Aspirin in pregnancy Guideline

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The latest approved version of this document is online.
If the review date has expired, please contact the author for advice.

Powys Teaching Health Board is the operational name of Powys Teaching Local Health Board
Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Version Control:

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	February 2021
2	Reviewed	30/05/2024

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Engagement & Consultation

Key Individuals/Groups Involved in developing this document.

Role / Designation
Powys Midwives
Consultant Midwife
Powys Senior Pharmacist

Circulated to the following for Consultation.

Date	Role / Designation
12/12/2023	Powys Midwives
12/12/2023	Medicines Management Team
04/03/2024	Maternity Guidelines and policies Group
DD/DD/2024	Women and Children's Guidelines Group

Groups approved at

Date	Role / Designation
04/03/2024	Maternity Guidelines and policies group
18/03/2024	Women and Children's Guidelines Group

Evidence Base

Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area?

- NICE (2019) Hypertension in Pregnancy (NG133) updated 2023.
- RCOG 'Care of Women with Obesity in pregnancy' Green Top Guideline No. 72.
- Midwifery-led care Guideline (Wales Maternity & Neonatal Network, 2022)
- NHS England (2023) Saving babies' lives version three: a care bundle for reducing perinatal mortality.
- Health and Care Standards:
  Theme 1 – Staying healthy
  Theme 3 – Effective care
  Theme 4 – Dignified care
  Theme 5 – Timely care

IMPACT ASSESSMENTS

Equality Impact Assessment Summary

	No impact	Adverse	Differentia	Positive	Statement
Age	X				Please remember policy documents are published to both the **intranet** and **internet.** The version on the internet must be translated to Welsh.
Disability	X				
Gender reassignment	X				
Pregnancy and maternity				X	
Race	X				
Religion/ Belief	X				
Sex	X				
Sexual Orientation	X				
Marriage and civil partnership	X				
Welsh Language	X				
Human Rights	X				

Risk Assessment Summary

Have you identified any risks arising from the implementation of this policy / procedure / written control document?

None identified

Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document?

None identified

Have you identified any training and / or resource implications as a result of implementing this?

Will need awareness sessions for staff picked up through group supervision, weekly brief and shire.

1. Introduction

The use of low dose aspirin daily from 12 weeks gestation until the birth of the baby can significantly reduce the incidence of pre-eclampsia by 75% in women who have been clinically risk assessed as being at moderate or high risk of pre-eclampsia and can prevent preterm delivery due to pre-eclampsia by 80% (Roberge et al., 2017). Aspirin is also considered to reduce the risk of hypertensive disorders, placental dysfunction as well as leading to a reduction in small for gestational age babies and fetal or neonatal death (Knight et al., 2019).

Despite the above evidence and recommendation, aspirin does not have a UK marketing authorisation for this indication. Aspirin for this indication must be prescribed or supplied under a Patient Group Direction (PGD). The prescriber should see the summary of product characteristics for the manufacturer's advice on use in pregnancy. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented.

2. Objective

This document outlines the use of aspirin in pregnancy including assessment of the need for aspirin and supply of aspirin.

3. Definitions

- **PTHB** – Powys Teaching Health Board
- **PGD**- Patient Group Direction
- **BMI**- Body mass index
- **BP**- Blood pressure
- **SGA**- Small for gestational age
- **DGH** – District General Hospital
- **WOREQ2**– Ward ordering requests – pharmacy ordering system

4. Roles and Responsibilities

4.1 Head of Midwifery and Sexual Health Services

The Head of the Department must:

- Ensure all staff read and understand this guideline.
- Ensure all staff who will be working to a Patient Group Direction for the supply of aspirin 75mg tablets at a daily dose of 150mg. for pregnant women considered at risk of pre-eclampsia and fetal growth restrictions have been authorised to work to the current version of the PGD.

	• Arrange regular reviews to monitor compliance with this procedure.
4.2	**Midwives** All Midwives working in Powys hold a recognised Midwifery qualification. Each midwife has responsibility to: • Ensure this guideline is followed. • Maintain their own knowledge and skills in this area through self-study, mandatory training, external study days and liaison with District General Hospitals (DGH) in relation to care received outside of Powys. • Appropriately assess women for the need for aspirin at booking. • When required, arrange a supply of aspirin. Complete all associated paperwork relating to aspirin in pregnancy.

5. Assessment

It is the responsibility of the midwife completing the booking appointment to risk assess every woman appropriately for the need for aspirin, recognising that aspirin is most beneficial when taken before 16 weeks gestation. There is no increased risk of adverse fetal or neonatal effects associated with low-dose aspirin exposure.

Pregnant women should be risk assessed against the criteria below to assess the need for antenatal aspirin (NICE, 2023; NHS England, 2023).

In some circumstances a 150mg dose may not be appropriate (see PGD 0171-A for a list of exclusions. Link to full PGD here). These patients should be referred to a prescriber. If working to a PGD, the health care professional must ensure the individual is within the required inclusion criteria, and there are no reasons for exclusion before proceeding with treatment.

High risk factors

If **any** of the following high-risk factors are present the woman is advised to take 150mg (unless a lower dose of 75mg is recommended by a prescriber) of aspirin daily from 12 weeks gestation until the end of pregnancy :

- Hypertensive disease during a previous pregnancy
- Chronic hypertension
- Type 1 or type 2 diabetes
- Chronic Kidney disease
- Systemic lupus erythematosus or antiphospholipid syndrome autoimmune disease

Moderate risk factors

If **two or more** of the following moderate risk factors are present the woman is advised to take 150mg (unless a lower dose of 75mg is recommended by a prescriber) of aspirin daily from 12 weeks gestation until the end of pregnancy:

- Nulliparity
- Age 40 years or older at booking
- Pregnancy interval of more than 10 years
- Body mass index (BMI) of 35kg/m^2 or more at first visit
- Family history of pre-eclampsia in a first degree relative
- Multiple pregnancy

Contraindications for aspirin

- Known allergy to aspirin or other Non-Steroidal Anti-inflammatory Drugs (NSAIDs) or to any of the product excipients
- Known active gastric ulcer
- Known asthma that is triggered by aspirin, Ibuprofen or other NSAIDs
- Individuals aged under 16 years of age
- Known bleeding disorder e.g. Von Willebrand's disease
- Haemophilia

Documentation should be completed within the pregnancy handheld record and reflected in the management plan, including the date aspirin was commenced.

It is the responsibility of the midwife to continually assess use, sensitivity and toleration and advise the woman to cease use if necessary and seek medical advice.

Advice for Women

Aspirin has been shown to have benefits where certain risk factors are present in pregnancy. Aspirin can have some minor side effects, such as indigestion. It is best taken in the evening, with food. Dispersible forms should be dispersed in a small amount of water; enteric and standard tablet forms should be swallowed whole. The recommendation is to continue taking aspirin until the onset of labour, or admission for induction or a planned caesarean birth.

We will provide the first 28 days' supply of aspirin, thereafter women are advised to obtain from their GP.

6. Arranging supply

When aspirin is indicated based on the risk assessment, an initial 28- day supply of 150mg aspirin daily can be supplied under PGD 0171 by the midwife. The midwife must be an authorised name as an approved practitioner under the current terms of the PGD and be responsible for ensuring that the patient is within the inclusion criteria and that there are no reasons for exclusion before proceeding with the treatment.

If there are contraindications present or the woman meets the exclusion criteria within the PGD for aspirin, then advice should be sought from the GP or obstetrician as appropriate. In case of any cautions, medical advice should be sought, and the woman referred.

Aspirin will be ordered via the WOREQ2 pharmacy ordering system.

The woman should be advised to start taking aspirin, at the advised dose, once daily, from 12 weeks gestation. The midwife should advise the woman of the date to start taking it based on her last menstrual period. The latest aspirin should be commenced is by 16 weeks, as evidence suggests there is little or no benefit to commencing it after then (Roberge, et al, 2017).

An email should be sent to the GP (Appendix A) to inform them of the initial supply and to request for aspirin to be made available on a repeat prescription. The woman should be advised to contact the GP surgery to arrange repeat prescription when required.

A copy of the letter should be retained in the midwifery records (tracer).

The handheld records should reflect that aspirin has been supplied.

At the 16-week appointment the midwife should check that eligible pregnant women are taking aspirin and follow up supplies have been arranged via the GP.

7. Intrapartum Considerations

Risk assessments regarding place of birth should be done on an individual basis.

Pregnant women taking antenatal aspirin that have no other clinical comorbidities or risk factors would be recommended to remain on a midwife-led care pathway and continue to birth in a midwife-led Birth Centre or home setting.

Pregnant women that have other clinical comorbidities (suggesting that Powys birth is not suitable) or risk factors and are also taking antenatal aspirin will be reviewed by a consultant obstetrician as appropriate. A clinical information sharing form (CIS) will be circulated to the midwifery team if a choice is made to birth in Powys.

8. Monitoring Compliance/ Audit

Record keeping audits are conducted regularly (10% of annual cases) and include a review of completion of handheld records, risk assessment and management plans.

9. Safeguarding

If any safeguarding concerns or significant risk factors are identified for a child or young person/vulnerable adult (*delete as appropriate), practitioners must follow Wales Safeguarding Procedures (2019) and SGP036 Safeguarding Policy Policies & Written Control Documents - SGP 036 Safeguarding Policy.pdf (sharepoint.com) . Advice and support concerning any safeguarding issue can be sought from PTHB Safeguarding Team via the Safeguarding Hub on 01686 252806 or email PowysTHB.Safeguarding@wales.nhs.uk (Monday-Friday 09:00-17:00, excluding Bank Holidays). Outside of office hours, Local Authority can be contacted on 0345 0544 847 or contact Silver on Call.

All registered practitioners should access appropriate safeguarding supervision and training as per guidance. Safeguarding Supervision (sharepoint.com)

10. Review and Change Control

This document will be reviewed every three years or earlier should audit results or changes to legislation / practice within PTHB indicate otherwise.

11. References/Bibliography

Small for Gestational Age and Fetal Growth Restricted Babies (2021). Wales Maternity and Neonatal Network.

Knight M, Bunch K, Tuffnell D, Shakespeare J, Kotnis R, Kenyon S, Kurinczuk JJ (Eds.) on behalf of MBRRACE-UK. *Saving Lives, Improving Mothers' Care - Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2015-17*. Oxford: National Perinatal Epidemiology Unit, University of Oxford 2019

National Institute for Health and Care Excellence. (2023). Hypertension in Pregnancy: NG133. London: NICE

NHS England (2023) Saving babies' lives version 3: care bundle for reducing perinatal mortality.

Roberge, S., Nicolades, K., Demers, S., Hyett, J., Chaillet, N. & Bujold, E. (2017). The role of Aspirin dose on the prevention of pre-eclampsia and fetal growth restriction: systematic review and meta-analysis. *American journal of Obstetrics and Gynaecology* Feb 2017, 110-120

Rolnik, D., Wright, D., et al. Aspirin versus placebo in pregnancies at high risk for preterm pre-eclampsia. *New England J of Med* 2017

Appendix A

Date:

Dear Doctor,

I have seen

Name:
Date of birth:
P Number

I have identified the following risk factors for pre-eclampsia and fetal growth restriction in pregnancy:

Women at high risk are those with any of the following: *(please circle)*	Women at moderate risk are those with two or more of the following risk factors: *(please circle)*
• Hypertensive disease in a previous pregnancy • Chronic hypertension • Type 1 or type 2 diabetes • Chronic Kidney disease • Autoimmune disease such as systemic lupus erythematosus or antiphospholipid syndrome	• First pregnancy • ≥ 40 years of age at booking • Pregnancy interval of more than 10 years • Body mass index (BMI) of 35kg/m^2 or more at first visit • Family history of pre-eclampsia in a first degree relative • Multiple pregnancy

In accordance with NICE guideline 133 (Hypertension in pregnancy: diagnosis and management, 2019) and NHS England's Saving Babies' Lives Care Bundle Version 3 (2023), treatment with aspirin is recommended from 12 weeks' gestation for women at high risk of pre-eclampsia and also for women with more than one moderate risk factor for pre-eclampsia.

Evidence from randomised controlled trials supports a 75-150mg once daily dose of aspirin. Despite the evidence and recommendation aspirin does not have a UK marketing authorisation for this indication (*off-label use*), therefore aspirin for this indication must be prescribed (the prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented).

I have discussed the national guidance and the benefits of aspirin treatment with the patient. I have also carried out a risk assessment and found no contraindications to treatment. I have therefore provided an initial 28-day supply of aspirin tablets, with directions to take 150mg daily (in accordance with PTHB PGD 0171). To ensure that treatment continues for the remainder of the pregnancy, I would be really grateful if you could provide repeat prescription for aspirin.
The patient is aware that they will need to contact their practice in order to access further supplies.

Thank you for your support. If you have any questions, please do not hesitate to contact a member of the midwifery team.

Yours sincerely

Powys Midwife

Appendix B

Quick reference to exclusion criteria outlined in PGD 0171-A. Link to full PGD here.