

The TYPHOON Study
**TONSILLECTOMY POSTOPERATIVE HAEMORRHAGE OUTCOMES
AND OBSERVATIONS NATIONAL COHORT STUDY**

Research and Development Department Letter

To whom it may concern,

We are requesting approval from the Research and Development Department of this Trust for the above study.

TYPHOON is an exploratory, national, prospective, multicentre collaborative cohort study of all consecutive adult patients undergoing tonsillectomy over a two-month period between 1st of August 2025 to 31st of July 2026. The study received ethics approval from IRAS on 10th of January 2025.

Study Background

Tonsillectomy is one of the most commonly performed surgical procedures in Ear, Nose, Throat (ENT) surgery with an estimated 28 000 procedures carried out in the UK in 2019/20. Historical data from the UK National Prospective Tonsillectomy Audit in 2005 suggested a post-tonsillectomy bleed (PTB) rate of 4.9% in adults, which has since been widely quoted to patients in the consent taking process. However, data collection for this audit concluded over 20 years ago, and recent unpublished data from Hospital Episode Statistics (HES) indicates a significant increase in the PTB rate to 15.6% over the period 2022-2023, the reasons for which are currently unclear and need to be urgently addressed.

Research Aim

The aim of this study is to better understand the risk factors associated with an increased risk of PTB and how we can change our practice to reduce this risk for patients.

Receiving Organisation

The study will be run by INTEGRATE, the UK ENT Trainee Collaborative Network (<https://entintegrate.co.uk/>). INTEGRATE aims to support trainee engagement in ENT research and audit through participation in large-scale meaningful research projects.

INTEGRATE has already delivered multiple national audits that have had a significant impact on current practice including the ENT UK Suspected Head & Neck Cancer Remote Triage Service Evaluation 2020 (10.1002/cncr.33800) and National Epistaxis Audit 2016 (10.1017/S002221511700202X). Sites will be recruited through the INTEGRATE platform via a dedicated mailing list to ENT trainees.

Data Collection

Collection of data will be recorded onto a password protected Excel spreadsheet tool. The completed Excel Data Tool allows data to be anonymised prior to secure submission to the Project Management Team (PMT) at ENT INTEGRATE. No identifiable patient information will be submitted to PMT.

All consecutive adult patients undergoing bilateral tonsillectomy in a two-month period between 1st of August 2025 to 31st of July 2026 will be included in the study. Eligible patients will be identified via the local theatre schedule and informatics department. Following informed consent, patients will be expected to fill in a questionnaire on how their sore throat is impacting their quality of life (TOI 14 – Tonsillectomy Outcome Inventory). We will collect granular data on patient characteristics, previous episodes of sore throat, surgical and anaesthetic characteristics and post-operative management including analgesia. We will also telephone the patient at 28 days following surgery to determine if they have had any episodes of bleeding and how this was managed.

Local sites will only be able to access their own data for the purposes of data entry and review, with only members of the PMT having access to the entire data set for the purpose of review and analysis. No patients will be identifiable in subsequent reports, presentations or publications. The only change to existing patient pathway, is the telephone phone call at 28 days following surgery, to determine if they have had any episodes of bleeding not captured on review of their patient records.

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. There will be no impact on

the management of patients following inclusion in the study. At the end of the archiving period, data will be deleted from shared server space and all backups will be overwritten or destroyed in line with NHS approved information destruction/deletion standards. Files will be securely deleted from computer systems (including any copies held on backup or archive media).

All members of the PMT at ENT INTEGRATE are employed by the NHS will have completed Information Governance training in accordance with their own Trusts requirements. The PMT does not receive any financial incentive for running this audit. Members of the PMT are aware of their obligations and legal requirements regarding personal confidential data. It is a condition of employment that all employees abide by their organisation's Data Protection Policy and confidentiality clause within their contract of employment.

Study Importance

This project would represent the first cohort study run by INTEGRATE, and has assurances of support from ENT UK, the British Otorhinolaryngology and Allied Sciences Research Society (BOARS) and the Royal College of England research surgical specialty lead. Our study is exploratory and we hope it will provide the basis for a larger study over a larger time frame in the future.

This trainee-led, voluntary study aims to empower ENT trainees with valuable research experience. Recognizing the crucial role of research skills in our training program and the limited opportunities for early-career involvement in large-scale projects, we have designed this study to be both accessible and impactful. We have streamlined the data collection process to minimize time commitment and disruptions to service activities. Importantly, active participation in collaborative research is now a recognized criterion for ST3 specialty applications, making this study an invaluable opportunity for professional development.

You can read more about ENT INTEGRATE here: <https://entintegrate.co.uk/>

If you require any further information, please contact the TYPHOON study team at: typhoonstudy@entintegrate.co.uk

Yours sincerely,

ENT INTEGRATE Head and Neck Committee