Women and Child Health Directorate

Protocol for the management of Women with epilepsy in pregnancy

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This document has been screened for relevance to equality. No potential negative impact has been identified so a full impact assessment is not required.

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1.0 Purpose of protocol

The purpose of this protocol is to provide guidance for midwives, general practitioners, obstetricians and specialist physicians on the management of women with epilepsy in pregnancy and the postnatal period. Information is also provided on the importance of pre – conceptual counselling.

2.0 Background:

Epilepsy remains the commonest serious neurological disease, and every year there are an estimated 2500 pregnancies in the UK in women with epilepsy (UK and Ireland Epilepsy and Pregnancy Register 2016). There remain concerns regarding the incidence of Sudden Unexplained Death in Epilepsy (SUDEP) in pregnancy, and that it may be higher than population estimates suggest (Edey, Moran et al.2014). Previous Confidential Enquiries have suggested that significant improvements in care are necessary to reduce mortality.
In 2013–2015, eight women with epilepsy died during pregnancy or in the immediate post-partum period, and five women died between six weeks and one year after delivery. The details of the care of these women were reviewed. In all of them, improvements in care were identified, and these may have influenced the outcome for seven women. Sudden Unexplained Death in Epilepsy (SUDEP) was the cause of death in 8 cases. One woman drowned in the bath.
(MBRRACE-UK 2017 Saving Lives, Improving Mothers'Care - Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2013–15)

3.0 Pregnancy and Epilepsy

3.1 Effects of pregnancy on epilepsy

Seizure frequency increases during pregnancy in between a quarter and a third of women due to a number of factors including changes in pharmacokinetics of Anti-Epileptic Drugs (AEDs) (Tomson et al, 1997). Poor adherence to treatment because of concerns about adverse effects on the foetus plays a part (Fairgrieve et al 2000).

Pregnancy is associated with pharmacokinetic changes including an increase in volume of distribution, an increase in drug metabolism through hepatic microsomal enzyme induction, a reduction in serum albumin concentration and an increase in renal clearance (Yerby et al 1992). There is a tendency for plasma levels of AEDs to fall in pregnancy but there is no evidence to support routine increase of AED doses (Richmond et al 2004).

3.2 Risks to the fetus from maternal epilepsy

Tonic clonic seizures increase the pressure in the pregnant uterus and lead to transient changes in CTG and may also lead to trauma if the woman falls (Vlinkainen et al 2006). Tonic clonic seizures can rarely result in lactic acidosis which is transferred to the foetus resulting in hypoxia. Reassuringly, recent reports suggest that the number of stillbirths in adequately treated women with epilepsy is similar to the background population (Tomson et al 2004).

Women should be made aware of the risks of uncontrolled seizures both to themselves and to the foetus and therefore the importance of compliance with medication.

3.2.1 Risks to the foetus from anti-epileptic drugs (AEDs)

Major and minor malformations occur more commonly in infants exposed to AEDs during pregnancy Fairgreave et al 2000; Katzo et al 2006; Artma et al 2005). The overall risk of major foetal malformations increases two to three fold in women taking AEDs. Polytherapy, particularly with certain combination of drugs, carries a much higher risk.

The most common major malformations associated with AEDs is neural tube defects, orofacial clefts, congenital heart anomalies. The incidence of epicanthic folds and digital hypoplasia is also increased with AED therapy.

‘’Foetal Anticonvulsant syndrome’’ comprising typical dysmorphic craniofacial appearances and a variety of musculoskeletal abnormalities have been described in association with AED treatment in pregnancy (Holmes et al, 2001; Kaneko et al, 1999). Although individual drugs have been associated with specific patterns, there is overlap between them and genetic factors may influence susceptibility (Morrow et al 2006).

Whether AEDs taken during pregnancy can affect the child’s intellectual development is uncertain (Clayton and Donnai, 1995; Moore et al 2000). However, more recent concern about the effects of valproate on infant development has recently been raised in the ‘Valproate pregnancy prevention programme’ where studies have found 30-40% of children exposed to Sodium Valproate will have developmental problems.ie being late in learning to walk and talk, lower IQ, poor speech and language skills, memory problems, autism and ADHD.

At present there is insufficient evidence on which to base advice about risks of most of the newer AEDs.

Table 1. Risks of epilepsy medicines causing major congenital abnormalities: UK Epilepsy and Pregnancy Register findings between 1996 and 2012

MONOTHERAPY:

Epilepsy Medicine	Daily dose	Approximate risk	% Risk
Carbamazepine	any	2-3 in 100	2.6
Lamotrigine	any	2-3 in 100	2-3
Levetiracetam	any	2 in 100	2
Sodium Valproate	Below 1,000mg	6 in 100	6
Sodium Valproate	Above 1,000mg	10 in 100	10
Topiramate	any	4-5 in 100	4-5

POLYTHERAPY: (ie a combination of x2 anti-epileptic drugs)

Epilepsy medicine combination	Approximate risk	% Risk
Sodium Valproate with any other epilepsy medicine	9 in 100	8.9
Any combination without Sodium Valproate	4 in 100	4.2

Where possible, epilepsy treatment should be reviewed before becoming pregnant. The effects of AEDs and risks of seizures should be explained:

- If the woman's epilepsy is in remission, the risk of recurrent seizures is low and the woman is aware of the consequences of recurrent seizures, consideration may be given to withdrawal of AEDS prior to conception.
- If possible the woman should conceive on the lowest effective dose of AEDs appropriate for her epilepsy syndrome. If she is already pregnant and has good seizure control there is no benefit in changing the dose.
- Any woman who has had a child with AED related malformation should be reviewed by an epilepsy specialist before becoming pregnant again.
- Sodium Valproate should only be prescribed for women of child bearing years if no other epilepsy medicine suits in accordance with the MHRA guidelines and pregnancy prevent programme.

4.0 Valproate pregnancy prevention programme

New regulations have been introduced by the Medicines and healthcare products Regulatory Agency (MHRA) regarding how Sodium Valproate is prescribed to women and girls of child bearing age. The new measures are designed to ensure that all women who are prescribed this drug for their epilepsy are fully informed of the risks. These women are advised on the importance of using effective contraception and are invited for annual reviews of their treatment to specialist epilepsy services for completion of an annual risk acknowledgement form.(MHRA 2018)

http://www.epilepsyandpregnancy.co.uk

5.0 Risk of inheritance

Genetics of most epilepsies are complex with multiple genes involved and interaction of environmental factors. The risk of epilepsy in the offspring is higher with idiopathic than with symptomatic epilepsies.

6.0 Pre conception counselling

Epilepsy is common in child bearing age and exposure to anti-epileptic drugs (AEDs) occurs in approximately 1 in 150 pregnancies. It is important that the primary care giver i.e. GP, epilepsy nurse, neurologist be alert to the possibility of conception and discuss this with women. A preconception consultation for women with epilepsy led by the Health Board's Epilepsy Specialist Nurses is available held in both Morriston and Princess of Wales Hospitals.

In those not planning a pregnancy, or in those who are being investigated or seizure control is not satisfactory, effective contraception should be prescribed.

Subjects to discuss in pre pregnancy counselling of women with epilepsy include:

- Women with epilepsy should be reassured that most will have a normal pregnancy and delivery
- Genetic counselling regarding risk of inheriting epilepsy which is low in most types of epilepsy
- Risk of congenital anomalies associated with AEDs
- Drug treatment – monotherapy is preferable at the lowest effective dosage. Good compliance with treatment is essential. Routine monitoring of AED levels in pregnancy is not recommended (NICE 2012). Although, there may be a role for this in individual cases.
- Folic acid – 5mg daily should be taken from 3 months before conception to at least the end of the first trimester to reduce the risk of neural tube defects and cognitive deficits.(Royal College of Obstetricians and gynaecology 2016)

Ideally this should be continued throughout pregnancy as there is a small risk of folate-deficiency anaemia.(Neurological problems 2015)

- Antenatal screening tests – ultrasound can detect most neural tube defects
- Expected course of epilepsy and risk of seizures – the frequency of seizures usually remains unchanged as prior to pregnancy. Drug doses may need to be increased in some women to maintain adequate seizure control
- Foetal and maternal risks associated with seizures – tonic clonic seizures carry risks to the mother and foetus and should be avoided
- Expected course of pregnancy and delivery – obstetric outcome is usually uneventful and caesarean section is needed only in the most difficult cases.
- Interactions between hormonal contraceptives and antiepileptic drugs – efficacy of contraception(both oestrogen and progesterone's) is reduced if on enzyme inducing AEDs

Table 2. List of hepatic enzyme and non-hepatic enzyme inducing anti-epileptic drugs

AEDs which induce hepatic enzymes	AEDs that DO NOT induce hepatic enzymes
Carbamazepine (Tegretol) Oxcarbazepine (Trileptal) Phenobarbital Phenytoin (Epanutin) Primidone (Mysolin) Topiramate (Topamax) Eslicarbazepine acetate (Zebinix) Perampanel (Fycompa)	Acetazolamide (Diamox) Benzodiazepines (Diazepam, Clobazam, Clonazepam Midazolam, Lorazepam) Ethosuximide (Zarontin) Gabapentin (Neurontin) Pregabalin (Lyrica) Lamotrigine (Lamictal) Levetiracetam (Keppra) Tiagabine (Gabiltril) Valproate*(Epilim) Vigabatrin(Sabril) Lacosomide (Vimpat) Brivaracetam (Briviact) Zonisamide (Zonegran)

7.0 Antenatal care

Freedom from seizures is the ultimate goal in the treatment of patients with epilepsy. With proper management before conception, during pregnancy, and after the birth, the vast majority of pregnancies in women with active epilepsy will have a favourable outcome (NICE 2012). This is only possible with a multi-professional approach between GPs, midwives, obstetricians, neurologists or specialist physicians.

7.1 Role of the midwife

Antenatal Booking Visit

All pregnant women with epilepsy should be referred to the epilepsy services at the antenatal booking visit. The community midwives will complete the electronic referral form to the epilepsy services (appendix 3).

The woman will be allocated the appropriate consultant obstetrician depending on the place of delivery.

The community midwife will arrange the dating scan at around 12 weeks and the anomaly scan at around 20 weeks to check for foetal anomalies. Further scans will be decided as clinical need arises by the obstetrician.

It is important that an early appointment is arranged in the appropriate hospital antenatal clinic for the woman to see the Consultant with interest in Medical Disorders (appendix 1.). The community midwife will complete and email a referral form to the Epilepsy Specialist Team (Neurologist and Epilepsy Specialist Nurse) at Morriston hospital for an early review (appendix 3)

At every point of contact with the patient, the opportunity should be taken to give information about the importance of continuing good adherence with AED and to ensure the woman is taking HIGH DOSE Folic acid (5mg). Information regarding women with epilepsy and having a baby can be downloaded from http://www.epilepsy.org.uk/info/women/

The community midwife will review women between hospital visits and liaise with the epilepsy specialist team and Obstetrician if any concerns are present.

7.2 UK Epilepsy and Pregnancy Register

All pregnant women with epilepsy, whether or not on medication, should be notified, with their consent, to the UK pregnancy register. This information is useful in assessing the safety of different drugs used to treat epilepsy. Women can self-register or a health professional can do this with the woman's consent by completing a hard copy or website from

(www.epilepsyandpregnancy.co.uk).

Tel 0800 389 1248.

7.3 Role of the obstetrician

The Obstetrician is responsible for the overall care of the woman and will see the women at regular intervals in the antenatal clinics for the obstetric care, referring to medical problems at each site and be responsible for inpatient care if the woman needs admission. The obstetrician will also liaise with the Neurologist and Epilepsy CNS to put an individualised plan in place.

7.4 Role of Epilepsy Specialist Team- (Consultant Neurologist and Epilepsy Clinical Nurse Specialist (CNS))

The epilepsy CNS will have active involvement in the management of epilepsy and in implementing the management plan. The Epilepsy CNS will aim to see the women as early as possible ie within 4-6 weeks following referral and will aim to see women at least once every trimester and 3 months post-natal. The Epilepsy CNS will offer to facilitate the registration of these women with the UK Epilepsy register.

Seizure frequency should be monitored carefully during the pregnancy and adjustments made to AED doses to minimise the number of seizures (particularly generalised tonic clonic seizures).

For emergency epilepsy referrals there is a 24/7 on call neurology service which can be accessed via switch board. Also, a Liaison neurology consultant, Monday-Friday 9am-5pm.

8.0 Intra-partum Care

Most women with epilepsy will have a normal labour and vaginal delivery, but stress, pain, sleep deprivation, hyperventilation and dehydration increase the risk of seizure in labour (1-4%). (Tomson et al 2004)

Women should deliver in the Central Deliver Suite with one to one care by a midwife in labour. It is important that both the Obstetric and Anaesthetic registrars are informed of the admission and the woman has taken her routine medication.

Factors predisposing to increased seizure should be minimised i.e. ensuring good support to reduce anxiety, adequate hydration and good analgesia.

The usual AED doses should be taken when in labour and continued in the postnatal period. In women unable to tolerate oral medication, AEDs can be given by other routes. Guidance can be downloaded from the e-BNF which can be accessed via the health board's intranet;

http://bnf.nice.org.uk

Epilepsy in itself is not an indication for Caesarean section. Caesarean is only performed for Obstetric reasons except if the woman has been having frequent tonic clonic or prolonged complex seizures towards the end of pregnancy.

Analgesia in labour: All of the available methods of labour analgesia can be used with women with epilepsy safely. There is no increased risk of seizures with administration of Pethidine in the doses used for labour.

8.1 Seizures in labour

The epilepsy society website quotes up to 2% of women (2-4% in every 100) with epilepsy may have a tonic clonic seizure during labour due to stress or during the 24 hours afterwards. Status epilepticus in labour is very rare but is associated with significant increase in maternal as well as foetal mortality and is a medical emergency.

The aim is to terminate seizure as soon as possible using IV Lorazepam or diazepam. Please see appendix 2 for guidance on treatment of seizure in hospital.

If status epilepticus is characterised by prolonged and persistent seizures, please see appendix 3 for guidance on treatment on Status Epilepticus.

If there is confusion whether epileptic fit or eclampsia- , also give slow IV Magnesium 4 g over 5-10 minutes followed by the infusion for 24 hours (refer to local Swansea Bay/ABMU pre-eclampsia guideline).

Delivery should be expedited after a seizure in labour according to clinical situation eg. Artificial rupture of the membranes, syntocinon augmentation, vaginal operative delivery if in second stage of labour. Caesarean section is usually reserved for obstetric indications, or if the woman has recurrent seizures or has status epilepticus.

9.0 Postnatal care

Following delivery the drug levels may change again leading to toxicity and the dosage needs to be adjusted accordingly. Seizures may be provoked due to fatigue and lack of sleep.

9.1 Safety with care of the baby

Parents of new babies should be informed that introducing a few simple safety precautions may significantly reduce the risk of accidents and minimise anxiety (NICE 2012). Useful information packs offered by Epilepsy CNS which includes the following: Epilepsy and having a baby booklet, pregnancy diaries, after the birth, giving birth all published by Epilepsy Action 2018 also included in this pack: seizure diary, Uk epilepsy and pregnancy register information and epilepsy advice line contact details.

9.2 Breastfeeding

Breast feeding is safe and encouraged. Blood levels of AED in infants are probably lower than in utero provided infant is born healthy and at term (Kuczkowski, 2006). If on phenobarbitone the infant may become sedated.

9.3 Contraception

As much as possible the pregnancies should be planned and appropriate contraception is important. Enzyme inducing drugs increase the metabolism and clearance of both oestrogens and progesterone's, therefore making them less effective leading to more break through bleeding and failures.

AEDs which induce hepatic enzymes	**AEDs that DO NOT induce hepatic enzymes**
Carbamazepine (Tegretol) Oxcarbazepine (Trileptal) Phenobarbital Phenytoin (Epanutin) Primidone (Mysolin) Topiramate (Topamax) Eslicarbazepine acetate (Zebinix) Perampanel (Fycompa)	Acetazolamide (Diamox) Benzodiazepines (Diazepam, Clobazam, Clonazepam Midazolam, Lorazepam) Ethosuximide (Zarontin) Gabapentin (Neurontin) Pregabalin (Lyrica) Lamotrigine (Lamictal) Levetiracetam (Keppra) Tiagabine (Gabiltril) Valproate*(Epilim) Vigabatrin(Sabril) Lacosomide (Vimpat) Brivaracetam (Briviact) Zonisamide (Zonegran)

In women on enzyme inducing AEDs, higher dose of oestrogens and progesterones are necessary, so Oral Contraceptive Pills should contain a minimum of 50mcg and

increased to 80 or 100 mcg of Ethinylestradiol if necessary. Tricycling the pills in order to reduce number of pill free intervals, is useful. Progesterone only pill or implanon are not recommended. The depot injection is effective but the interval should be shortened to 10 weeks from 12 weeks. Emergency contraception (Levonelle) dose should be increased (doubled) to be effective.

10.0 Written information for women

The Welsh Risk Pool Standard15: Maternity Services (2005) require women with epilepsy to be given written information during pregnancy relevant to safety measures.

Information leaflets for women provided by Epilepsy Action “Epilepsy and having a baby” contains important information relating to:

- Planning a baby
- Epilepsy medicines and birth problems
- Getting pregnant
- Source of support
  http://www.epilepsy.org.uk/info/women/

NHS Choices provide a web site containing information on epilepsy in pregnancy “The pregnancy care planner” (http://www.nhs.uk)

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Appendix 1

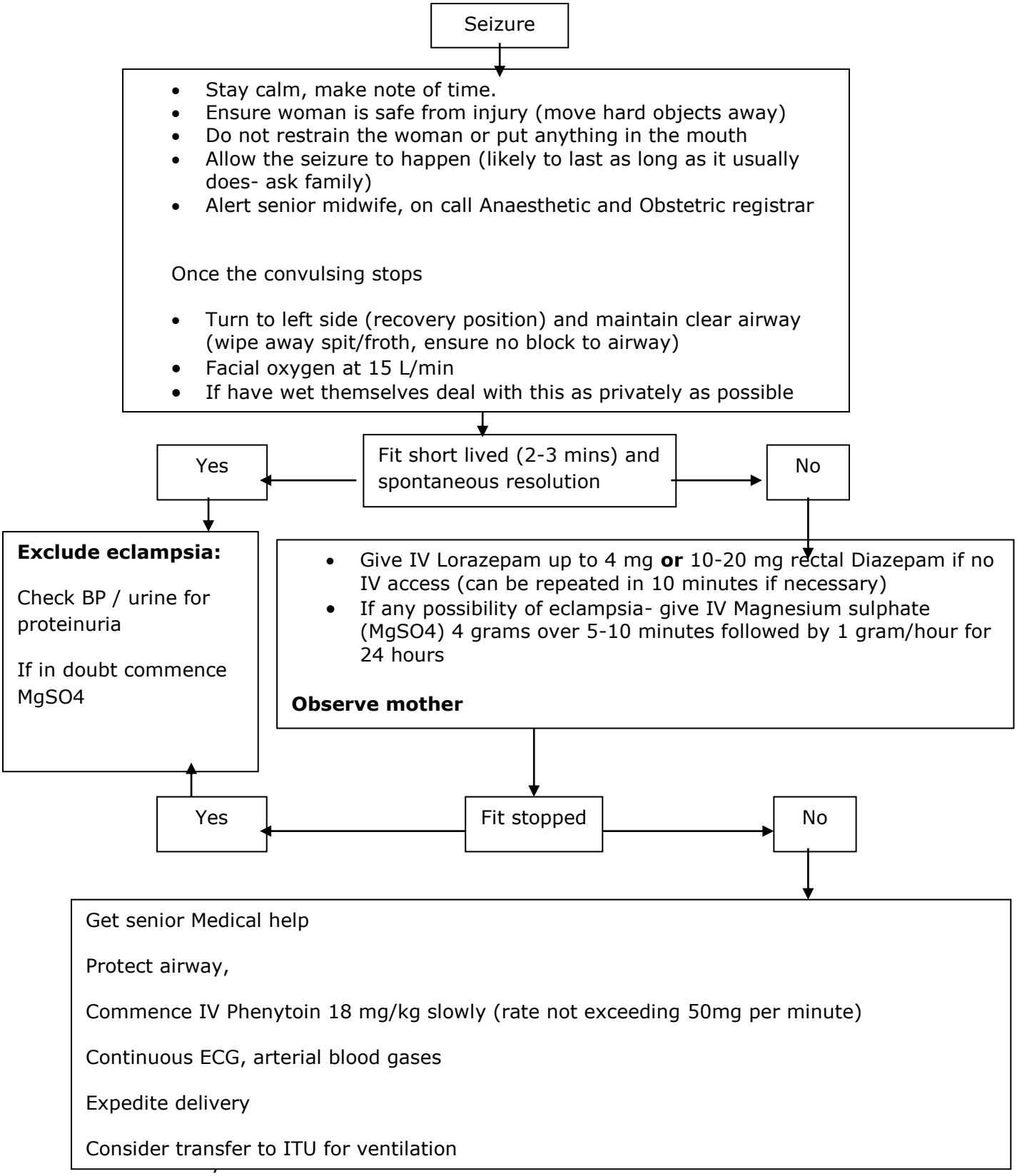
ABM University Health Board **Pathway of care for women with epilepsy in pregnancy**		
Midwifery Team	**Obstetric Team**	**Epilepsy Specialist Team**
1st Trimester		
Antenatal booking visit Give Epilepsy Action link re: epilepsy and pregnancy information High dose Folic Acid 5mgs daily, adherence with treatment Arrange dating and anomaly scan Arrange early appointment in Medical ANC Email referral to Epilepsy Specialist Team to each of these addresses: **ABM.SingPreRegistration@wales.nhs.uk and also to both alison.mead@wales.nhs.uk and rebecca.morcom@wales.nhs.uk**	Review and document obstetric care plan Check electronic referral form (appendix 3) has been sent to epilepsy services	Advice on: • Safety precautions for both mum and her baby • Life style choices • Medication and seizure review • With written information on epilepsy and pregnancy information given (Ante-Natal epilepsy information packs) • Blood monitored where needed • To facilitate to register pregnancy onto the UK Epilepsy register
2nd trimester		
16 week visit (NICE 2008) Reiterate advice-medication, personal safety etc. To continue with high dose Folic Acid 5mgs daily, adherence with treatment	Review of results, Amend care plan Monitor growth and development of foetus	Advice on: • Safety precautions for both mum and her baby • Life style choices • Medication and seizure review • Blood monitored where needed

3rd trimester		
Routine antenatal examinations Discuss labour, labour analgesia, infant care, breastfeeding etc. Arrange parent craft sessions To continue with high dose Folic Acid 5mgs daily, adherence with treatment	Finalise plan for mode of delivery Discuss queries about labour etc. Monitor growth and development of foetus	Advice on: • Safety precautions for both mum and her baby • Life style choices • Medication and seizure review • Blood monitored where needed
Intra-partum care		
Ensure taken AED medication Good hydration, analgesia, psychological support Avoid hyperventilation Inform on call doctors (Obstetrics, anaesthetics, neonatologists)	Early review by Obstetric and Anaesthetic registrar	
Postnatal care		
Review of labour events Encourage breast feeding Teach infant care and reiterate personal and infant safety. Ensure compliant with medication Strategies to cope with stress and good sleep hygiene To continue with high dose Folic Acid 5mgs daily, adherence with treatment	Review of labour events Examination to assess suitability for discharge Discuss and prescribe contraception Need for good seizure control and high dose Folic Acid 5mgs before embarking on next pregnancy	• Epilepsy frequency and medication review • AED alteration if necessary • Breastfeeding and contraception reviewed • Childcare and Personal safety review • Additional leaflets on above if required • Check completion of Epilepsy and pregnancy register

Appendix 2

Flow Chart for the management of Epileptic seizure in labour

(NB. In women with no prior history of epilepsy, eclampsia is the most common cause of seizure in labour)



Appendix 3 **Email referrals to**

ABM.SingPreRegistration@wales.nhs.uk and also to both alison.mead@wales.nhs.uk and rebecca.morcom@wales.nhs.uk

MIDWIFE REFERRAL FOR EPILEPSY SERVICES

PATIENT IDENTIFICATION LABEL NAME: POST CODE: NHS NUMBER: DATE OF BIRTH:	**INDICATE IF URGENT OR ROUTINE REFERRAL** **by answering yes/no to questions**		
	URGENT REFERRAL	YES	NO
	taking Sodium Valproate (Epilim)		
	Gestation > 12 weeks		
	Poor seizure control		
	Side effects of anti-epileptic drugs		
	ROUTINE REFERRAL		

NAMED MIDWIFE	CONTACT NUMBER

NAMED OBSTETRICIAN:	

EDD:	GESTATION AT REFERRAL:

EPILEPSY HISTORY INCLUDING DIAGNOSIS AS REPORTED TO MIDWIFE:

DESCRIPTION OF SEIZURES:

ANTI CONVULSANT MEDICATION BEING TAKEN AT TIME OF REFERRAL:

FOLIC ACID **5MG** BEING TAKEN AT TIME OF REFERRAL (circle)	YES	NO
IF NOT TAKING FOLIC ACID 5MG ADVISED TO COMMENCE IMMEDIATELY AND TO CONTINUE THROUGHOUT PREGNANCY AND CHILD BEARING YEARS.	YES	

NAME OF REFERRING MIDWIFE:	
DATE OF REFERRAL:	