Audit Registration Form

Date:	Clinical Auditor (s):	Consultant:
Department Audit Lead:	**Department:** Neurosurgery	
Speciality/Service Skull-base/Pituitary Neurosurgery	**Contact (email):**	

Clinical Audit Title	**CSF Rhinorrhoea After Endonasal Intervention to the Anterior Skull Base – A Prospective Service Evaluation on Incidence and Management**
Aims	We aim to prospectively evaluate contemporary practice and outcomes of: 1. Patients undergoing trans-sphenoidal surgery for pituitary adenoma – looking at the rates of CSF rhinorrhoea and which methods of skull base repair are used 2. Patients undergoing an expanded endoscopic endonasal approach for anterior skull base pathology – looking at the rates of CSF rhinorrhoea and which methods of skull base repair are used This service evaluation will be part of a collaborative project across all neurosurgical centres in the UK & Ireland – run by the Neurology and Neurosurgery Interest Group (NANSIG) - https://nansig.org/ and supported by the British Neurosurgical Trainee Collaborative (BNTRC). It is a multicentre, prospective service evaluation (see attached confirmation from the HRA). The ambition is to pilot the project at UCLH before dissemination to other centres. Data collection will be using the secure Castor Electronic Data Capture 2019 [Available from: https://www.castoredc.com] system. No identifiable information will be uploaded. Local data collectors will not have access to data collected from other centres and vice versa.
Background	CSF rhinorrhoea is a one of the common complications after anterior skull base surgery – particularly endoscopic transsphenoidal and expanded endoscopic endonasal approaches. It also represents a significant risk factor for headaches, pneumocephalus and meningitis. Re-establishment of a competent CSF barrier is then required however there is no consensus on approach (e.g. tissue-sealants, naso-septal flaps, dural suturing etc) nor are there any standards to direct neurosurgeons. Therefore, our contemporary practice is heterogenous and mostly based on surgeon preference. It is hoped that this international service evaluation will provide insight into the differing practice across neurosurgical centres in the UK & Ireland. Indeed, we hope this service evaluation will establish national benchmarks for future studies.
Clinical Audit Scope *Name of teams, services or units that will participate in this audit*	Neurosurgery: Skull base & Pituitary
Is this a National Audit?	Yes ☐ No ☒
Included in Divisional Audit Programme?	Yes ☐ No ☒
Is this a re-audit? *(Attach evidence of completed actions for un-met standards highlighted from previous audit)*	Yes ☐ No ☒

High Priority ☐ National Audits including NCEPOD, Quality Accounts, Legislation and contract requirements (Care Quality Commission etc.), Infection Control audits, High risk including Serious Incidents, Feedback / complaints received, Scheduled re-audits with high risk findings	**Medium Priority** ☐ NICE Audits, Response to incidents and complaints, Business plans, KPI's, Work identified by Professional Bodies, Professional Clinical Revalidation, National Service Frameworks, Scheduled re-audits where high risk findings have not been identified	**Service Led Priority** ☒ Audits that do not fit into the above, Identified at service level by professionals

Source of Clinical Audit Standards	*Where are the standards taken from?*	
No.	Please state the standards in the form of clearly measureable statements	Expected level of adherence %
1	Post-op CSF leak rate in endoscopic endonasal trans-sphenoidal surgery for pituitary adenoma. 1. Ivan C, Ann R, Craig B, Debi P. Complications of transsphenoidal surgery: results of a national survey, review of the literature, and personal experience. Neurosurgery. 1997;40(2):225-37. 2. Nishioka H, Haraoka J, Ikeda Y. Risk factors of cerebrospinal fluid rhinorrhea following transsphenoidal surgery. Acta neurochirurgica. 2005;147(11):1163-6.	Approximately 5% incidence
2	Post-op CSF leak rate in expanded endoscopic endonasal approach for anterior skull base pathology. 1. Dehdashti AR, Ganna A, Witterick I, Gentili F. Expanded endoscopic endonasal approach for anterior cranial base and suprasellar lesions: indications and limitations. Neurosurgery. 2009;64(4):677-89.	Approximately 20%
3	There are currently no established standards for method of CSF leak prevention/repair used but commonly cited methods include the use of fat grafts, fascia grafts, naso-septal flaps and lumbar drains (4). 1. Oakley GM, Orlandi RR, Woodworth BA, Batra PS, Alt JA, editors. Management of cerebrospinal fluid rhinorrhea: an evidence-based review with recommendations2016: Wiley Online Library.	No established standards

Methodology

Data collection on	Structure ☐ Process ☒ Outcomes ☒
Data collection will be	Retrospective ☐ Prospective ☒
Sample size *HQIP guidelines for selecting sample should be followed*	Total sample size: Sample based on time period of 6 months prospective recruitment and 6-month follow-up Inclusion criteria: Patients undergoing: - endonasal trans-sphenoidal surgery for sellar tumours (e.g. pituitary adenoma) - expanded endoscopic endonasal approach for skull base tumours (beyond trans-sellar approach). Includes large pituitary adenomas, craniopharyngiomas and meningiomas. Selection time period: March 2020 – June 2021 Exclusions: Pre-operative CSF leak, patients undergoing transcranial surgery.
Describe the data collection **tool** you intend to use?	Data will then be entered into a secure, online database: Castor https://uk.castoredc.com/. Data will be collated from patient case files, multidisciplinary team discussions, theatre lists/logbooks and/or local registries/databases including clinic databases. Only anonymised data will be collected by local teams and uploaded to Castor (no personal identifiable information will be uploaded). Only direct members of the local team will have access to the local data on the Castor system. Each case is given a unique Castor Record ID. Each local team will create a physical or Excel code identifier sheet containing patient NHS numbers and their corresponding unique Castor ID will be kept securely on site (i.e. locked in office X or on Trust computers) – upholding strict data governance principles. The sheet will be the responsibility of the local project team and only direct members of the local project team will have access to this sheet. The code identifier sheet will only be consulted if there is a query regarding a particular patient ID. Once the data analysis is complete, instruction will be given by the NANSIG CRANIAL Project Steering Committee to local teams to destroy the master sheet.
Please include all core staff and committees that this report will be disseminated to	X
I will ensure that information processing for Clinical Audit purposes is in accordance with National and Local Policies and Procedures e.g. Caldicott Principles, Data Protection Act 2018, and Health Records Policy etc.	☒

I agree that audit data, results and project findings will not include identifiable characteristics of individuals included within the clinical audit (patients, staff & the public).	☒

Timeline

Start date	01/03/2020		
Data collection completed by (Date only)	01/04/2021 (full project)	**Date final report to be submitted (Date only)**	
Name of person (s) completing the final report:			