Maternal and Child Healthcare

CHI Formulary Indication Review

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Council of Health Insurance

INDICATION UPDATE

ADDENDUM- September 2023

To the CHI Original Maternal and Child Healthcare Clinical Guidance- Issued February 2020

Contents

Related Documents

Related SOPs

- IDF-FR-P-02-01-IndicationsReview&IDFUpdates
- IDF-FR-P-05-01-UpdatedIndicationReview&IDFUpdates

Related WI:

- IDF-FR-WI-01-01SearchMethodologyGuideForNewIndications

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Abbreviations

ACOG	American College of Obstetricians and Gynecologists
CADTH	Canadian Agency for Drugs and Technologies in Health
CHI	Council of Health Insurance
EMA	European Medicines Agency
FDA	Food and Drug Administration
GTG	Green-Top Guideline
HAS	Haute Autorite de Sante
HTA	Health Technology Assessment
IDF	CHI Drug Formulary
IQWIG	Institute for Quality and Efficiency in Health Care
NICE	National Institute for Health and Care Excellence
NTD	Neural Tube Defect
PBAC	Pharmaceutical Benefits Advisory Committee
PMDA	Pharmaceuticals and Medical Devices Agency
PPH	Post-Partum Hemorrhage
SC	Subcutaneous
SFDA	Saudi Food and Drug Authority
SMFM	Society for Maternal-Fetal Medicine
USPSTF	U.S. Preventive Services Task Force
VKDB	Vitamin K Deficiency Bleeding

Executive Summary

Maternal and Child Health (MCH) care is the health services provided to mothers (women in their childbearing age) and children[1].

The targets for Maternal and Child Health are all women in their reproductive age groups, i.e., 15 – 49 years of age, children, school age population and adolescents[1].

Maternal and Child Health is a package of comprehensive health care services designed to meet the promotive, preventive, curative, and rehabilitative needs of pregnant women before, during, and after delivery, as well as infants and preschool children from birth to five years[1].

Objectives of Maternal and Child Health Programs[1]

- Provide basic health care to all mothers and children.
- Reduce maternal mortality and morbidity.
- Reduce prenatal and neonatal mortality and morbidity.
- Prevent malnutrition.
- Prevent communicable diseases.
- Promote reproductive health
- Regulate fertility so that desired and healthy children can be born when desired.
- Ensure the birth of a healthy child.
- Encourage healthy growth and development.

Components of Maternal and Child Health[1]

- Maternal health
- Child health
- Family planning
- School health
- Handicapped children
- Care of children in special setting such as day care

Factors Affecting Maternal and Child Health[1]

- Education level
- Knowledge of one's own right
- Sociocultural practices
- Cultural taboos
- Early marriage and pregnancy
- Gender based violence
- Women's internalization of patriarchal values
- Social services
- Provision of clean water and sanitation

- Health care access and utilization
- Health care quality
- Income/Employment
- Illiterate women's economic activity
- Water, food, and sanitation
- Unbalanced diet
- Family health
- Poor health status of family members
- Lack of accessibility family planning services

Importance of Maternal and Child Health[1]

- It ensures a healthy pregnancy and good health care.
- It aids in the delivery of a healthy baby by providing immunization services, guaranteeing a balanced diet, and maintaining sanitation.
- It safeguards reproductive rights and promotes a happy life.
- It ensures the health of both mother and child.
- It helps to reduce the preventable deaths among women and children.

Challenges in Ensuring Maternal and Child Health[1]

- Universalization of services
- Existing rural-urban differentiation
- Poor status of women in society
- Political and administrative will in this sector
- Acceptance of this issue as a social priority
- Ensure education and services.
- Proper leadership and workforce
- Evidence based approaches.
- Socio cultural and attitudes

The most common direct causes of maternal injury and death are excessive blood loss, infection, high blood pressure, unsafe abortion, and obstructed labor, as well as indirect causes such as anemia, malaria, and heart disease. Most maternal deaths are preventable with timely management by a skilled health professional working in a supportive environment. Every pregnancy and birth are unique. Addressing inequalities that affect health outcomes, especially sexual and reproductive health and rights and gender, is fundamental to ensuring all women have access to respectful and high-quality maternity care[2].

Secondary data from the following standard repositories were compiled for analysis: WHO, UN, UNICEF, and the Saudi Arabia Ministry of Health. The 6-part WHO health system framework was used to structure the analysis. The USA was chosen as a comparator country because KSA and the USA are both high-income OECD countries with predominantly Western-trained physicians and similar health

outcomes, yet the 2 nations diverge in 2 important ways: the KSA is a single payer, and its percent GDP healthcare spending is one-half that of the USA. Results: Life expectancy at birth increased nearly 30 years (from 45.6 years in 1960 to 74.9 years in 2019) among KSA citizens, narrowing the gap with the USA, which gained 8.7 years, from 69.8 to 78.5, during the same period. KSA had identical infant mortality to the USA (2/1,000 live births in both countries) and lower maternal mortality rates (17 vs. 23/100,000 live births) than the USA[3].

CHI issued Maternal and Child Healthcare clinical guidance after thorough review of renowned international and national clinical guidelines in February 2020. Updating clinical practice guidelines (CPGs) is a crucial process for maintaining the validity of recommendations.

This report functions as an addendum to the prior CHI Maternal and Child Healthcare clinical guidance and seeks to offer guidance for the effective management of Maternal and Child Healthcare. It provides an **update on the Maternal and Child Healthcare Guidelines** for CHI Formulary with the ultimate objective of updating the IDF (CHI Drug Formulary) while addressing **the most updated best available clinical and economic evidence related to drug therapies.**

Main triggers for the update are summarized, being **the issuance of updated versions of previously reviewed guidelines** namely, The national institute for health care and excellence (nice) guidelines for antenatal care [**2021**]**,** National Health Services (NHS) clinical guidelines for obstetrics hemorrhage [**2022**], NICE guidelines for intrapartum care for healthy women and babies [2014, updated **2022**], NICE guidelines for Ectopic pregnancy and miscarriage: diagnosis and initial management **2023.**

Moreover, the Saudi MOH pocket manual in obstetrics & gynecology as well as the Saudi Midwifery Clinic Standards (2021) were added to this report.

After carefully examining clinical guidelines and reviewing the SFDA drug list, it is advisable to include the SFDA registered drug **Econazole, Clotrimazole** in the CHI formulary while removing Acellular pertussis, diphtheria, tetanus. Benzylpenicillin. Diphtheria toxoid, hib conjugate, inactivated b pertussis, recombinant hepatitis b antigen, tetanus toxoid. Diphtheria toxoid, tetanus toxoid. Diphtheria toxoid, tetanus, toxoid, haemagglutinin, pertactin,acellular pertussis. Diphtheria toxoid, tetanus toxoid, pertussis toxoid,haemagglutinin,inactivated polio virus (ipv) type 1, inactivated polio virus (ipv) type 2,inactivated polio virus (ipv) type 3,hepatitis b virus hbsag surface antigen,haemophilus influenzae type b. Diphtheria, hemophilus influenzae b, hepatitis b, pertussis, tetanus. Diphtheria, hemophilus influenzae b, pertussis, poliomyelitis, tetanus. Diphtheria, hemophilus influenzae b, pertussis, tetanus. Ferrous gluconate. Haemophilus influenzae type b. Haemophilus influenzae type b. Haemophilus influenzae type b, tetanous toxoid. Influenza vaccine. Influenza vaccine surface antigen nymc x-181, nymc x-187, and nymc bx-35. Poliomyelitis

vaccine. Polysaccharide of neisseria meningitidis group a, polysaccharide of neisseria meningitidis group c as they are no longer registered on the SFDA Drug List of June 2023. There have been no changes or updates made to any of the previously listed drugs in terms of drug information and prescribing edits since February 2020.

All recommendations are well supported by reference guidelines, Grade of Recommendation (GoR), Level of Evidence (LoE) and Strength of Agreement (SoA) in all tables reflecting specific drug classes' role in the Maternal and Child Healthcare therapeutic management.

Below is a table summarizing the major changes based on the different Maternal and Child Healthcare guidelines used to issue this report:

Table 1. General Recommendations for the Management of Maternal and Child Healthcare

Management of Maternal and Child Healthcare		
General Recommendations	**Level of Evidence/Grade of Recommendation**	**Reference**
Nausea and Vomiting For pregnant women with mild-to-moderate nausea and vomiting who prefer a non-pharmacological option, suggest that they try ginger. For pregnant women with nausea and vomiting who choose a pharmacological treatment, offer an antiemetic. For pregnant women with moderate-to-severe nausea and vomiting: consider intravenous fluids, ideally on an outpatient basis; consider acupressure as an adjunct treatment**.**	Not graded	NICE guidelines for antenatal care, 2021
Heartburn Consider a trial of an antacid or alginate for pregnant women with heartburn. Elements of care: ➢ Offer simple lifestyle advice, including advice on healthy eating, weight reduction and smoking cessation.	Not graded	NICE guidelines for antenatal care, 2021

➢ Advise people to avoid known precipitants they associate with their dyspepsia where possible. These include smoking, alcohol, coffee, chocolate, fatty foods and being overweight. Raising the head of the bed and having a main meal well before going to bed may help some people.		
Symptomatic vaginal discharge Evaluate the cause of symptomatic vaginal discharge in pregnant women by conducting a vaginal swab if uncertainty exists. Consider oral or vaginal antibiotics to treat bacterial vaginosis in pregnant women. Offer vaginal imidazole (such as clotrimazole or econazole) to treat vaginal candidiasis in pregnant women.	Not graded	NICE guidelines for antenatal care, 2021
Unexplained vaginal bleeding after 13 weeks Offer anti-D immunoglobulin to women who present with vaginal bleeding after 13 weeks of pregnancy if they are: • rhesus D-negative and • at risk of isoimmunization • For pregnant women with unexplained vaginal bleeding after 13 weeks, assess whether to admit them to hospital, considering: ➢ the risk of placental abruption ➢ the risk of preterm delivery ➢ the extent of vaginal bleeding ➢ the woman's ability to attend secondary care in an emergency. • For pregnant women who present with unexplained vaginal bleeding, offer to carry out placental localization	Not graded	NICE guidelines for antenatal care, 2021

by ultrasound if the placental site is not known. ➢ For pregnant women with unexplained vaginal bleeding who are admitted to hospital, consider corticosteroids for fetal lung maturation if there is an increased risk of preterm birth within 48 hours. Consider gestational age.		
Post-Partum Hemorrhage (PPH) Clinicians should consider the use of intravenous tranexamic acid 1.0 g IV, in addition to Oxytocin at caesarean section to reduce blood loss in women at increased risk of PPH.	Not graded	NHS for obstetrics hemorrhage, 2022
Continuing Management of PPH **Management of uterine atony** Anticipate the problem - those women with risk factors should already be on Delivery Suite and have venous access and be receiving an Oxytocin infusion post-partum of 30 units of Oxytocxin in 500 mL 0.9% normal saline at 166 mL/hour as per Trust Guideline for the Management of the Third Stage of Labor including Retained Placenta Trustdocs ID: 818. Confirm that Syntometrine 5/500 IM was given in third stage - if not, do so. NB. In pre-eclampsia or patients with a history of cardiac disease give 5 IU Oxytocin by slow I.V. injection or 10 IU I.M. • Give 1g Tranexamic acid by slow I.V injection (~1mL/min). This is not uterotonic, so will not help uterine tone. However, it is an antifibrinolytic and has been shown to reduce blood loss in this situation, especially if given early.	Not graded	NHS for obstetrics hemorrhage, 2022

• Repeat Syntometrine 5/500 (or Oxytocin if hypertensive or cardiac disease). • Commence infusion of 30 units of Oxytocin in 500 mL 0.9% normal saline at 166 mL/hour if not already in progress. • If ongoing bleeding at 30min or re-bleeding within 24 hours give a further 1g IV Tranexamic Acid. • If the placenta is retained and uterus contracted, try controlled cord traction. If this fails, arrange manual removal of placenta – see guideline for management of third stage of labor. If atony persists, Carboprost (Hemabate), 250 mcg (1.0mL) may be given by deep I.M. injection at the discretion of the Obstetric Registrar. If successful, further doses (maximum of eight) may be required at 15-minute intervals, after discussion with the on-call Consultant.		
Management of miscarriage Offer vaginal micronized progesterone 400 mg twice daily to women with an intrauterine pregnancy confirmed by a scan, if they have vaginal bleeding and have previously had a miscarriage. [2021] If a fetal heartbeat is confirmed, continue progesterone until 16 completed weeks of pregnancy. [2021] For the medical management of missed miscarriage offer: • 200 mg oral mifepristone and • 48 hours later, 800 micrograms misoprostol (vaginal, oral or sublingual) unless the gestational sac has already been passed. [2012, amended 2023]	Not graded	NICE guidelines for for Ectopic pregnancy and miscarriage, updates 2023

Management of tubal ectopic pregnancy Offer surgery as a first-line treatment to women who are unable to return for follow-up after methotrexate treatment or who have any of the following: • An ectopic pregnancy and significant pain • An ectopic pregnancy with an adnexal mass of 35 mm or larger • An ectopic pregnancy with a fetal heartbeat visible on an ultrasound scan • An ectopic pregnancy and a serum hCG level of 5,000 IU/litre or more. [2012] Offer the choice of either methotrexate or surgical management to women with an ectopic pregnancy who have a serum hCG level of at least 1,500 IU/litre and less than 5,000 IU/litre, who are able to return for follow-up and who meet all the following criteria: • No significant pain • An unruptured ectopic pregnancy with an adnexal mass smaller than 35 mm with no visible heartbeat • No intrauterine pregnancy (as confirmed on an ultrasound scan). Advise women who choose methotrexate that their chance of needing further intervention is increased and they may need to be urgently admitted if their condition deteriorates. [2012]	Not graded	NICE guidelines for Ectopic pregnancy and miscarriage, updates 2023
• Offer systemic methotrexate to women who: ➢ Have no significant pain and ➢ Have an unruptured tubal ectopic pregnancy with an adnexal mass	Not graded	NICE guidelines for Ectopic pregnancy and miscarriage, updates 2023

smaller than 35 mm with no visible heartbeat and ➢ Have a serum hCG level less than 1,500 IU/litre and ➢ Do not have an intrauterine pregnancy (as confirmed on an ultrasound scan) and ➢ Are able to return for follow-up. Methotrexate should only be offered on a first visit when there is a definitive diagnosis of an ectopic pregnancy, and a viable intrauterine pregnancy has been excluded. Offer surgery where treatment with methotrexate is not acceptable to the woman. [2012, amended 2019]		
Maternal Immunization • Hepatitis B vaccination for all unvaccinated pregnant adults. Additionally. • Pneumococcal vaccination for pregnant individuals at increased risk of severe pneumococcal disease. • COVID-19 vaccination for all pregnant individuals who were not vaccinated prior to pregnancy. • Pregnant and recently pregnant people up to 6 weeks postpartum should receive a bivalent mRNA COVID-19 vaccine booster dose following the completion of their last COVID-19 primary vaccine dose or monovalent booster. COVID-19 vaccines are recommended for postpartum and lactating individuals who were not vaccinated prior to or during pregnancy.	Not graded	ACOG, 2022
Pregnant individuals who are at a high risk of developing preeclampsia,	Not graded	ACOG, 2021 reaffirmed 2022

especially if they have one or more of the following risk factors: A history of pre-eclampsia, especially if it resulted in adverse outcomes, Carrying multiple fetuses (multifetal gestation), Suffering from chronic hypertension., Having pre-existing type 1 or 2 diabetes, Dealing with kidney disease, Battling autoimmune diseases like systemic lupus erythematosus or antiphospholipid syndrome, Possessing combinations of multiple moderate-risk factors. ➢ These risk factors consistently show a strong association with the highest risk of developing preeclampsia. In a population of pregnant individuals with one or more of these risk factors, the incidence of preeclampsia is likely to be at least 8%. Pregnant individuals who have multiple moderate risk factors, including but not limited to: No prior pregnancies (nulliparity), Obesity, indicated by a body mass index (BMI) over 30, A family history of preeclampsia, such as a mother or sister who experienced it, Black ethnicity (used as a proxy for the presence of underlying racial disparities), Lower income, Age 35 years or older, Personal history factors like a previous low birth weight or being born small for gestational age, a history of adverse pregnancy outcomes, or an interval of more than 10 years between pregnancies, Having undergone in vitro fertilization.		
Vitamin K should be administered to all newborn infants weighing >1500 g as a single, intramuscular dose of 1 mg within 6 hours of birth.	Not graded	American Academy of Pediatrics, 2022
Folic acid supplementation	Strong, High.	

Health care providers should advise all women aged 12–45 years considering or planning a pregnancy about the benefits of taking an oral daily multivitamin containing folic acid (0.4-1mg) to optimize serum and red blood cell folate levels.		Journal of Obstetrics and Gynaecology Canada, 2022

At the end of the report, a **key recommendation synthesis section** is added highlighting the latest updates in **Maternal and Child Healthcare clinical and therapeutic management.**

Section 1.0 Summary of Reviewed Clinical Guidelines and Evidence

This section is divided into two parts: the first includes recommendations from **updated versions of guidelines** mentioned in the previous CHI Maternal and Child Healthcare report, and the second includes **newly added guidelines** that have helped generate this report.

1.1 Revised Guidelines

This section contains the **updated versions** of the guidelines mentioned in the February 2020 CHI Maternal and Child Healthcare Report and the corresponding recommendations:

Table 2. Guidelines Requiring Revision

Guidelines Requiring Revision	
Old Versions	**Updated versions**
Section A.1.0 Clinical Guidelines for Maternal and Child Supplementation of Micronutrients	
A.1.1 WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience (2016)	N/A*
A.1.2 The National Institute for Health Care and Excellence (NICE) Guidelines for Antenatal Care (2019)	The National Institute for Health Care and Excellence (NICE) Guidelines for Antenatal Care (2021)
A.1.3 Australian Clinical Practice Guidelines for Pregnancy Care (2018)	Australian Clinical Practice Guidelines for Pregnancy Care (2020)

A.1.4 The National Institute for Health Care and Excellence (NICE) Guidelines for Maternal and Child Nutrition (Updated in 2018) & Vitamin D: Supplement Use in Specific Population Groups (2014)	N/A* *Note that dates are wrong:* The National Institute for Health Care and Excellence (NICE) Guidelines for Maternal and Child Nutrition (Updated in **2014**) & Vitamin D: Supplement Use in Specific Population Groups (Updated in **2017**)
A.1.5 Global Consensus Recommendations on Prevention and Management of Nutritional Rickets (2016)	N/A*
A.1.6 American Academy of Pediatrics Guidelines for Prevention and Management of Rickets (Updated 2010)	American Academy of Pediatrics Guidelines for Prevention and Management of Rickets (Updated 2017) *No access to the guidelines*
A.1.7 WHO Guidelines for Iron Supplementation in Postpartum Women (2016)	N/A*
A.1.8 WHO Recommendations on Child Health (2017)	N/A*
A.1.9 Society of Obstetricians and Gynaecologists of Canada (SOGC) Clinical Practice Guideline: Pre-Conception Folid Acid and Multivitamin Supplementation for the Primary and Secondary Prevention of Neural Tube Defects and Other Folid Acid-Sensitive Congenital Anomalies (2015)	Guideline No. 427: Folic Acid and Multivitamin Supplementation for Prevention of Folic Acid–Sensitive Congenital Anomalies (2022)
A.1.10 WHO Essential Nutrition Actions: Improving Maternal, Newborn, Infant, and Young Child Health and Nutrition (2013)	N/A*
A.1.11 WHO Recommendations for Optimal Feeding of Low Birthweight Infants in Low- and Middle-Income Countries (2011)	N/A*
Section B.1.0 Guidelines for Perinatal, Peripartum, and Postnatal Care	

B.1.1 The American College of Obstetricians and Gynecologists (ACOG) Committee Opinion for Prevention of Group B Streptococcal Early-Onset Disease in Newborn (2019)	N/A*
B.1.2 American Academy of Pediatrics Guidelines for Management of Infants at Risk of Group B Streptococcal Disease (2019)	N/A*
B.1.3 Royal College of Obstetricians and Gynaecologists (RCOG) Guidelines for Prevention of Early Onset Neonatal Group B Streptococcal Disease (2017)	Royal College of Obstetricians and Gynaecologists (RCOG) Guidelines: Updated RCOG Group B Strep Guidelines (2022)
B.1.4 The International Federation of Gynecology and Obstetrics (FIGO) Initiative on Pre-Eclampsia: A Pragmatic Guide for First-Trimester Screening and Prevention (2019)	N/A*
B.1.5 The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal–Fetal Medicine: Low-Dose Aspirin Use During Pregnancy (2018)	American College of Obstetricians and Gynecologists (ACOG) Guideline on Low-Dose Aspirin Use for the Prevention of Preeclampsia and Related Morbidity and Mortality (Updated December 2021 and reaffirmed October 2022)
B.1.6 WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience (2016)	N/A* *This guideline was previously mentioned as section A.1.1*
B.1.7 British Committee for Standards in Hematology (BCSH) Guideline for the Use of Anti-D Immunoglobulin for the Prevention of Haemolytic Disease of the Fetus and Newborn (2013)	N/A*
B.1.8 American Family Physician (AAFP): First Trimester Bleeding: Evaluation and Management (2019)	N/A*
B.1.9 National Health Services (NHS) Clinical Guidelines for Obstetrics Hemorrhage (2019)	National Health Services (NHS) Clinical Guidelines for Obstetrics Hemorrhage (2022)

B.1.10 WHO Recommendation on the Use of Uterotonics for the Prevention of Postpartum Hemorrhage (PPH) (2018)	BMJ Global Health. WHO Recommendation on Uterotonics for Postpartum Haemorrhage Prevention: What Works, and Which One? (2019)
B.1.11 WHO Recommendation on Tranexamic Acid for the Treatment of Postpartum Haemorrhage (2017)	N/A*
B.1.12 Royal College of Obstetricians and Gynaecologists (RCOG) Guidelines for the Prevention and Management of Postpartum Hemorrhage (PPH) (2016)	N/A*
B.1.13 The American College of Obstetrics and Gynecologists (ACOG) Guidelines for Early Pregnancy Loss (2018)	N/A*
B.1.14 NICE Guidelines for Ectopic Pregnancy and Miscarriage (2017)	NICE Guidelines for Ectopic Pregnancy and Miscarriage: Diagnosis and Initial Management (Published 2019, Updated 2023)
B.1.15 NICE Guidelines for Preterm Labor and Birth Overview (Updated 2020), Preterm Labor and Birth (Updated 2019) & Induction of Labor (2018)	N/A*
B.1.16 WHO Recommendation on Maternal Health (2017)	N/A*
B.1.17 WHO Recommendations on Intrapartum Care for a Positive Childbirth Experience (2018)	N/A*
B.1.18 NICE Guidelines for Intrapartum Care for Healthy Women and Babies (2017)	NICE Guidelines for Intrapartum Care for Healthy Women and Babies (2014, Updated 2022)
B.1.19 Position Statement: Guidelines for Vitamin K Prophylaxis in Newborns, A Joint Statement of the Canadian Pediatric Society and the College of Family Physicians of Canada (2018)	N/A*

B.1.20 American Academy of Pediatrics Policy Statement: Controversies Concerning Vitamin K and the Newborn (2003)	American Academy of Pediatrics Policy Statement: Controversies Concerning Vitamin K and the Newborn (2022)
B.1.21 WHO Recommendations Newborn Health (2017)	N/A*
Section C.1.0 Immunization Clinical Guidelines	
C.1.1 ACOG Summary of Maternal Immunization Recommendations (2018)	This Practice Advisory serves as an update to the American College of Obstetricians and Gynecologists (ACOG) Committee Opinion No. 741, Maternal Immunization, originally published in 2018 (2022)
C.1.2 Center for Disease Control and Prevention (CDC) Immunization Schedule for Children from Birth Through 6 Years Old (2020)	Center for Disease Control and Prevention (CDC) Immunization Schedule for Children from Birth Through 6 Years Old (2023)

*: *No updated versions available*

1.1.1 The National Institute for Health Care and Excellence (NICE) Guidelines for Antenatal Care (2021)

*Please refer to **Section A.1.2** of CHI Maternal and Child Healthcare original clinical guidance.*

The 2021 revised edition of NICE's Guidelines for **Antenatal Care**[4] introduced a set of recommendations accompanied by a grading scheme, outlined as follows:

Table 3. NICE Guidelines Grade of Recommendations

Grade of Recommendation	Definition
High	We are *very confident that the true effect is close to the estimate.*
Moderate	We have *moderate confidence in the effect estimate*: The true effect is likely to be close to this effect estimate, but there is a possibility that it is substantially different.
Low	Our *confidence in the estimate of the effect is limited*: The true effect may be substantially different from the estimate.
Very Low	We have *very little confidence* in the estimate of the effect: The true effect is likely to be substantially different from the estimate.

The recommendations listed below are assigned the grades defined in the preceding table:

Interventions for common problems during pregnancy

Nausea and vomiting

- Reassure women that mild to moderate nausea and vomiting are common in pregnancy and are likely to resolve before 16 to 20 weeks.
- Recognize that by the time women seek advice from healthcare professionals about nausea and vomiting in pregnancy, they may have already tried several different interventions.
- For pregnant women with mild-to-moderate nausea and vomiting who prefer a non-pharmacological option, suggest that they try ginger.
- When considering pharmacological treatments for nausea and vomiting in pregnancy, discuss the advantages and disadvantages of different antiemetics with the woman. Consider her preferences and her experience with treatments in previous pregnancies. The below table summarizes the advantages and disadvantages of different pharmacological treatments for nausea and vomiting in pregnancy:

Table 4. Advantages and Disadvantages of Different Pharmacological Treatments for Nausea and Vomiting in Pregnancy. Retrieved from NICE 2021 Guidelines for Antenatal Care, www.nice.org.uk/guidance/ng201.

Medicine	Is this licensed for nausea and vomiting in pregnancy?	How effective is it likely to be at treating nausea and vomiting in pregnancy?	Is it associated with an increased chance of birth defects?	Other safety concerns See the BNF and manufacturers' information for full prescribing information
Chlorpromazine	No, but established practice and used for many years. Manufacturers advise it should not be taken during pregnancy unless considered essential.	No randomised controlled trial evidence on nausea and vomiting in pregnancy.	Available evidence does not suggest an increased chance of birth defects.	Use in the third trimester may sometimes cause nervous system side effects in newborn babies such as restlessness, trembling, muscle stiffness or spasm (known as extrapyramidal side effects) or withdrawal symptoms.
Cyclizine	No, but established practice and used for many years. Manufacturers say taking it in pregnancy is not advised because it has not been proven to be safe.	No randomised controlled trial evidence on cyclizine alone for nausea and vomiting in pregnancy. Older, low quality evidence found a combination product of cyclizine with pyridoxine relieved nausea and vomiting (but this is not available in the UK).	Available evidence does not suggest an increased chance of birth defects.	Use towards the end of the third trimester may sometimes cause side effects in newborn babies such as irritability and jitteriness (known as paradoxical excitability) and tremor.
Medicine	**Is this licensed for nausea and vomiting in pregnancy?**	**How effective is it likely to be at treating nausea and vomiting in pregnancy?**	**Is it associated with an increased chance of birth defects?**	**Other safety concerns** **See the BNF and manufacturers' information for full prescribing information**
Doxylamine/pyridoxine (combination drug)	The only product specifically licensed in the UK for nausea and vomiting in pregnancy. Not licensed for use by people aged under 18.	Some low or very low quality evidence showed symptom relief compared with placebo. Moderate or low quality evidence from a small study found it is less likely to be effective than ondansetron.	Available evidence does not suggest an increased chance of birth defects.	–
Metoclopramide	No, but established practice as second-line treatment for nausea and vomiting in pregnancy. Manufacturers say that it can be taken during pregnancy if necessary.	High quality evidence found benefits on overall symptom relief, nausea intensity and vomiting intensity compared with placebo.	Available evidence does not suggest an increased chance of birth defects.	Not recommended for more than 5 days' use or for people aged 18 or younger (except for specific conditions not related to nausea and vomiting in pregnancy) because of the risk of nervous system side effects in the woman. These include restlessness, trembling, muscle stiffness or spasm (known as extrapyramidal side effects).

Medicine	Is this licensed for nausea and vomiting in pregnancy?	How effective is it likely to be at treating nausea and vomiting in pregnancy?	Is it associated with an increased chance of birth defects?	Other safety concerns See the BNF and manufacturers' information for full prescribing information
	Manufacturers advise it should not be taken during pregnancy unless considered essential. The manufacturers of the Buccastem M brand say it should not be taken in pregnancy at all.			or spasm (known as extrapyramidal side effects) or withdrawal symptoms.
Promethazine	No, but established practice and used for many years. Manufacturers advise it should not be taken during pregnancy unless considered essential.	Limited, moderate quality evidence found similar benefits on vomiting frequency to a combination product of metoclopramide with pyridoxine (not available in the UK).	Available evidence does not suggest an increased chance of birth defects.	Use towards the end of the third trimester may sometimes cause side effects in newborn babies such as irritability and jitteriness (known as paradoxical excitability) and tremor.
				Use towards the end of the third trimester may sometimes cause extrapyramidal side effects in newborn babies.
Ondansetron	No, but established practice as treatment for severe nausea and vomiting in pregnancy. Manufacturers advise it should not be taken during the first trimester.	Moderate or low quality evidence from a small study found it is more likely to be effective than doxylamine/pyridoxine combination.	Increased chance of the baby being born with a cleft lip or cleft palate. This is an increase of 3 extra cases per 10,000 from 11 in 10,000 to 14 in 10,000, so with ondansetron 9,986 out of 10,000 babies would not have this. Some evidence suggests ondansetron may cause heart problems in babies but other evidence does not support this.	–
Prochlorperazine	No, but established practice and used for many years.	No randomised controlled trial evidence on nausea and vomiting in pregnancy.	Available evidence does not suggest an increased chance of birth defects.	Use in the third trimester may sometimes cause nervous system side effects in newborn babies such as restlessness, trembling, muscle stiffness

- For pregnant women with nausea and vomiting who choose a pharmacological treatment, offer an antiemetic (see table 4 on the advantages and disadvantages of different pharmacological treatments for nausea and vomiting in pregnancy).
- For pregnant women with moderate-to-severe nausea and vomiting:
  - consider intravenous fluids, ideally on an outpatient basis.
  - consider acupressure as an adjunct treatment.
- Consider inpatient care if vomiting is severe and not responding to primary care or outpatient management. This will include women with hyperemesis gravidarum.

Heartburn

- Give information about lifestyle and dietary changes to pregnant women with heartburn in line with the section on common elements of care in the NICE guideline on gastro-esophageal reflux disease and dyspepsia in adults mentioned as follows[5]:
  - Offer simple lifestyle advice, including advice on healthy eating, weight reduction and smoking cessation. [2004]
  - Advise people to avoid known precipitants they associate with their dyspepsia where possible. These include smoking, alcohol, coffee, chocolate, fatty foods and being overweight. Raising the head of the bed and having a main meal well before going to bed may help some people. [2004]
  - Provide people with access to educational materials to support the care they receive. [2004]
  - Recognize that psychological therapies, such as cognitive behavioral therapy and psychotherapy, may reduce dyspeptic symptoms in the short term in individual people. [2004, amended 2014]
  - Encourage people who need long-term management of dyspepsia symptoms to reduce their use of prescribed medication stepwise: by using the effective lowest dose, by trying 'as needed' use when appropriate, and by returning to self-treatment with antacid and/or alginate therapy (unless there is an underlying condition or comedication that needs continuing treatment). [2004, amended 2014]
- Consider a trial of an antacid or alginate for pregnant women with heartburn.

Symptomatic vaginal discharge

- Advise pregnant women who have vaginal discharge that this is common during pregnancy, but if it is accompanied by symptoms such as itching, soreness, an unpleasant smell, or pain on passing urine, there may be an infection that needs to be investigated and treated.
- Consider carrying out a vaginal swab for pregnant women with symptomatic vaginal discharge if there is doubt about the cause.
- If a sexually transmitted infection is suspected, consider arranging appropriate investigations.
- Offer vaginal imidazole (such as clotrimazole or econazole) to treat vaginal candidiasis in pregnant women.

- Consider oral or vaginal antibiotics to treat bacterial vaginosis in pregnant women in line with the NICE guideline on antimicrobial stewardship.

Unexplained vaginal bleeding after 13 weeks

- Offer anti-D immunoglobulin to women who present with vaginal bleeding after 13 weeks of pregnancy if they are:
  - rhesus D-negative and
  - at risk of isoimmunization.
- Refer pregnant women with unexplained vaginal bleeding after 13 weeks to secondary care for a review.
- For pregnant women with unexplained vaginal bleeding after 13 weeks, assess whether to admit them to hospital, taking into account:
  - the risk of placental abruption
  - the risk of preterm delivery
  - the extent of vaginal bleeding
  - the woman's ability to attend secondary care in an emergency.
- For pregnant women who present with unexplained vaginal bleeding, offer to carry out placental localization by ultrasound if the placental site is not known.
  - For pregnant women with unexplained vaginal bleeding who are admitted to hospital, consider corticosteroids for fetal lung maturation if there is an increased risk of preterm birth within 48 hours. Consider gestational age.
  - Consider discussing the increased risk of preterm birth with women who have unexplained vaginal bleeding.

1.1.2 National Health Services (NHS) Clinical Guidelines for Obstetrics Hemorrhage (2022)

*Please refer to **Section B.1.9** of CHI Maternal and Child Healthcare original clinical guidance.*

The 2022 revised edition of National Health Services' Guidelines for clinical guidelines for obstetrics hemorrhage[6] introduced a set of recommendations without detailing a grading scheme.

Post-Partum Hemorrhage (PPH)

- Measures for minor PPH (blood loss 500–1000 mL) without clinical shock:

• Intravenous access (one 16-gauge cannula).

• Urgent venipuncture (20 mL) for:

a. Group and screen.

b. Full blood count.

c. Coagulation screen.

• Pulse, respiratory rate, temperature, and blood pressure plus MEOWS score recording every 15 minutes.

• Commence warmed crystalloid infusion. Failure to recognize and adequately treat a primary PPH can quickly lead to Major obstetric Hemorrhage.

Failure to recognize and adequately treat a primary PPH can quickly lead to major obstetric Hemorrhage.

Initial Management of APH and PPH

- If managed inadequately or in an untimely manner, major APH and PPH will quickly lead to sudden maternal collapse.

Immediate Management

- The initial management of obstetric hemorrhage involves assessment and maternal resuscitation followed by treating the cause of hemorrhage – and this is common to both APH and PPH.

Speed is of the essence, so clear lines of communication between the midwifery, obstetric, anesthetic and the blood transfusion staffs is essential. Where feasible it is important to keep the patient and her birthing partner informed of what is happening and proposed management.

- The massive blood transfusion protocol should be followed, and laboratory staff alerted by ringing extension 2905 and use of the trigger phrase “I want to trigger the Massive Blood Transfusion Protocol”. This is linked to the trust guideline for massive blood loss in adults. This will obtain: 5 units of PRC and 4 of FFP.

1. Activate massive blood loss protocol and initiate transfusion State: ‘I want to trigger the massive blood loss protocol’ to request major blood loss pack (MBL)

   Give 4 units blood via fluid warmer:

   - Give Group O if immediate need and/ or blood group unknown.

- Blood transfusion lab will provide further group O / group specific / crossmatched red cells as required.

Clearly state: “I want to trigger the massive blood transfusion protocol”
Weekday extension: 2905/2906

- Aim to maintain Hb >8g/dL
- O Neg blood available immediately Group specific blood available in 25 minutes. Group O will be available until group specific blood is available. This may be O Pos for men > 18 years old and women > 50 years old.
- Crossmatched blood available in 45 minutes.

2. Continue transfusion with major blood loss packs.
    - MBL pack A) 5 units blood FFP
    - MBL pack B) If a second or subsequent Major Blood Loss Pack is required these will contain.
        - 5 units blood ·
        - 4 units FFP
        - 1 adult dose of platelets for adults, Cryoprecipitate

    IF COAG SCREEN IS NOT TAKEN, PLEASE DO SO!

    - Aim to maintain Hb > 8 g/dL.
    - Aim for PT and APTT 1.13 mmol/L
    - FFP thawed in 20 – 30 min.
    - Anticipate PLTs < 50 X 109 /L after 2 BV replacement, therefore.
    - Aim PLTs > 100 X 109 /L if there is ongoing active hemorrhage Cryoprecipitate replaces fibrinogen and factor 8 Aim for fibrinogen >1.5g/ L Fibrinogen < 0.5g/ L strongly associated with microvascular bleeding.
    - Cryoprecipitate thawed in 20 – 30 minutes.
    - NB. The blood bank will issue compatible FFP and PLTs which will not necessarily be the same group as patient. Ensure Electronic Blood Tracking system is used throughout.
3. Contact senior personnel: Consultant anesthetist, Consultant surgeon, gastroenterologist, obstetrician as appropriate, Blood bank.

4. Arrest bleeding
    - Remember simple measures (pressure/elevation) can be useful.
    - Early surgical intervention
    - Consider interventional radiology.
5. Repeat blood tests.
    - If continued oozing repeat FBC and Coag. screen every 4 hours or after every 5 units of blood given.
    - It is recommended to perform at least one set of tests after a major transfusion.
    - Serum Calcium and Potassium Hypocalcemia and hyperkalemia can occur especially with hypothermia and acidosis. Monitor ECG.
6. Suspect DIC
    - Treat underlying cause (i.e., of blood loss)
    - Shock, hypothermia, and acidosis increase risk.

Remember – **ABC**

1. Airway maintenance, if pregnant left lateral tilt. Chin lift.
2. Breathing - Administer oxygen 10 -15 L/min via a face mask
3. Circulation - Ensure IV access -16-gauge intravenous cannulae x 2.
4. Take bloods for FBC, U&E clotting and X-match (4 units) and Kleihauer if Rh negative. All patients should be given blood of their own blood group as soon as possible. If the blood bank is informed of the urgency, ABO and Rh D compatible blood can usually be made available on an emergency basis soon after receipt of the crossmatch sample. Additional colloid will be necessary if more than 3 units have been given. Only use un-crossmatched O Rh D negative blood if transfusion must be given immediately.
5. Initial fluid management. Rapid infusion of 2000 mL of warmed Hartmann's solution.
6. The anesthetist will normally supervise the management of fluid replacement.
7. An indwelling bladder catheter should be inserted with hourly measurement output.
8. Strict fluid balance is essential, and a fluid balance chart should be initiated and carefully maintained.
9. Postnatal women can be laid flat possibly with a head down tilt if there are signs of hypovolemia,

10. Regular haemoglobin and hematocrit assessment is helpful but restoration of normovolaemia is priority.
11. Fluid resuscitation and blood transfusion should not be delayed because of false reassurance from a single haemoglobin result; consider the whole clinical picture
12. Platelet counts, and coagulation studies should be performed as a guide to the need for replacement therapy with fresh frozen plasma, cryoprecipitate, or platelet concentrates.
13. A plasma fibrinogen level of greater than 2 g/L should be maintained during ongoing PPH.
14. Give 4g Fibrinogen Concentrate after first 4 units of blood transfused BEFORE considering FFP and/or cryoprecipitate.
15. Clinicians should consider the use of intravenous tranexamic acid 1.0 g IV, in addition to Oxytocin at caesarean section to reduce blood loss in women at increased risk of PPH.
16. In a woman who is bleeding and is likely to develop a coagulopathy or has evidence of a coagulopathy, it is prudent to give blood components before coagulation indices deteriorate and worsen the bleeding.
17. Keep the patient warm.
18. If bleeding is ongoing after the first 4 units of blood have been transfused and fibrinogen concentrate given, then the primary pack from the major obstetric hemorrhage protocol should be used (5 units RBC as indicated, 4 units FFP).
19. Ensure appropriate blood product replacement. Up to 1000 mL of fresh frozen plasma (FFP) and 10 units of cryoprecipitate (two packs) maybe given in the face of relentless bleeding, while awaiting results of coagulation studies.
20. Correct acidosis, hypothermia (clotting is prolonged with hypothermia – active warming measures should be considered) & hypocalcemia.
21. Involve consultant hematologist if coagulation defect before surgical intervention.
22. Monitor BP, pulse, urine output, O2 saturation, respiratory rate continuously and temperature every 15 minutes – Record on Mega chart. In cases of severe APH commence CTG. MEOWs Scores must be attributed to each set of observations.
23. Invasive intravascular monitoring may be initiated by the anesthetist.
24. Record keeping. Ensure records are up to date and complete following the event and that all drugs are prescribed.

Continuing Management of PPH

Management of uterine atony

1. Anticipate the problem - those women with risk factors should already be on Delivery Suite and have venous access and be receiving an **Oxytocin** infusion post-partum of 30 units of Oxytocxin in 500 mL 0.9% normal saline at 166 mL/hour.
2. "Rub-up" the uterine fundus to stimulate uterine contraction and consider removal of vaginal/uterine clots. Consider Bi-manual compression.
3. Confirm that **Syntometrine** 5/500 IM was given in third stage - if not, do so. NB. In pre-eclampsia or patients with a history of cardiac disease give 5 IU Oxytocin by slow I.V. injection or 10 IU I.M.
4. Give 1g **Tranexamic** acid by slow I.V injection (~1mL/min). This is not a uterotonic, so will not help uterine tone. However, it is an antifibrinolytic and has been shown to reduce blood loss in this situation, especially if given early.
5. Repeat Syntometrine 5/500 (or Oxytocin if hypertensive or cardiac disease).
6. Commence infusion of 30 units of Oxytocin in 500 mL 0.9% normal saline at 166 mL/hour if not already in progress.
7. If ongoing bleeding at 30min or re-bleeding within 24 hours give a further 1g IV Tranexamic Acid.
8. If the placenta is retained and uterus contracted, try controlled cord traction. If this fails, arrange manual removal of placenta – see guideline for management of third stage of labor.
9. If atony persists, **Carboprost** (Hemabate), 250 mcg (1.0mL) may be given by deep I.M. injection at the discretion of the Obstetric Registrar. If successful, further doses (maximum of eight) may be required at 15-minute intervals, after discussion with the on-call Consultant.
10. **Misoprostol** 800 mcg can be administered sub lingual.
11. Arrange urgent examination under anesthesia if:
    a. Significant hemorrhage continues despite a well contracted uterus.
    b. Above measures fail to produce a tonic uterine contraction.
    c. Bleeding is secondary to obvious genital tract trauma.
12. Consider Bakri Tamponade Balloon in selected cases.
13. Consider B-Lynch brace suture in selected cases.

14. Interventional radiology is available out of hours. If the bleeding persists, the Obstetric Consultant can contact the Interventional Radiology Consultant on-call.
15. If bleeding is not responsive to the standard medical, surgical, radiological treatment, rFVIIa may be considered. Discuss with consultant hematologist.
16. Cell salvage should be considered in selected cases after discussion with the anesthetist and the theatre staff.
17. Record keeping – procedures should be documented contemporaneously throughout the event using the emergency PPH record chart by a scribe. Documentation should include the persons present, tasks undertaken, drugs given, and observations recorded including fluids given and urine output. Strict
18. fluid balance charts should be continued following the event with regular review by the obstetrician.
19. If the emergency has occurred on the MLBU, the woman will be transferred to the Delivery Suite following discussion with the coordinator and a transfer form completed by the midwifery staff.
20. Communication: Document clear lines of communication between the consultant obstetrician, consultant anesthetist, hematologist, blood transfusion personnel, Delivery Suite coordinator and senior midwife on MLBU.
21. Ensure the woman and her family are reassured throughout and are debriefed after the event.

***** Notes**:

Oxytocin infusion is the recommended first line treatment for primary PPH. When used following prophylactic uterotonics, misoprostol and oxytocin infusion work similarly. Vaginal, sublingual or rectal misoprostol took 1.0–2.5 hours to increase uterine tone. Clinicians should be aware of this delay in the clinical effect of misoprostol. Guidelines from WHO and the International Federation of Gynecology and Obstetrics recommend that in the management of PPH, misoprostol is administered sublingually.

1.1.3 NICE Guidelines for Ectopic Pregnancy and Miscarriage: Diagnosis and Initial Management (Published 2019, Updated 2023)

*Please refer to **Section B.1.14** of CHI Maternal and Child Healthcare original clinical guidance.*

The grading scheme used for the 2023 NICE guidelines on ectopic pregnancy is detailed in table 3 above. The main recommendations are summarized below[7]:

Management of miscarriage

Threatened miscarriage

- Advise a woman with a confirmed intrauterine pregnancy with a fetal heartbeat who presents with vaginal bleeding, but has no history of previous miscarriage, that:
  - If her bleeding gets worse, or persists beyond 14 days, she should return for further assessment.
  - If the bleeding stops, she should start or continue routine antenatal care. [2012, amended 2021]
- Offer vaginal micronized progesterone 400 mg twice daily to women with an intrauterine pregnancy confirmed by a scan, if they have vaginal bleeding and have previously had a miscarriage. [2021]
- If a fetal heartbeat is confirmed, continue progesterone until 16 completed weeks of pregnancy. [2021]

Expectant management

- Use expectant management for 7 to 14 days as the first-line management strategy for women with a confirmed diagnosis of miscarriage. Explore management options other than expectant management if
  - The woman is at increased risk of hemorrhage (for example, she is in the late first trimester) or
  - She has previous adverse and/or traumatic experience associated with pregnancy (for example, stillbirth, miscarriage, or antepartum hemorrhage) or
  - She is at increased risk from the effects of hemorrhage (for example, if she has coagulopathies or is unable to have a blood transfusion) or
  - There is evidence of infection. [2012]
- If the resolution of bleeding and pain indicate that the miscarriage has completed during 7 to 14 days of expectant management, provide the woman or person with a urine pregnancy test to carry out at home 3 weeks after their

miscarriage, and advise them to return for individualized care if it is positive. [2012, amended 2023]

Medical management

- For the medical management of missed miscarriage ***offer***:
  - 200 mg oral **mifepristone** and
  - 48 hours later, 800 micrograms **misoprostol** (vaginal, oral, or sublingual) unless the gestational sac has already been passed. [2012, amended 2023]
- Advise the woman or person that if bleeding has not started within 48 hours after misoprostol treatment, they should contact their healthcare professional to determine ongoing individualized care. If there are concerns that they will not contact the service, then there should be arrangements for the service to follow up with these individuals. [2012, amended 2023]
- For the medical management of incomplete miscarriage, use a single dose of misoprostol 600 micrograms (vaginal, oral or sublingual). Misoprostol 800 micrograms can be used as an alternative to allow alignment of treatment protocols for both missed and incomplete miscarriage. [2012, amended 2023]
- Do not offer mifepristone as a treatment for incomplete miscarriage. [2012, amended 2023]
- Offer all women and people receiving medical management of miscarriage pain relief and anti-emetics as needed. [2012]
- Inform women and people receiving medical management of miscarriage about what to expect throughout the process. Include the length and extent of bleeding, potential side effects of treatment including pain, diarrhea, and vomiting, and when and how to seek help. [2012, amended 2023]
- Provide women and people who have had medical management of miscarriage with a urine pregnancy test to carry out at home 3 weeks after medical management of miscarriage unless they experience worsening symptoms, in which case advise them to return to the healthcare professional responsible for providing their medical management. [2012, amended 2021]
- Advise women and people with a positive urine pregnancy test after 3 weeks to return for a review by a healthcare professional to rule out a retained pregnancy, molar, or ectopic pregnancy, and assess the need for further investigations or treatment. [2012, amended 2023]
- If the pregnancy test after 3 weeks is negative but the woman or person is still bleeding heavily or has other symptoms (for example, pelvic pain or fever), then assess the need for further investigations or treatment. [2023]

Surgical management

- Where clinically appropriate, offer women undergoing a miscarriage a choice of
  - Manual vacuum aspiration under local anaesthetic in an outpatient or clinic setting or
  - Surgical management in a theatre under general anaesthetic. [2012]
- Provide oral and written information to all women undergoing surgical management of miscarriage about the treatment options available and what to expect during and after the procedure.

Management of tubal ectopic pregnancy

- Offer systemic methotrexate to women who:
  - Have no significant pain and
  - Have an unruptured tubal ectopic pregnancy with an adnexal mass smaller than 35 mm with no visible heartbeat and
  - Have a serum hCG level less than 1,500 IU/litre and
  - Do not have an intrauterine pregnancy (as confirmed on an ultrasound scan) and are able to return for follow-up.

    Methotrexate should only be offered on a first visit when there is a definitive diagnosis of an ectopic pregnancy, and a viable intrauterine pregnancy has been excluded. Offer surgery where treatment with methotrexate is not acceptable to the woman. [2012, amended 2019]
- Offer surgery as a first-line treatment to women who are unable to return for follow-up after methotrexate treatment or who have any of the following:
  - an ectopic pregnancy and significant pain
  - an ectopic pregnancy with an adnexal mass of 35 mm or larger
  - an ectopic pregnancy with a fetal heartbeat visible on an ultrasound scan
  - an ectopic pregnancy and a serum hCG level of 5,000 IU/litre or more. [2012]
- Offer the choice of either methotrexate or surgical management to women with an ectopic pregnancy who have a serum hCG level of at least 1,500 IU/litre and less than 5,000 IU/litre, who are able to return for follow-up and who meet all the following criteria:
  - no significant pain

- an unruptured ectopic pregnancy with an adnexal mass smaller than 35 mm with no visible heartbeat
- no intrauterine pregnancy (as confirmed on an ultrasound scan).

Advise women who choose methotrexate that their chance of needing further intervention is increased and they may need to be urgently admitted if their condition deteriorates. [2012]

- For women with ectopic pregnancy who have had methotrexate, take 2 serum hCG measurements in the first week (days 4 and 7) after treatment and then 1 serum hCG measurement per week until a negative result is obtained. If hCG levels plateau or rise, reassess the woman's condition for further treatment. [2012]

1.1.4 NICE Guidelines for Intrapartum Care for Healthy Women and Babies (2014, Updated 2022)

*Please refer to **Section B.1.18** of CHI Maternal and Child Healthcare original clinical guidance.*

The grading scheme used for the 2022 NICE guidelines on intrapartum care is detailed in table 3 above. The main recommendations are summarized below[8]:

Postpartum hemorrhage

Management

If a woman has a postpartum hemorrhage:

- Call for help.
- Give immediate clinical treatment:
  - emptying of the bladder and
  - uterine massage and
  - uterotonic drugs and
  - intravenous fluids and
  - controlled cord traction if the placenta has not yet been delivered.
- Continuously assess blood loss and the woman's condition and identify the source of the bleeding.
  - give supplementary oxygen.
  - arrange for transfer of the woman to obstetric-led care (following the general

- principles for transfer of care). [2014]

- Administer a bolus of one of the following as first-line treatment for postpartum hemorrhage:
  - oxytocin (10 IU intravenous) or
  - ergometrine (0.5 mg intramuscular) or
  - combined oxytocin and ergometrine (5 IU/0.5 mg intramuscular). [2014]
- Offer second-line treatment for postpartum hemorrhage if needed. No particular uterotonic drug can be recommended over any other; options include:

  Repeat bolus of:
  - **oxytocin** (intravenous)
  - ergometrine (intramuscular, or cautiously intravenously)
  - combined oxytocin and ergometrine (intramuscular)
  - **misoprostol**
  - oxytocin infusion
  - **carboprost** (intramuscular). [2014]
- Assess the need for adjuvant options for managing significant continuing postpartum hemorrhage, including:
  - **tranexamic** acid (intravenous)
  - rarely, in the presence of otherwise normal clotting factors, rFactor VIIa, in
  - consultation with a hematologist. [2014]
- Allocate a member of the healthcare team to stay with the woman and her birth companion(s), explain what is happening, answer any questions and offer support throughout the emergency situation. [2014]
- If the hemorrhage continues:
  - perform examination under anaesthetic
  - ensure that the uterus is empty and repair any trauma
  - consider balloon tamponade before surgical options. [2014]
- Be aware that no particular surgical procedure can be recommended over any other for treating postpartum hemorrhage. [2014]
- The maternity service and ambulance service should have strategies in place in order to respond quickly and appropriately if a woman has a postpartum hemorrhage in any setting. [2014]

1.1.5 Center for Disease Control and Prevention (CDC) Immunization Schedule for Children from Birth Through 6 Years Old (2023)

*Please refer to **Section C.1.2** of CHI Maternal and Child Healthcare original clinical guidance.*

The recommendations are outlined below[9]*:*

1. Birth to 15 months

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos
Hepatitis B (HepB)	1st dose	←2nd dose→			←3rd dose→			
Rotavirus (RV) RV1 (2-dose series); RV5 (3-dose series)			1st dose	2nd dose	See notes			
Diphtheria, tetanus, & acellular pertussis (DTaP: <7 yrs)			1st dose	2nd dose	3rd dose			←4th dose→
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See notes		←3rd or 4th dose, See notes→	
Pneumococcal conjugate (PCV13, PCV15)			1st dose	2nd dose	3rd dose		←4th dose→	
Inactivated poliovirus (IPV: <18 yrs)			1st dose	2nd dose	←3rd dose→			
COVID-19 (1vCOV-mRNA, 2vCOV-mRNA, 1vCOV-aPS)					2- or 3-dose primary series and booster (See notes)			
Influenza (IIV4)					Annual vaccination 1 or 2 doses			
or Influenza (LAIV4)								
Measles, mumps, rubella (MMR)					See notes		←1st dose→	
Varicella (VAR)							←1st dose→	
Hepatitis A (HepA)					See notes		←2-dose series, See notes→	
Tetanus, diphtheria, & acellular pertussis (Tdap: ≥7 yrs)								
Human papillomavirus (HPV)								
Meningococcal (MenACWY-D: ≥9 mos, MenACWY-CRM: ≥2 mos, MenACWY-TT: ≥2years)			See notes					
Meningococcal B (MenB-4C, MenB-FHbp)								
Pneumococcal polysaccharide (PPSV23)								
Dengue (DEN4CYD: 9-16 yrs)								

Figure 1. *CDC Immunization Schedules Birth to 15 months*

Retrieved from CDC Immunization Schedules. https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

2. 18 months to 18 years

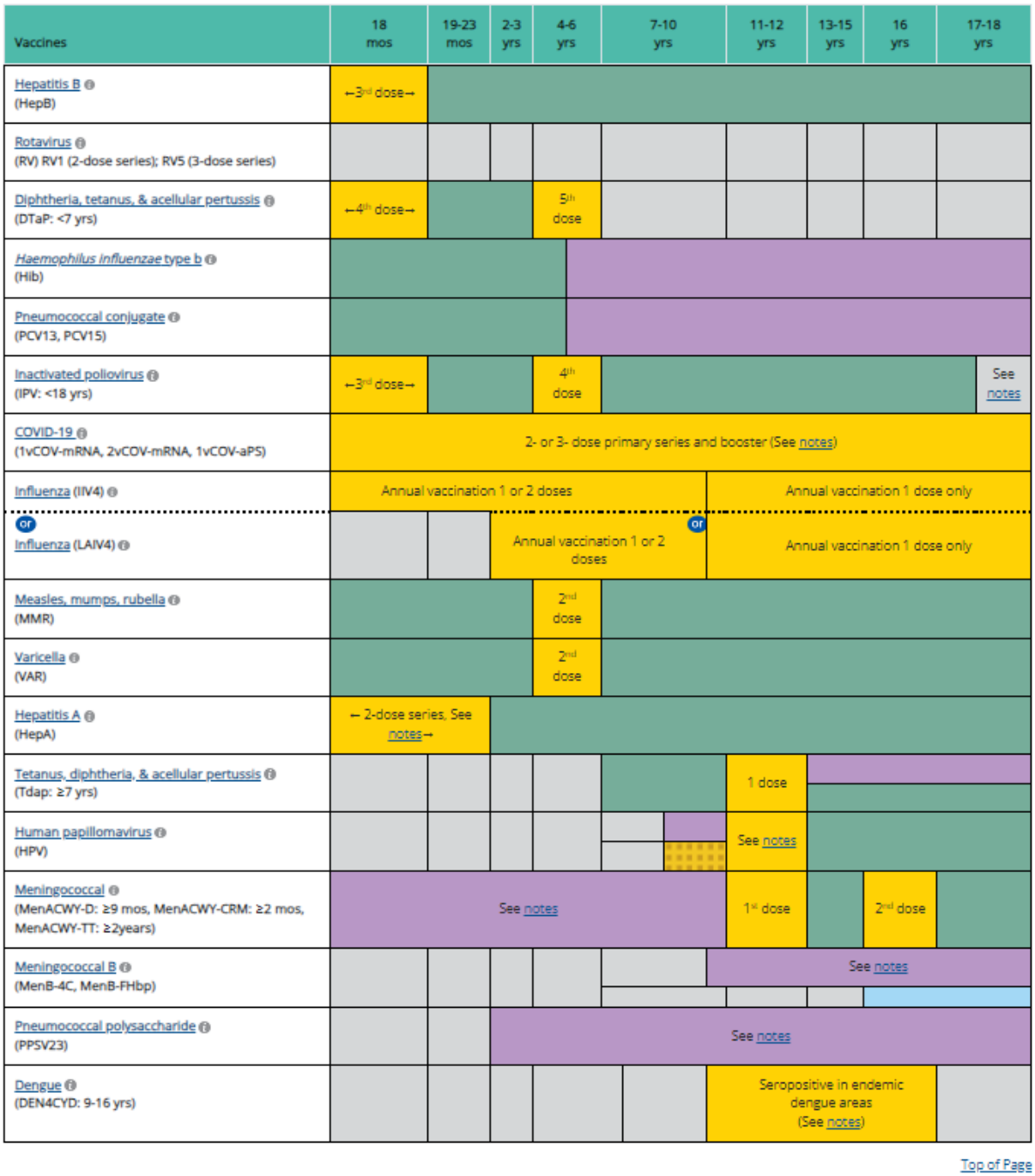

Figure 2. *CDC Immunization Schedule 18 Months to 18 Years*

Adapted from CDC Immunization Schedules. [*https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html*](https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html)

1.1.6 American College of Obstetricians and Gynecologists (ACOG) Committee Opinion No. 741, Maternal Immunization (2018, Updated 2022)

*Please refer to **Section C.1.1** of CHI Maternal and Child Healthcare original clinical guidance.*

This Practice Advisory serves as an update to the American College of Obstetricians and Gynecologists (ACOG) Committee Opinion No. 741, Maternal Immunization, originally published in 2018, and the main recommendations from the 2022 update are detailed below (ungraded)[10]:

- The CDC's 2022 adult immunization schedule 2 includes several updates to immunization recommendations impacting pregnant individuals.
- These updates include a universal recommendation for hepatitis B vaccination for all unvaccinated adults, including pregnant adults; changes to pneumococcal vaccine recommendations to reflect newly available vaccines; and added recommendations for COVID-19 vaccination.
- Based on the CDC's 2022 adult immunization schedule and its supporting evidence of benefit, ACOG recommends hepatitis B vaccination for all unvaccinated pregnant adults. Additionally, ACOG recommends pneumococcal vaccination for pregnant individuals at increased risk of severe pneumococcal disease.
- ACOG recommends COVID-19 vaccination for all pregnant individuals who were not vaccinated prior to pregnancy. Pregnant and recently pregnant people up to 6 weeks postpartum should receive a bivalent mRNA COVID-19 vaccine booster dose following the completion of their last COVID-19 primary vaccine dose or monovalent booster. COVID-19 vaccines are recommended for postpartum and lactating individuals who were not vaccinated prior to or during pregnancy.

Figure 3 summarizes the maternal immunization recommendations:

Vaccine*	Indicated During Every Pregnancy	May Be Given During Pregnancy in Certain Populations	Contraindicated During Pregnancy	Can Be Initiated Postpartum or When Breastfeeding or Both
COVID-19†,¶ (see footnote for recommendations)				
Inactivated influenza	X†,2,3			X§
Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap)	X†,4,5			X§
Pneumococcal vaccines		X‖,6		X‖,6
Meningococcal conjugate (MenACWY) and meningococcal serogroup B		X¶,7		X¶,7
Hepatitis A		X#,8		X#,8
Hepatitis B		X**,9,10		X**,9,10
Human papillomavirus (HPV)**				X††,11,12
Measles–mumps–rubella			X‡‡,13,14	X‡‡
Varicella			X‡‡,13,15,16	X‡‡

*An "X" indicates that the vaccine can be given in this window. See the corresponding numbered footnote for details.

†COVID-19 vaccination is recommended for pregnant individuals who have not previously been vaccinated. Pregnant individuals may receive any COVID-19 vaccine product available to them; however, Moderna, Pfizer-BioNTech, and Novavax vaccines are preferred over the Johnson & Johnson/Janssen vaccine. Vaccination may occur in any trimester and emphasis should be on vaccine receipt as soon as possible to maximize maternal and fetal health. Pregnant and recently pregnant people up to 6 weeks postpartum should receive a bivalent mRNA COVID-19 vaccine booster dose following the completion of their last COVID-19 primary vaccine dose or monovalent booster. COVID-19 vaccination is recommended for postpartum and/or lactating individuals who were not previously vaccinated.

‡Inactivated influenza vaccination can be given in any trimester and should be given each influenza season as soon as the vaccine is available. The Tdap vaccine is given at 27–36 weeks of gestation in each pregnancy, preferably as early in the 27- to 36-week window as possible. The Tdap vaccine should be given during each pregnancy in order to boost the maternal immune response and maximize the passive antibody transfer to the newborn. If not administered during pregnancy, the Tdap vaccine should be given immediately postpartum if the woman has never received a prior dose of Tdap as an adolescent, adult, or during a previous pregnancy.1–3

§Vaccination during every pregnancy is preferred over vaccination during the postpartum period to ensure antibody transfer to the newborn.3,4

‖There are two kinds of pneumococcal vaccines in the United States: pneumococcal conjugate vaccines (PCV13, PCV15, and PCV20) and pneumococcal polysaccharide vaccine (PPSV23). Pneumococcal vaccines (PCV15, PCV20, PPSV23) may be given to pregnant individuals at high risk of severe illness from pneumococcal disease. Clinicians should refer to CDC guidance for details on conditions that put individuals at high-risk for severe pneumococcal disease.5,6

¶Quadrivalent conjugate meningococcal vaccine is routinely recommended for adolescents aged 11–18 years, along with individuals with HIV infection, complement component deficiency (including eculizumab use), functional or anatomic asplenia (including sickle cell disease), exposure during a meningococcal disease outbreak, travel to endemic or hyperendemic areas, or work as a microbiologist routinely exposed to Neisseria meningitidis. If indicated, pregnancy should not preclude vaccination. The serogroup B vaccine should be deferred in pregnant individuals, unless the person is at increased risk of serogroup B meningococcal disease7 and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks.7

#Pregnant individuals with any of the conditions that increase the risk of either acquiring or having a severe outcome from hepatitis A infection (eg, international travelers, persons who use injection or noninjection drugs, persons who have occupational risk for infection, persons who anticipate close personal contact with an international adoptee, or persons experiencing homelessness) or for having a severe outcome from hepatitis A infection (eg, persons with chronic liver disease or persons with HIV infection) should be vaccinated during pregnancy if not previously vaccinated. Pregnant individuals at risk of hepatitis A infection during pregnancy should also be counseled concerning all options to prevent hepatitis A infection. Any person who wants to be protected from hepatitis A or has an indication for use may receive the vaccine during pregnancy or during the postpartum period.8

**Hepatitis B vaccination is recommended for all adults who have not previously been vaccinated. Importantly, Heplisav-B and PreHebrio are not recommended in pregnancy because of lack of safety data in pregnant individuals. Pregnant individuals at risk of hepatitis B infection during pregnancy should be counseled concerning other methods to prevent hepatitis B infection.1,9

††The HPV vaccination in pregnancy is not recommended; however, inadvertent HPV vaccination during pregnancy is not associated with adverse events for the pregnant individual or their fetus. The HPV vaccine can be given to postpartum and lactating individuals. The HPV vaccine should be administered to individuals through age 26 years who were not previously vaccinated. Vaccination timing and number of doses should follow Centers for Disease Control and Prevention and American College of Obstetricians and Gynecologists' guidance.11,12

‡‡Live attenuated vaccines, including measles–mumps–rubella, varicella, and live attenuated influenza vaccine, are contraindicated for pregnant individuals. If indicated (ie, among seronegative individuals), the measles–mumps–rubella vaccine and the varicella vaccine should be given during the postpartum period. Inadvertent administration during pregnancy has not been associated with congenital rubella or congenital varicella syndromes.13–16

Figure 3. *Summary of Maternal Immunization Recommendations*

Retrieved from Maternal Immunization's Practice Advisory 2022. ACOG - Maternal Immunization https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2022/10/maternal-immunization#

1.1.7 American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM): Low-Dose Aspirin Use for the Prevention of Preeclampsia and Related Morbidity and Mortality Guideline (Updated December 2021 and Reaffirmed October 2022)

*Please refer to **Section B.1.5** of CHI Maternal and Child Healthcare original clinical guidance.*

This Practice Advisory serves as an update to the American College of Obstetricians and Gynecologists (ACOG) guideline on Low-Dose Aspirin Use for the Prevention of Preeclampsia and Related Morbidity and Mortality [Updated December 2021 and reaffirmed October 2022]. Recommendations are ungraded and are detailed below[11]:

- Low-dose aspirin has been used during pregnancy most commonly to prevent or delay the onset of preeclampsia. The previous recommendation from the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and the U.S. Preventive Services Task Force (USPSTF) has been for low-dose aspirin (81 mg/d) prophylaxis after 12 weeks of gestation in pregnant individuals at high risk of preeclampsia and suggested low-dose aspirin prophylaxis in pregnant individuals with more than one moderate-risk factor.
- ACOG and SMFM also have provided more detailed information around timing, recommending that low-dose aspirin be initiated between 12 weeks and 28 weeks of gestation (optimally before 16 weeks) and continued daily until delivery.

According to the 2021 USPSTF recommendations:

- The USPSTF provided updated guidance regarding moderate-risk factors. Specifically, the USPSTF now recommends low-dose aspirin for individuals with more than one moderate-risk factor. Additionally, the USPSTF added one new moderate-risk factor, “In vitro conception,” and modified the previous “Sociodemographic characteristics” risk factor by splitting it into two distinct factors: “Black persons (due to social, rather than biological, factors)” and “lower income.”
- The USPSTF notes that “Black persons” and “lower income” are associated with increased risk due to environmental, social, and historical inequities shaping health exposures, access to health care, and the unequal distribution of resources, not biological propensities; low-dose aspirin can be considered without any additional moderate-risk factor if the patient has either of these risk factors.

Low-dose aspirin (81 mg/d) prophylaxis is recommended for:

- Pregnant individuals at high risk of preeclampsia with one or more of the following risk factors:
  - History of preeclampsia, especially when accompanied by an adverse outcome.
  - Multifetal gestation
  - Chronic hypertension
  - Pregestational type 1 or 2 diabetes
  - Kidney disease
  - Autoimmune disease (i.e., systemic lupus erythematous, antiphospholipid syndrome)
  - Combinations of multiple moderate-risk factors

  These risk factors are consistently associated with the greatest risk for pre-eclampsia. Preeclampsia incidence would likely be at least 8% in a population of pregnant individuals having one of these risk factors.
- Pregnant individuals with more than one of several moderate risk factors:
  - Nulliparity
  - Obesity (i.e., body mass index > 30)
  - Family history of preeclampsia (i.e., mother or sister)
  - Black race (as a proxy for underlying racism)
  - Lower income
  - Age 35 years or older
  - Personal history factors (e.g., low birth weight or small for gestational age, previous adverse pregnancy outcome, >10-year pregnancy interval)
  - In vitro fertilization

  These factors are independently associated with moderate risk for preeclampsia, some more consistently than others. A combination of multiple moderate-risk factors may place a pregnant person at higher risk for preeclampsia.
- Additionally, low-dose aspirin can be considered if the patient has one or more of the following moderate-risk factors: Black race (as a proxy for underlying racism), or lower income.
- When recommended, low-dose aspirin should be initiated between 12 weeks and 28 weeks of gestation (optimally before 16 weeks) and continued daily until delivery.

1.1.8 American Academy of Pediatrics Policy Statement: Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children Committee on Fetus and Newborn Controversies Concerning Vitamin K and the Newborn (2022)

*Please refer to **Section B.1.20** of CHI Maternal and Child Healthcare original clinical guidance.*

The recommendations published in the AAP policy statement are outlined below[12]:

VKDB (vitamin K Deficiency Bleeding) remains a significant concern in newborn and young infants. Parenteral vitamin K has been shown to be the most effective way to prevent VKDB of the newborn and young infant, and the AAP recommends the following:

- Vitamin K should be administered to all newborn infants weighing >1500 g as a single, intramuscular dose of **1 mg** within 6 hours of birth.
- Preterm infants weighing ≤1500 g should receive a vitamin K dose of 0.3 mg/kg to 0.5 mg/kg as a single, intramuscular dose. A single intravenous dose of vitamin K for preterm infants is not recommended for prophylaxis.
- Pediatricians and other health care providers must be aware of the benefits of vitamin K administration as well as the risks of refusal and convey this information to the infant's caregivers.
- VKDB should be considered when evaluating bleeding in the first 6 months of life, even in infants who received prophylaxis, and especially in exclusively breastfed infants.

1.1.9 BMJ Global Health: WHO Recommendations on Uterotonics for Postpartum Hemorrhage Prevention: What Works, and Which One? (2019)

*Please refer to **Section B.1.10** of CHI Maternal and Child Healthcare original clinical guidance.*

The 2019 new WHO recommendations guide skilled health personnel and other stakeholders on how best to use uterotonics to prevent PPH in women giving birth in facility or community settings in high-income, middle-income, or low-income countries.

The new set of recommendations was introduced without being accompanied by a grading scheme[13].

- It should be noted that the uterotonic options containing ***ergometrine*** (ergometrine alone, and oxytocin–ergometrine fixed-dose combination) are context-specific recommendations, on account of the need to exclude the

presence of hypertensive disorders prior to its use. This condition may limit their use in those settings where there is lack of screening for hypertensive disorders in pregnancy.

- Regarding the use of carbetocin for PPH prevention (use carbetocin only in contexts where its cost is comparable with other effective uterotonics).

  The use of *the heat-stable formulation of* ***carbetocin*** could offer cost reductions in avoiding the cold-chain transport and storage costs associated with heat-sensitive uterotonics.

The following figure shows the contextual considerations in selecting a uterotonic for postpartum hemorrhage prevention:

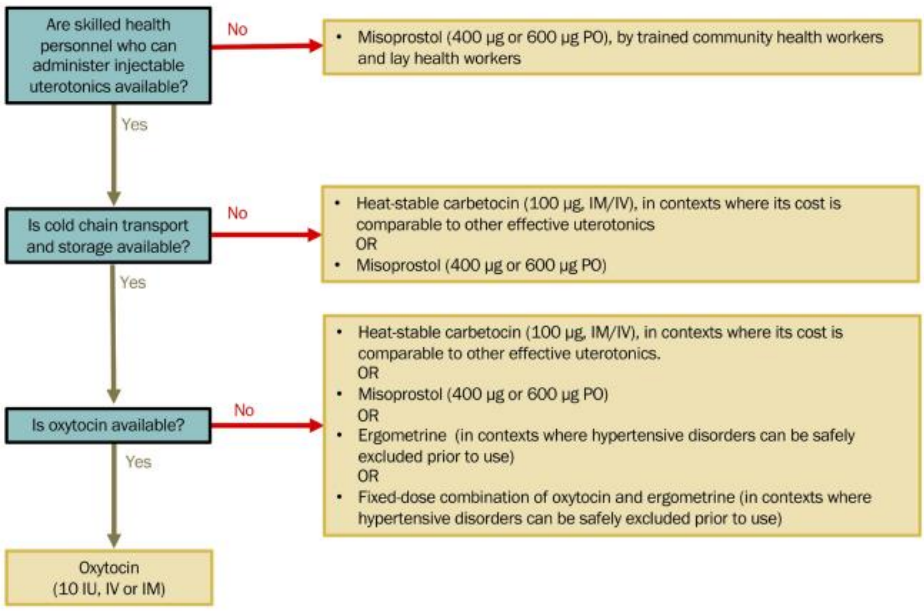

Figure 4. *Contextual considerations in selecting a uterotonic for postpartum hemorrhage prevention (only quality-assured medicines should be used regardless of which uterotonic option is selected). IM, intramuscular; IV, intravenous.*

Retrieved from WHO recommendations on uterotonics for postpartum hemorrhage prevention: What works, and which one? By Vogel JP, Williams M, Gallos I, Althabe F, Oladapo OT. BMJ Glob Health. 2019;4(2). doi:10.1136/bmjgh-2019-001466.

1.1.10 Australian Clinical Practice Guidelines for Pregnancy Care (2020)

Please refer ***to Section A.1.3*** *of CHI Maternal and Child Healthcare original clinical guidance.*

The main recommendations issued by the Australian clinical practice guidelines for pregnancy care are outlined below[14]:

Summary of advice for women about lifestyle considerations during pregnancy

Health behaviors

Nutrition

- Healthy dietary patterns are characterized by a high intake of fruits, vegetables, legumes, wholegrains, fish, seafood, unprocessed meats, dairy foods and water.
- Diets with a high intake of sweetened foods and drinks, foods high in saturated fats (e.g., fried foods), processed meats and refined grains are associated with poorer outcomes.

Physical activity

- Usual physical activity during pregnancy has health benefits and is safe.

Tobacco smoking

- Smoking and passive smoking can have negative effects on the pregnancy and the baby.

Alcohol

- Not drinking alcohol is the safest option for women who are pregnant.

Substance use

- Illicit substances and non-medical use of medications (e.g., opioids) have negative effects on the pregnancy and the baby.

Preventive health interventions

Folic acid

- Dietary supplements of 400 µg folic acid a day, ideally taken from 1 month before conception and throughout the first 3 months of pregnancy, reduce the risk of a baby having neural tube defect.

Other vitamins

- In the absence of identified deficiency, supplements of vitamins A, C and E are of little or no benefit during pregnancy and may cause harm.

Iron

- The need for iron supplementation is assessed through a blood test at 28 weeks.
- If an iron supplement is necessary, weekly supplementation (80-300 mg elemental iron) is as effective as daily supplementation (30-60 mg elemental iron) in preventing (but not treating) iron-deficiency anemia, with fewer adverse effects.

Calcium

- Calcium supplements are recommended for women at high risk of pre-eclampsia.

Iodine

- Iodine requirements increase during pregnancy and a supplement of 150 micrograms a day is advised.

Omega-3 fatty acids

- Supplementation with omega-3 long-chain polyunsaturated fatty acids (800 mg docosahexaenoic acid [DHA] and 100 mg eicosatetraenoic acid [EPA] per day) may reduce the risk of preterm birth among women who are low in omega-3.

Herbal preparations

- The effectiveness and safety of herbal preparations varies according to the herbal preparation and the condition being treated.

Medicines

- Use of medicines should be limited to circumstances where the benefit outweighs the risk.

General advice

Oral health

- Good oral health is important to a woman's health and treatment can be safely provided during pregnancy.

Sexual activity

- Sexual intercourse in pregnancy is not known to be associated with any adverse outcomes.

Travel

- The correct use of three-point seatbelts during pregnancy is to have the belt 'above and below the bump, not over it'.
- Long-distance air travel is associated with an increased risk of venous thrombosis.
- Pregnant women should discuss considerations such as air travel, vaccinations and travel insurance with their midwife or doctor if they are planning to travel overseas.
- If a pregnant woman cannot defer travel to malaria-endemic areas, she should use an insecticide-treated bed net.

- Some medications to prevent malaria can be safely used in pregnancy.
    - Beyond the first trimester, mefloquine is approved for use to prevent malaria. Neither malarone nor doxycycline are recommended for prophylaxis at any time during pregnancy. Chloroquine (or hydroxychloroquine) plus proguanil is safe but less effective so seldom used. For areas where only vivax is endemic, chloroquine or hydroxychloroquine alone is appropriate.

1.1.11 Guideline No. 427: Folic Acid and Multivitamin Supplementation for Prevention of Folic Acid–Sensitive Congenital Anomalies (2022)

Please refer to **Section A.1.9** of CHI Maternal and Child Healthcare original clinical guidance.

The recommendations are outlined below[15]:

Summary statements

- Prevention of folate-sensitive anomalies should be evidence-based, and the benefits of preventing anomalies should balance any risks of folic acid supplementation (*high*).
- Birth defects related to folate deficiency account for 2%–3% of prenatal or neonatal major anomalies and 4%–5% of total structural malformations or developmental conditions identified after birth. Folate-sensitive birth defects include neural tube defects, certain congenital heart and urinary tract defects, oral facial clefts, and limb-reduction anomalies (*high*).

Recommendations

- Any woman aged 12–45 years who can become pregnant should be advised by their health care provider to maintain a healthy, folate-rich diet and should undergo a brief periodic dietary review (*strong, moderate*).
- Health care providers can consider promoting regular consumption of choline-rich foods (meat, egg yolk) during wellness visits (such as for birth control renewal, Pap testing, gynecologic examination), whether the patient is contemplating pregnancy (*strong, moderate*).
- Health care providers should advise all women aged 12–45 years considering or planning a pregnancy about the benefits of taking an oral daily multivitamin containing folic acid (0.4–1.0 mg) to optimize serum and red blood cell folate levels (*strong, high*).
- Folic acid should be taken in a daily oral multivitamin that includes a 2.6-µg dose of vitamin B_{12} (*strong, high).*

- Any woman aged 12–45 years who can become pregnant and has *pre-conception obesity (body mass index >30.0 kg/m^2)* may require a more personal and focused assessment for folate supplementation to prevent fetal anomalies, such as a pre-conception fasting serum folate concentration assessment. If a woman with obesity has had a previous fetus or child with a folate-sensitive fetal anomaly other than a neural tube defect, she should take a folic acid supplement containing the recommended dosage for women at *increased risk* (4–5 mg) (*conditional, low*).
- **High-dosage folate supplementation** (oral dosage of 4–5 mg/d) should be used *only* for women at high risk; women who can become pregnant and who have had a previous pregnancy affected by a neural tube defect, have had a neural tube defect themselves, or have a first-degree relative with a neural tube defect (*strong, moderate*).
- **High-dosage supplementation** requires *2 separate periods of supplementation*: from pre-conception to 12 weeks gestation (see below), and from 12 weeks gestation until completion of breastfeeding, when the folic acid supplementation dosage reverts to the low-dosage regimen (*strong, high*).
- There are 2 options for supplementation in the first period:
    - **Standard option**: a total pre-conception oral daily dosage of 4 mg folic acid (1 oral multivitamin supplement that contains 1.0 mg of folic acid and 2.6 µg of vitamin B_{12}, an iron supplement of 16–20 mg/d, and 3 1.0-mg folic acid tablets); (*strong, high*) or
    - **Personalized option:** requires the patient to first take an oral daily multivitamin containing folic acid (0.4 - 1 mg) and vitamin B_{12} within the first 4–6 weeks of a 3-month pre-conception period, then complete a blood test to determine her fasting serum folate level. A daily dosage of folic acid supplementation (from this pre-conception period until 12 weeks gestation) of 0.4–1.0 mg would be chosen if results were in the optimal range, and a daily dosage of more than 1.0 mg, if the results were sub-optimal (*strong, moderate–high*).
- **Moderate-dosage folate supplementation**: Women who can become pregnant and have *either* an *increased risk* of having a fetus with an NTD (Neural Tube Defect) or other folate-sensitive congenital anomaly *or other medical-surgical conditions* associated with a risk of folate deficiency require *2 separate periods of supplementation (strong, high).*
    - From pre-conception to 12 weeks gestation, the supplementation dosage is 1.0 mg of folic acid daily (1 oral multivitamin supplement that contains 1.0 mg folic acid and 2.6 µg vitamin B_{12}, and an iron supplement of 16–20 mg/d).

    - After 12 weeks gestation, the folic acid supplementation dosage reverts to the low-dosage regimen.

- **Low-dosage folate supplementation**: Women who can become pregnant and are at low risk of having a fetus with an NTD or other folate-sensitive congenital anomaly should consume a pre-conception and first-trimester diet of folate-rich foods along with a daily oral multivitamin supplement that contains 0.4 mg (400 µg) of folic acid and 2.6 µg of vitamin B_{12}, and an iron supplement of 16–20 mg daily for at least 2–3 months before conception, throughout the pregnancy, and for 4–6 weeks postpartum or as long as breastfeeding continues (*strong, high*).

1.1.12 Royal College of Obstetricians and Gynaecologists (RCOG) Guidelines: Updated RCOG Group B Strep Guidelines (2022)

*Please refer **to Section B.1.3** of CHI Maternal and Child Healthcare original clinical guidance.*

The Royal College of Obstetricians and Gynaecologists (RCOG) published a major update to their clinical guideline on preventing group B Strep infection, their Green-top Guideline (GTG) No 361 on I3 September 20I7. There are substantial changes from the previous edition, published in 20I2. The main recommendations (ungraded) are outlined below[16]:

<u>What should you do during a woman's pregnancy?</u>

- Provide all pregnant women with a patient information leaflet about group B Strep (GTG 4.1).
- If a woman had a GBS urinary tract infection (>10^5 cfuml) during her pregnancy, treat her at diagnosis with oral antibiotics, and make sure also to offer her IV antibiotics in labor (GTG 6.1).

<u>Who should be offered antibiotics in labor?</u>

Women should be offered antibiotics effective against GBS in labor who:

- carried GBS in a previous pregnancy (or alternatively offered testing - see below) (GTG 5.3).
- had a previous baby who had GBS infection (GTG 5.4).
- had GBS in her urine during the pregnancy (GTG 7.l).
- had GBS found on a vaginal or rectal swab (via an NHS or other test) (GTG 6.3).
- are in preterm labor (before 37 completed weeks) (GTG 7.3).

- have a temperature of 38°C or greater (in which case, offer broad-spectrum antibiotics that also cover GBS) (GTG 7.2).

When is an offer of antenatal testing appropriate?

- If a woman carried GBS in a previous pregnancy and the baby did not develop GBS disease, an Enriched Culture Medium (ECM) swab test for GBS carriage at 35-37 weeks (or earlier if preterm delivery is anticipated) should be offered (GTG 5.3).
- The ECM test is not the same as a standard swab for a vaginal discharge. Swabs should be taken both from the low vagina and rectum (GTG 9.l), with samples cultured using enriched culture media (9.3) and processed ASAP (GTG 9.2). You should specifically state 'test for GBS' on the request form (GTG 9.3).
- If positive, the woman should be offered antibiotics in labor. If negative, she can be reassured that the risk of early onset neonatal GBS disease is very low (about l in 5,000). If she declines the test, she should be offered antibiotics in labor (GTG 5.3).

Which IV antibiotic should I use?

If the woman has agreed to have the IV antibiotics in labor, they should be given as soon as possible once labor has started, and at regular intervals until the baby is born (GTG 9.4).

- In penicillin-allergic women, a cephalosporin should be used (e.g., **Cefuroxime** I.5 g loading dose followed by 750 mg every 8 hours) unless she has had a severe allergic reaction (swelling of the skin or throat, difficulty breathing, and/or fainting/low blood pressure), in which case, **vancomycin** (Ig every I2 hours) should be used (GTG 9.5).

What happens around labor and delivery?

- Carrying group B Strep doesn't affect the method of induction - simply offer IV antibiotics as soon as labor is established (GTG 6.4).
- Carrying GBS does not mean that membrane sweeps are contraindicated (GTG 6.5).
- A woman having a planned Caesarean section doesn't need IV antibiotics specifically for GBS, as long as her waters haven't broken and she's not in labor (GTG 6.6 & 7.3).
- A woman carrying GBS whose waters break at term should be offered IV antibiotics immediately, and induction of labor as soon as reasonably possible (GTG 7.I).

- A woman not carrying GBS or whose GBS carriage status is unknown and whose waters break at term should be offered induction of labor immediately or at any time up to 24 hours after the waters broke, depending on her preference (GTG 7.I).
- Women whose waters break preterm (before 37 completed weeks) should be offered IV antibiotics once labor is confirmed or induced, regardless of whether or not they are known to carry GBS (GTG 8.I).
- As long as IV antibiotics are offered in labor to a woman carrying GBS, labor or birth in water (a waterbirth) is not contraindicated (GTG 7.5).
- Adverse effects of IV antibiotics in labor are rare but include allergy and possibly an effect on the microbiome (bacterial flora) of the newborn baby. Measured effects so far are slight and probably temporary (up to three months) if penicillin is used (GTG 9.7).
- Vaginal cleansing isn't recommended as there's no evidence it reduces the risk of GBS infection in the newborn baby (GTG I0)

After the baby is born:

- If a woman carrying GBS declined IV antibiotics in labor, her baby should be monitored very closely for I2 hours after birth, and Mum should be discouraged from very early discharge (GTG 9.6).
- If a mother carrying GBS gave birth at term and received IV antibiotics against GBS for over 4 hours before birth, her newborn baby doesn't need any special observations, as the risk of GBS infection is very low (GTG II.2).
- If a mother received broad-spectrum IV antibiotics in labor for reasons other than GBS, her newborn baby may still need investigation and treatment (GTG II.2).
- If a mother has previously had a baby who developed GBS infection (GTG II.6) OR had risk factors for EOGBS infection, but did not receive more than 4 hours of IV antibiotics before birth (GTG II.3) babies should be checked at birth for clinical indicators of infection, and their vital signs should be checked at 0, I, and 2 hours old, then every 2 hours until I2 hours old.
- Babies without signs of EOGBS infection and without known risk factors are at a low risk of developing EOGBS infection and shouldn't be given preventative antibiotics as routine (GTG II.4).
- Babies showing signs of EOGBS infection should be treated with penicillin and gentamicin within an hour of the decision to treat (GTG II.5).
- Women should be encouraged to breastfeed, whether they carry group B Strep or not (GTG II.7).

Signs of GBS infection to look out for in a newborn baby:

Families should be encouraged to seek urgent medical attention if their baby (GTG II.I):

- Is grunting, has noisy breathing, is not breathing at all, moaning, or seems to be working hard to breathe when you look at the chest or tummy.
- Is very sleepy and/or unresponsive.
- Has inconsolable crying
- Is unusually floppy.
- Is not feeding well or not keeping milk down.
- Has a high or low temperature, and/or their skin feels to be too hot or cold.
- Has changes in their skin color (including blotchy skin)
- Has an abnormally fast or slow heart rate or breathing rate
- Has low blood pressure (only identifiable by hospital tests)
- Has low blood sugar (only identifiable by hospital tests)

1.2 Additional Guidelines

This part includes the added guidelines to the previous CHI Maternal and Child Health report, along with their recommendations.

Table 5. List of Additional Guidelines

Additional Guidelines
Saudi MOH pocket manual in obstetrics & gynecology[17]
Saudi midwifery clinic standards (2021)[18]

1.2.1 Saudi MOH Pocket Manual in Obstetrics & Gynecology

The recommendations are outlined below[17]:

A. Post-partum hemorrhage

Multidisciplinary approach:

- Experienced midwife
- Senior Obstetrician
- Alert Consultant obstetrician on call.
- Alert Anesthesiologist
- Alert the Blood Bank

- Alert the Hematologist as needed
- Alert one member of the team to record events, fluids, drugs and vital signs.

Resuscitation by:

1. Assess airway, breathing: give oxygen mask at 10 – 15 L/minute.

2. Evaluate circulation.

a) Assess the vital signs every 10 – 15 minutes

b) Oxygen saturation

c) Foley's catheter

d) I.V. line with 2 big cannulas, infuse crystalloid solution (Ringer Lactate) – 3 Liters: for every 1 liter of blood loss. 2 Liters Crystolloid + 1 -2 colloid (Plasma Protein) until blood arrive.

e) Cross match 4 units of PRBC and 2 units of Fresh Frozen Plasma. Recombinant factor VIIa therapy should be based on the results of coagulation.

3. If patient is in hypovolemic shock:

3.1 Head tilt down.

3.2 Keep patient warm.

3.3 Check for Coagulation Profile (PT, PTT, Fibrinogen, FDP, D- Dimer)

3.4 Send for CBC, LFT, RFT, ABG as baseline every 30 minutes

3.5 Consider central, arterial line

3.6 ECG

4. Commence Record Chart.

Blood transfusion:

1. Blood transfusion is the volume replacement best and should be started as soon as possible.

Preparation of blood products should be as:

- 6 units of PRBC
- 6 units of Fresh Frozen Plasma
- 6 units of Platelets
- 10 units of cryoprecipitate

2. Aim to maintain:

- Hb> 8 g/dl
- Platelet > 75 x 10 9
- Prothrombin < 1.5

- Fibrinogen > 1 gm.

Identify the causes of postpartum hemorrhage:

A. If uterine atony is suspected:

- Bimanual uterine massage
- Empty the bladder
- Insert 2 large bore I.V. cannula
- Start syntocinon drip 40 units in 500 cc. LR
- Methergin 0.2 mg IM, if there are no contraindications, repeat it as needed.
- If still no response, start Carboprost Protocol - 0.25 mg (contraindicated in women with asthma) IM every 15 minutes for maximum 8 doses
- Misoprostol 1000 microgram per rectal (1 Tablet = 200 microgram) Total of 5 tabs.

If patient is still bleeding, initiate subsequent intervention.

1. Uterine Balloon Tamponade (Bakri Ballon) after ensuring if no placental remnants: insert either post vaginal delivery or during caesarean section.

2. Or intrauterine packing during caesarean section to control lower segment uterine bleeding.

If patient is still bleeding and/or is hemodynamically unstable, proceed for laparotomy.

Procedure during laparotomy to control hemorrhage of atonic uterus:

1. External uterine compression suture: B- lynch
2. Uterine artery ligation
3. Internal iliac artery ligation
4. Arterial embolization (If available and arranged before)
5. Hysterectomy, the last resort but it should be decided for patients who are unstable with persistent hemorrhage to prevent DIC and death. It must be decided after the opinion of two Consultants and informing the husband.

In case of retained product:

1. Manual removal of placenta under Ultrasound guidance.
2. Suction and evacuation.

In case of vaginal or cervical laceration or uterine rupture:

1. Patient should be taken for laparotomy for repair of the injury and control of bleeding.

2. Once the bleeding has been controlled, continuous monitoring and observation in ICU.

B. Pre-eclampsia

Treatment Goals

1. Prevent seizures:

Magnesium sulphate: Initial Dose: 4- 6 grams in 50 mL over 15 – 20 minutes followed by maintenance dose of 1 – 2 grams/hour.

Monitor for magnesium toxicity and corelate with serum magnesium level.

If significant toxicity is severe - give antidote (Calcium Gluconate 1 gram (10 mL of 10% solution slowly over 5 – 10 minutes).

Stop Magnesium Sulphate at least 24 hours after the last fits or 24 – 48 hours postpartum.

2. Lower blood pressure:

If severe hypertension (BP > 160/100) start:

Table 6. Agents Used for the Management of Severe Hypertension in Pre-Eclampsia. Retrieved from Saudi MOH Pocket Manual in Obstetrics and Gynecology.

AGENT	DOSAGE
1.) LABETALOL OR	Start with 20 mg. IV, repeat at 20 – 80 mg IV every 30 minutes or 1 – 2 mg/min, max (300 mg. (then switch to oral
2.) NIPEDIFINE OR	mg. capsule to be bitten and swal- 10 – 5 lowed or just swallowed every 30 minutes 10 mg. tablet orally every 45 minutes to a maximum 80 mg./day
3.) HYDRALAZINE	Start with 5 mg. IV, repeat 5 – 10 mg. IV every 30 minutes to a maximum of 20 . mg IV

In the case of mild hypertension start:

Table 7. Agents Used for the Management of Severe Hypertension in Pre-Eclampsia. Retrieved from Saudi MOH Pocket Manual in Obstetrics and Gynecology.

AGENT	DOSAGE
1.) METHYLDOPA OR	mg. Orally BID– QID (500 - 250 (max. 2 g/day
1.) LABETALOL OR	mg. Orally BID – TID 400 – 100 (Max. 1200 mg/day)
2.) NIPEDIFINE	Oral Tablets (10 – 20 mg. Orally (BID – TID (Max. 180 mg./day

ALERT:

- Avoid diuretics and Beta Blockers.
- Don't give Diazepam or Phenytoin to abort the fits.

C. Placenta previa & accreta

- Maintain preoperative Hb. > 9 – 10 g/dl.
- Asymptomatic minor previa follow up patient, till 36 weeks as outpatient, then admit to hospital and elective caesarean section at 38 weeks.
- Asymptomatic major previa, do proper counseling either to keep in hospital till delivery or follow up as outpatient provided proximity with the hospital.
- Symptomatic (history of bleeding) with major placenta previa, admit to hospital from 34 weeks of gestation.
- Give prophylactic thromboembolic stocking.
- Encourage gentle mobility.
- If at risk of DVT, give prophylactic anti-coagulant as hospital protocol.
- Elective caesarean section should be planned at 38 weeks unless severe bleeding occurs.
- If accreta is suspected, arrange for uterine artery embolization or internal iliac artery ligation depending on the facility and delivery at 36 – 38 weeks.

Placenta can be left in place or to proceed for hysterectomy if there is severe bleeding.

In massive hemorrhage:

- Give uterotonic agents
- Bi manual compression
- Uterine packing
- B-Lynch
- Uterine or internal iliac ligation
- Hysterectomy

D. Preterm labor

A plan of management should be decided by the most senior obstetrician available in conjunction with the Pediatrician team. In utero transfer, if needed it should be arranged.

Steroid therapy may be effective in maturing the fetal lungs, and to reduce the incidence and severity of neonatal respiratory distress syndrome, given up to 36 weeks gestational age (Dexamethasone 12 mg. I.M. every 12 hours for 2 doses).

Epidural analgesia is ideal if available. Other analgesia to be minimized.

Tocolytics when waiting for Corticosteroid action or intra – uterine transfer in presence of the uterine contraction.

<u>24 – 32 Week:</u>

Prostaglandin Synthetase Inhibitor:

Indomethacin 50 - 100 mg Rectally loading then 25 mg.

Orally every 4 – 6 hours x 48 hours

or Calcium Channel Blockers

Nifedipine - 20 mg orally then 10 – 20 mg. every 6 – 8 hours up to 48 hours

<u>32 – 34 Week:</u>

1- Nifedipine or 2-ß – Adenergic Receptor Agonist:

A. Ritodrine - 100 mg. Ritodrine HCL in 500 ml LR, 15 ml/ hr = 0.05 mg/min.

Monitor the patient to detect: FHR ≥ 180 baseline, Maternal pulse≥140, Maternal BP < 90/50, ECG changes, Hypotension unresponsive to position change, Respiratory symptoms: tachycardia, shortness of breath, chest pain, Excessive maternal nervousness, palpitations, tremors or headache, Vaginal bleeding.

B. Terbutaline IV Infusion - 2.5 - 5 mcg/min. increased by 1.5 – 5 mcg/min. every 20 – 30 minutes to a maximum dose 25 mcg/min. till uterine contraction stops.

Then reduce the dose to the lowest dose that maintain the uterine quiescence.

1. Atosiban (Tractocile) Initial bolus dose of 6.75 mg. over one minute followed by an infusion of 18 mg/hr. for 3 hours, then 6 mg./hr for up to 45 hours (to a maximum of 330 mg).

2. Magnesium Sulphate

3. 6 gms. Loading dose over 20 minutes

3. 4 gms continuous infusion

Antibiotics - Avoids broad spectrum antibiotic: Antibiotics are used as prophylaxis against Group B Beta – Streptococcus only (Ampicillin 2 grams IV every 6 hours)

E. Preterm premature rupture of membrane (PPROM)

1) Preterm PROM confirmed: delivery regardless of gestational age if evidence of intra amniotic infection, significant abruption, cord prolapsed or active labor and severe bleeding, life threatening medical disease, fetal demise.

2) 24 – 33 weeks: Expectant Management includes:

- Hospital admission.
- Periodic assessment for infection, abrupt placenta and cord prolapsed
- Fetal well being.
- Serial monitoring of leucocyte count and other markers of inflammation have not been proved to be useful and are non specific when there is no clinical evidence of infection. Delivery should be considered at 34 weeks of gestation.

Administer corticosteroid and antibiotics.

- **Dexamethasone** 12 mg. every 12 hours for 2 doses I.M.
- Antibiotics: **Ampicillin** 2 g. every 6 hours for 48 hours I.V and **Erythromycin** 250 mg. every 6 hours for 48 hours, followed by 250 mg **Amoxicillin** and 250 mg **Erythromycin** every 8 hours for 5 days orally.

➢ Patient with penicillin allergy: clindamycin 900 mg intravenously every 8 hours for 48 hours plus gentamicin 7 mg/ kg (ideal body weight) for two doses 24 hours apart, followed by oral clindamycin 300 mg every eight hours for five days.

3) Less than 24 weeks:

- Expectant management if patient is stable.
- Antibiotics are not recommended.
- Costicosteroids are not recommended.

If the patient opts for expectant management and is clinically stable with no evidence of infection, Outpatient follow up can be considered then admit to the hospital once pregnancy reached viability.

4) Maternal administration of Magnesium Sulfate used for fetal neuroprotection when birth is anticipated before 32 weeks of gestation reduces the risk of cerebral palsy.

5) Expectant Management includes:

- Hospital admission,
- Periodic assessment for infection, abrupt placenta and cord prolapsed,
- Fetal wellbeing,
- Serial monitoring of leucocyte count and other markers of inflammation have not been proved to be useful and are nonspecific when there is no clinical evidence of infection.

6) Term Premature Rupture of Membranes:

- It complicates approximately 8% of pregnancies.
- The most significant maternal consequence of the term PROM is intrauterine infection.
- Induction of labor reduces the time of delivery, the rate of chorioamnionitis and endometritis.
- There is insufficient evidence to justify the routine use of prophylactic antibiotics with PROM at term.

F. Peripartum hysterectomy

The obstetrician should be prepared for possibility of having to perform a peripartum hysterectomy, especially in high-risk situations or in the presence of heavy postpartum bleeding.

1. Scheduling the delivery for the early part of the day, if possible.

2. Cross-matching four to six units of packed red blood cells and 4 units of Fresh Frozen plasma.

3. Inserting a three-way Foley's catheter in the bladder to drain urine and to facilitate instillation of fluid integrity, if required intra operatively (methylene blue) must be available.

4. Placing intermittent compression stockings to reduce the risk of deep vein thrombophlebitis.

5. Administering prophylactic antibiotics to decrease the risk of post operative infection.

6. Informing the anesthesiologist of the increased possibility of hysterectomy.

7. Assembling an operating room staff with experience in the procedures that might be performed (e.g.: hysterectomy, uterine and iliac artery ligation, ureteral stenting, or surgery). At least two surgical assistants should be available, one capable of taking an active part in the operation and one who can provide adequate traction and exposure, Vascular surgeon and urologist must be ready in case you need theme in case of emergency hysterectomy, decision should be made by two (2) Consultants.

8. Control of persistent pelvic bleeding:

Bleeding in the deep pelvis may persist following hysterectomy. Hemostasis may be achieved by placing running and figure – of – eight sutures of heavy absorbable suture material in bleeding areas. If this does not control bleeding, then during waiting for vascular surgeon.

Pelvic Packing: Packing is a last resort that usually succeeds in controlling low pressure (microvascular or venous) bleeding confined to the pelvis. We tie several Kerlix bandages together end to end to form one long strip for packing. The dry bandages are packed firmly, but carefully, into the pelvic Packing is successful if no blood.

G. Induction of labor

Pharmacological Methods

Vaginal prostaglandin E2 (PGE2) is the preferred method of induction of labor, and should be administered as a gel, tablet, or controlled release pessary.

The Recommended regimens are:

- The patient Para 5 and more - Give PGE2 1.5 mg. Q 6 hours - Maximum = 4 doses
- Patient with previous scar - Give PGE2 1.5 mg. Q 6 hours - Maximum = 4 doses
- Patient who is Para 4 and less - Give PGE2 3 mg. Q 6 hours - Maximum = 4 doses Dose can be individualized according to Bishop Score.

A. **Previous Scar**: If 4 doses are given as Protocol and failed induction, the plan should be started by her consultant.

B. **Unscarred uterus on induction of labor:** Clear weekend plan should be written by the Consultant and whether to continue or rest.

Methods that are not recommended for Induction:

- The following should not be used for induction of labor:
- Oral PGE2
- Intravenous PGE2 • Extra - amniotic PGE2
- Intracervical PGE
- Intravenous oxytocin alone
- Hyaluronidase

Monitoring And Pain Relief for Induction of Labor

- Whenever induction of labor is carried out, facilities should be available for continuous electronic fetal heart rate and uterine contraction monitoring.
- Before induction of labor is carried out, Bishop score should be assessed and recorded, and a normal fetal heart rate pattern should be confirmed using electronic fetal monitoring.

After administration of vaginal PGE2, when contraction begins, fetal well-being should be assessed with continuous electronic fetal monitoring. Once the cardiotocogram is confirmed as normal, intermittent auscultation should be used unless there are clear indications for continuous electronic fetal monitoring.

- If fetal heart rate is abnormal after administration of vaginal PGE2, recommendations of management of fetal compromise should be followed.
- Bishop score should be reassessed 6 hours after vaginal PGE2 tablet or gel insertion or 24 hours after vaginal PGE2 controlled release pessary insertion, to monitor progress.
- Tocolysis should be considered if uterine hyperstimulation occurs during induction of labor.

H. Cardiac disease

Management:

- Notify the Specialist or Consultant Obstetrician to make the plan.
- Establish baseline examination (BP, Pulse, auscultate heart and lungs).
- Insert IV line.

- Continuous pulse oximetry, hourly BP, and pulse.
- Inform the Medical Specialist if needed.

First Stage of Labor:

- Epidural after discussion senior anesthetist, if available.
- If oxytocin is needed must be established by the senior doctor.
- Consider CVP line + / - intra-arterial monitoring if needed.: Give continuous oxygen, if hypoxic, Continuous CTG monitoring.
- If a caesarean section is required, it will be with a senior anesthetist.

Second Stage of Labor:

- Do not lie flat. If she needs to be in lithotomy, use a wedge. If pushing is contraindicated, use forceps or vacuum.

Third Stage of Labor:

- A physiological third stage is sometimes preferred. Give oxytocin, if needed. Cardiac failure most commonly occurs after delivery.
- Inform Specialist / Consultant, if PPH occurs.
- To remain in the High Dependent Unit for 24 hours after delivery.

Postpartum:

- Women at risk of cardiac failure should sit up as soon as possible after delivery. Women with significant congenital cardiac disease (including ASD, VSD, coartation of the aorta, Marfan's and complex cardiac disease) should be monitored on HDU for 24 hours post-delivery.
- Women with pulmonary hypertension may require transfer to cardiac HDU.
- Monitoring and Management:
    - Nasal oxygen 6 L/min.
    - Pulse oxymetry
    - ECG monitoring
    - Fluid balance
    - Pulse and BP every 30 minutes for 12 hours then hourly
    - Involve Physician / Anesthetist early if rise in pulse rate, fall in BP or drop in urine output.
    - Watch for early signs of pulmonary oedema and consider the use of diuretics early.

Management of Patients on Anti-Coagulant Therapy:

- Inform Consultant.

Warfarin is usually contraindicated during pregnancy- certainly during the first trimester (> 1% of embryopathy) and within 2 weeks of delivery. Wherever possible, women should be routinely changed to IV or SC LMWH unless advised otherwise by hematologist.

- Heparin should be suspended either on admission in labor or on the morning of induction or elective CS and restart after 6 hours of delivery.
- If a woman is admitted in labor < 36 weeks, perform clotting studies, and discuss the use of vitamin K/ FFP with Hematologist.
- Regional anesthesia is contraindicated with abnormal clotting studies.
- Woman on Warfarin or LMWH may breastfeed.

Endocarditis Prophylaxis:

Indications:

- Prophylaxis is mandatory for women with prosthetic heart valve.
- Prophylaxis is not recommended for women with the absence of infection, chorioamnionitis or pyelonephritis.

Regime: Ampicillin 1 gm. IV 6 hourly, Gentamycin 80 mg. IV 8 hourly, Duration for 24 hours or at least 6 hours after delivery

I. Management of patients on anti-coagulant therapy

During Pregnancy

- Warfarin is usually contra indicated during pregnancy – certainly during the first Trimester (6 – 9 weeks) (> 1 % of embryopathy) and within 2 weeks of delivery. Wherever possible, women should be changed to IV or SC LMWH unless advised otherwise by hematologist.
- Any woman who is at high risk of hemorrhage and in whom continuous heparin treatment is considered essential should be managed with intravenous, unfractionated heparin until the risk factors for hemorrhage have resolved.
- Therapeutic anticoagulant therapy should be continued for the duration of the pregnancy and for at least 6 weeks postnatally and until at least 3 months of treatment has been given in total.

During Labor

If spontaneous labor occurs in women receiving therapeutic doses of subcutaneous unfractionated heparin, careful monitoring of the APTT is required. If it is markedly prolonged near delivery, protamine sulfate may be required to reduce the risk of bleeding.

- S.C. unfractionated heparin should be discontinued 12 hours before and intravenous unfractionated heparin stopped 6 hours before induction of labor or regional anesthesia.
- The woman taking LMWH for maintenance therapy should be advised that once she is established labor or thinks that she is in labor, she should not inject any further heparin.
- Where delivery is planned, LMWH maintenance therapy should be discontinued 24 hours before planned delivery.
- Long term anti-coagulant should resume heparin 12 hours post CS and 6 hours post vaginal delivery if no bleeding.
- Labor or CS should be managed in close consultation with a hematologist.

After Delivery

- A thromboprophylaxis dose of LMWH should be given by 3 hours after a caesarean section (more than 4 hours after removal of the epidural catheter, if appropriate).
- Women should be offered a choice of LMWH or oral anticoagulant for postnatal therapy after discussion about the need for regular blood tests for monitoring a Warfarin, particularly during the first 10 days of treatment. •

  Postpartum, Warfarin should be avoided until at least the third day and for longer in women at increased risk of postpartum hemorrhage.
- Woman on Warfarin and LMWH may breast feed.

  Regional Anesthesia: Regional anesthetic or analgesic techniques should not be undertaken until at least 24 hours after the last dose of therapeutic LMWH.

  The epidural catheter should not be removed within 12 hours of the most recent injection.

J. Management of HIV in pregnancy

Management of preterm delivery and preterm labor rupture of membranes:

- All women with threatened or established preterm labor and those with preterm prelabour rupture of membranes (PPROM) should have a genital

infection screen performed and any infections, even if asymptomatic should be treated. The usual indications for steroids apply.

- Women should be counselled about the increased risk of preterm delivery associated with HAART.
- For women presenting with threatened preterm labor, multidisciplinary team advice (HIV physicians and pediatricians) should be sought so that, if preterm labor supervenes, there is a detailed plan of care.
- For women in preterm labor, urgent disciplinary team advice should be sought about the choice of antiretroviral therapy. Infants born below 32 weeks of gestation may be unable to tolerate oral medication, so administering anti – retroviral therapy to the mother just before and during delivery will provide prophylaxis to the neonate.
- Where PPROM occurs after 34 weeks of gestation, delivery should be expedited. Augmentation may be considered if the viral load is less than 50 copies/ml and there are no obstetric contraindications. Consideration should be given to starting broad spectrum intravenous antibiotics.
- Where PPROM occurs before 34 weeks of gestation, Consideration should be given to start broad – spectrum intravenous antibiotics. Evidence of chorioamnionitis and fetal distress are indications for prompt delivery. In other cases, the decision as to whether to expedite delivery should be made after multidisciplinary team consultation.

Management of delivery:

- A plan of care for anti – retroviral therapy and mode of delivery should be made at 36 weeks, following detailed discussion with the mother.
- A maternal sample for plasma viral load and CD4 count should be taken at delivery.
- Woman taking HAART should have their medications prescribed and administered before delivery and, if indicated, after delivery.
- Elective caesarean sections at 38 weeks to prevent labor or rupture membrane:
    - If intravenous ZDV is indicated, the infusion should be started 4 hours before beginning the caesarean section should continue until the umbilical cord has been clamped.
- The surgical field should be kept at hemostatic as possible, and care should be taken to avoid rupturing the membranes until the head is delivered through the surgical incision.

    - Peripartum antibiotics should be administered in accordance with national guidelines for the general population.
- Planned vaginal delivery:
    - Planned vaginal delivery should only be offered to women taking HAART who have a viral load of less than 50 copies/ ml.
    - When a woman presents in labor, her plan of care of delivery should be reviewed and recent viral load results should be confirmed as less than 50 copies/ml.
    - HAART should be prescribed and administered throughout labor.
    - Invasive procedures such as fetal blood sampling and fetal scalp electrodes are contraindicated.
    - If labor progress is normal, amniotomy should be avoided unless delivery is imminent.
    - Amniotomy and possible use of oxytocin may be considered for augmentation of labor.
    - If instrumental delivery is indicated, low - cavity forceps are preferable to ventouse.
- Prelabour rupture of membranes at term:
    - In the case of prelabour ruptured membranes at term, delivery should be expedited. If the viral lod is less than 50 copies/ml and there are no obstetric indications, augmentation may be considered.
    - Broad - spectrum intravenous antibiotics should be administered if there is evidence of genital infection or chorioamnionitis.
    - If PROM>4 hrs vaginal delivery is anticipated unless any obstetric indications for cs
- Prolonged pregnancy:
    - For woman on HAART with plasma viral load of less than 50 copies/ml, the decision regarding induction of labor for prolonged pregnancy should be individualized. There is no contraindication to membrane sweep or to use of prostaglandins.
- Vaginal birth after caesarean section:
    - A trial of scar may be considered for women on HAART whose plasma viral load is less than 50 copies/ml.

Postpartum management of women who are HIV positive

- Women should be given supportive advice about formula feeding.

- Women taking HAART should have their medication prescribed and administered.
- Guidance about contraception should be given in the immediate postpartum period.
- MMR and varicella zoster immunization may be indicated, according to the CD4 lymphocyte count.

K. Ectopic Pregnancy

1. Expectant:

- When we suspect ectopic pregnancy, but TVUS fails to reveal extrauterine findings and (hCG) is low (< 200 mIU/mL) or declining
- Patient must be willing and able to comply with follow - up.
- The upper limit of serum hCG level is 1000mIU/mL providing the patient is hemodynamically stable and asymptomatic.

  Follow-up: The hCG level every 48 hours for three measurements then weekly until it is undetectable.

Medical Treatment:

- By Methotrexate: 50 mg per square meter of body surface I.M single dose. Suitable for asymptomatic, hemodynamically stable patient and beta hCG < 5000 mIu/ml, no fetal cardiac activity and Ectopic mass size less than 3 to 4 cm.
- If beta hCG > 5000 mIu/ml, multiple dose methods of Methotrexate every other day and folinic acid needed.
- Before Methotrexate is applied some criteria must be applied (If liver function test and renal function test are normal and patient is hemodynamically stable)

Follow-up:

- Serum BHCG is monitored on day 4 and 7 after Methotrexate if the fall of BHCG is > 15%, then repeat BHCG on day 7. Until BHCG< 25 IU/L, but if fallen is less than 15% a second dose of Methotrexate should be given.
- Then weekly BHCG, on day 14 if decline is < 15% give 3rd Methotroxate dose (Maximum 3 doses).

Surgical Treatment:

Indications:

- Hemodynamic instability
- Impending or ongoing rupture of ectopic mass
- Contraindications to Methotrexate
- Coexisting intrauterine pregnancy
- Not able or willing to comply with medical therapy post treatment follow up
- Lack of timely access to a medical institution for management of tubal rupture
- Desire for permanent contraception
- Known tubal disease with planned in vitro fertilization for future pregnancy.
- Failed medical therapy.
- Salpingostomy versus Salpingectomy:

Salpingectomy, instead of salpingostomy in the following situations:

  - Uncontrolled bleeding from the implantation site
  - Recurrent ectopic pregnancy in the same tube
  - Severely damaged tube
  - Large tubal pregnancy (i.e., greater 5 cm)
  - Women who have completed childbearing or who will be treated with in vitro fertilization.

- Laparoscopy versus Laparotomy:

Laparoscopic surgery is the standard surgical approach for ectopic pregnancy. However, the surgical approach depends upon the experience and judgment of the surgeon and the anesthetist, and the clinical status of the patient.

L. Septic Shock in OB/GYNAE

Management:

1) Stabilization of airway and breathing by oxygen and monitor with oximeter.

2) Assess and restore perfusion:

- Insert arterial catheter.
- Insert central venous catheter (CVC)
- Target:

- Central or mixed venous oxyhemoglobin saturation > 70%
- Central Venous Pressure (CVP) 8 to 12 mmHg.
- Mean Arterial Pressure (MAP) > 65 mmHg.
- Urine output > 0.5 ml./kg/hr.

3) Intravenous Fluid:

- Mean infusion volume of five liters within six hours
- Crystalloid (Normal Saline or Ringer Lactate) 20 – 40 ml./ kg. 4)

4) Intravenous Vasopressor (Norepinephrine), Epinephrine for patients who remain hypotensive despite adequate fluid or who develop cardiogenic oedema.

5) Antimicrobial Regimen:

- Intravenous antibiotic therapy should be initiated after obtaining appropriate cultures.
- Broad spectrum antibiotic coverage directed against both gram – positive and gram-negative bacteria.
- If Pseudomonas is an unlikely pathogen, combining Vancomycin with one of the following:
    - Cephalosporin, 3rd generation (e.g., Ceftriaxone or Cefotaxime)
    - Beta – Lactam/ Beta- Lactamase inhibitor (e.g., Piperacillin)
    - Carbapenem (e.g., Imipenem, Meropenem)
- If Pseudomonas is possible pathogen, Vancomycin with two of the following:
    - Anti -Pseudomonal Cephalosporin (e.g., Ceftazidime or Cefepime)
    - Anti- Pseudomonal Carbapenem (e.g., Imipenem, Meropenem)
    - Anti – Pseudomonal Bata – Lactam / Beta Lactamase (e.g.
    - Piperacillin)
    - Aminoglycoside (e.g., Gentamycin, Amikacin)

6) Corticosteroid Therapy:

- Most likely to be beneficial to patients who have severe septic shock especially if begun within eight hours of onset of shock.

M. Third- and Fourth-Degree Perineal Tears

Antibiotic prophylaxis should be given:

- IV Amoxycillin /Clavulanate 1.2 g STAT at repair, followed by Oral amoxicillin / clavulanate 625 mg. Three times a day for 3 – 5 days.
- For patients with mild Penicillin allergy:
  - IV cefazolin 1g (or IV cefuroxime 750mg) and IV metronidazole 500mg STAT at repair, followed by Oral cefaclor 500mg TDS and metronidazole 200mg QID for 3-5 days.
- For patients with severe Penicillin allergy:
  - IV clindamycin 600mg and IV gentamicin 5-7mg/kg STAT at repair, followed by Oral clindamycin 300mg QID and ciprofloxacin 500 mg BD for 3-5 days.

Analgesia should be prescribed:

- Rectal diclofenac 100 mg. and Paracetamol 1.5 g STAT at completion of repair
- Oral non – steroidal anti – inflammatory and Paracetamol as required.

Additional recommendations:

- Bulking agents (e.g., Fybogel) and stool softeners (lactulose 10mls BD) after 24 hours and continue for two weeks before weaning off. for 10 days
- Educate the woman about the need for adequate fluid intake when using bulking agents (1.5-2L /day).
- Ice Therapy to reduce the swelling for the 1st 48 – 72 hours post op, for 20 minutes every 3 – 4 hours.
- Refer to the dietician for advice for a high fiber diet.
- Offer physiotherapy and pelvic floor exercise for 6 – 12 weeks after repair, Referral to the obstetric physiotherapist should be made on arrival to the Maternity Ward where the woman should remain an inpatient for 24 hours.
- Post delivery the obstetrician performing the repair should ensure that the woman has a full understanding of the implications of the tear and the plans for subsequent follow-up.
- All women who had a repair should be reviewed 4 - 6 weeks postpartum by OB/Gynae Consultant as outpatient.

- If a woman is experiencing incontinence and pain at follow up, she should be referred to the Colo rectal surgeon for endo anal U/S and ano rectal manometry.
- The mode of subsequent delivery should be discussed in the context of current symptoms or findings of postpartum sonography.

  Elective caesarean (LSCS) indicated if:

  1) Symptomatic or have abnormal endo anal U/S and /or abnormal manometry.

  2) Previous 4th degree perineal tear

  3) Other risk factors for sphincter damage (e.g., big baby, Occipito Posterior position)

  4) Woman's request

N. Gestational Trophoblastic Disease (GTD)

1. Suction curettage is the method of choice of evacuation for complete molar pregnancies.
2. Anti – D prophylaxis is required following evacuation of a molar pregnancy.
3. Preparation of the cervix immediately prior to evacuation is safe.
4. Excessive vaginal bleeding can be associated with molar pregnancy and a senior surgeon directly supervising surgical evacuation is advised.
5. The use of oxytocic infusion prior to completion of the evacuation is not recommended.
6. If the woman is experiencing significant hemorrhage prior to evacuation, surgical evacuation should be expedited and the need for oxytocin infusion weighed up against the risk of tumor embolization.
7. If symptoms are persistent, evaluation of the patient with hCG estimation and ultrasound examination is advised. Several case series have found that there may be a role for second evacuation in selected cases when the hCG is less than 5000 units/liter.

O. Investigation and Treatment of Couple with Recurrent First- and Second-Trimester Miscarriage

- Women with recurrent miscarriage should be referred to a specialist clinic.
- Pregnant women with antiphospholipid syndrome should be considered for treatment with low - dose aspirin plus heparin to prevent further miscarriage.

- Genetic Factors
    - The finding of an abnormal parenteral karyotype should prompt referral to a clinical geneticist.
- Cervical weakness and cervical cerclage
    - Women with history of second – trimester miscarriage and suspected cervical weakness is candidate for cervical cerclage.
- Heparin therapy during pregnancy may improve the live birth rate of women with second - trimester miscarriage associated with inherited thrombophilia.
- Unexplained recurrent miscarriage
    - Women with unexplained recurrent miscarriage have an excellent prognosis for future pregnancy outcome without pharmacological intervention if offered supportive care alone in the setting of a dedicated early pregnancy assessment unit.

Data suggest that the use of empirical treatment in women with unexplained recurrent miscarriage is unnecessary.

P. Menorrhagia

- For women with heavy menstrual bleeding requiring medical treatment, the first line of treatment is anti-fibrinolytics (Tranexamic Acid).
- Non-steroidal anti-inflammatory drugs (NSAID) is used for the treatment of chronic heavy or prolong uterine bleeding are prescribed to start on the first day of menses for five days or till the end of menses.

Combined oral contraceptive pills are effective in reducing bleeding and controlling cycle irregularities.

- Progestogens are effective when given at high doses (Norethisterone 5 mg.)
- Progestogens-Releasing Intra Uterine System (LNG-US) is well established treatment for heavy menstrual bleeding.

Second Line Drugs - when simpler measures have failed, are useful in the management of severe anemia e.g., GnRH Analogue. These approaches are limited to short term use because of their side effects. Long term satisfaction is high with hysterectomy, but it is associated with significant morbidity and mortality and should be offered only if simpler medical alternatives have failed.

Q. Management of Hematomas Resulting from Delivery

Initial approach and patient preparation:

1) Recognition of hematoma and prompt stabilization of the patient are the initial steps.

2) Physical examination of abdomen, vulva, vagina, and rectum.

3) Check vital signs:

- If hemodynamically stable: Place a large bore I.V. line to administer crystalloid.
- If hemodynamically unstable:
  - 2 large bore I.V. lines:
    - Start IVF with crystalloid and blood products (i.e., PRBC)
    - Prepare for surgical intervention.
    - Send blood for:
      - CBC
      - Fibrinogen Level
      - PT, PTT
      - Cross match 4 units PRBC
    - Anesthesiologist consultation to do regional or general anesthesia.

There is no data regarding the value of placing all patients with hematoma on antibiotics.

If surgical intervention is required, give surgical site prophylaxis.

If signs of infection are present, then give broad spectrum antibiotics.

- Endocarditis prophylaxis is not indicated for minor vulval or vaginal procedures.

<u>Management</u>:

1) Conservative Management:
   - Monitor vital signs.
   - Fix foley's catheter and check urine output hourly
   - Check for signs of decreased end – organ perfusion:

     e.g. – Lethargy

     - Decreased urine output
   - If any of the above signs re – examine the patient.
   - Give analgesia (including narcotics).

- Apply cold packs for 24 hours. ·
- Repeat laboratory studies every 4 – 6 hours.

2) Surgical Intervention:
   - If hematoma is expanding or falling hematocrit.
   - Skin over hematoma incised, and clot evacuated.
   - Suction / irrigation
   - Detect bleeding points and ligate.
   - Re approximate the space by interrupted or figure – of – eight stitches of fine, rapidly absorbable suture material.
   - Do not pack or drain the hematoma cavity.
   - Pressure maintained by placing a one-liter bag of IVF over the area for 12 hours.
   - In case of vaginal hematoma, apply vaginal packing with gauze or a balloon (e.g., Bakri) for 12 to 24 hours after surgical repair to aid in tamponade.

3) Selective arterial embolization

Post-operative care:

- Perineal hygiene with sitz baths and gentle cleaning with saline rinse.
- Pelvic rest for 4 – 6 weeks (no coitus or placement of tampons or vaginal medications).
- Rest primarily on her side or back to avoid pressure necrosis of swollen external genitalia.
- At discharge, advise to comeback if develop fever, new or worsening pain or bleeding.

R. Antenatal Care

Subsequent visits

1. The patient should be asked about fetal movements, and this should be recorded in the file.
2. Any complaint should be documented.
3. B.P. should be checked by the nurse while the patient is “sitting” (which is easier and quicker than left lateral position). If B.P. is > 130/90, it should be rechecked by the doctor.

4. The patient will be weighed regularly and her “weight gain” should be observed.
5. Routine urinalysis (chemical component ONLY: proteins, ketones, and sugar) should be routinely done for every patient upon arrival at the OPD.
6. Symphysis Fundal (S.F.) height should be checked routinely for gestations between 26 to 36 weeks. The S.F.H. should be within 3 cm. (+ or -) of the gestational age in weeks.
7. Presentation of the fetus should be documented.

An ultrasound scan should be done at 18 – 22 weeks (if not done earlier).

Medications:

1. Folic Acid 1mg. OD, during the first 3 months of pregnancy
2. Fe Fumarate (200 mg) or Sulphate (60 mg.)
    a) Once daily – If Hb. is > 10 gm/dl.
    b) Twice daily - If Hb is < 10 g/dl.

Prenatal Education:

- Information about physiologic changes that occur during pregnancy and preparation for the birthing process.
- Discuss care issues such as breastfeeding.
- Nutritional education should be provided according to the need of the case e.g., Iron deficiency anemia or diabetic patient.
- Genetic counseling and testing should be offered to couples with a family history of genetic disorders, a previously affected fetus or child, or a history of recurrent miscarriage.

S. Management of Diabetes in Pregnancy (GDM)

Management of elevated blood glucose:

1. The initial treatment of gestational diabetes should consist of medical nutritional therapy and daily exercise for 30 minutes.
2. Glucose monitoring and glycemic target:

Self-monitoring by measurement of blood glucose before and either 1- or 2-hours post meal and at bedtime:

a. Pre-Prandial Blood Glucose < 95 mg/dl.
b. 1 Hour Post Prandial < 140 mg/dl.

c. 2 Hours Post Prandial < 120 mg/dl.

3. Nutritional Therapy:

Patient should be referred to Dietician to be placed on proper diet. The goal is:

- To achieve normoglycemia
- To prevent ketosis
- To provide adequate weight gain

4. Non-Insulin Therapy: Gylburide is a suitable alternative to insulin for glycemic control.
5. Insulin Therapy:

   Insulin Dose:

   - 0.7 units/kg in the 1st Trimester
   - 0.8 units/kg in the 2nd Trimester
   - 0.9 units/kg in the 3rd Trimester

Note:

Target blood glucose levels 1h after the start of a meal < 140 mg/dl and 2h after the start of a meal > 120 mg/dl. without hypoglycemia and HBA1C < 7%.

6. Fetal Antenatal Testing usually initiated at 32 weeks of gestation.

Assessment of fetal growth: frequent ultrasounds to monitor fetal growth (28, 32 and 36 weeks of gestation).

7. Timing of Delivery:

Induction of labor at 39 weeks in women with good glycemic control.

If a concomitant medical condition is present or glycemic control is sub optimal, delivery should be undertaken as clinically indicated.

8. Scheduled Cesarean Section:

Scheduled for caesarean section is offered to women with GDM with fetal weight > 4.750 gms. and insulin or hyperglycemic drugs are withheld:

- Hold AM dose
- Start 5% DW to avoid ketosis (DW 5%, Normal Saline 4.5)
- Check RBS every hour
- Avoid hypoglycemia during surgery
- RBS every 2 hours post – op. Keep blood glucose level within 70 – 190 mg/dl.

- Start insulin infusion drip if RBS: 126 rates.
- HR 0.5 – 2 units /hour according to RBS result - Metformin or Glyburide can be started after 24 – 48 hours prior to discharge.

9. Labor and Delivery:

In established labor, blood glucose should be checked every two hours and begin insulin infusion if the values rise above 120 mg/dl. and adjust insulin dose according to the local Protocol:

Maternal BS	**IV Insulin**	**IV Solution**
RBS < 70	Hold	DW5% Normal Saline
RBS < 140	Hold	Normal Saline or Lactated Ringers
RBS> 140	10 units to 1000 ml.	5%DW5% Normal Saline In rate 100 – 125 /hour

- Measure RBS every 2 – 4 hours
- Any Hypoglycemia < 50 should be treated promptly
- Hyperglycemia > 180

1.2.2 The Saudi Midwifery Clinic Standards (2021)

This is the first version of the midwifery clinic standards, which the committee has made great efforts to accomplish. It has adopted the international references and the publications of the International Confederation of the Midwives (ICM) and the MOH in Saudi Arabia [18].

Aim of Midwifery Clinic Standards

The aim of the midwifery clinic standards is to promote and support the development and implementation and growth of midwifery clinics which provide holistic care to women and their family throughout Saudi Arabia. In addition, to improve the quality of midwifery care, reduce variation in practices and facilitate a family-centered model of care.

Topic 1: Philosophy and Model of Care

Standard 1: Midwifery practice is underpinned by a philosophy that protects and promotes the safety and autonomy of the woman and respects her experiences, choices, priorities, beliefs, and values.

Topic 2: Scope of Midwifery Clinic

Standard 2: Midwives practice in line with legislation and professional guidance and are responsible and accountable within their scope of midwifery practice.

Standard 3: Booking appointments should ideally occur before 10 weeks of pregnancy with a minimum of eight contacts/visits recommended.

Standard 4: In the midwife clinic, according to women age and risk factors, midwife should provide consultation, early detection, and preventative measure for antenatal care.

Standard 5: The midwife who will make the risk assessment and determine the case low or high risk and therefore she will transfer the case to the obstetrician/physician.

Standard 6: The midwife clinic has a system of clear referral pathways during antenatal care.

Standard 7: All women should be asked to fill in their individualized birth plan during their antenatal appointments.

Standard 8: Shortly after birth an identified lead midwife, should be responsible for reassessing individual needs and coordinating the postnatal care of all babies and women.

Standard 9: Postnatal care should be arranged according to national postnatal care guidelines.

Standard 10: The midwife clinic has systems are in place to provide women and their babies with an individualized postnatal care plan.

Standard 11: The midwife clinic has a system of clear referral pathways during postnatal care.

Standard 12 Midwives should implement a structured program that encourages breastfeeding, using the Baby Friendly Initiative as a minimum standard.

Standard 13 Midwives should advise and provide printed information to the family about newborn postnatal care.

Standard 14 In the midwife clinic, according to women age and risk factors, the midwife should provide consultation, early detection, and preventative measure for sexual and reproductive health.

Standard 15 In the midwife clinic, according to women age and risk factors, midwife should provide consultation, early detection, and preventative measure for basic women's health.

Topic 3: Physical Location and Structure

Standard 16 The midwife clinic shall be in the Primary Health Care (PHC), Outpatient Departments (OPD), or polyclinics.

Topic 4: Policy and Procedure and Training Requirements

Standard 17 The midwife clinic has a clear policy and procedures, training and skills required of midwives in place.

Standard 18 Midwives should have demonstrated competency in the essential competencies for basic midwifery practice, keep up to date with midwifery practice by undertaking relevant Continuing Professional Development (CPD), and sufficient ongoing clinical midwifery training.

Standard 19 There is a written agreed list of knowledge, skills and competencies required of midwives to work in a midwifery clinic.

Topic 5: Staffing and Workload

Standard 20 Qualified midwives shall be responsible for managing the midwife clinic.

Topic 6: Supplies and Equipment

Standard 21 The midwife clinic has equipment, medications, and tools that meet the needs of mother and newborn.

Topic 7: Clinical Governance

Standard 22 The midwife clinic has a robust information system.

Standard 23 The midwife collects and documents comprehensive assessments of the woman and/or baby's health and wellbeing.

Standard 24 The midwife keeps purposeful, ongoing, and updated records and makes them available to other relevant health professionals.

Standard 25 An established consultation, collaboration, or referral system to meet the needs of a woman or baby outside the scope of midwife clinic practice in both emergency and non- emergency circumstances.

Standard 26 The midwife should be accountable to herself, the woman, the profession, and the wider community.

Standard 27 Midwives should provide respect, dignity, and informed choices.

Standard 28 The midwife negotiates her role as a caregiver and identifies mutual responsibilities.

Standard 29 The midwife clinic provides evidence-based practices and avoids potential harmful practices.

Section 2.0 Drug Therapy in Maternal and Child Healthcare

This section comprises four subsections: the first contains the newly recommended drugs, the second covers drug modifications, the third outlines the drugs that have been withdrawn from the market, and the fourth details drugs that have been approved by the FDA and/or EMA but have not been SFDA registered.

2.1 Additions

Two antifungal agents, **Econazole and Clotrimazole,** were registered in the SFDA list and submitted to the CHI for evaluation. Hence, relevant information pertaining to this drug can be found below.

- Econazole
- Clotrimazole

This section includes pertinent information regarding the use of **Econazole and Clotrimazole** in Symptomatic Vaginal Discharge[19]:

2.1.1 Econazole

Table 8. Econazole Drug Information

SCIENTIFIC NAME **Econazole**	
SFDA Classification	Prescription
SFDA Approval	Yes
US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	No
Indication (ICD-10)	Z34, Z34.8, Z34.9, Z76.2, Z35, Z76.1, O35, O36, O34, O33, O32, O26
Drug Class	Antifungal Agent
Drug Sub-class	Imidazole Derivative
ATC Code	G01AF05
Pharmacological Class (ASHP)	Antifungals
DRUG INFORMATION	
Dosage Form	Vaginal capsule, soft

Route of Administration	Vaginal
Dose (Adult) [DDD]*	Insert 1 vaginal capsule (150 mg) once daily in the evening for 3 days.
Maximum Daily Dose Adults*	150 mg once daily
Dose (pediatrics)	Adolescents ≥16 years: Suppository [International product]: Intravaginal: Insert 1 suppository (150 mg) once daily in the evening for 3 days.
Maximum Daily Dose Pediatrics*	150 mg once daily
Adjustment	**For Altered Kidney Function:** There are no dosage adjustments provided in the manufacturer's labeling. **For Hepatic Impairment:** There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	AGE
AGE (Age Edit): Econazole should be used in adolescents ≥16 years and adults	
CU (Concurrent Use Edit): N/A	
G (Gender Edit): N/A	
MD (Physician Specialty Edit): N/A	
PA (Prior Authorization): N/A	
QL (Quantity Limit): N/A	
ST (Step Therapy): N/A	
EU (Emergency Use Only): N/A	
PE (Protocol Edit): N/A	
SAFETY	
Main Adverse Drug Reactions (Most common and most serious)	**Most common:** • 1% to 10%: Dermatologic: Burning sensation of skin (3%), erythema (3%), pruritus (3%), stinging of the skin (3%) • <1%, post marketing, and/or case reports: Application site reaction, pruritic rash **Most serious:** • Irritation: Discontinue if sensitivity or irritation occurs.
Drug Interactions	**Category C:** • Acenocoumarol

	• Phenindione • Phenprocoumon [INT] • Warfarin
Special Population	**Additional Pediatric Considerations** Some dosage forms may contain propylene glycol; in neonates' large amounts of propylene glycol delivered orally, intravenously (e.g., >3,000 mg/day), or topically have been associated with potentially fatal toxicities which can include metabolic acidosis, seizures, renal failure, and CNS depression; toxicities have also been reported in children and adults including hyperosmolality, lactic acidosis, seizures, and respiratory depression; use caution.
Pregnancy	Information related to econazole use in pregnancy is primarily from use for other indications and route of administration. Until more data is available, it is suggested to avoid use in the first trimester and apply sparingly during the second and third trimesters if needed for topical fungal infections.
Lactation	• It is not known if econazole is present in breast milk. • According to the manufacturer, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and benefits of treatment to the mother.
Contraindications	Cream, foaming solution [International product], vaginal/topical cream (eg, Gyno-Pevaryl [International product]), vaginal suppository [International product]: Hypersensitivity to econazole, other imidazoles, or any component of the formulation

Monitoring Requirements	Reassess diagnosis if no clinical improvement after completion of treatment course.
Precautions	Other warnings/precautions: ➢ Appropriate use: For topical use only; avoid contact with eyes, mouth, nose, or other mucous membranes
Black Box Warning	N/A
REMS	N/A

HTA analysis – Econazole:

CADTH: N/A

HAS[20]**:** N/A

PBS[21]: N/A

NICE[22]: N/A

IQWIG[23]: N/A

Conclusion – Econazole: No HTA recommendations available for Econazole

2.1.2 Clotrimazole

Table 9. Clotrimazole Drug Information

SCIENTIFIC NAME **Clotrimazole**	
SFDA Classification	OTC
SFDA Approval	Yes
US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	No
Indication (ICD-10)	Z34, Z34.8, Z34.9, Z76.2, Z35, Z76.1, O35, O36, O34, O33, O32, O26
Drug Class	Antifungal Agent
Drug Sub-class	Imidazole Derivative
ATC Code	D01AC01
Pharmacological Class (ASHP)	Imidazole
DRUG INFORMATION	

Dosage Form	Cream, Vaginal tablet, Vaginal cream
Route of Administration	Vaginal and Topical
Dose (Adult) [DDD]*	A longer duration of up to 14 days may be necessary in patients with complicated infection (ie, recurrent or severe infection, infection with non-albicans Candida, or infection in an immunocompromised host) (CDC [Workowski 2021]; HHS [OI adult 2020]). Not effective against Candida glabrata (IDSA [Pappas 2016]). Cream 1%: Intravaginal: Insert 1 applicatorful (~5 g) once daily (at bedtime) for 7 days (CDC [Workowski 2021]). May also apply externally twice daily for 7 days, as needed, for itching and irritation. Canesten 6-day intravaginal cream 1% [Canadian product]: Intravaginal: Insert 1 applicatorful (~5 g) once daily (at bedtime) for 6 days. Cream 2%:Intravaginal: Insert 1 applicatorful (~5 g) once daily (at bedtime) for 3 days (CDC [Workowski 2021]). May also apply externally twice daily for 7 days, as needed, for itching and irritation. Cream 10% [Canadian product]: Intravaginal: Insert 1 applicatorful (~5 g) as a single dose (at bedtime). Tablet [Canadian/International product]: Note: When tablets are used in conjunction with an external cream, apply cream over the irritated area 1 to 2 times/day, as needed, for up to 7 days. 100 mg tablet: Intravaginal: Insert 2 tablets once daily at bedtime for 3 consecutive days. Alternatively, may insert 1 tablet once daily at bedtime for 6 consecutive days.

Maximum Daily Dose Adults*	Cream 1%: Intravaginal: twice daily for 7 days, as needed. Canesten 6-day intravaginal cream 1% [Canadian product]: Insert 1 applicatorful (~5 g) once daily (at bedtime) for 6 days. Cream 2%: Intravaginal: twice daily for 7 days, as needed, for itching and irritation. Cream 10% [Canadian product]: Intravaginal: as a single dose (at bedtime). Tablet [Canadian/International product]: Note: When tablets are used in conjunction with an external cream, apply cream over the irritated area 1 to 2 times/day, as needed, for up to 7 days. 100 mg tablet: Intravaginal: Insert 2 tablets once daily at bedtime for 3 consecutive days. Alternatively, may insert 1 tablet once daily at bedtime for 6 consecutive days.
Dose (pediatrics)	Cream (1%): Children ≥12 years and Adolescents: Insert 1 applicatorful of 1% vaginal cream daily (preferably at bedtime) for 7 consecutive days; some patients may require 14 days (CDC [Workowski 2015]). May also apply externally twice daily for 7 days as needed for itching and irritation. Cream (2%): Children ≥12 years and Adolescents: Insert 1 applicatorful of 2% vaginal cream daily (preferably at bedtime) for 3 consecutive days. May also apply externally twice daily for 7 days as needed for itching and irritation. Tablet [International product]: Adolescents ≥16 years: Refer to adult dosing.
Maximum Daily Dose Pediatrics*	Cream (1%): twice daily for 7 days as needed for itching and irritation.

	Cream (2%): daily (preferably at bedtime) for 3 consecutive days. May also apply externally twice daily for 7 days as needed for itching and irritation. Tablet [International product]: Adolescents ≥16 years: Refer to adult dosing.
Adjustment	**For Altered Kidney Function:** There are no dosage adjustments provided in the manufacturer's labeling. **For Hepatic Impairment:** There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	AGE
AGE (Age Edit): Clotrimazole should be used in adolescents ≥12 years and adults	
CU (Concurrent Use Edit): N/A	
G (Gender Edit): N/A	
MD (Physician Specialty Edit): N/A	
PA (Prior Authorization): N/A	
QL (Quantity Limit): N/A	
ST (Step Therapy): N/A	
EU (Emergency Use Only): N/A	
PE (Protocol Edit): N/A	
SAFETY	
Main Adverse Drug Reactions (Most common and most serious)	**Most common:** • 1% to 10%: Genitourinary: Vulvovaginal burning • <1% (Limited to important or life-threatening): Burning sensation of the penis (of sexual partner), polyuria, pruritus vulvae, vaginal discharge, vulvar pain, vulvar swelling. **Most serious:** • Local irritation: If irritation/sensitivity develops, discontinue therapy and institute appropriate alternative therapy.

Drug Interactions	**<u>Category X:</u>** • Progesterone Depends on Dosage Form **<u>Category C:</u>** • Sirolimus (Conventional) • Tacrolimus (Systemic)
Special Population	**Older Adult Considerations** No specific information for the elderly. **Reproductive Considerations** Vaginal products may weaken latex condoms and diaphragms
Pregnancy	**Pregnancy Considerations** Clotrimazole is minimally absorbed following topical or vaginal administration.
Lactation	• It is not known if clotrimazole is present in breast milk; however, clotrimazole is minimally absorbed following topical or vaginal administration. • Clotrimazole ointment or cream may be used for the topical treatment of nipple or breast candidiasis
Contraindications	Hypersensitivity to clotrimazole or any component of the formulation. OTC labeling: When used for self-medication, do not use vaginal cream if you have never had a vaginal yeast infection diagnosed by a doctor.
Monitoring Requirements	Instruct patients on proper administration. Monitor for severe skin irritation
Precautions	**Self-medication (OTC use):** Vaginal: When used for self-medication (OTC), consult a health care provider before use if experiencing vaginal itching and discomfort for the first time, frequent vaginal yeast infections (e.g., monthly, 3 in 6 months), or exposure to HIV. A mild increase in vaginal itching, burning, or

	irritation may occur with use; a health care provider should be consulted before switching to another agent if patient does not experience complete relief. Discontinue use and contact a health care provider if symptoms do not improve in 3 days or last more than 7 days, or if symptoms of a more serious condition occur (eg, abdominal pain, back/shoulder pain, fever, chills, nausea, vomiting, foul-smelling vaginal discharge). For vaginal use only; do not use tampons, douches, spermicides, or other vaginal products or have vaginal intercourse during treatment.
Black Box Warning	N/A
REMS	N/A

HTA analysis – Clotrimazole:

CADTH: N/A

HAS[20]**:** N/A

PBS[21]: N/A

NICE[22]: **19 August 2021** Offer vaginal imidazole (such as clotrimazole or econazole) to treat vaginal candidiasis in pregnant women.

IQWIG[23]: N/A

Conclusion – Clotrimazole: One favorable recommendation for the use of Clotrimazole to treat vaginal candidiasis in pregnant women.

2.2 Modifications

No modifications have been made since February 2020.

2.3 Delisting

The medications below are no longer SFDA registered[24], therefore, it is advisable to delist the following drugs from CHI formulary. Please refer to **Section 2** of CHI Maternal and Child Healthcare clinical guidance.

- POLYSACCHARIDE OF NEISSERIA MENINGITIDIS GROUP A, POLYSACCHARIDE OF NEISSERIA MENINGITIDIS GROUP C
- FERROUS GLUCONATE
- INFLUENZA VACCINE SURFACE ANTIGEN NYMC X-181, NYMC X-187, AND NYMC BX-35

2.4 Other Drugs

After February 2020, there have been a vaccine that has received FDA approval but is not SFDA registered.

2.4.1 Abrysvo

U.S. FDA Approves ABRYSVO™, Pfizer's Vaccine for the Prevention of Respiratory Syncytial Virus (RSV) in Infants Through Active Immunization of Pregnant Individuals 32-36 Weeks of Gestational Age.

Section 3.0 Key Recommendations Synthesis

Nausea and Vomiting:[4]

- Inform expectant mothers that experiencing mild to moderate nausea and vomiting during pregnancy is a common occurrence and is likely to improve before the 16 to 20-week mark.
- Understand that when women seek guidance from healthcare providers regarding pregnancy-related nausea and vomiting, they may have already attempted various remedies.
- If pregnant women with mild-to-moderate nausea and vomiting prefer a non-pharmacological approach, suggest trying ginger.
- When contemplating pharmaceutical solutions for pregnancy-related nausea and vomiting, engage in a discussion with the woman regarding the pros and cons of different antiemetic medications, considering her personal preferences and past treatment experiences in previous pregnancies.
- In cases of severe and unresponsive vomiting that does not improve with primary care or outpatient management, consider the possibility of inpatient care, particularly for women diagnosed with hyperemesis gravidarum.

Symptomatic Vaginal Discharge:[4]

- Evaluate the cause of symptomatic vaginal discharge in pregnant women by conducting a vaginal swab if uncertainty exists.
- If there is suspicion of a sexually transmitted infection, consider arranging appropriate diagnostic tests.
- Offer vaginal imidazole treatments (such as clotrimazole or econazole) to address vaginal candidiasis in pregnant women.

Unexplained Vaginal Bleeding after 13 Weeks:[4]

- For pregnant women experiencing unexplained vaginal bleeding after surpassing the 13-week mark, assess the need for hospitalization, taking into account factors like the risk of placental abruption, preterm delivery, the volume of vaginal bleeding, and the woman's accessibility to secondary care in case of emergencies.
- In instances where pregnant women with unexplained vaginal bleeding are admitted to the hospital, contemplate the use of corticosteroids for fetal lung development if there is an elevated likelihood of preterm birth within the next 48 hours, while also considering gestational age.

Post-Partum Hemorrhage (PPH):[6]

- Initial Fluid Management:

- Start with an immediate infusion of 2000 mL of warmed Hartmann's solution for fluid resuscitation.
- Emphasize the importance of strict fluid balance and the need to initiate and meticulously maintain a fluid balance chart.
- Ensure that the plasma fibrinogen level remains above 2 g/L throughout the course of ongoing PPH.
- Administer 4g of Fibrinogen Concentrate after the first 4 units of blood transfusion, before considering the use of fresh frozen plasma (FFP) and/or cryoprecipitate.
- Consider the inclusion of intravenous tranexamic acid at a dose of 1.0 g IV, in conjunction with Oxytocin, during caesarean sections to minimize blood loss in women at an elevated risk of PPH.
- Ensure the appropriate replacement of blood products, with the possibility of administering up to 1000 mL of fresh frozen plasma (FFP) and 10 units of cryoprecipitate (equivalent to two packs) in cases of persistent bleeding, while awaiting coagulation study results.

- Continuing Management of PPH:

Oxytocin infusion is the recommended primary treatment for primary PPH. When used after prophylactic uterotonics, misoprostol and oxytocin infusion produce similar results. It's important to note that vaginal, sublingual, or rectal misoprostol may take 1.0–2.5 hours to have an effect on uterine tone, and clinicians should be mindful of this delayed clinical response to misoprostol.

Management of Miscarriage:[7]

- Instruct women with a confirmed intrauterine pregnancy showing fetal heartbeat and presenting with vaginal bleeding (without a history of previous miscarriage) to:
  - Return for further assessment if bleeding worsens or persists beyond 14 days.
  - Resume or continue routine antenatal care if the bleeding stops.
- Avoid the use of mifepristone as a treatment for incomplete miscarriage.
- Provide pain relief and anti-emetics as needed to all women and individuals undergoing medical management of miscarriage.

- Supply women and individuals who have undergone medical management of miscarriage with a urine pregnancy test to be conducted at home three weeks after the procedure, unless they experience deteriorating symptoms, in which case, advise them to consult the healthcare professional responsible for their medical management.

Low-Dose Aspirin Use for the Prevention of Preeclampsia and Related Morbidity and Mortality[11]

- Low-dose aspirin (81 mg per day) is advised for the following situations:
  1. Pregnant individuals who are at a high risk of developing preeclampsia, especially if they have one or more of the following risk factors:
     - A history of pre-eclampsia, especially if it resulted in adverse outcomes.
     - Carrying multiple fetuses (multifetal gestation).
     - Suffering from chronic hypertension.
     - Having pre-existing type 1 or 2 diabetes.
     - Dealing with kidney disease.
     - Battling autoimmune diseases like systemic lupus erythematosus or antiphospholipid syndrome.
     - Possessing combinations of multiple moderate-risk factors.

     These risk factors consistently show a strong association with the highest risk of developing preeclampsia. In a population of pregnant individuals with one or more of these risk factors, the incidence of preeclampsia is likely to be at least 8%.
  2. Pregnant individuals who have multiple moderate risk factors, including but not limited to:
     - No prior pregnancies (nulliparity).
     - Obesity, indicated by a body mass index (BMI) over 30.
     - A family history of preeclampsia, such as a mother or sister who experienced it.
     - Black ethnicity (used as a proxy for the presence of underlying racial disparities).
     - Lower income.
     - Age 35 years or older.

- Personal history factors like a previous low birth weight or being born small for gestational age, a history of adverse pregnancy outcomes, or an interval of more than 10 years between pregnancies.
- Having undergone in vitro fertilization.

These factors independently increase the moderate risk of developing preeclampsia, with some being more consistently associated with this risk than others. When multiple moderate-risk factors are present, the risk of pre-eclampsia becomes higher.

3. Additionally, pregnant individuals may consider low-dose aspirin if they have one or more of the following moderate-risk factors: Black ethnicity (as an indicator of potential underlying racial disparities) or lower income.
4. When low-dose aspirin is recommended, it should be started between the 12th and 28th weeks of gestation, ideally before the 16th week, and should be taken daily until the time of delivery.

Vitamin K and the Newborn Infant

- Vitamin K should be administered to all newborn infants weighing >1500 g as a single, intramuscular dose of 1 mg within 6 hours of birth.
- Preterm infants weighing ≤1500 g should receive a vitamin K dose of 0.3 mg/kg to 0.5 mg/kg as a single, intramuscular dose. A single intravenous dose of vitamin K for preterm infants is not recommended for prophylaxis.

Folic Acid Supplementation

- Health care providers should advise all women aged 12–45 years considering or planning a pregnancy about the benefits of taking an oral daily multivitamin containing folic acid (0.4-1mg) to optimize serum and red blood cell folate levels (*strong, high*).
- Folic acid should be taken in a daily oral multivitamin that includes a 2.6-µg dose of vitamin B_{12} (*strong, high).*

Section 4.0 Conclusion

This report serves as **an annex to the previous CHI Maternal and Child Healthcare report** and aims to provide recommendations to aid in the management of Maternal and Child Healthcare. It is important to note that these recommendations should be utilized to support clinical decision-making and not replace it in the management of individual patients with Maternal and Child Healthcare. Health professionals are expected to consider this guidance alongside the specific needs, preferences, and values of their patients when exercising their judgment.

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Section 6.0 Appendices

Appendix A. Prescribing Edits Definition

I. Prescribing Edits (ensure consistent use of abbreviations, e.g., CU, ST)

Some covered drugs may have additional requirements, rules, or limits on coverage. These requirements and limits may include:

Prescribing edits Tools	Description
AGE (Age):	Coverage may depend on patient age
CU (Concurrent Use):	Coverage may depend upon concurrent use of another drug
G (Gender):	Coverage may depend on patient gender
MD (Physician Specialty):	Coverage may depend on prescribing physician's specialty or board certification
PA (Prior Authorization):	Requires specific physician request process
QL (Quantity Limits):	Coverage may be limited to specific quantities per prescription and/or time period
ST (Step Therapy):	Coverage may depend on previous use of another drug
EU (Emergency Use only):	This drug status on Formulary is only for emergency use
PE (Protocol Edit):	Use of drug is dependent on protocol combination, doses, and sequence of therapy

Appendix B. Maternal and Child Healthcare Scope

Maternal and Child Healthcare Scope

Section	Rationale/Updates
Section 1.2. THE NATIONAL INSTITUTE FOR HEALTH CARE AND EXCELLENCE (NICE) GUIDELINES FOR ANTENATAL CARE [2019]	**THE NATIONAL INSTITUTE FOR HEALTH CARE AND EXCELLENCE (NICE) GUIDELINES FORANTENATAL CARE [2021]** Routine antenatal care for women and their babies: summary of NICE guidance BMJ 2021; 375 doi: https://doi.org/10.1136/bmj.n2484 (Published 29 October 2021) Cite this as: BMJ 2021;375:n2484 THE NATIONAL INSTITUTE FOR HEALTH CARE AND EXCELLENCE (NICE) GUIDELINES FORANTENATAL CARE [2021] Interventions for common problems during pregnancy Nausea and vomiting 1.4.1 Reassure women that mild to moderate nausea and vomiting are common in pregnancy and are likely to resolve before 16 to 20 weeks. 1.4.2 Recognize that by the time women seek advice from healthcare professionals about nausea and vomiting in pregnancy, they may have already tried a number of different interventions. 1.4.3 For pregnant women with mild-to-moderate nausea and vomiting who prefer a non-pharmacological option, suggest that they try ginger. 1.4.4 When considering pharmacological treatments for nausea and vomiting in pregnancy, discuss the advantages and disadvantages of different antiemetics with the woman. Consider her preferences and her experience with treatments in previous pregnancies. See table 1 on the advantages and disadvantages of different pharmacological treatments for nausea and vomiting in pregnancy to support shared decision making. The below table summarizes the advantages and disadvantages of different pharmacological treatments for nausea and vomiting in pregnancy: 1.4.5 For pregnant women with nausea and vomiting who choose a pharmacological treatment, offer an antiemetic (see table 1 on the advantages and disadvantages of different pharmacological treatments for nausea and vomiting in pregnancy). 1.4.6 For pregnant women with moderate-to-severe nausea and vomiting: • consider intravenous fluids, ideally on an

	outpatient basis • consider acupressure as an adjunct treatment. 1.4.7 Consider inpatient care if vomiting is severe and not responding to primary care or outpatient management. This will include women with hyperemesis gravidarum. Heartburn 1.4.8 Give information about lifestyle and dietary changes to pregnant women. with heartburn in line with the section on common elements of care in the NICE guideline on gastro-esophageal reflux disease and dyspepsia in adults. 1.4.9 Consider a trial of an antacid or alginate for pregnant women with heartburn. . Symptomatic vaginal discharge 1.4.10 Advise pregnant women who have vaginal discharge that this is common during pregnancy, but if it is accompanied by symptoms such as itching, soreness, an unpleasant smell, or pain on passing urine, there may be an infection that needs to be investigated and treated. 1.4.11 Consider carrying out a vaginal swab for pregnant women with symptomatic vaginal discharge if there is doubt about the cause. 1.4.12 If a sexually transmitted infection is suspected, consider arranging appropriate investigations. 1.4.13 Offer vaginal imidazole (such as clotrimazole or econazole) to treat vaginal candidiasis in pregnant women. 1.4.14 Consider oral or vaginal antibiotics to treat bacterial vaginosis in pregnant women in line with the NICE guideline on antimicrobial stewardship. Unexplained vaginal bleeding after 13 weeks 1.4.16 Offer anti-D immunoglobulin to women who present with vaginal bleeding after 13 weeks of pregnancy if they are: • rhesus D-negative and • at risk of isoimmunization. 1.4.17 Refer pregnant women with unexplained vaginal bleeding after 13 weeks to secondary care for a review. 1.4.18 For pregnant women with unexplained vaginal bleeding after 13 weeks, assess whether to admit them to hospital, taking into

	account: · the risk of placental abruption · the risk of preterm delivery · the extent of vaginal bleeding · the woman's ability to attend secondary care in an emergency. 1.4.19 For pregnant women who present with unexplained vaginal bleeding, offer to carry out placental localization by ultrasound if the placental site is not known. 1.4.20 For pregnant women with unexplained vaginal bleeding who are admitted to hospital, consider corticosteroids for fetal lung maturation if there is an increased risk of preterm birth within 48 hours. Consider gestational age (see the section on maternal corticosteroids in the NICE guideline on preterm labor and birth). 1.4.21 Consider discussing the increased risk of preterm birth with women who have unexplained vaginal bleeding.
B.1.9 National Health Services (NHS) clinical guidelines for obstetrics hemorrhage [2019]	**National Health Services (NHS) clinical guidelines for obstetrics hemorrhage [2022]** <u>Post-Partum Hemorrhage (PPH)</u> ➢ Measures for minor PPH (blood loss 500–1000 mL) without clinical shock: • Intravenous access (one 16-gauge cannula). • Urgent venipuncture (20 mL) for: a. Group and screen. b. Full blood count. c. Coagulation screen. • Pulse, respiratory rate, temperature, and blood pressure plus MEOWS score recording every 15 minutes. • Commence warmed crystalloid infusion. Failure to recognize and adequately treat a primary PPH can quickly lead to Major obstetric Hemorrhage. <u>Remember – **ABC**</u> 1. Airway maintenance, if pregnant left lateral tilt. Chin lift. 2. Breathing - Administer oxygen 10 -15 L/min via a face mask 3. Circulation - Ensure IV access -16-gauge intravenous cannulae x 2. 4. Take bloods for FBC, U&E clotting and X-match (4 units) and Kleihauer if Rh negative. All patients should be given blood of their own blood group as soon as possible. If the blood bank is informed of the urgency, ABO and Rh D compatible blood can usually be made available on an emergency basis soon after receipt of the crossmatch

	sample. Additional colloid will be necessary if more than 3 units have been given. Only use un-crossmatched O Rh D negative blood if transfusion must be given immediately. 5. Initial fluid management. Rapid infusion of 2000 mL of warmed Hartmann's solution. 6. The anesthetist will normally supervise the management of fluid replacement. 7. An indwelling bladder catheter should be inserted with hourly measurement output. 8. Strict fluid balance is essential, and a fluid balance chart should be initiated and carefully maintained. 9. Postnatal women can be laid flat possibly with a head down tilt if there are signs of hypovolemia, 10. Regular haemoglobin and hematocrit assessment is helpful but restoration of normovolaemia is priority. 11. Fluid resuscitation and blood transfusion should not be delayed because of false reassurance from a single haemoglobin result; consider the whole clinical picture 12. Platelet counts, and coagulation studies should be performed as a guide to the need for replacement therapy with fresh frozen plasma, cryoprecipitate, or platelet concentrates. 13. A plasma fibrinogen level of greater than 2 g/L should be maintained during ongoing PPH. 14. Give 4g Fibrinogen Concentrate after first 4 units of blood transfused BEFORE considering FFP and/or cryoprecipitate. 15. Clinicians should consider the use of intravenous tranexamic acid 1.0 g IV, in addition to Oxytocin at caesarean section to reduce blood loss in women at increased risk of PPH. 16. In a woman who is bleeding and is likely to develop a coagulopathy or has evidence of a coagulopathy, it is prudent to give blood components before coagulation indices deteriorate and worsen the bleeding. 17. Keep the patient warm. 18. If bleeding is ongoing after the first 4 units of blood have been transfused and fibrinogen concentrate given, then the primary pack from the major obstetric hemorrhage protocol should be used (5 units RBC as indicated, 4 units FFP). 19. Ensure appropriate blood product replacement. Up to 1000 mL of fresh frozen plasma (FFP) and 10 units of cryoprecipitate (two packs) maybe given in the face of relentless bleeding, while awaiting results of coagulation studies. 20. Correct acidosis, hypothermia (clotting is prolonged with hypothermia – active warming measures should be

	considered) & hypocalcemia. 21. Involve consultant hematologist if coagulation defect before surgical intervention. 22. Monitor BP, pulse, urine output, O2 saturation, respiratory rate continuously and temperature every 15 minutes – Record on Mega chart. In cases of severe APH commence CTG. MEOWs Scores must be attributed to each set of observations. 23. Invasive intravascular monitoring may be initiated by the anesthetist. 24. Record keeping. Ensure records are up to date and complete following the event and that all drugs are prescribed. **Continuing Management of PPH** Management of uterine atony 1. Anticipate the problem - those women with risk factors should already be on Delivery Suite and have venous access and be receiving an **Oxytocin** infusion post-partum of 30 units of Oxytocxin in 500 mL 0.9% normal saline at 166 mL/hour as per Trust Guideline for the Management of the Third Stage of Labor including Retained Placenta Trustdocs ID: 818. 2. "Rub-up" the uterine fundus to stimulate uterine contraction and consider removal of vaginal/uterine clots. Consider Bi-manual compression. 3. Confirm that **Syntometrine** 5/500 IM was given in third stage - if not, do so. NB. In pre-eclampsia or patients with a history of cardiac disease give 5 IU Oxytocin by slow I.V. injection or 10 IU I.M. 4. Give 1g **Tranexamic** acid by slow I.V injection (~1mL/min). This is not a uterotonic, so will not help uterine tone. However, it is an antifibrinolytic and has been shown to reduce blood loss in this situation, especially if given early. 5. Repeat Syntometrine 5/500 (or Oxytocin if hypertensive or cardiac disease). 6. Commence infusion of 30 units of Oxytocin in 500 mL 0.9% normal saline at 166 mL/hour if not already in progress. 7. If ongoing bleeding at 30min or re-bleeding within 24 hours give a further 1g IV Tranexamic Acid. 8. If the placenta is retained and uterus contracted, try controlled cord traction. If this fails, arrange manual removal of placenta – see guideline for management of third stage of labor. 9. If atony persists, **Carboprost** (Hemabate), 250 mcg (1.0mL) may be given by deep I.M. injection at the discretion of the Obstetric Registrar. If successful, further

	doses (maximum of eight) may be required at 15-minute intervals, after discussion with the on-call Consultant. 10. **Misoprostol** 800 mcg can be administered sub lingual. 11. Arrange urgent examination under anesthesia if: a. Significant hemorrhage continues despite a well contracted uterus. b. Above measures fail to produce a tonic uterine contraction. c. Bleeding is secondary to obvious genital tract trauma. 12. Consider Bakri Tamponade Balloon in selected cases 13. Consider B-Lynch brace suture in selected cases 14. Interventional radiology is available out of hours. If the bleeding persists, the Obstetric Consultant can contact the Interventional Radiology Consultant on-call. . 15. If bleeding is not responsive to the standard medical, surgical, radiological treatment, rFVIIa may be considered. Discuss with consultant hematologist. 16. Cell salvage should be considered in selected cases after discussion with the anesthetist and the theatre staff 17. Record keeping – procedures should be documented contemporaneously throughout the event using the emergency PPH record chart by a scribe. Documentation should include the persons present, tasks undertaken, drugs given, and observations recorded including fluids given and urine output. Strict fluid balance charts should be continued following the event with regular review by the obstetrician. 18. If the emergency has occurred on the MLBU, the woman will be transferred to the Delivery Suite following discussion with the coordinator and a transfer form completed by the midwifery staff. 19. Communication: Document clear lines of communication between the consultant obstetrician, consultant anesthetist, hematologist, blood transfusion personnel, Delivery Suite coordinator and senior midwife on MLBU. 20. Ensure the woman and her family are reassured throughout and are debriefed after the event. ***** Notes**: Oxytocin infusion is the recommended first line treatment

	for primary PPH. When used following prophylactic uterotonics, misoprostol and oxytocin infusion work similarly. Vaginal, sublingual or rectal misoprostol took 1.0–2.5 hours to increase uterine tone. Clinicians should be aware of this delay in the clinical effect of misoprostol. Guidelines from WHO and the International Federation of Gynecology and Obstetrics recommend that in the management of PPH, misoprostol is administered sublingually.
B.1.14 NICE guidelines for ectopic pregnancy and miscarriage [2017]	NICE guidelines for Ectopic pregnancy and miscarriage: diagnosis and initial management 2019 [Updated 2023] <u>Management of miscarriage</u> <u>Threatened miscarriage.</u> • Advise a woman with a confirmed intrauterine pregnancy with a fetal heartbeat who presents with vaginal bleeding, but has no history of previous miscarriage, that: ➢ if her bleeding gets worse, or persists beyond 14 days, she should return for further assessment. ➢ if the bleeding stops, she should start or continue routine antenatal care. [2012, amended 2021] • Offer vaginal micronized progesterone 400 mg twice daily to women with an intrauterine pregnancy confirmed by a scan, if they have vaginal bleeding and have previously had a miscarriage. [2021] • If a fetal heartbeat is confirmed, continue progesterone until 16 completed weeks of pregnancy. [2021] <u>Expectant management</u> • Use expectant management for 7 to 14 days as the first-line management strategy for women with a confirmed diagnosis of miscarriage. Explore management options other than expectant management if o The woman is at increased risk of hemorrhage (for example, she is in the late first trimester) or o She has previous adverse and/or traumatic experience associated with pregnancy (for example, stillbirth, miscarriage or antepartum

	hemorrhage) or o she is at increased risk from the effects of hemorrhage (for example, if she has coagulopathies or is unable to have a blood transfusion) or there is evidence of infection. [2012] • If the resolution of bleeding and pain indicate that the miscarriage has completed during 7 to 14 days of expectant management, provide the woman or person with a urine pregnancy test to carry out at home 3 weeks after their miscarriage, and advise them to return for individualized care if it is positive. [2012, amended 2023] <u>Medical management</u> • For the medical management of missed miscarriage *offer*: ➢ 200 mg oral mifepristone and ➢ 48 hours later, 800 micrograms misoprostol <u>(vaginal, oral or sublingual)</u> unless the gestational sac has already been passed. [2012, amended 2023] • Advise the woman or person that if bleeding has not started within 48 hours after misoprostol treatment, they should contact their healthcare professional to determine ongoing individualized care. If there are concerns that they will not contact the service, then there should be arrangements for the service to follow up with these individuals. [2012, amended 2023] • For the medical management of incomplete miscarriage, use a single dose of misoprostol 600 micrograms (vaginal, oral or sublingual). Misoprostol 800 micrograms can be used as an alternative to allow alignment of treatment protocols for both missed and incomplete miscarriage. [2012, amended 2023] • Do not offer mifepristone as a treatment for incomplete miscarriage. [2012, amended 2023] • Offer all women and people receiving medical management of miscarriage pain relief and anti-emetics as needed. [2012] • Inform women and people receiving medical management of miscarriage about what to

	expect throughout the process. Include the length and extent of bleeding, potential side effects of treatment including pain, diarrhea, and vomiting, and when and how to seek help. [2012, amended 2023] • Provide women and people who have had medical management of miscarriage with a urine pregnancy test to carry out at home 3 weeks after medical management of miscarriage unless they experience worsening symptoms, in which case advise them to return to the healthcare professional responsible for providing their medical management. [2012, amended 2021] • Advise women and people with a positive urine pregnancy test after 3 weeks to return for a review by a healthcare professional to rule out a retained pregnancy, molar, or ectopic pregnancy, and assess the need for further investigations or treatment. [2012, amended 2023] • If the pregnancy test after 3 weeks is negative but the woman or person is still bleeding heavily or has other symptoms (for example, pelvic pain or fever), then assess the need for further investigations or treatment. [2023] <u>Surgical management</u> • Where clinically appropriate, offer women undergoing a miscarriage a choice of ➢ Manual vacuum aspiration under local anaesthetic in an outpatient or clinic setting or ➢ Surgical management in a theatre under general anaesthetic. [2012] • Provide oral and written information to all women undergoing surgical management of miscarriage about the treatment options available and what to expect during and after the procedure. <u>Management of tubal ectopic pregnancy</u> • Offer surgery as a first-line treatment to women who are unable to return for follow-up after methotrexate treatment or who have any of the following: ➢ an ectopic pregnancy and significant pain

	➢ an ectopic pregnancy with an adnexal mass of 35 mm or larger ➢ an ectopic pregnancy with a fetal heartbeat visible on an ultrasound scan ➢ an ectopic pregnancy and a serum hCG level of 5,000 IU/litre or more. [2012] • Offer the choice of either methotrexate or surgical management to women with an ectopic pregnancy who have a serum hCG level of at least 1,500 IU/litre and less than 5,000 IU/litre, who are able to return for follow-up and who meet all the following criteria: ➢ no significant pain ➢ an unruptured ectopic pregnancy with an adnexal mass smaller than 35 mm with no visible heartbeat ➢ no intrauterine pregnancy (as confirmed on an ultrasound scan). • Advise women who choose methotrexate that their chance of needing further intervention is increased and they may need to be urgently admitted if their condition deteriorates. [2012] • For women with ectopic pregnancy who have had methotrexate, take 2 serum hCG measurements in the first week (days 4 and 7) after treatment and then 1 serum hCG measurement per week until a negative result is obtained. If hCG levels plateau or rise, reassess the woman's condition for further treatment. [2012]
B.1.18 NICE guidelines for intrapartum care for healthy women and babies [2017]	**NICE guidelines for intrapartum care for healthy women and babies [2022]** **<u>Postpartum hemorrhage</u>** <u>Management</u> If a woman has a postpartum hemorrhage: • Call for help • Give immediate clinical treatment: - emptying of the bladder and - uterine massage and - uterotonic drugs and - intravenous fluids and - controlled cord traction if the placenta has not yet been delivered. • Continuously assess blood loss and the woman's

	condition and identify the source of the bleeding. - give supplementary oxygen. - arrange for transfer of the woman to obstetric-led care (following the general - principles for transfer of care). [2014] • Administer a bolus of one of the following as first-line treatment for postpartum hemorrhage: - oxytocin (10 IU intravenous) or - ergometrine (0.5 mg intramuscular) or - combined oxytocin and ergometrine (5 IU/0.5 mg intramuscular). [2014] • Offer <u>second-line treatment</u> for postpartum hemorrhage if needed. No particular uterotonic drug can be recommended over any other; options include: · repeat bolus of: - **oxytocin** (intravenous) - ergometrine (intramuscular, or cautiously intravenously) - combined oxytocin and ergometrine (intramuscular) - **misoprostol** - oxytocin infusion - **carboprost** (intramuscular). [2014] • Assess the need for adjuvant options for managing significant continuing postpartum hemorrhage, including: - **tranexamic** acid (intravenous) - rarely, in the presence of otherwise normal clotting factors, rFactor VIIa, in - consultation with a hematologist. [2014] • Allocate a member of the healthcare team to stay with the woman and her birth companion(s), explain what is happening, answer any questions and offer support throughout the emergency situation. [2014] • If the hemorrhage continues: - perform examination under anaesthetic - ensure that the uterus is empty and repair any trauma - consider balloon tamponade before surgical options. [2014] • Be aware that no particular surgical procedure can be recommended over any other for treating postpartum hemorrhage. [2014]

	• The maternity service and ambulance service should have strategies in place in order to respond quickly and appropriately if a woman has a postpartum hemorrhage in any setting. [2014]
C.1.2 Center for disease control and prevention (CDC) immunization schedule for children from birth through 6 years old [2020]	**Center for disease control and prevention (CDC) immunization schedule for children from birth through 6 years old [2023]**

Appendix C. MeSH Terms PubMed

C.1 PubMed Search for Maternal and Child Healthcare:

Query	Filters	Search Details	Results
Search: ((Maternal Health [MeSH Terms]) OR (Maternal Health [Title/Abstract])) OR (Health, Maternal[Title/Abstract]) Filters:	Guideline, in the last 5 years	("maternal health"[MeSH Terms] OR "maternal health"[Title/Abstract] OR "health maternal"[Title/Abstract]) AND ((y_5[Filter]) AND (guideline[Filter]))	6
Search: ((((((((((Child Health[MeSH Terms]) OR (Child Health[Title/Abstract])) OR (Health, Child[Title/Abstract])) OR (Childrens Health[Title/Abstract])) OR (Health, Childrens[Title/Abstract])) OR (Children's Health[Title/Abstract])) OR (Health, Children's[Title/Abstract])) OR (Child Well Being[Title/Abstract])) OR (Well Being, Child[Title/Abstract])) OR (Child Well-Being[Title/Abstract])) OR (Well-	Guideline, in the last 5 years	("child health"[MeSH Terms] OR "child health"[Title/Abstract] OR "health child"[Title/Abstract] OR "childrens health"[Title/Abstract] OR "health childrens"[Title/Abstract] OR "children s health"[Title/Abstract] OR "health children s"[Title/Abstract] OR "child well being"[Title/Abstract] OR "well being child"[Title/Abstract] OR "child well being"[Title/Abstract] OR "well being child"[Title/Abstract] OR "child wellbeing"[Title/Abstract] OR	11

Being, Child[Title/Abstract])) OR (Child Wellbeing[Title/Abstract])) OR (Wellbeing, Child[Title/Abstract])		"wellbeing child"[Title/Abstract]) AND ((y_5[Filter]) AND (guideline[Filter]))	

Appendix D. Treatment Algorithm

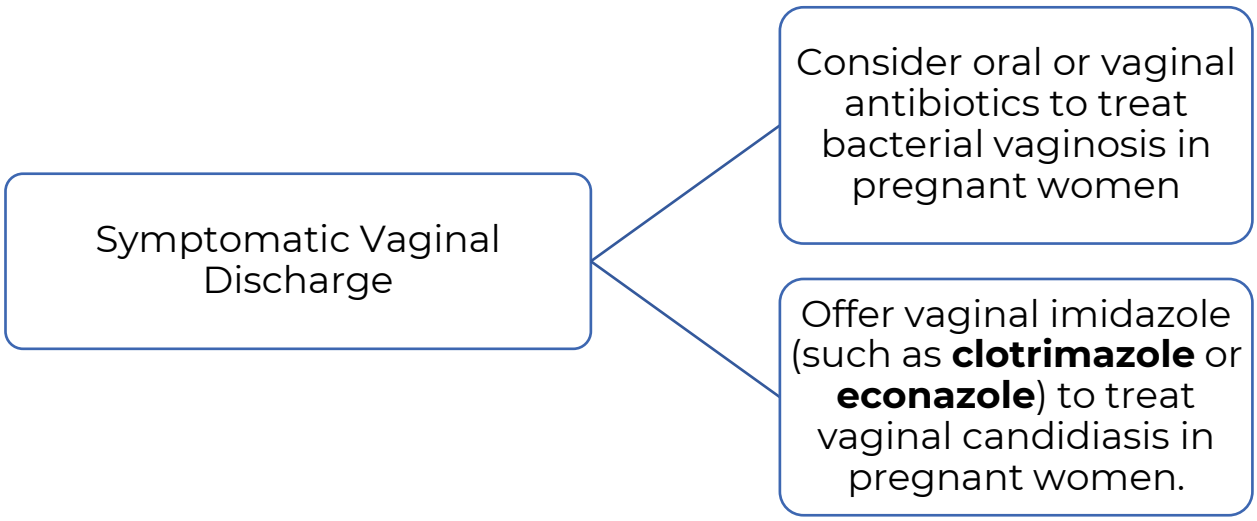

Figure 5. *Treatment Algorithm for the Management of Symptomatic Vaginal Discharge*

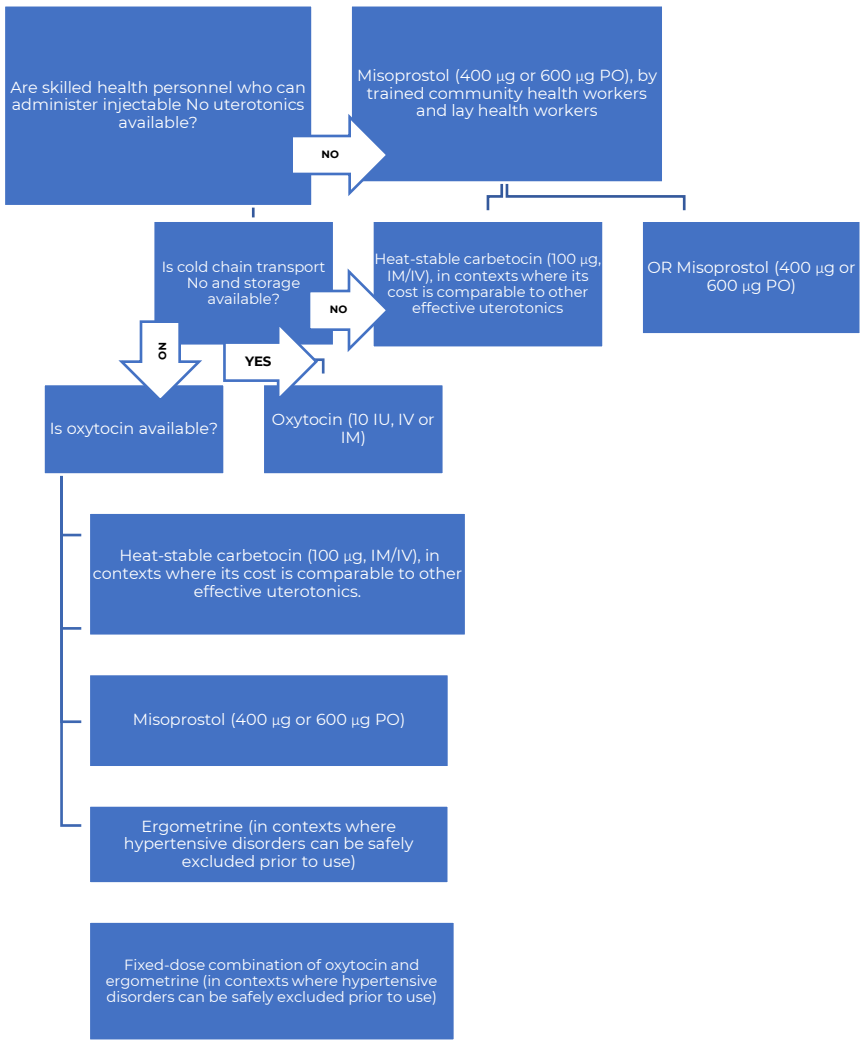

Figure 6. *Contextual Considerations in Selecting a Uterotonic for Postpartum Hemorrhage*