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| **Clinical Audit Proposal Form** | | | | | | | |
| **Audit Title:** | Maternal Audit on ThRombosis Outcome and DecisioN (MATRON) | | | | | | |
| **Audit Rationale:** | National Guidelines/Standards | | | | | | |
| **Audit Location:** | *Insert here site* | | | | | | |
| **Trust Priority:** | National Clinical Audit/Enquiry | | | | | | |
| **Directorate/Specialty:** | Haematology | | | | | | |
| **Start Date:** |  | | | | **Completion date:** |  | |
| **Audit Aims/Methods:** | Aims  1.To assess current management of high-risk/intermediate high-risk PE during pregnancy and puerperium in the UK and whether this adheres to RCOG guidelines.  2.To assess obstetric and foetal outcomes post high risk/intermediate high-risk PE.  Methods  This a multi-centre audit. It is a collaboration between the HaemSTAR and UKARCOG, the trainee research networks for haematology and obstetrics and gynaecology, respectively.  Patients will be identified via selecting positive computed tomography pulmonary angiograms (CTPA) or ventilation-perfusion scans (VQ) in female patients of childbearing age (16-49 years of age). Local existing database are also permitted as source of data if this is anonymised. Pregnant patients and those up to 6 weeks post-delivery will then be selected to be included in the database. The high-risk and intermediate high-risk PE are defined as per the European Cardiology Society (ESC) criteria:   * High-risk PE: acute pulmonary embolism with presence of at least one of   + Cardiac arrest   + Haemodynamic shock: (Systolic BP <90 mmHg (or vasopressors requirement) and end-organ hypoperfusion (altered mental status; cold, clammy skin; oliguria/anuria; increased serum lactate)).   + Persistent hypotension: (Systolic BP < 90 mmHg or systolic BP drop >\_40 mmHg, lasting longer than 15 min and not caused by new-onset arrhythmia, hypovolaemia, or sepsis). * Intermediate high-risk PE: acute pulmonary embolism with evidence of myocardial necrosis (troponin rise) or right ventricle dysfunction, without haemodynamic instability.   Information collected will include demographics, maternal/obstetric characteristics, PE features, treatment received, maternal and foetal outcomes. Data collection will be gathered in a central database using REDCap data entry platform to ensure uniformity and facilitate multi-source data input on a national level.  Timeline  Retrospective data collection from cases of PE in pregnancy/puerperium diagnosed between 01/12/2014 and 01/12/24. | | | | | | |
| **Data Governance** | Data will be recorded retrospectively and collated on a dedicated, encrypted, web-based platform. This will be password protected, and no personal data that can identify the individual patient will be recorded. Registered local investigators will have individual password-protected access to all their centre’s data entered during the audit. Centres will use an identification number assigned by the secure platform to identify each individual patient and allow re-accessing of an individual’s records to allow it to be amended and updated, whilst also preventing duplication of patient entry to the audit. No linkable patient identifier will be held on the database. As such it will not be possible for the central investigating team to identify the patients. Local investigators will only have access to their own site’s data.  The Research Electronic Data Capture (REDCap) system has been used to design, host and support the online data collection tool (www.project-redcap.org). This system has been previously used extensively to electronically capture and store sensitive health data in a secure and encrypted format for similar projects within the NHS in the UK. Data will be stored securely and on encrypted and certified servers for a minimum of five years. The data may be used for future research although it should be noted that the anonymised nature of the database means individual patients will not be reverse-identifiable in the future.  Note: higher ethnic groups categories will be collected as part of this audit. There is a strong justification to collect this information as the MBRRACE-UK report has clearly outlined a disparity in mortality, with higher rates in Black and Asian women. | | | | | | |
| **Name of the Directorate clinical standard/ guideline/policy which you will help to deliver against:** | * Thromboembolic Disease in Pregnancy and the Puerperium: Acute Management - Green-top Guideline No. 37b April 2015. * Knight M. et al. MBRRACE-UK report. 2023. | | | | | | |
| **1.Local audit Lead / Applicant details** | | | | | | | |
| **Full Name:** | | *Insert here main data collector (person who will input data on RedCAP)* | | | | | |
| **Job Title:** | |  | | | | | |
| **Email:** | |  | | | | | |
| **2.Local audit sponsor** | | | | | | | |
| **Full Name:** | | | *Insert here local supporting consultant* | | | | |
| **Job Title:** | | |  | | | | |
| **Email:** | | |  | | | | |
| **3.HaemSTAR project lead** | | | | | | | |
| **Name and contact** | | | | Dr Giulia Simini – giulia.simini@nhs.net | | | |
| **4.Project supervisor** | | | | | | | |
| **Name and contact** | | | | Dr Sajida Kazi - sajida.kazi@nhs.net | | | |
| **Information Governance Requirements - Checklist**  **(If you are able to answer Yes or N/A to all of these questions then your audit proposal can proceed without formal Information Governance team approval otherwise you should contact the Information Governance Team)** | | | | | | | |
| 1. **If patient paper records are used, will they ONLY be stored on secure Trust premises (e.g. locked offices)?** | | | | | | | **Yes** |
| 1. **Where Personal Confidential Data (PCD) is recorded on a spread-sheet or database; please confirm that this will only be stored on the Trust infrastructure in a secure area accessible only to those within the clinical team.**   **YES -** *‘I confirm that I will never store information on a personal drive or on a non-networked workstation; this includes the network of a non-Trust third party (including Imperial College London), a home PC or Laptop or any memory stick or mobile device.* | | | | | | | **Yes** |
| 1. **Where PCD is transferred by email this will only be between nhs.net to nhs.net accounts**   *(Transfer between nhs.net to another email server, or using other email servers is not permitted)* | | | | | | | **Yes** |
| 1. **I confirm that PCD will not be transferred out with the clinical team or department (e.g. external organisations/ Royal Colleges) – this is any information that may be used to identify an individual patient or carer?**   *(The clinical team includes those with a direct care relationship with the patient or working within the department responsible for the patient)* | | | | | | | **Yes** |
| 1. **Will patient data be de-identified?**   *‘De-identification’ is the process of removing elements of the data such that the individual cannot be identified. Names, addresses, dates of birth, NHS numbers, full postcodes and National Insurance Numbers should not be used*  *The use of the Medical Record Number (MRN) as the sole identifier is acceptable for audit within the clinical team or department. Please see the guidance for further advice.* | | | | | | | **Yes** |
| 1. **Will the PII only be stored until the finalised audit report is presented?** | | | | | | | **Yes** |