; source of referral
- **MDT details:** unit type (tertiary referral or district general); frequency of MDT; platform; same-day clinic; specialties present; allied healthcare professionals
- **Cancer pathway dates:** date of referral; date of first specialist clinic; date of biopsy; date of MDT outcome; date patient was informed of diagnosis; date treatment commenced; FDS
- **Diagnostic biopsies:** date of biopsy(s); subsite(s); anaesthesia; location (clinic or operating theatre)
- **Imaging for diagnosis**: modality, body site
- **Diagnosis:** subsite; clinical T stage; clinical N stage; clinical M stage; TNM 8; new or recurrence; p16 and HPV status; EBV status; PDL-1 status; presence of clinical ENE; presence of synchronous head and neck tumour
- **Presence of synchronous HNSCC:** subsite; clinical T stage; TNM 8; new or recurrence; p16 and HPV status; EBV status; PDL-1 status
- **Treatment:** modality of treatment (including surgical and/or oncological technique, timings or doses); treatment intent
- **Recurrence:** recurrent or residual disease; nature of recurrence (local, regional or distant); timing of recurrence after completion of treatment; treatment of recurrence
- **Surveillance:** timing of post-treatment surveillance imaging; modality
- **Follow-up:** time to last follow-up and/or death; cause of death

### *8.6.1 Classification of residual and recurrent disease*

The following time frames will be used to classify tumours treated after management of the primary disease:

- <12 months: Residual disease
- ≥12 months, <5 years: Recurrent disease
- <5 years >3cm from primary: New primary disease, separate site
- ≥5 years New primary disease

## 8.7 Data collection

Anonymised data will be locally entered into the Excel Data Tool spreadsheet in accordance with local governance guidelines. This uses restricted data fields and data validation to improve data completeness and homogeneity. The PMT will securely and confidentially combine datasets from each centre for the pooled analysis.

Additionally, each site lead will be requested to complete the 'Head and Neck MDT Snapshot Survey' that assesses the participating unit's Head and Neck MDT workforce and resource availability.

## 8.8 Anticipated numbers/workload

| **Activity** | **Cohort** | **Anticipated numbers for mid-large MDT discussing 10-20 patients / week and diagnosing 200 SCC /yr** |
|---|---|---|
| Initial identification | Patients discussed at MDT | - up to 200 / 3-month period / unit |
| Eligibility criteria | New or recurrent histologically confirmed HNSCC | - up to 50 / 3-month period / unit |
| Data collection | Documented MDT outcome between 1st September, 2021 and 30th November, 2021 | - up to 50 / 3-month period / unit |
| | 2 years of follow-up date available | - up to 50 / 3-month period / unit |

# 9 Data Management

## 9.1 Data collection tools and source document identification

### *9.1.1 Source documents*

Source documents will vary by participating site. An Excel Data Tool will be used to collate study data. No new data will be generated for the patient record as a result of this study.

### *9.1.2 Excel Data Tool*

Data will be read from source documentation (e.g. Electronic Patient Record) and entered onto a standardised Excel Data Tool, supplied to the participating sites by the PMT. This tool has restricted data fields and data validation to improve data completeness and homogeneity. The completed Excel Data Tool allows data to be anonymised prior to secure submission to the PMT. The tool will be available to download from the project website.

### *9.1.3 Missing data*

The PMT will check the submitted data for completeness and integrity. If necessary, the PMT will give feedback to the local team where any data fields are inadequate. The submitting team will be asked to provide the missing data where possible. If data is not available, the data point will be treated as null, and that record will be excluded from any subsequent relevant analysis where necessary.

## 9.2 Data handling and record keeping

The anonymised Excel Data Tools will be submitted by each centre and received by the PMT. The anonymised data from each local Excel Data Tool will be combined into a master national Excel Data Tool, with each update saved as a separate version and old versions retained.

Anonymised data may be made available to applicants who submit a project proposal to the project PMT, and which subsequently receives approval from: the PMT, and the INTEGRATE committee.

# 10 Statistics and data analysis

This study is an audit of current practice which will be judged against pre-specified standards derived from relevant published guidelines:

- British Association of Head and Neck Oncologists (BAHNO) standards, 2020 (15)
- 'Streamlining NHS Multidisciplinary Team Meetings: Guidance for Cancer Alliances', NHS England and NHS Improvement 2020 (16)
- 'NHS Cancer Programme: Faster Diagnosis Framework', NHS England and NHS Improvement from 2022, although first published in 2019 (17)
- Head and Neck Cancer: United Kingdom National Multidisciplinary Guidelines, BAHNO 2016 (18)

## 10.1 Sample size

The final sample size will be dependent on the number of centres submitting data and so there is no a priori estimation.

## 10.2 Pooled analysis

All cases will be entered into a pooled analysis. No individual centre will be identifiable from the analysis.

## 10.3 Sub-group analysis

Sub-group analysis may include, but not be limited to:

- Patients with primary and recurrent HNSCCs, respectively
- Patients with HPV-positive and negative oropharyngeal tumours, respectively, confirmed via p16 immunocytochemistry or fluorescent in-situ hybridisation
- Patients with a histologically confirmed primary HNSCC with an N3 neck nodal staging
- Patients with a histologically confirmed primary or recurrent HNSCC and an additional synchronous primary or recurrent HNSCC
- Patients with a histologically confirmed primary HNSCC who had diagnostic biopsy performed under local anaesthetic in the outpatient clinic

## 10.4 Analysis exclusion criteria

Patients for whom 2-year follow-up data is unavailable will not be included in the subsequent 2-year follow-up analysis.

## 10.5 Statistical analysis

Patient demographic data will be presented with mean and SD for continuous variables and counts and proportions for categorical variables. Categorical data will be analysed with the Chi-square or Fisher's Exact test as appropriate. Quantitative continuous variables will be analysed using descriptive statistics such as

mean, standard deviation, median, quartiles, minimum/maximum and range. Continuous variables will be assessed with Student's t-test, Mann-Whitney U test, Kruskal-Wallisor the Wilcoxon test as appropriate.

Survival curves will be produced using the Kaplan-Meier method. Sensitivity analyses will be undertaken. Comparison of survival outcomes for sub-groups will be performed using the log rank test and Cox Proportional Hazard model.

# 11 Ethical considerations

This audit will report on the outcomes of investigative management that has already taken place. There will be no effect on the management of patients as a result of inclusion in the study. All data will be anonymised, and no patients will be identifiable in any subsequent reports, presentations or publications. As such, consent from individual patients will not be required.

This project has been determined to be an audit using the HRA decision tool available at http://www.hra-decisiontools.org.uk/research/ (Appendix 1). The output from this process is available in the Appendix. This should be discussed locally for study participation approval on request.

Local centres are asked to register the audit with their audit department and/or Caldicott guardian, in keeping with local protocol.

# 12 Authorship policy

## 12.1 Criteria for inclusion as a PubMed citable collaborator

Authorship will be in line with INTEGRATE policy on multi-centre collaborative projects. Each Centre will have a named Consultant Lead and a Trainee Lead; They will be eligible for collaborative co-authorship of publications that result from the project.

## 12.2 Acknowledgements

All individuals contributing to data collection will be acknowledged in any subsequent presentations and publications.

# 13 Funding

The PMT has received no financial support for the research, authorship, and/or publication of this project.

# 14 References


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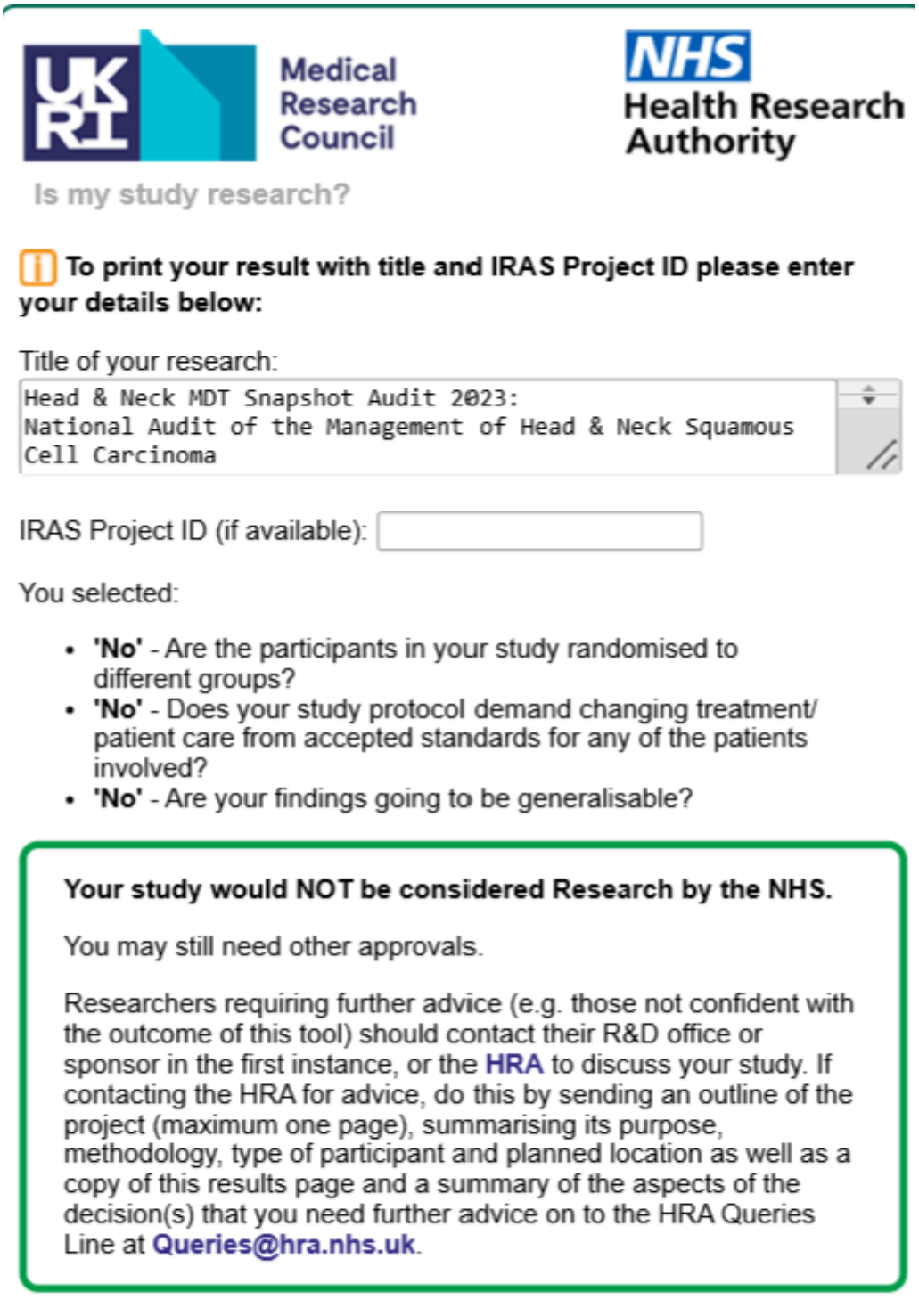
# 15 Appendix



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Title of your research:

Head & Neck MDT Snapshot Audit 2023:
National Audit of the Management of Head & Neck Squamous Cell Carcinoma

IRAS Project ID (if available):

You selected:

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- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

**Your study would NOT be considered Research by the NHS.**

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at Queries@hra.nhs.uk.

For more information please visit the Defining Research table.

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