

CRANIAL: CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base – A National Prospective Service Evaluation on Incidence and Management

Local Project Guide

a) Local Set Up:

1) Initial team meeting: Successful applicants will receive an email introducing them to their local team and providing documents to help with local set up. We would encourage local team members to meet once the project is registered locally to make introductions.

2) Local service evaluation registration: Procedures vary slightly from place to place so it is advisable to clarify the process at your department. In general, you will need to fill out a form(s) explaining what CRANIAL is, what it is trying to achieve; over what time span; on which patient population(s) etc. **An example of a completed audit/service evaluation proforma will be shared with all local teams** – N.B. forms do vary from place to place but please use this document as guidance. Local departments will also require a copy of the protocol and the data collection proforma (this will be supplied as part of your acceptance package). If you get into difficulty with project registration, please contact the local service evaluation office or your consultant supervisor. Additionally, you may also contact us at cranialnansig@gmail.com

3) Local Caldicott guardian approval: This should be sought prior to data collection (if not already integrated into the project registration process).

5) Project initiation: Once registered and approved, please inform us at cranialnansig@gmail.com. Data will be collected using an online proforma (Castor EDC) and we will send you unique log-in details for the platform. A step-by-step PowerPoint guide will also be shared in the welcome pack.

b) Process:

General team roles are as follow:

- Student leads [**must have access to the clinical portal at their local trust**]:
 - Registers service evaluation.
 - Assists local data collection (e.g. gathers operative lists and identifies relevant cases each week)
 - Seeks support and mentorship from senior team members regularly.
 - Keeps a strict and accurate patient code identifier sheet.
- Trainee leads (neurosurgical ST trainees or clinical fellows):
 - Provides day-to-day support to local student lead(s).
 - Leads in data collection and maintains data accuracy (they must review all data points collected by medical students on Castor).
- Local supervising consultant(s):
 - Approves and oversees service evaluation
 - Meets with local CRANIAL lead for: mid-point review (3 month) and end-of-recruitment review (6 month) and end of project review (9-12 months).
 - Provides support and guidance as necessary.



Collaborators will be cited as a group name "NANSIG" (if student) or "BNTRC" (if trainee) with an expandable list of all collaborators available below the article authorship by-line. As with author names, the name of each collaborator serves as a search link in PubMed. Permission will be asked of all collaborators before citation in publications as part of our collaborator cohort. Similarly, we would welcome local presentation of the data collected by the local project teams. Please email cranialnansig@gmail.com if you are thinking about presenting the data outside of local trust meetings.

c) Castor guidelines: See our separate PowerPoint for more step-by-step info.

Castor is our software of choice for data collection. It is safe, secure and user-friendly. On 'My Studies', please select 'CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base'. In the 'Records' tab, select '+New record'. From here on in, you will be able to submit your data in a similar fashion to filling out an online survey. Selecting your Institute will automatically generate a unique Record ID. This allows you to input patient data without the patient being identifiable. It should be stressed that Castor should only contain anonymised data.

As the unique Record ID will be the only way for us to identify patients if needed, it is important that you make a physical/excel list of patient NHS numbers and their corresponding Record IDs. This 'coded identifier sheet' should be kept secure and on-site e.g. locked in the neurosurgical doctor's office. Only direct members of the local CRANIAL project team should have access to the data. This code identifier sheet will only be consulted if there is a query regarding a particular patient ID. When the data collection and analysis is complete, your local team will receive instructions to destroy the master sheet, thereby ensuring patient confidentiality, as all remaining data will be anonymised.

It is important that the student members of the team receive data collection assistance and day-to-day support from neurosurgical trainees/clinical fellows. All data points collected by medical students **must** be approved for accuracy by one of the neurosurgical trainees/clinical fellows before final submission into the Castor system.

Furthermore, it is critical that specific operative data points must be discussed with the operating surgeons before population into the Castor system and this is highlighted by the Castor data sheet – e.g. presence and grading of intra-op CSF leak, exact methods of intra-op skull base repair used).

Tips:

- During our pilots, we found that collecting queries (data points that need confirmation) for each case on a secure document which can be sent to or discussed with operating surgeons periodic lumpsums was an efficient method of ensuring data accuracy.
- Try using our illustrations & definitions document to better understand skull base repair techniques and the terminology we are using for the project

We advise local teams to meet with the supervising consultant(s) at **3, 6 and 9-12 months** to review data collected, a progress update and to troubleshoot any problems encountered.

d) Service evaluation completion:

Send your team's completed **collaborator checklist** to our email address to:

- Sign off on data (declaration of accuracy, security and governance).
- Provide details of the team members who would like to be listed as a collaborator on published materials.
- Kindly disclose intentions regarding presentation of project data (please email us if you are considering presenting the data outside of local trust meetings).



Process Summary:

