Milton Keynes University Hospital NHS Foundation Trust

Epilepsy in Pregnancy Guideline

Classification:	Guideline
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Guideline to be followed by (target staff):

To be read in conjunction with the following documents: None

Are there any eCARE implications? No

CQC Fundamental standards:
Regulation 9 – person centered care
Regulation 10 – dignity and respect
Regulation 11 – Need for consent
Regulation 12 – Safe care and treatment
Regulation 13 – Safeguarding service users from abuse and improper treatment
Regulation 14 – Meeting nutritional and hydration needs
Regulation 15 – Premises and equipment
Regulation 16 – Receiving and acting on complaints
Regulation 17 – Good governance
Regulation 18 – Staffing
Regulation 19 – Fit and proper

Disclaimer -

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care; the document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material **lies solely with you** as the medical practitioner.

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Guideline Statement

Epilepsy is one of the most common neurological conditions seen pregnancy, with a prevalence of 0.5–1% in women of child-bearing age [RCOG]. MBRRACE-UK (Confidential Enquiries into Maternal Deaths and Morbidity) report has highlighted the increase in maternal deaths in the last three years; with 22 women losing their life in 2016 - 2018 compared with 13 in previous triennium. The main cause of death was SUDEP (sudden unexplained death of women with epilepsy in pregnancy), which is associated with poorly controlled seizures and is more commonly seen in women managed with lamotrigine.

Women with epilepsy (WWE) need consultant led care during pregnancy, with input from an obstetrician and neurologist. Whilst the majority of women will have straightforward pregnancies and have a health baby, their risk of complications during pregnancy and labour is higher than that for women without epilepsy. Ideally, WWE need access to pre-pregnancy counselling to discuss the impact of their condition on the pregnancy, particularly with regards to anti-epileptic medication (AEDs) and the potential impact on fetal development as well as have education and support to promote optimum outcomes.

Executive Summary

Key messages

- All women with Epilepsy should be encouraged to register their pregnancy on the National Epilepsy and Pregnancy database. This can be found at http://www.epilepsyandpregnancy.co.uk
- Woman should have pre-pregnancy counselling discussing the impact epilepsy can have on pregnancy and if requiring AED, the potential impact on the development of their baby
- All women prescribed sodium valproate should be advised of significant impact on fetal neurological and cognitive development and adequate contraception provided to avoid pregnancy [MHRA]
- WWE trying to conceive need 5mg folic acid daily from at least 6 week preconception until 16 weeks of pregnancy.
- Refer to Maternal Medicine clinic for antenatal care, with Consultant led neurology input.
- Patients on AEDs should have a four chamber view of the heart as part of their routine anomaly scan. Referral to Fetal Medicine must be organized if an anomaly is detected at the 20 week scan.
- Serial growth scans at 30, 34, 38 weeks due to the small increase of fetal growth restriction and higher chance of pre-eclampsia
- Women and their family need to be alerted to the risk of SUDEP and support given to encourage good seizure control and avoidance of triggers
- Referral to paediatricians - Baby Alert - to be done antenatally if woman is taking AEDs.
- Breastfeeding is safe and is encouraged with all AEDs.

1.0 Roles and Responsibilities

- Doctors – decision making, discussion, planning care
- Midwives, nurses and student midwives – ante-, intra- and postpartum care

2.0 Implementation and dissemination of document

Guideline is available on the Intranet

3.0 Processes and procedures

Multidisciplinary team to manage the women with epilepsy:

- Obstetrician (specialist interest in epilepsy and/or maternal medicine trained)
- Neurologist (with working knowledge of the management of pregnant women with epilepsy)
- Obstetric physician where available
- General practitioner
- Anaesthetist
- Midwife
- Epilepsy nurse specialist

3.1 Diagnosis of epilepsy

Most women with epilepsy will have been seen and diagnosed by a neurologist, however some women may present with seizures for the first time in pregnancy.

In pregnant women presenting with seizures in the second half of pregnancy, treat the woman as having eclampsia using IV magnesium sulphate in the first instance. Should the diagnosis of eclampsia then been discounted, a full neurological assessment with brain imaging and review by Neurology will be required before a definitive diagnosis of epilepsy can be made. Other cardiac, metabolic and intracranial conditions should be considered in the differential diagnosis. Neuropsychiatric conditions including non-epileptic attack disorder should also be considered.

3.1.1 Differential diagnosis of a first fit in pregnancy

- Eclampsia
- Drug toxicity, for example aminophylline or local anaesthetics
- Infection, such as encephalitis or meningitis
- Fever leading to febrile convulsion
- Metabolic disturbances, such as hypoglycaemia, hyponatraemia, hypocalcaemia or hypoxia
- Withdrawal from drugs (anticonvulsants and sedatives such as alcohol, barbituates and benzodiazeopines)
- Space-occupying lesions in the brain (abscesses, tumours)
- Strokes may cause seizures, with embolic strokes more likely to present with seizures
- Cerebral vein thrombosis
- Thrombotic thrombocytopenic purpura
- Multiple sclerosis sufferers may rarely experience seizures
- Head injury

3.1.2 Classification of Seizure Type

Different types of seizures can be associated with different levels of risk for the mother and baby**. See Appendix 1**.

Poorly controlled tonic-clonic seizures (particularly at night) are the highest risk for SUDEP and potentially can be associated with brief periods of fetal hypoxia. An increase in absence seizures can be a precursor to having a tonic-clonic seizure.

Women who have remained seizure-free for at least 10 years and have not required AEDs for the last 5 years or those with a childhood epilepsy syndrome who have reached adulthood and are now seizure-free off medication can be considered as no longer having epilepsy and treated as low risk [RCOG].

3.2 Pre-pregnancy counselling

This should include verbal and written information regarding impact of epilepsy on pregnancy, Including:

- Most women have healthy pregnancies, although WWE have slightly higher chance of pre-eclampsia with fetal growth restriction.
- Controlling seizures is most important prior to pregnancy. The aim is to use one AED, with lowest teratogenic effect, at lowest dose to control symptoms.
- During pregnancy, the dose of AEDs may need to increase to maintain a normal therapeutic range
- AEDs can increase the chance of fetal anomaly, dependent on the type and dose, however 5mg folic acid from pre-conception to 16 weeks can reduce this.
- Sadly, WWE have a higher chance of death in pregnancy compared to other women, this can be minimised by good seizure control and safety considerations (showers not baths, avoid triggers, ensure compliance with medication; see patient leaflet on safety in pregnancy)
- WWE can aim for a vaginal birth and safely breastfeed

3.2. Impact of AEDs

- Women with epilepsy (WWE) should be reassured that most have normal healthy babies

- Women should be informed that the risk of congenital abnormalities in the fetus is dependent on the type and dose of AEDs, with higher risk for women on high-dose polytherapy.

- Using some AEDs can increase the chance of major congenital anomalies from a background rate of 2-3%, but for many AEDs (eg lamotrigine < 325mg /day or levetiracetam) the risk is only just above the background rate [Veroniki].

- Carbemazapine conferred a 2 fold risk of congenital abnormality compared to the background rate [Weston]

- There is some evidence that AEDs may impact cognitive development, particularly sodium valproate, and a small increase in the diagnosis of autism if using lamotrigine, however levetiracetam appear not to associated with developmental delay [Veroniki]

- Women are advised to take **5 mg/day of folic acid** 6 week prior to conception and to continue to 16 weeks to reduce the incidence of major congenital malformation.

- The most common major congenital malformations associated with AEDs are **neural tube defects, congenital heart malformation, urinary tract and skeletal abnormalities and cleft palate**

- **Sodium valproate** has overwhelming evidence of causing major anomalies in 10% of exposed children as well as up to 40% chance of impacting neurocognitive development (eg Autistic spectrum disorder) Due to this, woman must be carefully counselled if considering pregnancy whilst on this medication and ideally changed to a different AED prior to pregnancy if possible [BNF].

- The lowest effective dose of the most appropriate AED should be used. Currently low doses of lamotrigine and levetiracetam do not appear to significantly increase the risk of major congenital malformations in the fetus. Less data is available on less commonly used AEDs

3.3 What is the effect of pregnancy on seizures in Women with Epilepsy (WWE)?

- For WWE, 66% women have no change in seizure frequency
- Approximately 30% women will experience an increase in seizure frequency in pregnancy and will require increase in AED dosage, particularly if managed on lamotrigine.
- Those women who were having frequent seizures prior to pregnancy require close monitoring as are likely to need increasing AED dosage.

- There is a small chance of seizures in labour (1-2%) and postnatally in the first 24 hours (1-2%) where often seizure triggers (eg tiredness, pain, missing AEDs doses) need to be minimised.

. Possible reasons for a pregnancy-related increase in seizure activity include:

  - non-compliance with medication – this needs careful exploration and explanation

  - sleep deprivation

  - alteration in antiepileptic drug pharmacokinetics particularly increased drug clearance (lamotrigine)

3.4 Antepartum management

- Refer for consultant led care in Maternal Medicine clinic
- All pregnant women with epilepsy (WWE) should be provided with information about the UK Epilepsy and Pregnancy Register and invited to register.
- Woman have routine ultrasound scans (12 and 20 weeks) and invited for combined screening test
- Any concern regarding fetal anomaly should be referred to the Fetal Medicine unit
- Routine monitoring of serum AED levels in pregnancy is not recommended although individual circumstances may be taken into account, particularly to ensure lamotrigine is within therapeutic range
- WWE should be discouraged to not stop or change AEDs abruptly without an informed discussion
- WWE should have regular review with a midwife and consultant to discuss reducing triggers for seizures (eg sleep deprivation and stress); adherence to AEDs; change in seizure type or frequency.
- Routine antenatal surveillance for change in blood pressure is requiredd
- Organise serial growth scans at 30, 34 and 38 weeks to identify fetal growth restriction
- If admitted to hospital these women need care in open bay and not in a side room unless provision for partner to stay.
- **Baby alert form** should be filled and sent

3.4.1 Questions to be asked at first antenatal visit:

- When was epilepsy diagnosed and with which investigations?
- What types of seizures are experienced?(e.g. a) focal, b) generalized)
- What is the frequency of seizures?

- When was the last seizure?
- Is a neurologist overseeing the care?
- What AEDs are taken and at what dose?
- What other features of seizures (triggers, aura, activity during seizure) occur?
- Is there a history of status epilepticus or ITU admission?

3.4.2. Vitamin K

- Enzyme-inducing AEDs (carbamazepine, phenytoin, phenobarbital, primidone, oxcarbazepine, topiramate and eslicarbazepine) theorically increase the risk of haemorrhagic disease of the newborn due to inhibiting production of clotting factors. These women can be offered oral Vitamin K 10 mg daily from 36 weeks after discussion, however there is **insufficient evidence** to recommend this.

- All babies born to WWE taking enzyme-inducing AEDs should be offered **1 mg of intramuscular vitamin K** to prevent haemorrhagic disease of the newborn.

3.5 Timing and mode of Birth [RCOG]

- WWE should be reassured that most will have an uncomplicated labour and birth.

- The diagnosis of epilepsy *per se* is **not** an indication for planned caesarean section or induction of labour. Normal induction agents can be used.

- In WWE taking AEDs who are at risk of preterm delivery, the normal dose of antenatal corticosteroid can be used.

3.6 Intrapartum management

- The risk of seizures in labour is low (<2%), however WWE are recommended to labour in a consultant-led unit with facilities for one-to-one midwifery care, maternal and neonatal resuscitation
- Waterbirth is discouraged due to the difficulty of management if a seizure occurs in a birthing pool. Although individual birth plans can be discussed with woman with good control
- Analgesia should be discussed antenatally as a way to minimise triggers for seizures such as fatigue, stress and dehydration.
- Normal AEDs dose should be continued during labour. If this cannot be tolerated orally, a parenteral alternative should be administered.
- Long-acting benzodiazepines such as clobazam can be considered if there is a very high risk of seizures in the peripartum period.
- Prophylactic clobazam is considered in the following circumstances-
  - recent convulsive seizures
  - significant history of seizure provocation by stress or sleep deprivation
  - seizures in previous labour
- The risks from clobazam causing respiratory depression in the newborn, need to be balanced against the benefit due to seizure prevention.

3.6.1 What are the recommended methods of analgesia in labour for WWE?

Pain relief in labour should be prioritised in WWE, with options including transcutaneous electrical nerve stimulation (TENS), nitrous oxide and oxygen (Entonox), and regional analgesia. Often WWE will ask for an early epidural to reduce possible triggers for seizure such as pain and fatigue. This should be prioritized by the Anaesthetic Team

- Pethidine should be avoided in WWE for analgesia in labour.

3.7 Postpartum management

- There is a 1-2% risk of a seizure in the postpartum period due to potential triggers (sleep deprivation, pain, stress of caring for newborn).
- Provision for minimising triggers should be considered including good pain relief, partner support
- WWE should be advised to continue their AEDs postnatally.
- Postpartum women in hospital should not be accommodated in single rooms unless provision for a partner to stay with the woman is made.

3.7.1 Is there a need to modify the dose of AED after delivery?

- If the AED dose was increased in pregnancy, there is a potential for postpartum toxicity. A plan to reduce the AED dose by 14 days should be made antenatally, and a review by the Neurology or Maternal Medicine Team organised.

3.8 How should babies of WWE taking AEDs be monitored?

- Neonates born to WWE taking AEDs should be monitored for adverse effects associated with AED exposure *in utero*. A baby alert should have been completed and Paediatrician made aware
d
- Any concern regarding poor feeding or lethargy in the baby should be escalated to the Paediatric Team.
- WWE should be encouraged to breastfeed as the doses of AED in breast milk are lower than in utero exposure, however aim for avoiding breast feeding straight after an AED dose.

3.9 What advice should be given regarding safety strategies and care of the baby?

- Postpartum safety advice should be part of the antenatal and postnatal discussions with the mother alongside breastfeeding, avoidance of triggers to reduce seizure deterioration and continued AED intake, please ensure has patient safety leaflet.
    - Advise feeding whilst sitting
    - Advise WWE against co-sleeping with baby.
    - Bathing of baby using a sponge down method rather placing the baby in a bath.
    - Change the baby on the floor
    - Babies should be carried up the stairs in a carrycot.
    - Consider a pushchair with automatic brake

3.10 What contraception can be safely offered to women taking AEDs (see Table 1)?

- Long acting reversible contraception including Copper coil (IUDs), the levonorgestrel-releasing intrauterine system (LNG-IUS) and medroxyprogesterone acetate injections (depots) should be suggested as contraception for all women with epilepsy and are not affected by enzyme-inducing AEDs

- Women using enzyme inducing AEDs (e.g. carbamazepine, phenytoin, phenobarbital, primidone, oxcarbazepine and eslicarbazepine) need to be aware of the reduction in efficacy of oral contraceptives (combined hormonal contraception, progestogen-only pills), transdermal patches, vaginal ring and progestogen-only implants and advised to use **WITH** barrier contraception. If deciding to use the combined oral contraceptive pill a higher dose of oestrogen (50mcg) is required in a tricycling regime. (3 packets of the pill "back to back" and then have a FOUR day break before restarting)

- The copper IUD is the preferred choice for emergency contraception as emergency contraception pills with levonorgestrel (Levonelle) and ulipristal acetate (Ella-One) are affected by enzyme-inducing AEDs.

- All methods of contraception may be offered to women taking non-enzyme-inducing AEDs (e.g. sodium valproate, levetiracetam, gabapentin, vigabatrin, tiagabine and pregabalin).

- Women taking lamotrigine monotherapy and oestrogen-containing contraceptives should be informed of the potential increase in seizures due to a fall in the levels of lamotrigine.

- WWE need to contact DVLA and be advised against driving if having seizures

Suitability of contraception for women taking anticonvulsant therapy (adapted from FSRH)

Combined hormonal methods	Not recommended for women using hepatic enzyme-inducing antiepileptic drugs (carbamazepine, phenobarbitone, phenytoin, primidone and topiramate) If chosen by women using hepatic enzyme-inducing antiepileptic drugs they should take 50 microgram estrogen daily (e.g.one 20 and one 30 microgram combined oral contraceptives) and also use barrier contraception Oestrogen reduces plasma concentrations of lamotrigine. Use of combined hormone methods are not recommended in women on lamotrigine monotherapy due to the risk of loss of seizure control and the potential for toxicity in the combined hormone free week
Progesterone-only pill/implant	Not recommended for women using hepatic enzyme-inducing antiepileptic drugs
Progesterone only injectable Levonorgestrel-releasing intrauterine system (LNG-IUS)	Suitable for all women taking anticonvulsant therapy. Efficacy of depot medroxyprogesterone acetate, norethisterone enantate and LNG-IUS is unaffected by enzyme-inducing drugs
Non-hormonal methods	Suitable for all women taking anticonvulsant therapy, however may not be effective
Emergency contraception	Women taking hepatic enzyme-inducing antiepileptic drugs should be advised that an Copper coil is the preferred option

3.11 What is the management of epileptic seizures?

Seizures occurring in the antenatal period or during labour should be medically terminated as soon as possible to avoid maternal and fetal hypoxia and acidosis. Benzodiazepines are the drugs of choice. Fetal monitoring is recommended in women, once stabilised, following a seizure to ensure fetal wellbeing. Any seizure lasting more than 5 minutes is unusual and represents a high risk of progressing to convulsive status epilepticus, a life-threatening medical emergency which affects around 1% of pregnancies in WWE

Call for help from the obstetric team and anaesthetic team.

- Maintenance of airway and adequate oxygenation
- Use manual uterine displacement to reduce aorto-caval compression if possible
- Lorazepam given as an intravenous dose of 0.1 mg/kg (usually a 4 mg bolus, with a further dose after 10−20 minutes) is preferred.
- Diazepam 5–10 mg administered slowly intravenously is an alternative
- If there is no intravenous access, diazepam 10−20 mg rectally repeated once 15 minutes later if there is a continued risk of status epilepticus, or midazolam 10 mg as a buccal preparation are suitable.

Status Epilepticus:

- Status epilepticus is defined as a seizure that lasts for more than 5 minutes, or recurrent seizures without full recovery of consciousness in between.

- Status represents a medical emergency and should be treated as a non-pregnant patient as per NICE guidelines. During the tonic phase the contraction of the respiratory muscles results in reduced maternal oxygenation, leading to fetal hypoxia. During the clonic phase, metabolic acidosis occurs. Rhabdomyolysis may precipitate acute renal failure.

First line: Lorazapam 4mg bolus IV or IM midazolam 0.1 mg/kg

Second line: Phenytoin 15–18 mg/kg, maximum rate 50 mg/min,

Anaesthetist team to be considering General Anaesthesia

- If there is persistent uterine hypertonus, consider administration of tocolytic agent

- If the fetal heart rate does not begin to recover within 5 minutes or if the seizures are recurrent, expedite delivery. This may require caesarean section under general anaesthetic if vaginal delivery is not imminent

- The neonatal team should be informed, as there is a risk of neonatal withdrawal syndrome with the maternal use of benzodiazepines and AEDs.

Appendix 1

Common types of epilepsy/seizures	Clinical presentation	Effects on mother and baby
Tonic-clonic seizures (previously known as. grand mal)	Dramatic events with stiffening, then bilateral jerking and a post-seizure state of confusion and sleepiness	Sudden loss of consciousness with an uncontrolled fall without prior warning. .Associated with a variable period of fetal hypoxia This seizure type is associated with the highest risk of SUDEP.
Absence seizures	Generalised seizures that consist of brief blank spells associated with unresponsiveness, which are followed by rapid recovery	Effects mediated through brief loss of awareness although physiological effects are modest. Worsening absence seizures places women at high risk for tonic-clonic seizures.
Juvenile myoclonic Epilepsy **Focal seizures** previously defined as, 'complex partial' if seizures impair consciousness and simple partial' if retained consciousness and may impair consciousness. Primary focal (An epileptic aura only). They can be seizures can undergo secondary associated with a variable period of hypoxia consciousness	Myoclonic jerks are the key feature of this form of epilepsy and often precede a tonic-clonic convulsion These jerks present as sudden and unpredictable movements and represent a generalised seizure. Symptoms are variable depending on the regions and networks of the brain affected. Within an individual, the attacks are recognisable and stereotypical	Occurs more frequently after sleep deprivation and in the period soon after waking or when tired. The sudden jerks may lead to falls or to dropping of objects including the baby Impairment of consciousness increase risk of injury such as long bone fracture ,dental or head injury, electrocution or burns This can be associated with a variable period of hypoxia and risk of SUDEP

Appendix 2: Safety leaflet

Safety leaflet

Staying safe in pregnancy and after birth

During pregnancy

Use showers rather than a bath to reduce any risk of drowning.

Do not lock the bathroom door, so people can come to help you

Remember to take your medications on time, set an alarm if necessary

Discuss any increase in auras or seizure frequent with your medical team

Do not drive if you have had a seizure in the last year, and inform the DVLA

After the birth

Try to organise people to support you with looking after your baby in the early days

Be aware of your triggers (e.g sleep deprivation, tiredness, stress, pain) and try to ensure support from friends and family to minimise these as much as possible

Set reminders to take your AEDs medicine, try to avoid missing doses

If breast feeding, sit with your back well supported and soft furnishings/ cushions around you

Do not bathe the baby in the bath alone, use a top/tail approach on a mat

Change the baby on a mat on the floor and avoid high changing tables

Avoid co-sleeping with your baby

Avoid slings or carrying the baby up/down stairs, use a carrycot

Consider a pushchair with automatic brakes

4.0 Statement of evidence:

References:

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5.0 Governance

5.1 Record of changes to document

Version number	Review date	Reviewed by	Changes made
5	04/2017	Kate Ewing	Complete Review
6	05/2021	Anja Johansen-Bibby / Anupama Rammohan/ Faryal Nizami	Complete Review

5.2 Consultation History

Stakeholders Name/Board	**Area of Expertise**	**Date Sent**	**Date Received**	**Comments**	**Endorsed Yes/No**
Rukindar Birk	Consultant Anaesthetist and critical care medicine	11/02/2021	24/02/2021	Availability of IV Midazolam and Diazepam in theatre. Definition of Status epilepticus	Yes
Women's review group	Maternity	02/03/2021	16/03/2021		
Maternity guideline group	Maternity	25/06/2021			
Women's Health clinical improvement group	Maternity	07/07/2021			

5.3 Audit and monitoring

This Guideline outlines the process for document development will be monitored on an ongoing basis. The centralisation of the process for development of documents will enable the Trust to audit more effectively. The centralisation in recording documents onto a Quality Management database will ensure the process is robust.

Audit/Monitoring Criteria	**Tool**	**Audit Lead**	**Frequency of Audit**	**Responsible Committee/Board**
Clinical Practice	Statistics, generated risk forms	Risk Midwife	Annually	Labour Ward Forum

5.4 Equality Impact Assessment

As part of its development, this Guideline and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified. Equality Impact assessments will show any future actions required to overcome any identified barriers or discriminatory practice.

Equality Impact Assessment			
Division	Women and Children	Department	Maternity
Person completing the EqIA	Anja Johansen-Bibby Anupama Rammohan	Contact No.	
Others involved:	Faryal Nizami	Date of assessment:	11/02/21
Existing policy/service	Yes	New policy/service	No

Will patients, carers, the public or staff be affected by the policy/service?	Yes
If staff, how many/which groups will be affected?	*All maternity staff*

Protected characteristic	Any impact?	Comments
Age	NO	Positive impact as the policy aims to recognise diversity, promote inclusion and fair treatment for patients and staff
Disability	NO	
Gender reassignment	NO	
Marriage and civil partnership	NO	
Pregnancy and maternity	NO	
Race	NO	
Religion or belief	NO	
Sex	NO	
Sexual orientation	NO	

What consultation method(s) have you carried out?
Teams meeting, womens guideline group
How are the changes/amendments to the policies/services communicated?
Teams meeting womens guideline and CIG
What future actions need to be taken to overcome any barriers or discrimination?

What?	Who will lead this?	Date of completion	Resources needed
Review date of EqIA	25/06/2024		