2 WEEK WAIT TELEPHONE TRIAGE: SERVICE EVALUATION

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1 VERSION HISTORY

Protocol version no.	Date	Version
0.1	24/03/2020	First draft
1.0	30/03/2020	Project management team approval
1.1	07/04/2020	Incorporating investigations into objectives

2 TABLE OF ACRONYMS

Acronym	Meaning
COVID-19	**CO**rona **VI**rus **D**isease 20**19**
eCRF	Electronic case report form
H&N	Head and neck
HaNC-RC - v2	Head and neck cancer risk calculator - version 2
HRA	Human Research Authority
MRN	Medical record number

3 RATIONALE AND BACKGROUND INFORMATION

The NHS guidance for managing cancer referrals during COVID-19 pandemic recommend a telephone triage to minimise interactions and appointments with health services and stream patients for investigations where appropriate.[1] Additionally, a telephone appointment with a specialist clinician is accepted as a first appointment for the purposes of recording cancer waiting times. Head and neck cancer referrals pose an additional challenge with most patients needing endoscopic assessment with full scale PPE, as recommended by ENTUK.[2]

Most ENT UK members will be aware of the head and neck cancer risk calculator that has been generated and iteratively validated using data from over 10,000 patients across the UK.[3–5] The calculator uses patient demographics, tobacco and alcohol use, alongside 12 symptoms, all of which can be elicited over the telephone, to provide a robust personalised probability of head and neck cancer.

ENT UK recommend this decision-making process be used and the data recorded appropriately to allow evaluation of this new service. Patients will be classified as low (<7%) or high (≥7%) probability for cancer. Using this probability of 7% as the recommended cut off, the model estimates that the chance of missing cancer in this population by a telephone consultation compared to a routine face to face consultation is 1.4%.[5] Low risk patients can have their appointment deferred until after the pandemic issues have settled or be discharged from the service. High risk patients may then be seen in an urgent face to face consultations.

The BAHNO National Audit of Head and Neck Cancer Surveillance completed in 2018 with data contributed from over 5,000 follow up appointments taking place in 89 centres across the UK.[6] Data from these consultations are currently undergoing peer review, but are made available to help guide follow up consultations in head and neck cancer cases following completion of treatment.

In both these scenarios, clinical judgement and patient preference are taken into consideration alongside any information provided by the decision aids.

This structured triaging system has been endorsed by ENTUK Head & Neck Society and the ENT UK executive. ENT UK have recommended the use of an Excel spreadsheet, produced alongside this recommendation, to allow data capture as part of local service evaluation. Patients should be followed up for at least 6 months after the telephone triage is performed, to determine the safety and effectiveness of using this process during these unprecedented times.

4 AIMS, OBJECTIVES AND OUTCOME MEASURES

4.1 Aim

To assess the effectiveness of telephone triage for prioritising new patients referred with suspected H&N cancer and patients under surveillance following previous treatment for H&N cancer.

4.2 Objectives

Primary objective

To report the rates of patients triaged to urgent appointments or investigations, deferred appointments and discharged from the service based on telephone assessment.

Secondary objectives

To report the rates of cancer at 6 months in those triaged to urgent appointments or investigations, deferred appointments and discharged from the service.

To report the rates of low and high risk new patients referred with suspected H&N cancer.

To report the rates of clinicians overriding the calculator outcome for new referrals.

To report the rates of patients overriding the advice of the clinician for new and follow up patients.

To report the rates of patients undergoing further investigation or follow up, subsequent to their urgent outpatient appointments.

5 PROJECT DESIGN AND SETTING

5.1 Project design

National service evaluation of telephone consultations to triage new patients referred with suspected H&N cancer and patients under surveillance following previous treatment for H&N cancer.

5.2 Project setting

UK secondary care ENT departments.

6 PARTICIPANT ELIGIBILITY

6.1 Inclusion criteria

- New patients referred with suspected H&N cancer.
- Follow up patients under surveillance following previous treatment for H&N cancer.

6.2 Exclusion criteria

- Patients seen in face to face clinic appointments a first contact.
- Patients specifically dissenting to the collection of anonymised data.

7 PROJECT PROCEDURES AND METHODOLOGY

7.1 Registration of project

This is an investigator-led, non-commercial, non-interventional project and is extremely low risk. This study does not collect any patient identifiable information (including dates) and data analysis will not identify hospitals individually.

- Identify a Consultant at your trust who will take responsibility for the project at your hospital. This person will be known as the 'lead consultant'.
- Identify one member of clinical staff who will be responsible for collating the data and submitting the anonymised data to the project management team. This person will be known as the 'site lead'. This may be the same person as the lead consultant.
- Identify clinical staff who will be performing telephone triage and inform them of the project and procedures.
- Register the project with your local Clinical Governance Department responsible for the conduct of local service evaluations. This may be done by the lead consultant and/or the site lead.
- Data collection can begin in anticipation of local approvals, but data cannot be submitted to the project management team until local approvals are in place.

Identification of patients

Patients will be identified from outpatient clinic lists at participating trusts.

All consecutive patients should be recorded from the time the trust commences data collection.

Consent

Patients will not be consented as part of this project as it constitutes a service evaluation and collects only anonymised data.

Service evaluation

'Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service.'[7]

This project is designed and conducted to judge current care. Patient care is not determined by following a set protocol, rather, decisions are made jointly by the clinician and the patient. There is no current standard for comparison, but the project aims to assess the quality of the current service. Centres from across the UK are invited to take part to assess the service offered to all new and follow up patients with suspected or previously treated H&N cancer. As such, the results are not produced to be generalisable to any other patient group. Please see appendix for outcome of the HRA decision tool regarding classification of research versus audit and service evaluation [appendix 1].

Anonymised data

No patient identifiable data will leave the hospital trust. The electronic case report form (eCRF) will collect a patient ID to allow tracking, prevent duplication on data amalgamation and allow follow up data to be collected. Prior to submission to the project management team, all patient identifiable data will be removed from the eCRF.

No dates are recorded.

No identifiable hospital level analysis will be conducted.

Follow up

In order to establish the appropriateness of the telephone triage service, the clinical team will contact the patient's GP at least 6 months following the triage, to record the presence of H&N or oesophageal cancer at any point since the triage was performed. No additional patient contacts will be required.

Dataset

Patients will be asked about their symptoms based on factors in the 'Head and neck cancer risk calculator (HaNC-RC) v2' [new and follow up patients] and from the proforma used in the BAHNO H&N cancer surveillance audit 2018 [follow up patients only].[5,6] Responses will be recorded in the electronic case report form (eCRF) [https://entintegrate.co.uk/entuk2wwtt]. Additionally, clinician override of the calculator outcome, patient preference and final outcome of the triage will be recorded. Subsequently, the outcome of the outpatient appointment will be recorded and the presence of cancer at 6 months.

Withdrawal criteria

Patients can choose to withhold their anonymised data at any time.

This investigator-led, non-commercial, non-interventional study is extremely low risk. This study does not collect any patient identifiable information (including dates) and data analysis will not identify hospitals individually.

7.2 Data entry

Please see separate 'User Guide' for advice on completing and handling the eCRF [https://entintegrate.co.uk/entuk2wwtt].

8 DATA ANALYSIS

8.1 Sample size

No prospective sample size determination will be made.

8.2 Duration of service evaluation

The service evaluation will continue for as long as telephone triage is being utilising in this patient group. The original eCRF and invitation letter were distributed to ENT UK members on the 24th March 2020. It is anticipated the period of disruption/telephone triage may last for at least 3 months. Though this time period is amenable to extension as above.

8.3 Statistical analysis plan

For the purposes of this project, descriptive analysis only will be reported. Results for the primary and secondary objectives will be expressed as proportions with 95% confidence intervals. The project management team, alongside ENT UK, may perform further analysis of the anonymised data as part of subsequent studies.

9 DATA MANAGEMENT

9.1 Data collection tools and source document identification

Source documents

The referral document and/or patient notes will provide the patient age, gender, time since completion of treatment (if applicable) and primary site of cancer (if applicable).

Data will also be entered directly onto the eCRF and the patient record, see below.

Electronic case report form (eCRF)

The telephone triage will allow structured questions to be asked that would form part of a normal consultation for suspected H&N cancer or for follow up of H&N cancer following completion of treatment. Data will be recorded on the eCRF and participating trusts will also follow usual practices in recording this information on the patient record, e.g. a clinic letter and/or an entry in the paper/electronic notes. As such the data will be duplicated on the eCRF allowing appropriate destruction at the end of the service evaluation, see below.

The eCRF should be stored by the local team on an NHS trust computer. Patient ID may be the NHS number or local Medical Record Number (MRN), assigned as part of standard of care.

9.2 Data handling and record keeping

The data entered onto the eCRF should be held on an NHS trust computer, in a folder with security systems to protect against unauthorized access. At the end of the project, once follow up data has been recorded, the patient ID should be removed, and the fully anonymised data submitted to the project management team via nhs.net email.

The project management team will assign sequential IDs to all eCRFs (AA, AB, AC etc) and records received (001, 002, 003 etc) with no reference to the site submitting the data. A log will be kept of which hospitals have submitted data to prevent duplication.

9.3 Access to data

Local sites will have full access to their identifiable data prior to submission. Only the project management team and ENT UK will have access to the anonymised collated data for the purposes of analysis.

9.4 Archiving

Local eCRFs should be kept according to local data governance for 12 months following submission to allow appropriate local analysis and scrutiny from the project management team. At the end of this period, local eCRFs should be destroyed/deleted in line with local data governance policy.

The anonymised collated data will be held by the project management team for at least 5 years to allow for appropriate scrutiny and reanalysis.

10 MONITORING AND QUALITY ASSURANCE

10.1 Monitoring

No interim monitoring is proposed by the project management team as data will only be received once the local service evaluations have completed.

10.2 Quality assurance

The eCRF will only allow data entry from drop down menus to ensure consistency. Only the patient ID is a free field, and this will be removed prior to submission. Sites submitting inadequate follow up data will be challenged and attempts made to improve data completeness in this field. Sites with exceptionally low levels of data completeness for follow up will be highlighted anonymously in the subsequent analysis.

11 ETHICAL CONSIDERATIONS

This project has been determined as service evaluation using the HRA decision tool available at http://www.hra-decisiontools.org.uk/research/.

The output from this process is available in appendix 1.

12 DISSEMINATION POLICY

Data arising from the project are owned by the individual trusts. Anonymised collated data will be owned by the project management team and ENT UK. Results from the service evaluation will aim to be presented at an ENT UK national meeting, subject to approval. Findings may also be submitted for publication to a relevant H&N peer reviewed journal.

Authorship will be granted in line with criteria defined by The International Committee of Medical Journal Editors. Collaborators from each participating site to submit data will be recognised on any resulting publications as PubMed-citable co-authors using a corporate authorship model.

13 REFERENCES

1. NHS England and NHS Improvement coronavirus. Cancer alliance information on managing cancer referrals [Internet]. 2020 [cited 2020 Mar 24]. Available from: https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/cancer-alliance-information-on-managing-cancer-referrals-19-march-2020.pdf

2. Guidance for ENT during the COVID-19 pandemic [Internet]. [cited 2020 Mar 24]. Available from: https://www.entuk.org/guidance-ent-during-covid-19-pandemic

3. Tikka T, Pracy P, Paleri V. Refining the head and neck cancer referral guidelines: a two-centre analysis of 4715 referrals. Clin Otolaryngol. 2016 Feb;41(1):66–75.

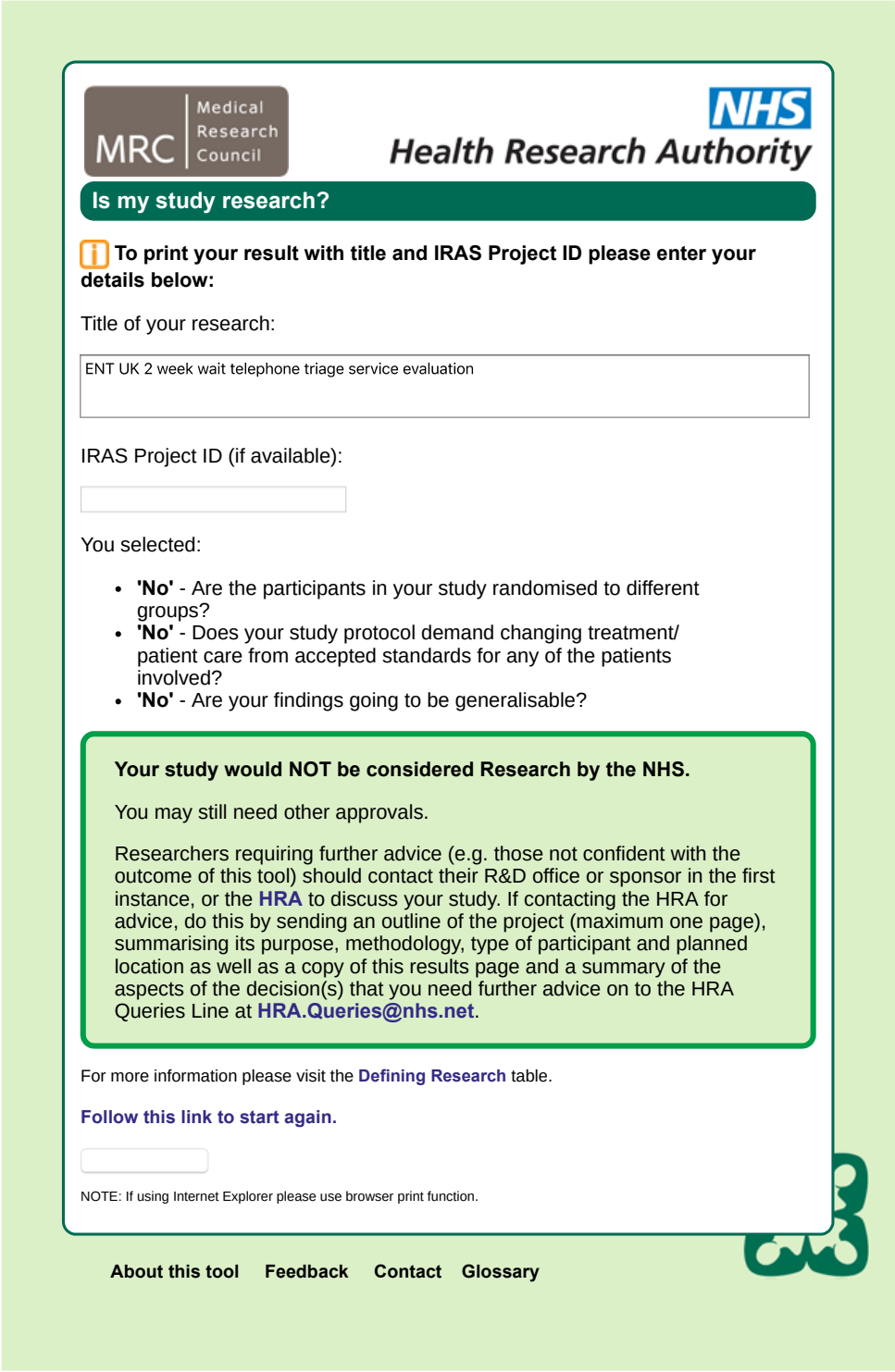
4. Tikka T, Paleri V, MacKenzie K. External validation of a cancer risk prediction model for suspected head and neck cancer referrals. Clin Otolaryngol. 2018;43(2):714–7.

5. Tikka T, Kavanagh K, Lowit A, Jiafeng P, Burns H, Nixon IJ, et al. Head and neck cancer risk calculator (HaNC-RC)-V.2. Adjustments and addition of symptoms and social history factors. Clin Otolaryngol. 2020 Jan 27;

6. Hardman J, Tikka T, on behalf of INTEGRATE (The UK ENT Trainee Research Network). United Kingdom Head and Neck Cancer Surveillance study 2018 [Presentation]. Presentation presented at: BAHNO 2019 Annual Scientific Meeting; 2019 May 17; Royal College of Physicians, London, UK.

7. Twycross A, Shorten A. Service evaluation, audit and research: what is the difference? Evidence-Based Nursing. 2014 Jul 1;17(3):65–6.

14 APPENDIX 1



MRC 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:

ENT UK 2 week wait telephone triage service evaluation

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 **HRA.Queries@nhs.net**.

For more information please visit the **Defining Research** table.

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