The National Prospective Head and Neck Robotic Surgery Audit

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Funding	None
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1 Version History

Protocol Version	Date	Notes
0.1	25/05/2024	First draft for review by the project management team
0.2	21/06/2024	Second draft for review by the project management team, with changes made to background, study design/setting, data management and appendices
0.3	20/07/2024	Third draft for review by the project management team following further changes as suggested by consultant supervisors
1.0	09/08/2024	Protocol prepared with final dataset in appendix 1 for distribution to national collaborators

2 Table of Acronyms

Acronym	Meaning
CT	Computed Tomography
ERAS	Enhanced Recovery After Surgery
FNA	Fine Needle Aspiration
FNE	Flexible Nasendoscopy
HPV	Human Papillomavirus
MDT	Multidisciplinary Team
MRI	Magnetic Resonance Imaging
NGT	Nasogastric Tube
OPSCC	Oropharyngeal Squamous Cell Carcinoma
PEG Tube	Percutaneous Endoscopic Gastrostomy Tube
PMT	Project Management Team
PRN	Pro Re Nata (as required)
SCC	Squamous Cell Carcinoma
TORS	Transoral Robotic Surgery
TXA	Tranexamic Acid
UAT	Upper Aerodigestive Tract
USS	Ultrasound Scan
VTE	Venous Thromboprophylaxis

3 Project Summary

Study Title	The National Head and Neck robotic surgery Audit
Short Title	TORS Audit
Study Leads	INTEGRATE Head and Neck Subspecialty Committee
Study Design	Multi-Centre Prospective National Audit
Study Participants	Patients > 18 years old undergoing Head and Neck robotic surgery in the UK
Planned Sample Size	No a priori calculation
Follow up Duration	30 days
Planned Study Period	6th January 2025 to 7th July 2025 (6 months)
Aim	To assess the current real-world perioperative management of patients undergoing Head and Neck robotic surgery in the UK
Primary Objectives	To describe variations in the standard of perioperative care of Head and Neck robotic surgery patients throughout the UK
Secondary Objectives	Describe variations in selection of post-operative analgesic agents Describe rates of 30-day postoperative haemorrhage and major haemorrhage (necessitating return to the operating theatre) Describe variations in methods used to prevent postoperative haemorrhage Describe rate of perioperative tracheostomy use Describe rate of perioperative NG/feeding tubes use Describe 30-day readmission, complication, and mortality rates Describe the scope and range of indications for Head and Neck robotic surgery within the UK
Methods	Identification of patients undergoing Head and Neck robotic surgery within the study period in the UK Central submission of anonymised cases for pooled analysis

4 Background

Over the past two decades, robotics have transformed the field of surgery and become the gold standard in many gynaecological, urological and general surgical procedures (1). In otorhinolaryngology, the primary application of robotics has been in transoral robotic surgery (TORS). This was first developed in the early 2000s by O'Malley and Weinstein, who first described its use in performing laryngeal surgery in animal models and mannequins (2–5). Since then, the technique has been employed in various head and neck pathologies, including resection of primary and recurrent head and neck cancers, particularly oropharyngeal SCC (OPSCC), as part of the diagnostic pathway for head and neck SCC from an unknown primary, to facilitate minimally invasive thyroidectomy, and in the management of obstructive sleep apnoea (1,6–8).

Compared to endoscopic and open surgical techniques for operating in the upper aerodigestive tract, Head and Neck robotic surgery has the advantage of superior 3D visualisation of the operative field, greater degrees of movement and the ability to preserve anatomical structures without significant morbidity (9,10). Such advantages make this technique appealing in the management of upper aerodigestive tract SCCs, in which there has been growing interest in the use of Head and Neck robotic surgery as both a therapeutic and de-escalation treatment, allowing potential avoidance of adjuvant chemoradiotherapy (11).

Despite the minimally invasive nature of Head and Neck robotic surgery, oropharyngeal resection can result in significant postoperative pain comparable to that following bilateral tonsillectomy in adult patients (9,12,13). Available studies suggest that this pain typically peaks in the postoperative period and resolves within 6-12 months following the operation; it is also speculated that adjuvant chemoradiotherapy has an additive effect in worsening the post-operative pain (13). Unfortunately, the literature on postoperative analgesic regimes in Head and Neck robotic surgery patients is limited due to the heterogeneity of study design, measures of pain and a lack of randomised controlled trials (11,13). Currently, a multi-modal analgesic regimen involving regular paracetamol, ibuprofen, and gabapentin is popular with studies reporting improved pain control and reduced opioid usage (14,15). However, efficacy is not universally reported with multi-modal analgesia and caution is advised due to the association of gabapentin with sedative and addictive side effects (16).

An important complication of TORS is post-operative bleeding, which has been reported to occur at a rate of 5.78% for primary and 12% in salvage cases (17–22). For this reason, tranexamic acid is often given post-operatively and pharmacological venous thromboprophylaxis is not widely used (9,23,24). Ligation of external carotid artery branches is also recommended, with a meta-analysis of 619 patients finding that the risk of major and severe bleeding was significantly reduced (RR 0.28) following prophylactic ligation (21,25,26). Conversely, some authors have noted that arterial ligation may only decrease the severity, not the frequency of bleeding (24).

Overall, there has been little research on developing a perioperative management regime to mitigate the risks of Head and Neck robotic surgery and consolidate the research on existing individual practices (15). In other surgical specialities, there has been an increasing adoption of the Enhanced Recovery After Surgery (ERAS) programme (15,27). ERAS encompasses a series of perioperative measures to accelerate recovery following an operation, such as preoperative

carbohydrate drinks, prophylactic antiemetics/analgesia, and early mobilisation (27). For Head and Neck robotic surgery, the use of an ERAS or standardised peri-operative programme has been described by some institutions (9,15,23). For example, Ganti et al conducted a retrospective chart review comparing Head and Neck robotic surgery patients managed with an ERAS and traditional peri-operative regime (15). From this comparison, the authors reported improved pain scores and reduced postoperative opioid usage. However, using an ERAS programme for Head and Neck robotic surgery patients is not widely reported, with a survey of 49 American H&N fellows revealing 46% used a standardised peri-operative programme managing Head and Neck robotic surgery patients (28).

In addition, other areas of variation in practice include the placement of perioperative tracheostomy tubes. Some authors report regular tracheostomy placement to help protect the airway from post-operative swelling and bleeding whilst other units report their use on an as-needed basis (9,29,30). A survey of French surgical teams found that common factors that led to the placement of prophylactic tracheostomies included previous radiotherapy with residual oedema, concurrent antiplatelet/anticoagulation medication and tumour size/location (31).

Similarly, nasogastric tube placement does not appear to be routine and is only required in high-risk patients, such as cases with large tumours, bilateral resections, or salvage surgery (32–34).

The aim of this prospective, multi-centre audit will be to evaluate the perioperative management of patients undergoing Head and Neck robotic surgery throughout the United Kingdom.

5 Aims and Objectives

5.1 Aims

To assess the current real-world perioperative management of patients undergoing Head and Neck robotic surgery in the UK.

5.2 Primary Objectives

To describe variations in the standard of perioperative care of Head and Neck robotic surgery patients throughout the UK.

5.3 Secondary Objectives

1. Describe variations in selection of post-operative analgesic agents.
2. Describe rates of 30-day postoperative haemorrhage and major haemorrhage (necessitating return to the operating theatre).
3. Describe variations in methods used to prevent postoperative haemorrhage.
4. Describe rate of perioperative tracheostomy use.
5. Describe rate of perioperative NG/feeding tubes use.
6. Describe 30-day readmission, complication, and mortality rates.
7. Describe the scope and range of indications of Head and Neck robotic surgery within the UK.

6 Study Design and Setting

6.1 Study Design

Prospective, multicentre observational audit of practice.

6.2 Study Setting

UK head and neck cancer centres performing Head and Neck robotic surgery.

7 Patient Eligibility Criteria

7.1 Inclusion Criteria

1. 18 years and older
2. Undergoing Head and Neck robotic surgery for any benign or malignant indication between 6th January 2025 to 7th July 2025.

7.2 Exclusion Criteria

1. Patients under 18 years old

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 identifiable patient information will be collected by the PMT and data analysis will not identify hospitals or patients individually. As such, the anticipated risks to 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 prospectively identify all consecutive patients undergoing Head and Neck robotic surgery during the study period who meet the inclusion criteria. Local investigators are recommended to acquire their patients via the operating theatre schedule or through reviewing MDT lists.

When necessary, the PMT will be able to provide further guidance to local investigators on request: torsaudit@entintegrate.co.uk.

The clinic notes and investigation results for these patients will be reviewed by the local team and full eligibility criteria applied. All eligible patients will be recorded using the Alea data entry system hosted by University of Southampton. All screened patients and reasons for exclusions will be recorded.

8.3 Sampling Time Frame (Start/End date)

Start Date: 6th January 2025 7th July 2025

End Date: 7th July 2025

Submission Deadline – 4th August 2025

*Final submission of data will be at the discretion of the PMT, with scope to extend in order to promote data completeness

8.4 Consent

This audit will report on the treatment patients will receive and outcomes of management. 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 Alea Data Tool. This tool will collect data in the following areas and is detailed in appendix 1:

- Patient Demographics - Details regarding the patient's background and comorbidities, e.g. Age, Gender, BMI, Smoking History, Alcohol History, ECOG status, pre-operative analgesia use, Charlson comorbidity index (or similar)
- Tumours details (if applicable) - e.g. subsite, HPV/p16 status, TNM staging, reconstruction, neck dissection
- Operative details - Information regarding the procedure performed e.g. Indication, Grade of operative surgeon, Pre-operative analgesia given, Type of Procedure performed, Arterial Ligation (including artery ligated), use of a tongue suture, Use of intraoperative haemostatic agents, Tracheostomy Insertion, and NGT or gastrostomy insertion
- Post-operative care - Details regarding the care patient received, e.g. Type of analgesia prescribed, TXA use, Steroid Use, Length of stay, Use of Antibiotics , post-operative day of first oral intake, post-operative day of cessation of NG or gastrostomy feeding
- Complications - e.g. Postoperative bleeding, return to theatre, readmission rates, mortality rates, other complications

8.6.1 Severity of postoperative haemorrhage

The following definitions will be used to classify the severity of postoperative haemorrhage as detailed by Pollei et al (2013) (35)

Classification	Description
Normal	Blood-tinged mucus, flecks of blood, red streaks, brown mucus
Minor	Bright red blood or blood clots, resolving without intervention
Intermediate	Diffuse venous or small arterial bleeding, requiring theatre Managed with monopolar or bipolar cautery
Major	Brisk or copious bleeding, requiring theatre Managed with vessel ligation or interventional radiology
Severe	Bleeding causing life threatening complications, e.g., airway obstruction

	leading to tracheostomy, cardiac arrest, haemodynamic instability

8.7 Data Collection

Anonymised data will be locally entered into the Alea data tool 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.

9 Data Management

9.1 Data collection tools and source document identification

9.11 Source documents

Source documents will vary by participating site. A bespoke data tool will be used to collate study data. No new data will be generated as a result of this study.

9.12 Alea Data Tool

Data will be read from source documentation (e.g. Electronic Patient Record) and entered directly onto a bespoke Alea data entry system. This is an online password protected database, of which personal login details and passwords will be supplied to the participating sites by the PMT.

This tool has restricted data fields and data validation to improve completeness and homogeneity. Data entered will be anonymised and no personal identifiable information will be stored.

9.13 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 required to keep a local log of patients and study level-ID should they be asked to clarify or provide missing data points. If data is not available, it 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

Data tools will be completed with information entered directly from source data by each centre and received by the Project Management Team. Local centres login details will be used for data entry and review of local records only. Only members of the INTEGRATE project management team will be able to view the amalgamated dataset for the purposes of data cleaning and review.

10 Statistics and Data Analysis

10.1 Sample Size

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

10.2 Pooled Analysis

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

10.3 Sub-group Analysis

This may include, but not be limited to the following

- Indication for Head and Neck robotic surgery
- Tumour subsite
- Patients who have postoperative haemorrhage
- Patients who require an unplanned tracheostomy formation
- Patients who require an unplanned NGT or gastrostomy insertion
- Patients who are readmitted within 30 days of the procedure
- Mortality within 30 days of the procedure

10.4 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 the Wilcoxon rank-sum test.

Complication rates will be expressed as percentages and relative risks calculated as a ratio of the complication rate. Multilevel multiple logistic regression will be used to adjust for potential confounding factors (such as age, sex and grade of operating surgeon) for data that conforms to normality testing. P-values of <0.05 will be considered significant.

11 Ethical Considerations

This audit will report on the outcomes of management that is already scheduled to take 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 2). 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.

The audit has been adapted from a pre-existing Head and Neck robotic surgery database hosted by University Hospitals Dorset NHS foundation trust and University of Southampton which has previously received regulatory approval from the UK Health research authority.

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, Trainee Lead and up to two local collaborators. All will be eligible for collaborative co-authorship of publications that result from the project. A minimum of 5 patients is required for a centre to be entitled to authorship. Citable pubmed authorship will be granted to the project management team consisting of the INTEGRATE head and neck committee members and supervising consultants.

12.2 Acknowledgements

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

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15 Appendix

Appendix 1

Patient characteristics	Gender assigned at birth	Male, Female, Not documented
	Age at TORS procedure	<Free number text>
	Alcohol consumption status	None, <14 units/ week, >14 units/ week, Not documented
	Smoking status	Current smoker, Ex-smoker, Non-smoker, Not documented
	ECOG Performance Status	0, 1, 2, 3, 4, Not documented
	MUST score	0, 1, ≥2, Not documented
	Charlson Comorbidity index	0, 1, 2, 3, 4, ≥5, Not documented
	Indication for TORS	Oropharyngeal cancer, Laryngeal cancer, Hypopharyngeal cancer, Unknown Primary cancer, Other UAT Malignancy, Parapharyngeal Space tumours, Retropharyngeal Node Dissection, Obstructive sleep apnoea, Thyroid lesion, Parathyroid lesion, Other, Not documented
	If other, please specify	<Free text>
	Pre-operative PSS HN Normalcy of Diet Score	100 (Full diet no restrictions), 90 (Full diet liquid assist), 80 (All meat), 70 (Raw carrots, celery), 60 (Dry bread and crackers), 50 (Soft chewable foods), 40 (Soft foods requiring no chewing), 30 (Pureed foods), 20 (Warm liquids), 10 (Cold liquids), 0 (Non-oral feeding e.g. NG), Not documented
Tumour Characteristics (If indication for TORS= Cancer)	Tumour subsite	Oropharynx: Tonsil, Tongue base, Glossotonsillar sulcus, Posterolateral oropharyngeal wall
		Oral Cavity- lip, alveolus, hard palate, oral tongue, floor of the mouth, retromolar trigone, buccal mucosa

		Larynx- supraglottis, glottis, subglottis
		Hypopharynx- piriform fossa, hypopharyngeal wall, postcricoid region
		Other
		Not documented
	Tumour Presentation	Primary, Recurrent Residual disease (<6 months), Recurrent disease (>6 months, <5 years), New primary disease (>5 years), New primary disease (<5 years, >1cm from original subsite), Not documented
	Tumour Histology	Squamous Cell Carcinoma, Other, Not documented
	If other, please specify	<Free text>
	P16 status (Oropharyngeal and unknown primary SCC only)	Positive, Negative, Not documented
	HPV status (Oropharyngeal and unknown primary SCC only)	Positive, Negative, Not documented
	cT (TNM8)	cTx, cT0, cT1, cT1a, cT1b, cT2, cT3, cT4, Not documented
	cN (HPV positive) (TNM8)	cNx, cN0, cN1, cN2, cN3, Not documented, Not applicable
	cN (all other) (TNM8)	cNx, cN0, cN1, cN2a, cN2b, cN2c, cN3a, cN3b, Not documented, Not applicable
	pT (TNM8)	Tx, T0, T1, T2, T3, T4, Not documented
	pN (HPV positive) (TNM8)	pNx, pN0, pN1, pN2, Not documented, Not applicable
	pN (all other) (TNM8)	pNx, pN0, pN1, pN2a, pN2b, pN2c, pN3a, pN3b, Not documented, Not applicable
	M (TNM8)	M0, M1, Not documented
	Radiotherapy treatment	Adjuvant, None, Not documented
	Chemotherapy treatment	Adjuvant, None, Not documented

	Other treatment	Yes, No, Not documented
	If yes please specify	<Free text>
Surgical characteristics	Date of TORS	dd/mm/yyyy
	Date of discharge	dd/mm/yyyy
	Grade of operating surgeon	Consultant, Non-training / associate specialist, Specialist registrar, Other, Not documented
	Laterality of surgical procedure	Unilateral, Bilateral, Not documented
	Index surgical procedure (can select more than one)	Tonsillectomy, Tongue base mucosectomy (Unknown primary), Benign Tongue base resection (e.g. OSA), Robotic Oropharyngectomy, Robotic laryngeal resection, Robotic hypopharyngeal resection, Robotic oral resection, Robotic nasopharyngeal resection, Robotic thyroidectomy, Robotic parathyroidectomy, Other, Not documented
	Please specify surgical procedure	<Free text>
	Soft Tissue Reconstruction	None, Local tissue transfer, Free tissue transfer, Split thickness skin graft, Other, Not documented
	Haemostatic agents	Yes, No, Not documented
	If yes please specify	<Free text>
	Artery Ligation	None, Lingual artery, Facial artery, Ascending Pharyngeal artery, Other, Not documented
	If other, please specify vessel	<Free text>
	Tracheostomy insertion	Yes - preplanned, Yes - unplanned, No, Not documented
	Date of tracheostomy insertion (if relevant)	dd/mm/yyyy
	Date of tracheostomy removal (if relevant)	dd/mm/yyyy

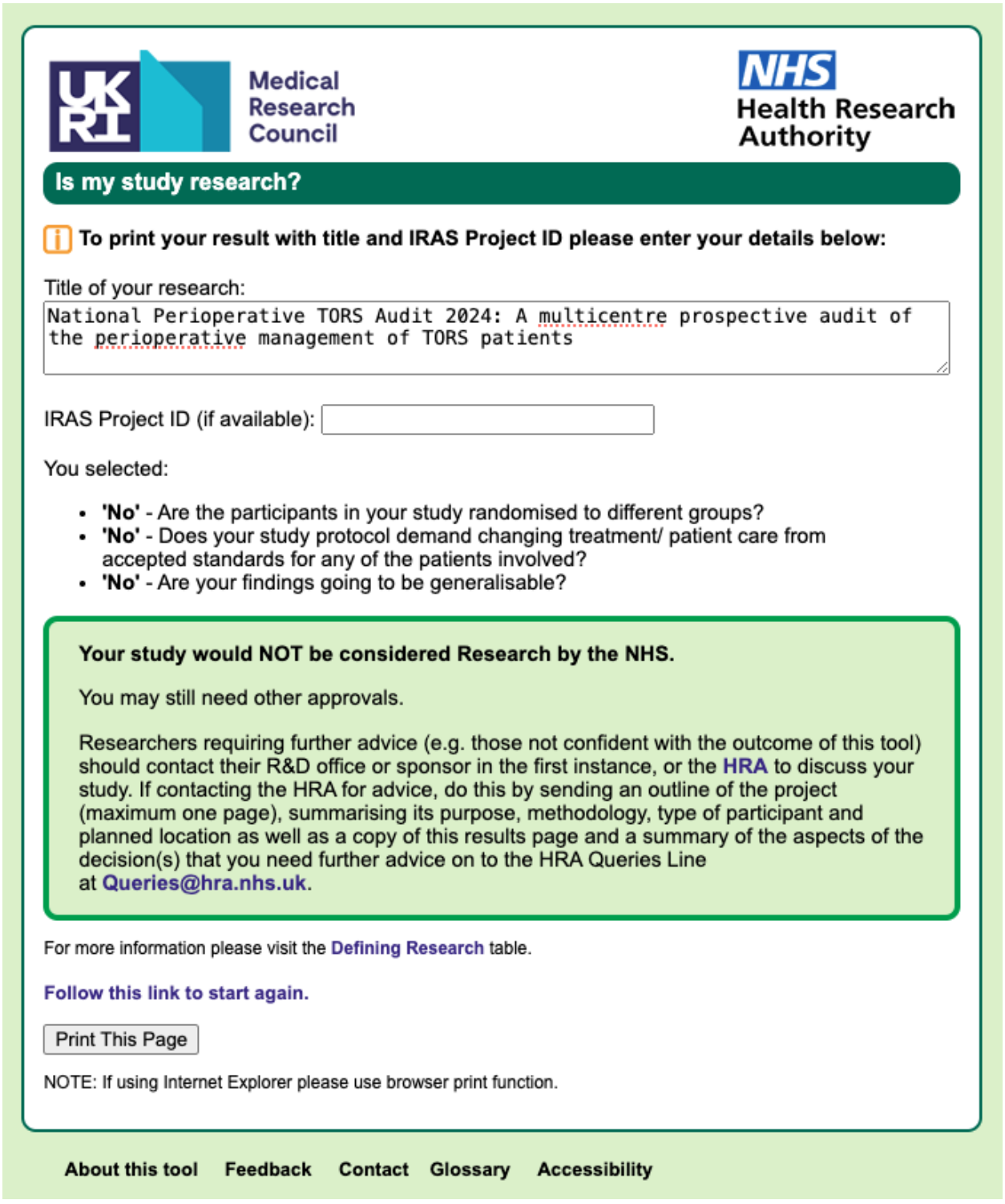
	Feeding tube insertion	NG - preplanned, NG - unplanned, Gastrostomy, No, Not documented
	Date of tracheostomy insertion (if relevant)	dd/mm/yyyy
	Date of tracheostomy removal (if relevant)	dd/mm/yyyy
Post-operative medications	Steroids	Yes, No, Not documented
	If yes, steroid type	Dexamethasone, Prednisolone, Methylprednisolone, Other, Not documented
	If yes, steroid dose (mg)	<Free text>
	If yes, steroid duration (days)	<Free text>
	Tranexamic acid	Yes, No, Not documented
	If yes, Tranexamic acid dose (mg)	<Free text>
	If yes, Tranexamic acid duration (days)	<Free text>
	Paracetamol	Yes, No, Not documented
	If yes, Paracetamol dose (mg)	<Free text>
	If yes, Paracetamol duration (days)	<Free text>
	Ibuprofen	Yes, No, Not documented
	If yes, Ibuprofen dose (mg)	<Free text>
	If yes, Ibuprofen duration (days)	<Free text>
	Co-codamol	Yes, No, Not documented
	If yes, Co-codamol dose (mg)	<Free text>
	If yes, Co-codamol duration (days)	<Free text>
	Oral morphine	Yes, No, Not documented

	If yes, Oral morphine dose (mg)	<Free text>
	If yes, Oral morphine duration (days)	<Free text>
	Gabapentin	Yes, No, Not documented
	If yes, Gabapentin dose (mg)	<Free text>
	If yes, Gabapentin duration (days)	<Free text>
	Other Analgesia	Yes, No, Not documented
	If yes please stage type, dose and duration	<Free text>
	Antibiotics	Yes, No, Not documented
	If yes, Antibiotic type	Co-amoxiclav, Penicillin, Clarithromycin, Clindamycin, Ceftriaxone, Cefotaxime, Levofloxacin, Ciprofloxacin, Metronidazole, Other, Not documented
	If yes, Antibiotic dose (mg)	<Free text>
	If yes, Antibiotic duration (days)	<Free text>
Complications	Complication? (for bleeding see “Post-operative Haemorrhage”)	Yes, No, Not documented
	Date of complication	dd/mm/yyyy
	Type of complication (for bleeding see “Post-operative Haemorrhage”)	Salivary fistula, Neck collection/ abscess, flap compromise/ failure, Respiratory tract infection, Venous thromboembolism, Haematoma, Wound dehiscence, Wound infection, Chyle leak, Airway oedema, Other, Not documented
	Clavien Dindo classification	I, II, IIIa, IIIb, IVa, IVb, V, Not documented
	Return to the operating theatre?	Yes, No, Not documented
	If yes, indication for Return to theatre	Emergency Tracheostomy, Salivary fistula repair, Abscess drainage, Flap revision, New or replacement flap, Evacuation of haematoma, Wound

		revision/ debridement, Chyle leak repair, Other, Not documented
	If Other, please specify	<Free text>
Post-operative Haemorrhage	Post-operative haemorrhage?	Yes, No, Not documented
	If yes, date of haemorrhage	dd/mm/yyyy
	If yes, grade of postoperative haemorrhage	Minor, Intermediate, Major, Severe, Not documented
	If yes, treatment of haemorrhage	Conservative and medical management only, Transoral surgery, Vessel embolisation, Vessel ligation, Other, Not documented
	If yes, was iron supplementation required	Yes, No, Not documented
	If yes, was blood transfusion required	Yes, No, Not documented
30-day Readmission rate	30 day postoperative readmission	Yes, No, Not documented
	Date of readmission	dd/mm/yyyy
	Date of discharge from readmission	dd/mm/yyyy
	Reason for readmission	Pain, Postoperative Bleeding, Salivary fistula, Neck collection/ abscess, flap compromise/ failure, Respiratory tract infection, Venous thromboembolism, Haematoma, Wound dehiscence, Wound infection, Chyle leak, Airway oedema, Other, Not documented
	If other please specify	<Free text>
Follow-up status	Date of last follow up	dd/mm/yyyy
	Status at 30 day follow-up	Alive without disease, Alive with disease, Died of Head and Neck Cancer, Died of Other Causes, Cause of death, Other, Not documented
	Cause of death (if relevant)	<Free text>

	Feeding tube status at 30 days	No feeding tube, NGT feeding, PEG feeding, Not documented
	Tracheostomy status at 30 days	Tracheostomy, No Tracheostomy, Not documented
	PSS HN Normalcy of Diet Score at 30 days	100 (Full diet no restrictions), 90 (Full diet liquid assist), 80 (All meat), 70 (Raw carrots, celery), 60 (Dry bread and crackers), 50 (Soft chewable foods), 40 (Soft foods requiring no chewing), 30 (Pureed foods), 20 (Warm liquids), 10 (Cold liquids), 0 (Non-oral feeding e.g. NG), Not documented

Appendix 2



Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

National Perioperative TORS Audit 2024: A multicentre prospective audit of the perioperative management of TORS patients

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'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.

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