Document Control

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Maternity Services Risk Management Policy				
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1. Purpose

The purpose of this document is to detail the processes for risk management within the Maternity Services

It provides a robust framework to ensure a consistent, systematic approach within the maternity services to providing safe, high quality care.

The policy applies to all staff who work in the maternity services. Risk management is everyone's business.

This policy must be read in conjunction with the Trust's Risk Management Policy and Risk Management Strategy.

1.1. Implementation of this policy will ensure that:

- A framework is provided for risk management in maternity services.
- The local risk management process fits with the wider trust approach.
- A positive risk management culture is supported.
- All maternity staff make a positive contribution to risk management.
- Risk management is everybody's business.

2. Definitions

The Trust

Northern Devon Healthcare NHS Trust.

Risk Management

Risk management is a systematic method of identifying, analysing, treating and evaluating risk associated with service activity.

Risk

A risk is something that could go wrong. The Trust categorises things that could go wrong into 9 domains:

- Impact on the safety of patients, staff or public (physical/ psychological harm)
- Quality/ complaints/ audit
- Human resources/ organisational development/ staffing/ competence
- Statutory duty/ inspections
- Adverse publicity/ reputation
- Business objectives/ projects
- Finance including claims
- Service/ business interruption Environmental impact

- Information Governance

The consequence of each risk is scored on a scale of 1to 5:

Consequence Score (severity levels) and examples of descriptors				
1	2	3	4	5
None	Minor	Moderate	Major	Catastrophic

See Appendix 1 for the Trust's Risk Scoring Matrix.

3. Responsibilities

3.1. The Role of the Lead Clinician for Obstetrics:

Jointly shares responsibility for clinical risk management for the maternity service with the Divisional Director of Clinical Support, Community & Specialist Services and the Head of Midwifery.

Responsible for the provision and delivery of safe maternity services.

Contributes to the effective management of risk within Maternity Services personally and by appropriate delegation.

Ensure that risk issues within the maternity services are considered at executive level within the Trust.

Contributes to the production and implementation of corporate policies and procedures locally and ensures that staff are provided with appropriate training and information to fulfil their responsibilities.

To advise consultant colleagues on their responsibility for the supervision of non-consultant medical staff and ensure adherence to the principles of the risk management strategy.

Undertake informal/formal discussions with staff when risk issues have been identified.

3.2. The Role of the Divisional Director of Clinical Support, Community & Specialist Services

Jointly shares responsibility for clinical risk management for the maternity service with the Lead Clinician for Obstetrics and the Head of Midwifery.

Ensures that all non-medical staff working within the maternity service understands, and carry out their individual responsibilities for the management of risk.

Ensures risk issues within the maternity service are considered at executive level within the Trust via the Northern Devon Healthcare NHS Trust's risk management arrangements.

3.3. The Role of the Head of Midwifery

Jointly shares responsibility for clinical risk management for the maternity service with the Divisional Director of Clinical Support, Community & Specialist Services and the Lead Consultant Obstetrician

The Head of Midwifery will ensure that all staff working within Maternity Services understand and carry out their individual responsibility for the management of risk.

Manage clinical and environmental risk related issues arising out of Trust's risk management systems such as incidents, complaints, claims, risk assessments, audits and information received from other agencies.

Ensures that all incidents and near misses within maternity services are investigated in accordance with Trust Policy and that an investigation is completed for serious incidents in accordance with the Trust's Incident Management and Investigation Policy

Review complaints, claims, incident summaries and trend analysis to ensure issues are discussed, action plans produced, implemented and monitored.

Monitor staff attendance at mandatory risk training in accordance with the Training Needs Analysis (TNA).

Provide advice on Trust wide policies and protocols.

Ensure that the Corporate Risk Register is reviewed and updated and identify related resource issues.

Ensure effective communication links on risk related issues within Maternity Services and feedback to the Corporate Governance Team.

Undertake informal/formal discussions with staff when risk issues have been identified

3.4. Consultant Obstetrician Lead for Delivery Suite

Obstetric Lead for clinical risk management within Maternity

Jointly shares responsibility for clinical leadership on the Delivery Suite in relation to risk management for the maternity service with the Lead Midwives and Maternity Risk Midwife.

Provides obstetric clinical expertise to the Maternity Speciality Governance Group.

Works collaboratively with the Lead Clinician to deliver learning & development to the multi-disciplinary team, identified from incident reviews, investigations, complaints and claims.

Provides feedback to obstetric colleagues of recommendations arising from risk management and the Maternity Speciality Governance Group.

Participates in the production and updating of obstetric policies and procedures.

The development of and participation in local, regional and national audit including national reporting systems.

3.5. Consultant Obstetricians

Reporting incidents, trends and issues of concern in keeping with Trust Policy,

Investigation and analysis of obstetric incidents as requested by the Maternity Speciality Governance Group.

Support the Lead Clinician and Lead Obstetrician for Delivery Suite in delivering the risk management agenda.

Undertake delegated responsibility relating to risk management function in absence of Lead Obstetrician for Delivery Suite

Provide Clinical and educational supervision of junior, specialty doctors and Associate Specialists.

Provide support to junior, specialty doctors and Associate Specialists, involved in clinical incidents, and facilitate their reflection on the event.

Provide explanations and apologies to patients involved in clinical incidents events in line with Duty of Candour Trust ‘Being Open’ Policy.

The development, review and monitoring of NDDH Maternity guidelines.

The development of and participation in local, regional and national audit including national reporting systems.

3.6. Lead Midwives

Assist the Maternity Speciality Governance Group in developing and delivering a program of risk management.

Have delegated responsibility in the absence of the Head of Midwifery.

Provide clinical leadership and operational management of designated areas.

Monitor trends of clinical incidents within maternity services.

Prioritises identified risks within the Maternity Services and the use of resources to minimise these risks.

3.7. Lead Consultant Obstetric Anaesthetist (Professional Lead)

Responsible for all aspects of anaesthetic provision in Maternity services.

Responsible for the production and review of anaesthetic procedural documentation.

Provides a pivotal role in providing pathway of communication between the anaesthetic and maternity teams.

3.8. Maternity Services Clinical Risk Manager

Completes the initial opening and noting of incident reports.

Undertakes initial review of all maternity incidents as reported to Datix, informing other members of the Multi-disciplinary team (MDT) where relevant expertise is indicated by the nature of the incident.

Allocates Datix reviews on an equitable basis.

Works in partnership with the MDT to complete 72 hour reports and Concise Investigation reports where incidents are escalated.

Provides feedback from incident reporting, investigations, complaints and litigation to staff.

Reports trends of incidents, analyses and provides statistical information to MDT as required.

Provides monthly risk reports to the Maternity Speciality Governance Group.

Distributes Device and Medical Alerts and NPSA alert notices ensuring the completion of baseline assessment and that action taken is appropriate and provide feedback to the Corporate Governance Team.

Coordinates appropriate clinical and non-clinical risk assessments for maternity and produces action plans to minimise levels of risk.

Supports individual risk assessors in each area.

Produces an alternate monthly risk newsletter for the service.

Works in partnership with the Head of Midwifery and Lead Midwives, to ensure the Trust wide incident reporting process is adhered to.

3.9. Practice Development Midwife

Underpins the provision of safe and effective care through education support and training days, including emergency skills training,.

Supports Midwives and Medical staff in enhancing skills in Delivery Suite practices and plays a pivotal role in educating, training and the development of staff in the multidisciplinary team.

Contributes to the department clinical audit programme.

Provision of additional training or education programmes for individuals as identified by the risk process.

3.10. All Staff

Includes all Medical staff, Midwives, Maternity Care Assistants, Ward Clerks and any other member of staff working within the Maternity Services

Risk management is everyone's responsibility and as such, it is a fundamental requirement of all staff to carry out their duties effectively.

All staff have a responsibility to identify and assess and report risk, taking appropriate action to reduce risks to an acceptable level.

All staff have a responsibility to inform managers or a member of the risk management team of any unacceptable levels of risk outside their sphere of responsibility or authority.

All staff have a responsibility to report clinical and non-clinical risks and to complete incident reporting forms in accordance with the Trust Incident Management and Investigation Policy.

3.11. Divisional Management Team

The Directorate Management Team retains responsibility for ensuring that:

3.12. All risks and relevant information are documented on the Trust's Corporate Risk Register.

The Trust system for incident management is implemented and monitored.

A specialty specific Maternity Speciality Governance Group exists and appropriate members attend.

There is a system for approval of specialty guidelines and that a system for review exists.

They actively lead risk management within the specialty and that they show a positive management commitment.

Staff are trained in the relevant aspects of risk management.

Specific responsibilities for risk management are allocated along with specific work projects arising from NHSR, risk management standards, high level enquiries and confidential reports e.g. Maternity Matters and MBRRACE.

4. Role of the Maternity Speciality Governance Group

The Maternity Speciality Governance Group is responsible for monitoring all risk management activity within the service.

The Maternity Specialist Governance Group Terms of Reference identifies the full detail of the responsibilities of this group.

Appendix 2 Lists the membership of the Maternity Speciality Governance Group.

5. Risk Identification

Risks will be identified by a number of sources:

Internal: Risk Assessments; Incident Reporting; Complaints; Claims; Staff consultation; Clinical audit.

External: Other NHS providers; Clinical Commissioning Groups; CQC, National Audits; national guidance;

5.1. Immediate Escalation of Risks to Trust Board

Where issues are such that immediate escalation to Trust Board is required e.g. maternal death, serious allegation against a member of staff; the following process is initiated:-

Telephone Call to:

- Head of Midwifery
- Chief Nurse (or deputy)
- Medical Director.

Out of Hours telephone call to:

- Head of Midwifery
- Consultant Obstetrician
- On Call/Duty Manager
- On call Trust Executive Director.

In all cases Email to:

- Chief Nurse or deputy
- Medical Director.
- Head of Midwifery
- Duty Consultant Obstetrician
- Lead Clinician for Obstetrics

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5.2. Incident Reporting

All staff must report incidents where there is a risk of harm or potential harm. Incidents are reported electronically, accessed through the homepage of the Trust's intranet BOB. The Trust's risk management system is Datix.

All staff within maternity have access to Datix.

A trigger list of all clinical incidents which must be reported is displayed in each clinical area. (See Appendix 3).

The Datix system electronically notifies the following as soon as a Midwifery, Community Midwifery or Obstetric incident is reported:

- Head of Midwifery
- Lead Clinician
- Consultant Obstetrician Lead for Delivery Suite
- Lead Midwife Outpatients
- Lead Midwife for Inpatients
- Maternity Services Clinical Risk Manager

5.3. Incident Investigation

Incidents must be opened by the Clinical Risk manager within 2 working days. Incidents will be allocated for review across the multidisciplinary team with a log being kept to ensure that the workload is equitably distributed and to ensure that the whole senior team participates in the reviewing of clinical incidents.

The level of investigation should be proportionate to the incident and the harm caused. The national framework describes 4 levels:

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- **Informal Managers local Investigation** – suited to no harm / minor incidents which are managed within the team by the local manager.
- **Concise investigation** – suited to less complex incidents which can be managed by individuals or a small group of individuals at a local level.
- **Comprehensive (our SI)** – suited to complex issues which should be managed by a multidisciplinary team involving experts and fully trained investigators.
- **Independent** – suited to incidents where the integrity of the internal investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally.

Incidents which are likely to have resulted in moderate harm (Appendix) or above will be discussed as a senior team at the Maternity Safety Huddle. This takes place every Wednesday in the Bassett Ward meeting room at 10:30. The meeting notes are presented to the monthly Maternity Speciality Governance Group for noting.

See Appendix 4 for the membership of the Maternity Safety Huddle

A **Concise Investigation Report** will be completed in all cases where moderate harm is identified.

Serious incidents resulting in major or catastrophic harm may require reporting on the Strategic Executive Information System (StEIS).
A **72 hour Investigation Report** must be submitted to the Corporate Governance team to triage the incident and to identify the correct investigation methodology to identify learning. A **Serious Incident Investigation Report** will be completed for any incident reported on StEIS.

Please see Incident reporting, analysing, investigating and learning policy and procedures for further detail.

5.4. Actions following an investigation

All Root Cause Analysis (RCA) Investigations must identify actions that are recorded in a **SMART** action plan. An action lead will be assigned to each action. The actions will be recorded on Datix .

Learning from all investigations will be published in the maternity service's risk management newsletter which is published on alternate months.

Learning for individual clinicians will be supported by the use of the NHS Improvement's 'Just Culture' tool.

5.5. Incident Monitoring

The Maternity Speciality Governance Group is responsible for monitoring actions arising from investigations.

5.6. Risk Assessment

Formal Risk Assessments are undertaken in line with the organisation wide 'Risk Management Policy', using the Trust Risk Assessment forms available on 'Bob' and rated using the Risk Matrix. These are entered onto the Trust's Corporate Risk Register at the appropriate level based on the risk score, and action plans are developed to manage the risk within the department/Directorate.

5.7. Complaints

All Complaints regarding the maternity services are processed with in line with the 'Management of Complaints, Concerns and Comments' by the Trusts Customer Services department. Complaints are entered into the DATIX system.

Complaint investigations are coordinated by the Maternity Clinical risk manager. Monthly reports are sent to the Maternity Speciality Governance Group.

5.8. Duty of Candour

Duty of Candour is a contractual and legal duty under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.

The Duty of Candour applies to patient safety incidents which results in moderate harm, severe harm or death. However, low / no harm incidents should still be reported to the patient if appropriate and an apology given.

Duty of Candour <u>must be completed by a registrant</u>:

1, Tell the woman something has gone wrong.

2, Apologise to the woman and give them the duty of candour information leaflet.

3, Offer an appropriate remedy or support to put things right (if possible).

4, Explain fully to the woman the short or long- term effects of what has happened.

5, Identify a point of contact for the woman; this would usually be the Risk Manager or Lead Midwife.

6, Invite the woman to be involved in the investigation process.

7, Document the conversation in the healthcare records. In an inpatient setting the Duty of Candour sticker should be used.

8, A letter must be sent to the woman within 10 working days to summarise the Duty of Candour conversation. The letter must be recorded in Datix.

5.9. Never Events

Never Events are serious, largely preventable patient safety incidents that should not occur if healthcare providers have implemented existing national guidance or safety recommendations. The Never Events policy and framework – revised January 2018 suggests that Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes.

Never Events must be reported to the Trust's Corporate Governance Team. The Corporate Governance Team will report Never Events and Serious Incidents to StEIS and all patient safety incidents to the National Reporting and Learning System (NRLS)

Possible Never Events that may occur in maternity are:

- Retained foreign object post procedure
- Mis-selection of a strong potassium solution
- Overdose of insulin due to abbreviations or incorrect device
- Failure to install functional collapsible shower or curtain rails
- Falls from poorly restricted windows
- Chest or neck entrapment in bed rails
- Transfusion of ABO-incompatible blood components
- Misplaced naso- or oro-gastric tubes
- Scalding of patients
- Unintentional connection of a patient requiring oxygen to an air flowmeter. .

- Undetected oesophageal intubation (Temporarily suspended as a Never Event)

5.10. Board Level Maternity Safety Champions

Launched in April 2018, the Maternity Safety Support Programme (MSSP) aims to help maternity services achieve sustained improvement across the five CQC domains. (Safe, effective, caring, responsive to people's needs, and well-led?).

Safer maternity care called on maternity providers to designate and empower three individuals to champion maternity safety in their organisation: a board-level maternity champion as well as one obstetrician and one midwife to be jointly responsible at unit level. The board-level maternity safety champion (who could be a non-executive director) will act as a conduit between the board and the obstetric and midwifery champions.

The Board Level Maternity Safety Champions:

- Champion maternity safety in the Trust and contribute to the implementation of the locally developed safety improvement plan.
- Ensure there are appropriate links to the board-level champion, Local Maternity System, the Maternity Clinical Network and the Maternal and Neonatal Health Quality Improvement Programme.

6. Monitoring Compliance with and the Effectiveness of the Guideline

6.1 National Standards

- Care Quality Commission reporting (CQC)
- National Health Service Litigation Authority (NHS LA)
- Confidential Enquiries into Maternal and Child Health (MBRRACE)
- Achievement of national targets from the Department of Health
- National Maternity Survey
- CNST Compliance

Process for Implementation and Monitoring Compliance and Effectiveness

6.1. This policy has been written to describe the risk management processes in place following a period of sustained external management support.

As such these processes are now embedded in practice.

6.2. All risk management activity is monitored by the Maternity Speciality Governance Group.

7. References

Improving Patient Safety -Risk management for maternity and gynaecology clinical governance advice. no. 2 September 2009 https://www.rcog.org.uk/globalassets/documents/guidelines/clinical-governance-advice/cga2improvingpatientsafety2009.pdf

8. Associated Documentation

Incident reporting, analysing, investigating and learning policy and procedures:

APPENDIX 2: CORE LIST OF NEVER EVENTS 2018

APPENDIX 15 – Process to be followed for Duty of Candour

Risk Management Policy

Risk Management Strategy.

Appendix1 Risk Matrix

	Consequence Score (severity levels) and examples of descriptors				
	1	2	3	4	5
Domains	**None**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Impact on the safety of patients, staff or public (physical/ psychological harm)	Minimal injury requiring no/minimal intervention or treatment. No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for less than 7 days Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Requiring time off work for over 7 days Increase in length of hospital stay by 4-15 days Externally reportable	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients
Quality/ complaints/ audit	Peripheral element of treatment or service suboptimal Informal complaint/ inquiry	Overall treatment or service suboptimal Formal complaint (stage 1) Local resolution Single failure to meet internal standards Minor implications for	Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) complaint Local resolution (with potential to go to independent review) Repeated failure to meet internal standards	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review Low performance	Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on Inquest/ombudsman inquiry Gross failure to meet national standards
Human resources/ organisa-tional development/ staffing/ competence	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending
Statutory duty/ inspections	No or minimal impact or breach of guidance/ statutory duty	Breach of statutory legislation Reduced performance rating if unresolved	Single breach in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breaches in statutory duty Improvement	Multiple breaches in stat.duty Prosecution Complete systems change required Zero performance rating Severely
Adverse publicity/ reputation	Rumours Potential for public concern	Local media short-term reduction in public confidence Elements of public	Local media coverage – long-term reduction in public confidence	National media with <3 days service well below reasonable public expectation	National media coverage >3 days service well below reasonable public expectation. MP concerned (questions in the House) Total
Business objectives/ projects	Insignificant cost increase/ schedule slippage	<5 per cent over project budget Schedule slippage	5–10 per cent over project budget Schedule slippage	Non-compliance with national 10–25 per cent over project budget Schedule slippage	Incident leading >25 per cent over project budget Schedule slippage Key objectives not met

Finance including claims	Small loss Risk of claim remote	Loss of 0.1–0.25 per cent of budget Claim less than £10,000	Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000	Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget Claim(s) between	Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage
Service/ business interruption Environmental impact	Loss/interruption of >1 hour Minimal or impact on the environment	Loss/interruption of >8 hours Minor impact on environment	Loss/interruption of >1 day Moderate impact on environment	Loss/interruption of >1 week Major impact on environment	Permanent loss of service or facility Catastrophic impact on environment
Information Governance	No personal data lost	Limited demographic data Less than 10	Celebrity /VIP involved. Basic demographic data Limited clinical	Sensitive personal data, high level of stress / financial loss,	Highly sensitive personal data, multiple occurrences of loss, 100

	Liklihood Score				
	1	**2**	**3**	**4**	**5**
Descriptor	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost certain**
Frequency How often might it/does	This will probably never happen/recur (< once per year)	Do not expect it to happen/ recur but it is possible it	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting	Will undoubtedly happen/recur, possibly frequently
Examples of frequency	*Not expected to occur for years or <once/year*	*Expected to occur at least annually*	*Expected to occur at least monthly*	*Expected to occur at least weekly*	*Expected to occur at least daily*
EPRR Risks Stated chance in	*Between 1 in 20,000 and 1 in 2,000*	*Between 1 in 2,000 and 1 in 200*	*Between 1 in 200 and 1 in 20*	*Between 1 in 20 and 1 in 2*	*1 in 2 or more*

	Rare 1	**Unlikely 2**	**Possible 3**	**Likely 4**	**Almost certain 5**
5 Catastrophic	**5**	**10**	**15**	**20**	**25**
4 Major	**4**	**8**	**12**	**16**	**20**
3 Moderate	**3**	**6**	**9**	**12**	**15**
2 Minor	**2**	**4**	**6**	**8**	**10**
1 None	**1**	**2**	**3**	**4**	**5**

Appendix 2 Lists the membership of the Maternity Speciality Governance Group.

- Head of Midwifery (Chair)
- Lead Midwife for Inpatient Services
- Lead Midwife for Outpatient services
- Maternity Risk Manager
- Lead Clinician O&G
- Practice Development Midwife
- Consultant Obstetrician, LW Lead
- Consultant Obstetrician, Guideline Lead
- Group Manager
- Consultant Anaesthetist
- Consultant Paediatrician
- Lead Pharmacist for Maternity
- Head of Clinical Coding
- Maternity Governance Co-ordinator

Appendix 3 Maternity Reporting Triggers

This list is not exhaustive. Staff must feel that they are able to report any clinical or patient safety concerns.

Maternal incident	Fetal/neonatal incident	Organisational incident
Maternal death Undiagnosed breech in labour Shoulder dystocia Manual Removal of Placenta Blood loss >1000 ml Return to theatre Eclampsia Hysterectomy/laparotomy Medication error Anaesthetic complications Retained swab or instrument Intensive care admission Venous thromboembolism Pulmonary embolism Third-/fourth-degree tears Unsuccessful forceps or ventouse Uterine rupture Readmission of mother Significant infections – maternal Unplanned home birth Born before arrival Maternal resuscitation Trauma to bladder or other organs Cord accident / cord prolapse / presentation	Stillbirth Neonatal death Apgar score 6 or below at 5 minutes Birth trauma Fetal laceration at caesarean section Cord pH <7.05 arterial or <7.1 venous Neonatal seizures Term baby admitted to neonatal unit Undiagnosed fetal anomaly Significant infections – neonatal Re-admission of baby	Unavailability of health record Delay in responding to call for assistance Faulty equipment Conflict over case management Potential service user complaint Hospital-acquired infection Inoculation injury Violation of local protocol Loss of clinical waste e.g., swabs, needle OR surgical foreign body left in-situ Unavailability of any facility or equipment (including neonatal unit cots) Temporary closure of maternity beds/units Unavailability of medication Staffing levels Sustained staffing deficits Issues relating to CTG interpretation Sustained and persistent team conflict that has the potential to impact on service provision Any incident that may generate media attention Antenatal & newborn screening not offered or not completed within the correct timeframe

Appendix 4 Maternity Safety Huddle Membership

The Maternity Safety Huddle meets every Wednesday at 10:30 in the Bassett Ward Meeting room.

- Head of Midwifery (Chair)
- Lead Midwife for Inpatient Services
- Lead Midwife for Outpatient services
- Bassett Ward Manager
- Maternity Risk Manager
- Consultant Obstetrician,
- Maternity Governance Co-ordinator