National Mastoiditis Audit - Site Instructions

A Step-by-step guide can be found at the end of this document

Background

Acute mastoiditis (AM) is a serious and potentially life-threatening complication of acute otitis media, with incidence estimated to be between 1.2-4.2 per 100,000 per year**.** Acute mastoiditis is a disease of childhood, with 28% occurring in children less than 1 year of age. AM is associated with acute otitis media, and upper respiratory tract viral infections may provoke this, including possible COVID-19 infection. While the mainstay of management within the UK has been surgical, recently a more conservative approach with antibiotic therapy with or without needle aspiration has been used in some cases. The concern over COVID-19 spread via aerosol generation during mastoid surgery has increased interest in more conservative approaches.

AM is uncommon, and even a large tertiary referral NHS hospital would only expect to admit 1-3 cases per month, with smaller centres see far fewer cases. It has therefore been difficult to build larger datasets for AM, and the comparative outcomes with different management techniques are not known. The role of COVID infection in AM and its impact on outcome is also not known.

The British Society of Otology (BSO) and British Association for Paediatric Otolaryngologists (BAPO), working with INTEGRATE (The UK ENT Trainee Research Network) have developed an audit to investigate current practice and patient outcomes, covering a period both before and during the COVID-19 pandemic.

Primary audit standard:

> Has the UK management of acute mastoiditis changed in line with March 2020 BSO / ENTUK guidance on limiting the use of aerosol generating procedures during the COVID-19 pandemic?

Secondary questions:

1. What is the relative effectiveness of conservative and surgical management of acute mastoiditis?
2. Is COVID-19 infection identified in children undergoing treatment for acute mastoiditis (AM) above the population prevalence?
3. What are the disease and individual characteristics of children found to be COVID-19 positive at the time of receiving treatment for acute mastoiditis?
4. What are the long-term outcomes (>14 days, e.g. hearing) of acute mastoiditis in children, and does COVID-19 status affect these?

Audit design

Multi-site UK combined prospective and retrospective audit

Population

All children (age <18 years) managed as inpatients in participating centres with acute mastoiditis. For the purposes of this audit acute mastoiditis is defined according to the local treating team, based on clinical examination with or without diagnostic imaging.

Audit period

An 18 month period will be studied:
- Retrospective data collection period 1st November 2019 – 31st October 2020 (12m)
- Prospective data collection period 1st November 2020 – 30th April 2021 (6m)

Local audit lead role

Each participating site will require an ENT consultant site lead, with or without a trainee site lead. The site lead(s) have responsibility for data collection and submission and are accountable for data completeness and validity. Site leads are also required to register the audit locally and ensure the required approvals are in place (see below).

Data collection

- Only routinely collected clinical data will be captured by review of patient medical records.
- Cases will be identified by the sites leads and routine clinical care teams both retrospectively and prospectively.
- As part of site registration on REDcap an initial survey will need to be completed. This one-time data collection will profile the local site, and will be used to reduce the data entry required for each case.

Case identification

The primary method for **retrospective case identification** will be a search of admission ICD-10 coding using the codes derived from the H70 - 'mastoiditis and related conditions'. In addition, it is recommended that sites able to review daily inpatient handover sheets search these to identify any additional cases improperly coded. This will also enable assessment of the validity of the coding search method.

For **prospective case identification** awareness of clinicians within the department will facilitate contemporary recording of case details. It is hoped that the data collected prospectively will be more complete, not being solely reliant on medical records. In addition, the ICD-10 coding search will be repeated following the end of the 6 month prospective period to identify any missed cases.

Data submission

- Data collection will be via online electronic case report forms (eCRF) utilising REDCap.
- Each site lead will be provided with login details for REDCap.
- Quality of the data entered into the eCRF data fields will be controlled by limited data entry, drop down options and predefined data formats. Range checks for chosen fields will automatically appear where data points are outside of a pre-specified range.
- Site leads will be able to edit entries that are incomplete, and it is encouraged that site leads enter data contemporaneously during admissions in the prospective period, returning to complete follow up data at a later point.

Data analysis

- Data will be analysed centrally by the steering committee after automatic anonymisation at the point of data download from REDCap.
- No patient or clinician will be identifiable in any audit reports, and site-specific data will not be publicly released.
- Audit findings will be assessed for associated risk and this will be fed back to participating sites for clinical governance purposes.

Data security

Case data will only be available to the site lead submitting it, and to the audit steering committee. Prior to data entry, the only identifiable data, NHS numbers, will be converted to an anonymous code. The data will be stored on the AIMES Health Cloud which is only connected to the Secure NHS Network (N3/HSCN), allowing protection of sensitive patient data (ISO 27001 certified).

Dissemination of findings

A report will be provided to all site leads. Findings will be presented at national and international meetings, and published in a peer reviewed journal. Results will also be shared via BSO, BAPO and INTEGARATE newsletters and social media. Findings may be used to develop new consensus management guidelines with key stakeholders.

Authorship and acknowledgement

All site leads, consultants and trainees, will be included as authors in all publications and presentations, as per INTEGRATEs terms of reference.

Audit team

Lead organisations: **British Association of Otology** (BSO)
                            British Association for Paediatric Otolaryngology (BAPO)
In association with: **INTEGRATE**, the UK ENT Trainee Research Network

Chief Investigators: **Professor Iain Bruce**. Consultant Paediatric Otolaryngologist. Royal Manchester Children's Hospital.
                            Professor Peter Rea. Consultant Otolaryngologist. Leicester Royal Infirmary.

Co-Investigators: **Mrs Jaya Nichani.** Consultant Paediatric Otolaryngologist. Royal Manchester Children's Hospital.
                            Mrs Sadie Khwaja. Consultant ENT surgeon. Manchester Royal Infirmary & Greater Manchester CRN ENT group.
                            Mr Matthew Smith. Senior Clinical Fellow in Skull base, otology and hearing implant surgery and Chair of INTEGRATE (UK ENT Trainee Research Network)
                            Mr Huw Jones. Specialist Registrar ENT, INTEGRATE otology subcommittee member

Further information

Please address any queries to the Audit Steering Committee, contactable via https://www.entintegrate.co.uk/mastoiditis. Further information including the protocol and sign-up details can be found here.

Step-by-step guide to the mastoiditis audit

1) Before starting data collection
- Inform all ENT clinicians within your Trust that the audit will be performed
- Gain approval from the ENT department audit lead
- Contact the Trust audit department with the protocol and register the audit locally
- Contact the Trust Caldicott guardian with the protocol and gain approval for the transfer of data
- Gain REDcap login details using the link at https://www.entintegrate.co.uk/mastoiditis
- Register on REDcap and complete the site profiling questionnaire.

2) Data collection
Data collection can begin once local approvals are obtained. All data collection will be coordinated online using REDcap software on INTEGRATE's secure server.

Prior to submitting data, the NHS number should be converted to a 20 digit anonymized code. This should be done by downloading the Excel spreadsheet provided on the INTEGARTE website https://www.entintegrate.co.uk/mastoiditis.

Once an entry has been started, the site lead can return to add to it at a later date. The site lead may wish to securely store a copy of the anonymised NHS number codes for later reference. A site-specific online list will be visible to the site lead, to indicate local cases where follow up or additional data are required.

For the retrospective period:
- The retrospective audit can be completed at any time during the audit period, and you may wish to do this at the end of the prospective 6 months to facilitate a single search
- With the assistance of your audit department perform a coding search to identify patients managed in the period 1st November 2019 - 1st November 2020
- The relevant codes begin H70.x 'mastoiditis and related conditions'
- Enter case details online via REDcap, ensuring fields are as complete as possible

For the prospective period:
- Record consecutive cases managed with acute mastoiditis 1st November 2020 – 1st May 2021
- At the end of the audit period please run the code search to identify any missed cases
- The medical records of all included cases should be reviewed at least 14 days after discharge to ensure follow up data are captured

3) Following data submission
- The audit steering committee will provide an audit report. Please forward the provided report to your Trust audit department
- We suggest that the audit findings are presented at your local clinical governance meeting