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REVIEW

Medical Diseases in Pregnancy: An Acute on Chronic Focus

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Abstract

In the last decade or so obstetric care has evolved and become more complex. This can be attributed to a combination of factors including rising obesity rates, maternal age and medical treatment advances. Clinicians are caring for more pregnant women with chronic medical disease in addition to any de novo presentations which may occur, emphasising the need for the general medicine body to feel confident and skilled in the management of medical problems before, during and after pregnancy. One of the difficulties faced by clinicians in the assessment and management of pregnant women is the differentiation between symptoms of a normal pregnancy vs symptoms of clinical significance which warrant further investigation, particularly in mothers with background medical disease. Careful consideration and knowledge of normal pregnancy physiology is required when assessing a pregnant women/birthing person to avoid closed thinking and adverse outcomes. Unfortunately, clinician inertia around the care of pregnant women is a common feature in maternal mortality reviews. The most recent maternal mortality report discusses common themes around cardiovascular disease in pregnancy, alongside management of acute and acute-on-chronic presentations in the context of common endocrine, gastrointestinal and neurological disease in pregnancy. This article discusses some of these themes and the management of common medical problems in pregnancy.

Key words: obstetric medicine; maternal medicine; medical problems in pregnancy; chronic disease in pregnancy; acute problems in pregnancy

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Introduction

The mothers and babies: reducing risk through audits and confidential enquires across the UK (MBRRACE-UK) is a national body which provides an annual report on causes of maternal mortality via triennial review (Knight et al, 2023). The report addresses common themes encountered during a review period with the aim of raising awareness and providing future recommendations around obstetric care to improve outcomes. Cardiac disease, infection and embolism are well recognised as the leading causes of maternal death. The MBRRACE-UK report released in October 2023 specifically identifies diabetic ketoacidosis (DKA), adrenal insufficiency and neurological disease as areas for improvement.

A common message repeated year after year via the MBRRACE-UK report is based around clinical caution and uncertainty in the management of the pregnant woman. Too often there are delays in the assessment and management of pregnant women presenting to the unscheduled care setting. In some cases, care is not

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just delayed but withheld due to concern over the impact assessment and treatment may have on the fetus, thus compromising the care of the woman and providing substandard care as a consequence.

The aim of this article is to highlight the latest guidelines, evidence and current practice of some of the conditions identified by the 2023 report. This article also aims to build confidence when assessing a pregnant woman to avoid untimely delays, support concordance of medications and direct the reader to useful resources to support decision making in this context. The key goal is to prevent avoidable maternal death and adverse outcomes.

Infection and Vaccination

The 2023 MBRRACE-UK report incorporates the earlier waves of the COVID-19 pandemic. While this article doesn't focus on SARS-CoV2, it is important to recognise a salient point generated from the latest review—prevention is better than cure. Of the 45 women who died from COVID-19 during this period, 27 were eligible for vaccination but did not receive it (Knight et al, 2023). Due to physiological changes that occur during pregnancy, women become immunocompromised. Respiratory disease and acute respiratory infections are poorly tolerated in the latter stages of pregnancy with increased fetal risks of prematurity, stillbirth and growth restriction and maternal risks of increased morbidity and mortality (Nelson-Piercy, 2020). Vaccination status should be discussed and recommended at each patient encounter (RCOG, 2022).

Cardiac Disease and Venous Thromboembolism (VTE)

If COVID-19 cases are removed from the latest MBRRACE-UK report, cardiac disease and VTE remain the leading indirect and direct causes of maternal death across the UK respectively. In the context of cardiac disease, only 10% of cases were known to have a pre-existing cardiac diagnosis (Knight et al, 2023).

Palpitations and shortness of breath are common symptoms experienced during a normal healthy pregnancy. However, they may be symptoms that are representative of a more significant underlying condition. Careful consideration should be given when assessing a pregnant woman with any of the following symptoms: chest pain, palpitations, breathlessness or pre-syncope. The Royal College of Physicians (2019) Acute care toolkit 15: Managing acute medical problems in pregnancy | RCP London is a useful resource to highlight red flag features associated with these symptoms. Fig. 1 highlights some common misconceptions of assessments in pregnancy in this context.

Endocrine Emergencies

The 2023 MBRRACE-UK report highlighted several maternal deaths as a consequence of endocrine emergencies and acknowledged that improvements in care may have led to better outcomes (Knight et al, 2023). Five women died secondary

Myth	True/False	Rationale
A raised troponin is normal in pregnancy	False	Troponin levels are not affected by pregnancy, therefore an elevated level should be further investigated. It may suggest underlying cardiac disease, pre-eclampsia (PET) or sepsis (RCP 2019; Regitz-Zagrosek V et al 2018)
A heart rate over 110bpm is normal in pregnancy	False	A rise of 10-20bpm from a woman's baseline is the current accepted normal variation of heart rate in pregnancy. A recent study identified a wide variation in resting heart rate at different gestations (63-105bpm at 14 weeks compared to 65-114bpm at 40 weeks). (Green L et al 2020). In essence, heart rate varies significantly woman to woman in pregnancy, an accepted upper limit would therefore be somewhat unsafe and miss potential women at risk. A tachycardia and/or symptom of palpitation should be reviewed for potential underlying causes, particularly if there are accompanying red flag symptoms. Causes may include anaemia, thyroid disease, VTE and cardiac disease.
Hypotension is normal in pregnancy; therefore - syncope can be explained by this without the need to further investigate	False	The 4P study database demonstrates a modest decrease in blood pressure at 12 weeks (median 114/70mmHg), reaching nadir at 18-19 weeks' gestation (median 113/69mmHg) with a rise noted thereafter (reaching a median of 121/78mmHg at 40 weeks) (Green L et al 2020). Syncope is a red flag symptom (RCP 2019) and warrants further investigation for underlying causes. History and examination should help guide how to investigate appropriately. VTE can occur at any gestation, therefore if considered, proceed with either a V/Q scan or CTPA depending on your hospital's availability.
D Dimer is reliable in pregnancy	False	There is some disparity and dispute over the use of a D Dimer in pregnancy across various VTE guidelines. The DiPEP study compares biomarkers for PE in pregnancy and postpartum; there was no significant biomarker identified to aid clinical decision making for VTE (Hunt B et al 2017). The study also highlighted some women had a radiologically proven PE with a normal D Dimer. Therefore, biomarkers and clinical decision rules are not currently validated or recommended in pregnancy.

Fig. 1. This image challenges some of the common misconceptions around observation parameters and investigations in pregnancy (RCP, 2019; Regitz-Zagrosek et al, 2018; Green et al, 2020; Hunt et al, 2018). bpm, beats per minute; V/Q scan, ventilation-perfusion scan; CTPA, computed tomography pulmonary angiogram; VTE, venous thromboembolism; 4P Study, pregnancy physiology pattern prediction study; DiPEP study, diagnosis of pulmonary embolism in pregnancy.

to diabetic ketoacidosis (DKA) with a 30% fetal mortality, while two women died from an Addison's disease crisis.

Diabetes in Pregnancy

Pregnancy is a state of ketosis, physiological stress and insulin resistance, the latter particularly as the gestational age increases. Therefore, glycemic control typically becomes more difficult from the time of conception for those with pre-existing diabetes. A pregnant woman's glycaemic control and insulin requirements can significantly change from week to week. The situation may be complicated further, particularly during the first trimester, if they are experiencing nausea and vomiting. If breastfeeding, while insulin resistance improves following delivery, those with pre-existing diabetes may still have some difficulty postpartum due to the energy requirements of lactation.

It is well recognised that poor diabetic control is associated to adverse maternal and fetal outcomes in pregnancy (NHS England, 2023). In the context of pre-existing diabetes, women are at higher risk of miscarriage, pre-eclampsia, infection and diabetic end organ damage (including retinopathy (a pregnant woman should be screened each trimester) and nephropathy which often manifests as a worsening in proteinuria and renal function—in the later stages of pregnancy this can be difficult to distinguish from pre-eclampsia) (Nelson-Piercy, 2020). Fetal risks include congenital abnormalities, large for gestational age, increased neonatal morbidity/mortality and stillbirth. Tighter glucose monitoring and ranges are recommended in pregnancy to help prevent these potential adverse outcomes. Pregnant women are advised to target a fasting glucose level of <5.3 mmol/litre. They are asked to monitor their blood glucose postprandially and to achieve <7.8 mmol/litre 1 hour after food (NICE, 2020).

Diabetic Ketoacidosis (DKA)

Due to the physiological and hormonal changes of pregnancy, pregnancy can impact glucose homeostasis. As a result, pregnant women with diabetes have a higher susceptibility to develop DKA. In addition to type 1 diabetes, it is not uncommon for pregnant women with type 2 diabetes and gestational diabetes to develop DKA. Furthermore, pregnant women with DKA may have only mildly elevated blood glucose levels or may even be euglycaemic compared to the typical very high blood glucose levels seen in the non-pregnant population. Therefore, a higher index of suspicion is recommended when assessing an unwell pregnant woman with diabetes. As ketones are toxic to the fetus, prompt recognition and management is key to help reduce the risk of stillbirth (Nelson-Piercy, 2020; NHS England, 2023).

The management of DKA in pregnancy is largely the same as the non-pregnant women as per the latest Joint British Diabetes Societies for inpatient care (2023), with some cautionary caveats:

- A pregnant woman with DKA requires high dependency unit/level 2 care.
- Early involvement of the wider multidisciplinary team (MDT), particularly if term is approaching:
    - Endocrinology.
    - Obstetrics & maternal medicine team.
    - Consider anaesthetics and neonatologists if near term.
- Use the woman's current weight to dose the fixed rate insulin infusion.
- Caution with intravenous (IV) fluids is advised particularly in the later stages of pregnancy.

Adrenal Insufficiency (AI)

Pregnancy is considered a physiological stress, therefore women with well managed AI can present with an acute decompensation of their disease following conception. This highlights the importance of pre-pregnancy counselling in women with known disease. If a pregnant woman has an infection or nausea and vomiting, she should double her steroid dose until the symptoms resolve. With regard to vomiting, if oral medication is not tolerated, intramuscular (IM)/IV steroids are recommended, as would be the case outside pregnancy. For onward antenatal care, current recommendations suggest increasing maintenance steroid doses by 20–40% at 24 weeks' gestation (Bornstein et al, 2016) with escalation to an IV regime in the intrapartum period.

Pregnancy may unmask underlying disease in an otherwise well woman. In the context of AI, this can be difficult to recognise and diagnose for several reasons. During pregnancy physiological changes occur to both the hypothalamic-pituitary-adrenal axis and the renin-angiotensin-aldosterone system (Lee and Torpy, 2023; Nelson-Piercy, 2020). Due to these hormonal changes, raised levels of cortisol and renin are seen in pregnancy and therefore their use for diagnostic purposes is not reliable. Symptoms and some clinical features of AI overlap with symptoms considered normal in pregnancy such as nausea, vomiting, fatigue, weakness and hyperpigmentation of skin, leading to a risk of delay in diagnosis and by default a delay in life saving treatment. Objective and quantitative data that can be used to help

support a suspected diagnosis of AI in pregnancy is weight gain (is it appropriate for pregnancy?), potassium levels (reference ranges are the same as non-pregnant women) and blood pressure.

If AI is suspected, treat with IV hydrocortisone as in a non-pregnant woman and refer to endocrinology, alongside ongoing antenatal care (Bornstein et al, 2016). As cortisol levels are difficult to interpret during pregnancy, an adrenocorticotropic hormone (ACTH) simulation test is the preferred investigation, with a higher target cortisol response for an 'adequate test' in pregnancy.

Hypercalcaemia

While hypercalcaemia is not common in pregnancy, there are significant fetal and maternal complications in those that are affected (Appelman-Dijkstra et al, 2021). In cases of severe hypercalcaemia (Ca^{2+} >3.5 mmol/L), the rate of fetal mortality is as high as 40% (Nelson-Piercy, 2020). Other potential risks include hypertension, pre-eclampsia, pancreatitis and pre-term labour.

Due to the cardiovascular changes and dilutional intravascular effect that occurs during pregnancy, as well as the fetal calcium demand, the severity of hypercalcaemia can be masked antenatally. Upon delivery a mother with hyperparathyroidism is at risk of a rebound hypercalcaemia following birth and should have calcium levels monitored postpartum.

It can be difficult to differentiate between normal symptoms of pregnancy/postpartum and those of hypercalcaemia as many of the symptoms are non-specific; constipation, fatigue, thirst and altered mood (Appelman-Dijkstra et al, 2021). Blood tests with a bone profile to check the calcium level is recommended in the first instance if you are concerned.

Further investigation and treatment is the same as for the non-pregnant population. This should include blood tests to investigate the underlying driving factor of the hypercalcaemia (vitamin D, parathyroid hormone, thyroid function tests and screening for malignancy). Acute first line treatment is with intravenous fluids (cautiously in the later stages of pregnancy to avoid fluid overload); with clinical review between each 6-hourly 1L infusion. Furosemide can also be considered to aid fluid management as well as calcium excretion. Current data on bisphosphonates in pregnancy is limited, of the data that is available in approximately 100 women, no adverse outcomes were noted in the babies of the exposed women (UKTIS, 2022). Bisphosphonates are not currently routinely recommended in pregnancy, although a balance of risk and benefit may need to be considered depending on the severity of hypercalcaemia alongside involvement of endocrinology and obstetric teams.

Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is often diagnosed in young women before they have considered family planning and having their own children. Active IBD is associated with adverse outcomes during pregnancy, including higher rates of miscarriage, growth restriction, preterm delivery and pre-eclampsia (BSG, 2020). For patients with frequent 'acute flares', reliable contraception should be discussed to avoid higher risk unplanned pregnancies. Women that enter pregnancy with qui-

Table 1. Risk factors for the development of pre-eclampsia.

High risk factors	Moderate risk factors
Hypertension	First pregnancy
Chronic kidney disease	Age (≥40 years)
Diabetes	Pregnancy interval (>10 years)
Autoimmune disease	BMI (≥35 kg/m^2)
Previous acute kidney injury (Tangren et al, 2017), while this is not in the current NICE guidelines studies suggest adverse pregnancy outcomes and increased rates of pre-eclampsia in women who have previously had an acute kidney injury	Family history of pre-eclampsia
	Multiple pregnancy

Interpretation of risk factors: A patient with one high risk factor or 2 or more moderate risk factors should receive aspirin prophylaxis. NICE, National institute for Health and Care Excellence; BMI, Body mass index.

escent disease have the same maternal outcomes as the background population of healthy women (Cao and Grimm, 2021).

It is routinely recommended women with IBD take low-dose aspirin (150 mg daily) for the prevention of pre-eclampsia from 12–36 weeks' gestation, as is recommended for all women with an underlying autoimmune disease (Table 1) (NICE, 2023a). There is often concern over the safety of disease modifying and biological therapies in pregnancy. The majority of these medications are recognised as safe, and women are encouraged to continue taking them during pregnancy to avoid a disease flare. For further information on drugs during pregnancy the UK teratology information service has a useful website resource with the latest available data (UKTIS – Evidence-based safety information about medication, vaccine, chemical and radiological exposures in pregnancy). The British Society of Gastroenterology has produced a table highlighting the safety of medication during pregnancy and the breastfeeding period for women with IBD (Fig. 2 is adapted from this guidance) (BSG, 2020).

An acute deterioration in symptom control should be managed in the same manner as the non-pregnant woman (Lamb et al, 2019). Initial assessment should include blood tests for inflammatory markers, a stool microscopy, culture and sensitivity (MC&S) and calprotectin. Patients with ulcerative colitis can be scored for severity with the Truelove and Witt's classification. If required, flexi-sigmoidoscopy can be performed and is considered safe in pregnancy. An acute disease flare can be treated with steroids and 5-aminosalicylates. In the case of prolonged use of steroids, screening for gestational diabetes should be considered. All patients with an acute flares of their chronic inflammatory disease should be treated with venous thromboembolic prophylaxis unless there is a clear contraindication (RCOG, 2015). Finally, while abdominal imaging is more restrictive and not without risk in pregnancy, pregnancy is not an absolute contraindication if the benefit outweighs the

risk based on the clinical picture (Wiles et al, 2022). Wider MDT discussion should be sought with obstetric teams and obstetric physicians where available to support decision making.

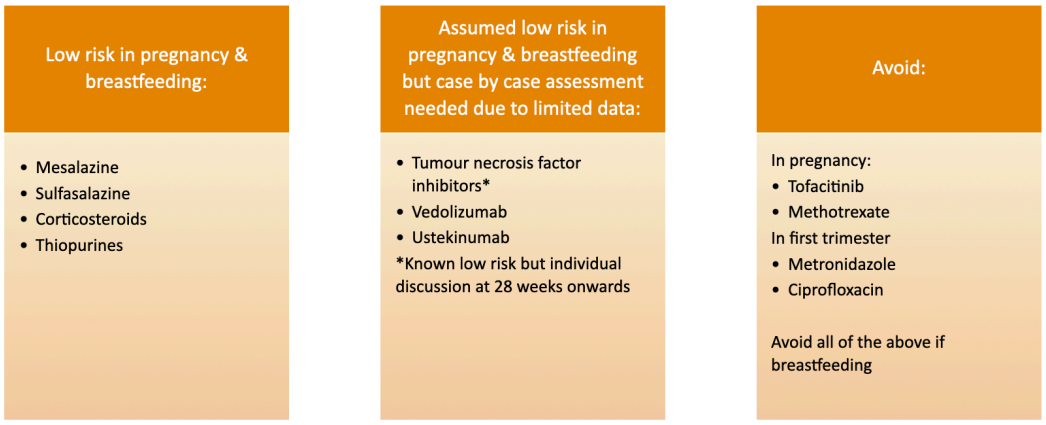

Fig. 2. Guidance on disease modifying drugs for inflammatory bowel disease in pregnancy/if breastfeeding based on BSG (2020).

It is worth noting there is an increased risk of an acute flare in patients with ulcerative colitis in the postpartum period (Nelson-Piercy, 2020). The woman should be advised to monitor symptoms in this period and to ensure that she has access to counselling services and gastroenterological follow-up. Breastfeeding can be encouraged in women with IBD with most medications considered safe or low risk (Fig. 2).

Headache

Headaches are commonly experienced during pregnancy, and it's worth noting that the differential diagnosis of the underlying cause for a headache in pregnancy is simply wider as a pregnant woman is subject to obstetric and non-obstetric causes of a secondary headache. Secondary headaches are more commonly seen in the third trimester and postpartum period, therefore care should be taken when assessing pregnant women during this phase of maternal care. To aid diagnosis the Royal College of Physicians (2019) acute care toolkit and recently published Scotland guidelines (National Maternity Network, 2023) have highlighted red flag symptoms that warrant further assessment in pregnancy (Fig. 3). Common causes of headache observed during pregnancy or postpartum have been highlighted below alongside current practise to aid assessment and treatment plans.

Migraine

Most women who suffer from migraines notice a marked improvement in attack frequency during pregnancy. Many migraine sufferers experience a warning aura lasting up to 1 hour followed by a unilateral, throbbing headache which is typically aggravated by activity and light. Paracetamol and triptan therapy is safe in pregnancy. The UK Teratology Information Service (2024) has recently updated its

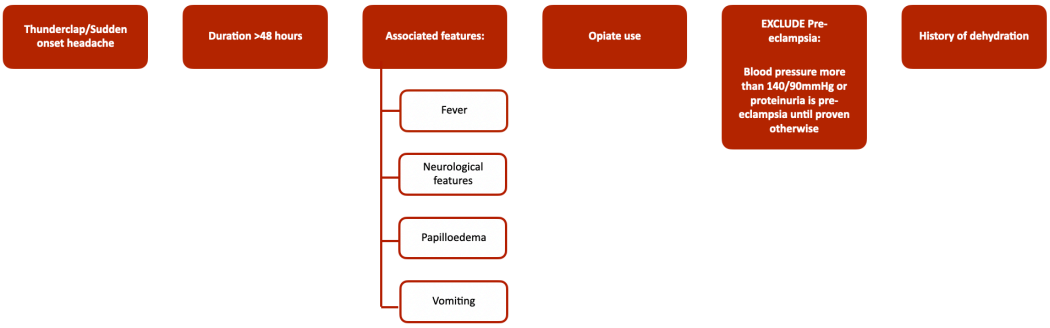

Fig. 3. Red flag symptoms of headache in pregnancy.

guidance on the use of non-steroidal anti-inflammatory drugs during pregnancy and recommends avoidance after 20 weeks' gestation. Preventative treatment should be offered to women experiencing more than 4 days of migraine symptoms per month (BASH, 2019). Amitriptyline and propranolol would be appropriate choices in pregnancy, while candesartan and topiramate are contraindicated.

Meningitis

Meningitis can occur at any point during pregnancy and should be considered in any pregnant woman presenting with a headache and fever. Investigation would routinely include cerebral imaging and a lumbar puncture. When prescribing antibiotics, listeria should also be covered as pregnant women are at higher risk of contracting this due to the immunosuppression effect of pregnancy (NICE, 2023b).

Pre-Eclampsia, Posterior Reversible Encephalopathy Syndrome (PRES) and Reversible Cerebral Vasoconstriction Syndrome (RCVS)

In these three conditions there is an association between headache and hypertension. The normal parameters for hypertension are narrower during pregnancy than in the normal adult population. Blood pressure >140/90 mmHg warrants immediate treatment while blood pressure >160/110 mmHg is deemed an emergency (NICE, 2023a). To support early recognition of hypertension in pregnancy a modified early warning score (MEWS) chart should be used for pregnant women admitted to hospital to prompt early action.

Pre-eclampsia and PRES are in essence a diagnosis of continuum, both of which are most commonly seen in the third trimester (RCP, 2019). Blood tests to assess organ dysfunction (full blood count, renal function, liver function and clotting) and a urine sample for protein:creatinine ratio should be sent if a diagnosis of pre-eclampsia is suspected. Early involvement of the obstetric team is recommended alongside prompt management of blood pressure. Labetolol and nifedipine are the preferred choices for initial blood pressure management as per NICE guidance (NICE, 2023a).

RCVS is more frequently seen postpartum. Women present with a thunderclap headache, associated hypertension +/– neurological symptoms. It is not uncommon to see an ischaemic or haemorrhagic stroke in association with RCVS. Diagnosis is made with magnetic resonance angiography. Nimodipine is the agent of choice

for blood pressure treatment (National Maternity Network, 2023). Wider MDT involvement with neurology and obstetrics is also advised.

Idiopathic Intracranial Hypertension (IIH)

An IIH headache usually presents with a frontal headache and may be accompanied with tinnitus and visual disturbances. The headache is often worse when lying down or in the morning. IIH can be precipitated by rapid weight gain, therefore may present de novo or symptoms may recur during pregnancy (usually from 20 weeks' gestation) in those known to suffer with the condition (National Maternity Network, 2023).

When assessing women, fundoscopy or retinal imaging should be preformed to assess for papilloedema (Mollan et al, 2018). Investigations would include computed tomography (CT) imaging to assess for other potential causes of raised intracranial pressure followed by a diagnostic and therapeutic lumbar puncture if no contraindication (urgently if there is papilloedema). There should be joint management between obstetric and neuro-ophthalmology teams and should include weight gain advice with regular visual field and acuity testing to monitor disease. Treatment may include repeating a therapeutic lumbar puncture, consideration of a ventriculoperitoneal shunt or pharmaceutical management.

Cerebral Vein Thrombosis (CVT)

The coagulopathic changes that occur during pregnancy increase the likelihood of VTE and therefore CVT. Other risk factors include smoking status, a raised body mass index, family history of VTE or medical co-morbidities. The condition is predominantly seen in the third trimester and postpartum period. Symptoms may include a headache, focal neurology, vomiting, reduced consciousness and seizures (National Maternity Network, 2023). Diagnosis can be confirmed with a venogram and treatment is with low molecular weight heparin (LMWH) twice a day. A pregnant woman would need to complete a treatment course and remain on VTE prophylaxis for the remainder of this pregnancy and 6 weeks postpartum. They should also be counselled on needing LMWH for any future pregnancies as soon as they become pregnant. A pregnant woman diagnosed with a CVT will need discussion with neurosurgical, haematology and obstetric teams.

Subarachnoid Haemorrhage (SAH)

A subarachnoid haemorrhage is up to three times more common in pregnancy and even more common postpartum (Nelson-Piercy, 2020). The latest MBRRACE-UK report highlighted 10 women died due to a SAH during pregnancy or up to 1 year after delivery. The subsequent recommendations following review highlighted the need for early recognition and assessment in women with red flag symptoms of headache (Knight et al, 2023).

A SAH will present with a traditional thunderclap headache that peaks within a few minutes of onset. Investigation is by CT scan, which is highly sensitive for SAH diagnosis if performed within 6 hours of the onset of headache (NICE, 2022). A head CT performed after 6 hours of headache onset would require a lumber punc-

ture testing for the presence of xanthochromia (to be performed from 12 hours of headache onset). If SAH is confirmed, treatment with nimodipine and an urgent neurosurgical opinion is advised.

Conclusion

The leading causes of direct and indirect maternal morbidity and mortality have ultimately remained unchanged for many years and the health of the reproductive population has become more complex. Often when the term obstetric medicine is used, there is often a tendency to automatically think of a pregnant woman with a medical problem. Pre-conception and postpartum care should be equally considered, and time taken to discuss any new diagnosis and potential treatment(s) in reproductive women with the view 'they may become pregnant one day'. While this article has primarily focused on acute flares of chronic disease, it would be a missed opportunity not to highlight the important, key role of the physician in clinic. If a woman enters a pregnancy with quiescent disease, maternal and fetal outcomes are improved. As a women's regular practitioner and in a position of trust, routine outpatient clinic consultations can be used to offer pre-pregnancy counselling to manage maternal risk prior to conception, to encourage concordance of medication during pregnancy and provide reassurance. In an ideal world, pre-pregnancy counselling would be offered to every woman to help mitigate any potential obstetric risks.

In the context of acute presentations, to identify a high risk pregnant woman, clinicians need to recognise red flag symptoms that warrant further assessment in the unscheduled care setting. It can be difficult to tease out the symptoms associated with a healthy pregnancy and those associated to an underlying disease due to the systemic effect pregnancy has on major systems. One of the limitations clinicians face when caring for pregnant women, either acutely or chronically is the limited data, evidence and guidelines that have historically been available to support decision making. This directly feeds into clinical uncertainty and inertia. A further consideration is the differential diagnosis is simply wider in pregnancy as a disease process may be non-obstetric or obstetric in nature. Therefore, pregnant women should be assessed with caution and with involvement of a wider MDT to ensure medical and obstetric care is working in synergy. Engaging a wider MDT early is essential as each care provider will add and consider layers of care from their view point. Antenatal care is complex due to pregnancy physiology, considerations around timing and mode of delivery, as well as neonatal factors depending on gestation, therefore team working is a key factor in maternal care. In the last couple of years maternal medicine networks have been set up across the UK to assist in the preconceptual counselling, management and care of maternal medicine patients and support MDT working.

Key Points

- Treat the woman as if she is not pregnant to avoid delays (unless there is a very good reason not to).
- Doing nothing is still a choice and may cause more harm.
- Early MDT involvement to ensure care is managed as a whole.
- Familiarise yourself with your maternal medicine network and specifications on who should be referred.
- Perform a VTE risk assessment at every patient encounter as antenatal care is dynamic and risk profile may change.

Availability of Data and Materials

All data generated or analyzed during this study are included in this article.

Author Contributions

AH produced the original draft. AH, CB and FN made substantial contributions to the conception and design of the work and important editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

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Conflict of Interest

The authors declare no conflict of interest.

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