National Women & Infants Health Programme

National Clinical Practice Guideline

Management of rheumatic diseases in the preconception, antenatal and postnatal periods

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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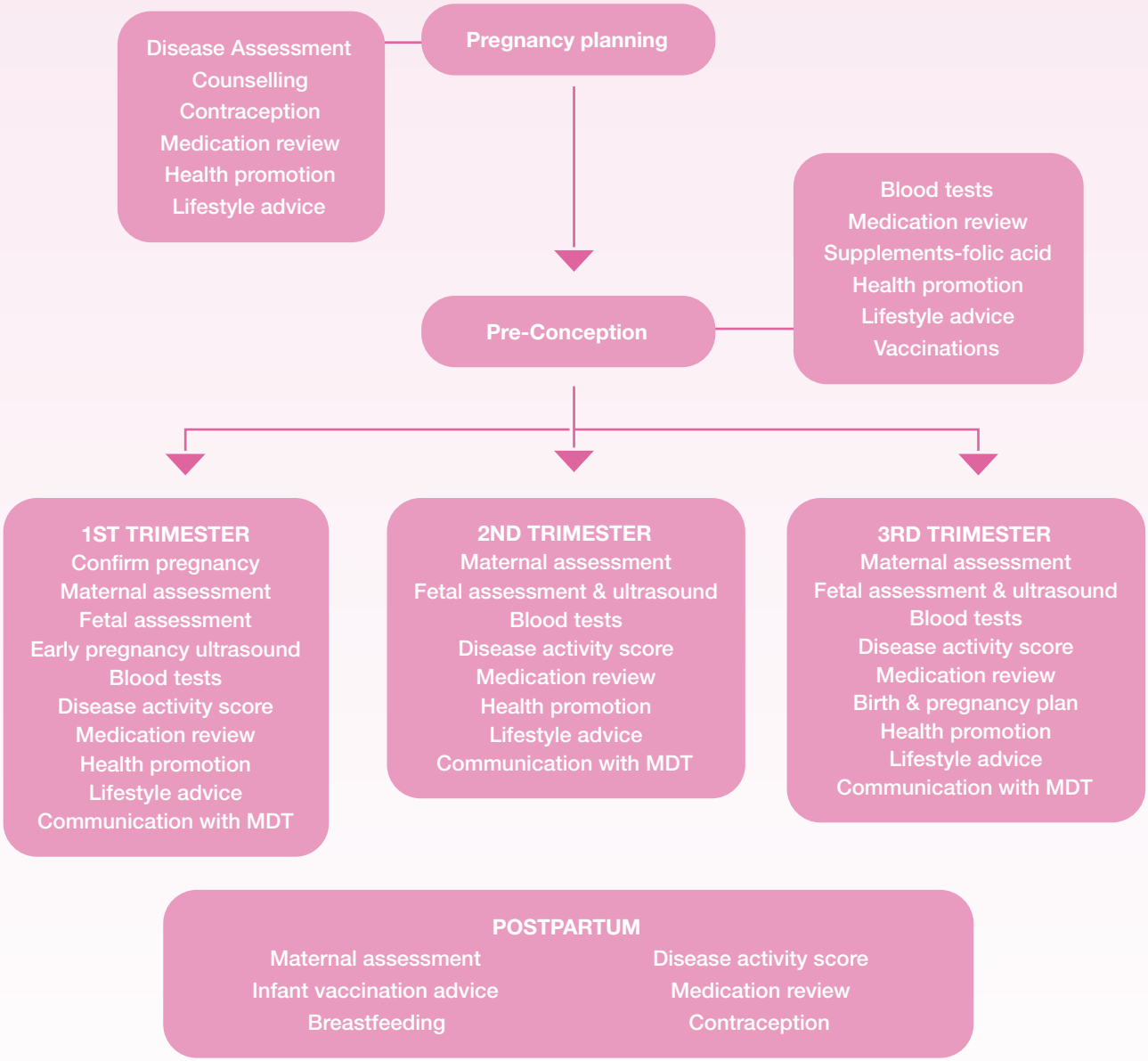
Algorithm

Management of women with rheumatic musculoskeletal disease of reproductive age.



Counselling should include the safety of rheumatic musculoskeletal disease (RMD) medicines in pregnancy and breastfeeding to support informed decision making. Disease activity score are measures of disease activity in rheumatic disease. They are measured over time to assess disease activity and response to medications.

Key Recommendations

1. Risk stratification and pregnancy planning are vital to assisting individuals with rheumatic musculoskeletal disease (RMD) to have successful pregnancy outcome whilst minimising pregnancy complications. *Best practice*
2. Disease activity should be assessed pre-pregnancy and be optimised prior to pregnancy with appropriate medication which is compatible with pregnancy. *Best practice*
3. All women and their healthcare providers should have access to pre-pregnancy advice and counselling with input from rheumatology and obstetrics services. *Best practice*
4. All women with rheumatic musculoskeletal disease should have the following baseline blood tests prior to pregnancy or in early pregnancy: anti-extractable nuclear antibodies (ENA) for anti-RO and anti-LA antibodies, antiphospholipid antibody syndrome screening, full blood count, renal and liver function, erythrocyte sedimentation rate (ESR) and c-reactive protein (CRP). *Best practice*
5. All women should be monitored for disease activity during pregnancy. *Best practice*
6. Optimal care should include at least one rheumatology review during the pregnancy. *Best practice*
7. Antenatal care should include regular assessment of blood pressure, urinalysis, and assessment of fetal wellbeing. Consideration should be given to low dose aspirin 75-150mg to reduce pre-eclampsia risk in women deemed to have risk factors. *Best practice*
8. We recommend that individual obstetric factors should guide the timing/mode of birth. *Best practice*
9. We recommend information and/or counselling should be provided to women on the safety of medication in pregnancy and breastfeeding to support informed shared decision making. *Best practice*
10. We recommend that to optimise the health of women and infants, postpartum care, and support with input from rheumatology, midwifery and obstetrics services, should be tailored to each woman's individual needs. *Best practice*
11. Drug therapy should be reviewed prior to conception and during pregnancy and again during breastfeeding. The risks and benefits of drug treatment to the woman and fetus should be discussed and documented by all healthcare professionals involved in the woman's care. A review of medication by a specialist pharmacist should be undertaken where available. *Best practice*

Chapter 1: Initiation

The National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) define clinical guidelines as systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.[1]

1.1 Purpose

This Guideline outlines considerations for the assessment, management, and care of women with rheumatic disease before, during and after pregnancy (up to six weeks postnatal). It provides advice for healthcare professionals about providing safe, evidence-based care to women of reproductive age with inflammatory rheumatic disease. These guidelines are designed to guide clinical judgement, but not replace it.

1.2 Scope

Target Users

The Guideline is a resource for all clinicians, doctors, midwives, nurses, advanced midwifery practitioner[2], and allied health professionals such as physiotherapists and occupational therapists, in general practice, obstetrics, maternity care, and rheumatology.

Target Population

Women of reproductive age with inflammatory rheumatic disease.

1.3 Objective

To provide evidence-based recommendations for the care of women with rheumatic diseases during preconception, antenatal and postpartum periods as well as promote a standardised approach nationally across all general practice, rheumatology, and obstetrics departments.

1.4 Guideline development process

The Guideline Developers agreed to undertake this work under the direction of the Guideline Programme Team (GPT). The GPT commissioned an Expert Advisory Group (EAG). Their role was to critically review the Guideline prior to submission to the National Women and Infants Health Programme (NWIHP) for final approval.

See Appendix 1 for EAG membership and Appendix 2 for Guideline Programme Process.

1 National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) (2015) National quality assurance criteria for clinical guidelines. Version 2. Dublin: NCEC and HIQA. https://www.hiqa.ie/sites/default/files/2017-01/National-Quality-Assurance-Criteria.pdf

2 Nursing and Midwifery Board of Ireland (NMBI) (2018) Advanced Practice (Midwifery) Standards and Requirements. Dublin.

The clinical practice guideline writing group members were Dr Áine Gorman (Rheumatology Research Registrar), Ms. Louise Moore (Advanced Nurse Practitioner in Rheumatology), Ms. Celine O'Brien (Clinical Midwife Specialist), Ms. Benedetta Soldati (Senior Pharmacist), Professor Fionnuala M. McAuliffe (Obstetrician and Maternal Medicine Specialist) and Professor Douglas J. Veale (Rheumatology Consultant).

1.5 Stakeholder involvement

Stakeholders are people who have a common interest in improving health services. This includes persons that are responsible for delivering and those who receive services related to the clinical guideline.

The Guideline Development Group was made up of rheumatologists, obstetricians, rheumatology advanced nurse practitioner and midwives with a special interest in rheumatic disease and pregnancy.

The Expert Advisory Group has members from pharmacology, general practice and public/patient representatives.

The following additional stakeholders were consulted regarding the guideline: Dr Kieran Murray, Consultant Rheumatologist University Hospital Limerick; Professor Mary Higgins, Consultant Obstetrician & Gynaecologist, The National Maternity Hospital (NMH), Dr Siobhan Corcoran, Consultant Obstetrician & Gynaecologist, The National Maternity Hospital Dublin, Dr Fergal O'Shaughnessy, Senior Pharmacist, Rotunda Hospital, Dublin.

1.6 Disclosure of interests

Guideline developers and reviewers bring a range of experiences and perspectives to the work of the national Guideline Programme. It is likely that both Guideline developers and stakeholders/reviewers will have a variety of interests, arising from different contexts and activities done in a professional or personal capacity. These can include employment and other sources of income, speaking engagements, publications and research, and membership of professional or voluntary organisations. The involvement of individuals with relevant content expertise is essential for enhancing the value of Guideline recommendations, but these individuals may also have interests that can lead to conflicts of interest, as may peer reviewers, patient representatives and researchers.

All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the clinical practice guideline in question.[3] Declaring an interest does not mean there is a conflict of interest.

It is important that interests are openly declared so they can be appropriately managed. Conflicts of interest can bias recommendations and ultimately be harmful to women and the health system. Disclosures of interests and appropriate management of conflicts of interest, when identified, are therefore essential to producing high-quality, credible health guidelines.[4]

3 NICE (2019) Policy on declaring and managing interests for NICE advisory committees https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf

4 CMAJ 2021 January 11;193:E49-54. doi: 10.1503/cmaj.200651 https://www.cmaj.ca/content/193/2/E49

The Guidelines International Network (GIN), a global network of Guideline developers that aims to promote best practices in the development of high-quality guidelines, developed a set of 9 principles to provide guidance on how financial and non-financial conflicts of interest should be both disclosed and managed. It is recommended that Guideline developers follow the GIN principles.[5]

For this National Clinical Practice Guideline, all Guideline developers are asked to complete a conflict-of-interest declaration form. The response to declared interests will be managed by the Guideline programme team, in accordance with GIN principles. Conflicts of interest may be reported in the published Guideline and declarations of interest can be made available.

1.7 Disclaimer

These guidelines have been prepared to promote and facilitate standardisation and consistency of good clinical practice, using a multidisciplinary approach. Information in this guideline is current at the time of publication.

The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the Clinician in light of clinical data presented by the woman and the diagnostic and treatment options available.

Clinical material offered in this guideline does not replace or remove clinical judgment or the professional care and duty necessary for each specific woman.

Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise.

This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible for:

- Discussing care with women in an environment that is appropriate and which enables respectful confidential discussion. This includes the use of interpreter services where necessary
- Advising women of their choices and ensure informed consent is obtained
- Provide care with professional scope of practice, meeting all legislative requirements and maintaining standards of professional conduct
- Applying standard precautions and additional precautions, as necessary, when delivering care
- Documenting all care in accordance with local and mandatory requirements.

5 Annals of Internal Medicine, Schünemann HJ, Al-Ansary, LA, Forland F, *et al.* Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines, 163(7), 548-53. Copyright © 2015 American College of Physicians. https://www.acpjournals.org/doi/10.7326/m14-1885

1.8 Use of language

Within this guidance we use the terms 'woman' and 'women's health'. However, it is important to acknowledge that people who do not identify as cis-gender women are excluded from this descriptor, including people who identify as transgender, gender diverse and gender non-binary[6]. We also appreciate that there are risks to desexing language when describing female reproduction[7 8]. Services and delivery of care must be appropriate, inclusive, and sensitive to the needs of people whose gender identity does not align with the sex they were assigned at birth. This includes training and education regarding diverse pathways to pregnancy and the use of practices which affirm the sexual and gender identities of all people using Obstetrics and Gynaecology services.

Language use is key to effectively communicate options, recommendations, and respectfully accept a woman's fully informed decision[9]. With this in mind, the use of birth is preferable to the term delivery in all circumstances and is used consistently where possible throughout the guidelines. It is acknowledged that in some circumstances (e.g., in the case of a medically indicated intervention or surgery) and in some contexts, substituting with the term delivery is considered appropriate and this term may be used instead.

6 Moseson H, Zazanis N, Goldberg E, *et al.* The Imperative for Transgender and Gender Nonbinary Inclusion. Obstet Gynecol. 2020;135(5):1059-1068. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7170432/

7 Brotto LA, Galea LAM. Gender inclusivity in women's health research. BJOG: An International Journal of Obstetrics & Gynaecology. https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17231

8 Gribble KD, Bewley S, Bartick MC, *et al.* Effective Communication About Pregnancy, Birth, Lactation, Breastfeeding and Newborn Care: The Importance of Sexed Language. *Frontiers in Global Women's Health*. 2022;3. Accessed June 9, 2022. https://www.frontiersin.org/article/10.3389/fgwh.2022.818856

9 https://blogs.bmj.com/bmj/2018/02/08/humanising-birth-does-the-language-we-use-matter/

Chapter 2:
Clinical Practice Guideline

Background

Rheumatic and musculoskeletal diseases (RMDs) are a diverse group of diseases that commonly affect the joints but can also affect the muscles, other tissues and internal organs.[1] Table 1 outlines common types of RMD seen in pregnancy and impact of pregnancy on disease activity. RMDs can occur frequently in women of reproductive age.[2-4]

In women with RMD, pregnancy can be associated with both maternal and fetal adverse outcomes such as pre-eclampsia, low birth weight and preterm birth. [5] The management of a woman with RMD is guided by the disease she has, disease activity and medication management. [6] Active RMDs are associated with worse pregnancy outcomes. [7] In women with systemic lupus erythematosus (SLE), the risks of preeclampsia, and preterm labour are between two and four times higher than in women without this disease.[3] However, women with SLE in remission are associated with a normal pregnancy outcome. [3] Disease activity and corticosteroid treatment are associated with low birth weight and preterm birth in women with inflammatory arthritis. [3]

Healthcare providers' (HCP) task is to assist women with RMD with their decision-making about the timing of pregnancy, disease and pregnancy management, as well as monitoring.[8,9] The algorithm (page 3) outlines the suggested management of women with rheumatic musculoskeletal disease of reproductive age.

Figure 1: Key stakeholders in shared decision making in the management of women with rheumatic disease of reproductive age.

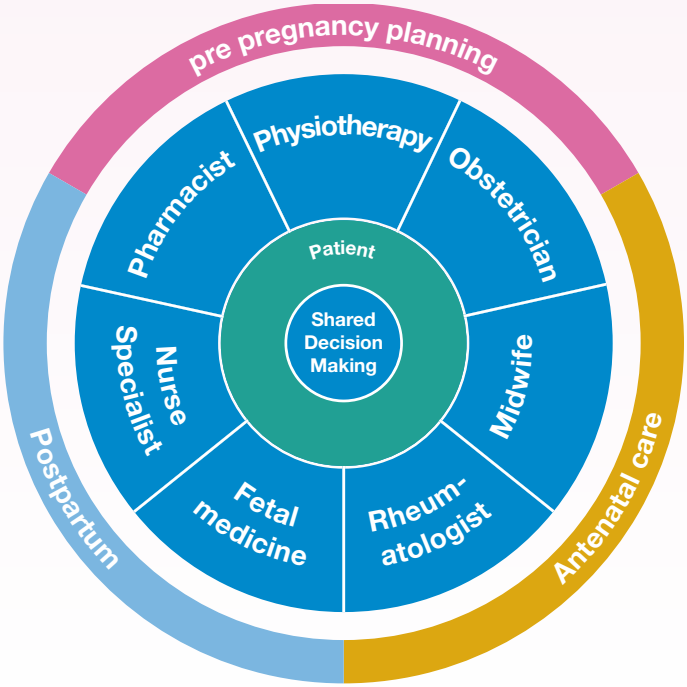


Table 1: Common types of RMD seen in pregnancy and impact of pregnancy on disease activity [2,10]

Disease	Major clinical symptom	Impact of pregnancy on disease activity	Need for medication during pregnancy
Rheumatoid arthritis	Joint pain, swelling, early morning stiffness	Improvement in 40-50% of RF/ACPA + women Improvement in 75% of RF/ACPA – women	Continuation recommended for disease control if appropriate. Dose modification can be considered.
Psoriatic arthritis	Joint pain, swelling, early morning stiffness, rash	Variable	Continuation recommended for disease control if appropriate. Dose modification can be considered.
Ankylosing spondylitis	Nocturnal back pain, early morning stiffness	Variable	Continuation recommended for disease control if appropriate. Dose modification can be considered.
Juvenile Idiopathic arthritis	Joint pain, swelling, early morning stiffness	Variable	Continuation recommended for disease control if appropriate. Dose modification can be considered.
Systemic lupus erythematosus (SLE) and vasculitis	Skin arthritis, renal, haematological, Central nervous system (CNS)	Can become more active	Continuation recommended for disease control if appropriate. Dose modification can be considered.
Sjogren's syndrome	Dry eyes and dry mouth	Pregnancy complication can occur due to presence anti Ro or LA antibodies causing neonatal lupus and congenital heart block (CHB)	Initiation/continuation of hydroxychloroquine recommended for reduced risk of congenital heart block (CHB) if anti Ro or LA positive.
Anti-phospholipid syndrome	Obstetric and thromboembolic events	Increased risk of thrombosis	Anticoagulation and anti-platelet therapy required.

Section 1: Pre-conceptual care for women with rheumatic disease

Introduction

For women living with a RMD, it is essential that pre-conceptual care is offered to ensure the best outcome for the woman and baby.[7] It is acknowledged that good disease control is the cornerstone of this critical aspect of care, with all relevant healthcare providers involved in the care of the woman bearing a responsibility to address family planning issues and concerns regularly. Ideally, to ensure optimum care for the woman, this consultation should be shared by both obstetric and rheumatology multi-disciplinary teams. [8]

Clinical Question 2.1: **What are the key areas that should be considered during a pre-pregnancy consultation?**

Evidence Statement

The maternal mortality surveillance programme (MBRRACE-UK) highlights the need for effective pre-pregnancy counselling.[4] It is recommended that it is seen as the responsibility of all healthcare professionals to facilitate opportunistic pre-and post- pregnancy counselling and appropriate framing of the advice when women with pre-existing conditions attend any appointment.[8]

Clinical Practice

The pre-pregnancy consultation can be broken down into the following areas:

Obstetric & medical history examination and investigation

- Past obstetric history including outcomes of all previous pregnancies, including preeclampsia, pre-term birth, birth weight, and fetal complications
- Medical history such as co-existing medical diagnoses such as hypertension, renal disease, diabetes, and clotting disorders
- Current medications and medication history
- Baseline urine examination
- Baseline blood tests including full blood count, urea and electrolytes, liver function tests, inflammatory markers such as erythrocyte sedimentation rate (ESR) or c-reactive protein (CRP) and thyroid function tests (TFTs), if applicable.

Disease activity

- Current disease activity with a focus on achieving and maintaining good RMD control
- Pre-existing organ damage, e.g., lung, cardiac, renal
- Serological profiles pertinent to specific rheumatological disease which may include the following: anti-extractable nuclear antibodies (ENA/anti-Ro antibodies), antiphospholipid antibodies, anti-cardiolipin antibodies, anti-β2 glycoprotein, lupus anticoagulant, CRP, ESR
- Consider referral to other members of a multidisciplinary team such as physiotherapy or occupational therapy.

Medication review and management

- A complete medication history should be documented in early pregnancy and maintained up to date throughout pregnancy
- An individualised approach to pharmacological management of RMD is recommended which balances the benefits and risks of medication exposure in pregnancy.
- Effectiveness of current medicines should be assessed and therapy optimised including discontinuation of unnecessary medicines and optimising doses to lowest dose needed.
- Substitute any teratogenic medications such as methotrexate (MTX), cyclophosphamide, and mycophenolate mofetil with pregnancy-compatible drugs. See Table 2 for recommendations on timelines of stopping medications when pregnancy planning.
- Addition of Folic acid 0.4mg daily for at least 3 months pre-pregnancy and up to 14 weeks' gestation to reduce the chance of a fetal neural tube defect.
- Folic Acid 5mg daily should be prescribed for women exposed to MTX 3 months prior to pregnancy, who are taking sulfasalazine, who have a BMI (Body Mass Index) ≥ 30, or who have a history of a neural defect in themselves or a previous pregnancy, for 3 months prior to conception and up to 14 weeks' gestation.
- Information/counselling on the safety of RMD medicines in pregnancy and breastfeeding to support informed decision making should be given.

Health promotion and counselling

- Smoking cessation
- Discontinuation alcohol intake
- Importance of a healthy balanced diet and discussion around the importance of regular exercise
- Aim for a BMI from 18.5 to 24.9kg/m^2
- Screening, including cervical screening
- Checking rubella and varicella immunity and address this as needed
- Vaccines during pregnancy.

Recommendations

1. **Risk stratification and pregnancy planning are vital to assisting individuals with rheumatic musculoskeletal disease (RMD) to have successful pregnancy outcome whilst minimising pregnancy complications.**
2. **Disease activity should be assessed pre-pregnancy and be optimised prior to pregnancy with appropriate medication which is compatible with pregnancy.**
3. **All women and their healthcare providers should have access to pre-pregnancy advice and counselling with input from rheumatology and obstetrics services.**
4. **All women with RMD should have the following baseline blood tests prior to pregnancy or in early pregnancy: anti-extractable nuclear antibodies (ENA) for anti-RO and anti-LA antibodies, antiphospholipid antibody syndrome screening, full blood count, renal and liver function, erythrocyte sedimentation rate (ESR) and c-reactive protein (CRP).**

Section 2: Antenatal care for women with rheumatic disease

Introduction

Caring for women with RMD during pregnancy can be challenging. In order to reduce adverse pregnancy outcomes, close surveillance should occur during pregnancy, and an individualised management approach should be used.[9] The best way to ensure a good pregnancy outcome for the woman and fetus is by having reasonable disease control at the time of conception and by ensuring that any medication being taken is not contra-indicated in pregnancy.[7]

Clinical Question 2.2: **What are the key considerations during the care of women with RMD in pregnancy?**

Evidence Statement

During pregnancy, maintaining good disease control is vital because active inflammatory disease is associated with adverse maternal and fetal outcomes.[7,10]

Most women with inflammatory RMD should continue pregnancy-compatible treatments with pregnancy to maintain control of their inflammatory disease.[8,10,11] Support should be provided for women to make informed decisions regarding medicines use in pregnancy.

There is a higher risk of complications such as pre-eclampsia and preterm birth with a high dose corticosteroids (>20 mg prednisolone); therefore, doses should be titrated to the minimum tolerable dose which maintains disease control.[8]

All women should be monitored for disease flare regardless of whether their disease is stable or active, monitoring should be individualised, stratified according to risk, and whether there is organ involvement. Each woman should have access to rheumatology services for at least one visit during pregnancy.

Congenital heart block (CHB) is a rare complication affecting up to 5% of babies born to mothers with anti-Ro/La antibodies. If there is a history of a CHB in a previous pregnancy, the risk increases up to 17%.[12]

Clinical Practice

- All women should have a blood pressure check and urine dipstick looking for evidence of urinary tract infection and proteinuria at each clinic attendance. Consideration should be given to low dose aspirin 75-150mg to reduce pre-eclampsia risk in women deemed to have risk factors such as hypertension, chronic kidney disease, from early pregnancy to 34 weeks' gestation. For recommendations refer to the National Guideline for the Management of Hypertension in Pregnancy currently under preparation within the NWIHP/IOG guideline programme (due 2024). Regular assessment of fetal wellbeing is advised.
- Risk factor screening should occur to assess the need for testing for gestational diabetes.
- Venous Thromboembolism (VTE) risk assessment should be performed to determine need for antenatal thromboprophylaxis.

- Consider referral to other members of a multidisciplinary team such as physiotherapy if needed.
- Vaccinations in pregnancy such as flu vaccine and pertussis vaccine should be administered during pregnancy as per the national guidelines.

Fetal monitoring – anti-Ro/La antibodies

- All women with anti-Ro/La (anti-SSA/SSB antibodies) require fetal heart rate monitoring every week from 16 through 26 weeks' gestation. Women with anti-Ro/La (anti-SSA/SSB antibodies) should be offered hydroxychloroquine to reduce the risk of fetal congenital heart block.

Planning birth

- The timing/mode of birth should be guided by individual obstetric factors such previous Caesarean section, pre-eclampsia, and breech position as well as preference of the woman.
- A care plan should be documented before 36 weeks in women where there are considerations likely to affect birth/post-partum management. These should include:
  a. Anaesthetic considerations
  b. Care plan for the management of Low Molecular Weight Heparin (LMWH) where indicated.
  c. Plan for IV hydrocortisone for the prevention of adrenal crisis in women on long term steroids when indicated.

Intrapartum management

- Vaginal birth should be the mode of choice if possible. A Caesarean birth should be considered for obstetric reasons. Women's preferences should also be considered.
- There is no contraindication to the use of labour analgesia, including epidural anaesthesia
- A haematology care plan for women prescribed Low Molecular Weight Heparin should be documented by 36 weeks.
- For women planning a vaginal birth who have adrenal insufficiency or who are taking long-term oral corticosteroids (equivalent to 5 mg or more prednisolone daily for more than 3 weeks):
  - continue their regular oral corticosteroids and when they are in established first stage of labour, add intravenous (IV) or intramuscular (IM) hydrocortisone.
  - consider a minimum dose of 50 mg every 6 hours until 6 hours after the baby is born. [13]
- For women having a planned Caesarean birth or who have and emergency Caesarean birth who have adrenal insufficiency or who are taking long-term oral corticosteroids (equivalent to 5 mg or more prednisolone daily for more than three weeks):
  - continue their regular oral corticosteroids and give intravenous hydrocortisone when starting anaesthesia; the dose will depend on whether the woman has received hydrocortisone in labour:
  - consider giving 50 mg if she has had hydrocortisone in labour.
  - consider giving 100 mg if she has not had hydrocortisone in labour.
  - give a further dose of hydrocortisone 6 hours after the baby is born[13]
- To prevent adrenal crisis in women taking >5mg of prednisolone daily, intravenous hydrocortisone 100mg should be considered during labour 6 hourly until oral medication can be recommenced if fasting. Oral prednisolone dose should be continued if not fasting.[13]

Recommendations

5. All women should be monitored for disease activity during pregnancy.
6. Optimal care should include at least one rheumatology review during the pregnancy.
7. Antenatal care should include regular assessment of blood pressure, urinalysis, and assessment of fetal wellbeing. Consideration should be given to low dose aspirin 75-150mg to reduce pre-eclampsia risk in women deemed to have risk factors.
8. We recommend that individual obstetric factors should guide the timing/mode of birth.
9. We recommend information and/or counselling should be provided to women on the safety of medication in pregnancy and breastfeeding to support informed shared decision making.

Section 3: Postpartum care of women with rheumatic disease

Introduction

The postpartum period in women with RMD is associated with an increased risk of complications compared to the general population.[11]

Women with RMD may experience an exacerbation of their symptoms. [11] Disease activity in the second and third trimesters is a risk factor for postpartum flaring. [11] The rate of flare varies depending on the rheumatic disease. [11] Active RMD may impact a mother's ability to look after her newborn and complete daily activities.

Research suggests that women with rheumatic diseases may be at a higher risk of developing postpartum depression, and it is important for physicians and the multi-disciplinary team to be aware of this, in order to provide appropriate support.[14]

Clinical Question 2.3: **What are important aspects surrounding postnatal care of women with rheumatic diseases?**

Evidence Statement

To optimise the health of the mother and baby, postpartum care should be an ongoing process rather than a single encounter with services, and support should be tailored to an individuals' needs.[1] Optimum postpartum care should focus on promoting overall health and well-being for the mother and baby. [15]

Women with RMD are at higher risk of complications in the postpartum period, including disease flare and thrombotic events. [11] In order to minimise the risk of disease flare a treatment plan for the postpartum period should be developed taking maternal preferences about breastfeeding into account. [11]

Breastfeeding can be a challenge for new mothers with rheumatic diseases. Active disease can make it difficult to hold and feed the baby. Research has shown that breastfeeding can have many benefits for both the mother and the baby, including reducing rheumatic disease activity, improving maternal mental health, and promoting bonding between mother and baby.[19] A discussion should occur around breastfeeding and the preference of the woman must be considered and they should be supported whatever they decide.

To manage the challenges of breastfeeding with a rheumatic disease, it is important for new mothers to work closely with their healthcare provider to develop a treatment plan. This may include adjusting medications to ensure safety during breastfeeding.

After giving birth, all women need to have a postpartum VTE risk assessment. Pregnant women are at a fivefold higher risk compared to non-pregnant women of developing a systemic thrombosis. According to the MBRRACE reports, thrombosis and thromboembolism are the cause of 4% of maternal mortalities in postpartum women. Research has shown that women with rheumatic diseases are at an increased risk of VTE postpartum. [16]

Some immunosuppressants given during pregnancy e.g., biologic Disease-modifying antirheumatic drugs (DMARDS), may cross the placenta particularly if given during the third trimester. There is a theoretical concern regarding immunosuppression in the newborn. In this setting, administration of the neonatal bacille Calmette-Guerin (BCG) vaccine in the first six months of life is contraindicated, currently BCG is not part of routine neonatal vaccinations.

There are little data available regarding the use of rotavirus vaccines in infants of mothers who received immunosuppressants in pregnancy. In general, given the current prevalence of rotavirus infection, the risks associated with wild type infection exceed potential risks associated with the vaccine. Infants of women treated with corticosteroids in pregnancy can receive rotavirus vaccine. Live vaccines (e.g., BCG vaccine) should not be given to infants after in utero exposure to infliximab for 12 months after birth. If there is a clear clinical benefit for the individual infant, administration of a live vaccine might be considered at an earlier timepoint if infant infliximab serum levels are undetectable or if infliximab administration was limited to the first trimester of pregnancy. Consideration may be given to administration of rotavirus vaccine if maternal infliximab did not extend beyond the first trimester in a non-breastfed infant.[17]

Clinical Practice

- Breastfeeding should be encouraged and actively supported.
- Medications which are compatible with breastfeeding should be continued.
- Postpartum VTE risk assessment should be completed.
- Screening for mood and emotional well-being, including postpartum depression, should be performed.
- Women should be assessed for comfort and confidence with caring for new-born.
- Women should be followed closely by their rheumatology team as they are at higher risk of flares in the postpartum period.
- Women should be informed the importance of preconception care when planning future pregnancies.
- Women should be given information about contraceptive options.
- Vaccination advice should be given

Recommendations

10. **We recommend that to optimise the health of women and infants, postpartum care, and support with input from rheumatology, midwifery and obstetrics services, should be tailored to each woman's individual needs**

Section 4: Medications compatibility during pre-conception, pregnancy, and breastfeeding

Evidence Statement

As the number of medications used in RMD expands, there can be uncertainty about the use of these drugs during pregnancy and breastfeeding. Discontinuation of treatment can lead to an increased risk of disease flares during and after pregnancy. [18]

Most women with inflammatory RMD should continue pregnancy-compatible treatments to maintain control of their inflammatory disease.[8,10,11].

The following recommendations (Table 2) are supported by the British Society of Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR) guidelines on prescribing drugs in pregnancy and Breastfeeding and also by National Immunisation Advisory Committee guidance (NIAC) [17,18]

Clinical Practice

Table 2: Guidelines on prescribing drugs in pregnancy and breastfeeding[17,18]

	Pre-conception	First trimester	Second/third trimester	Breast-milk Exposure	Paternal exposure
Prednisolone	Yes	Potential risk: Recommended case specific assessment. If indicated, treatment should not usually be withheld on account of pregnancy.	Yes: If mother received >20mg/day for 2/52 or longer in 2nd or 3rd trimester, defer BCG for minimum 3 months. No issue with rotavirus vaccine.	Yes	Yes
Antimalarials					
Hydroxy-chloroquine (≤400mg/day)	Yes	Yes: compatible throughout pregnancy.	Yes	Yes	Yes
Disease-modifying antirheumatic drugs (DMARDs)					
Sulfasalazine (with 5mg of folic acid during the 1st trimester)	Yes	Yes: compatible throughout pregnancy.	Yes	Yes	Potential Risk: sulfasalazine may adversely affect spermatogenesis in male patients. Sperm counts and motility are both reduced and require ≥2 months after the drug is stopped to return to normal levels.
Methotrexate	Stop ≥ 3 month pre-conception*	No: current evidence indicate increased rate of congenital malformation.	No	No	Yes: paternal exposure to low-dose (25 mg/week) MTX is compatible with pregnancy.
Leflunomide	No: a washout procedure should be completed before pregnancy, and leflunomide should be avoided during pregnancy.	No: current evidence is insufficient in a planned pregnancy.	No	No	Yes

	Pre-conception	First trimester	Second/third trimester	Breast-milk Exposure	Paternal exposure
Azathioprine	Yes	Yes: compatible throughout pregnancy.	Yes	Yes	Yes
Cyclosporin					
	Yes	Yes: compatible throughout pregnancy with monitoring of maternal blood pressure, renal function, blood glucose and drug level.	Yes	Yes	Yes
Tacrolimus	Yes	Yes: compatible throughout pregnancy with monitoring of maternal blood pressure, renal function, blood glucose and drug level/drug interactions.	Yes	Yes	Yes
Cyclo-phosphamide	No: cyclo-phosphamide must be withdrawn before a planned pregnancy	No: current evidence indicates an increased rate of congenital malformation.	Exceptional circumstances: the use of cyclo-phosphamide might be justified to treat life-threatening conditions in the second and third trimester.	No	No
Myco-phenolate mofetil	Stop ≥ 6 weeks pre conception	No: current evidence indicate an increased rate of congenital malformation.	No	No	Yes
Intravenous immuno-globulin	Yes	Yes: compatible throughout pregnancy.	Yes	Yes	Yes

	Pre-conception	First trimester	Second/third trimester	Breastmilk Exposure	Paternal exposure
Tumor necrosis factor (TNF)-alpha inhibitors					
Infliximab	Yes	Yes	Yes**	Yes **	Yes
Etanercept	Yes	Yes	Yes***	Yes	Yes
Adalimumab	Yes	Yes	Yes***	Yes	Yes
Certolizumab	Yes	Yes	Yes***	Yes	Yes
Golimumab	Yes	Yes	Yes***	Yes	Yes
Other Biologics					
Rituximab	Consider stopping at conception	Severe disease if no alternatives	Severe disease if no alternatives	Potential toxicity***	Yes
Il-6 inhibitors	Consider stopping at conception	Severe disease if no alternatives	Severe disease if no alternatives	Yes	Yes
Il-1 inhibitors	Consider stopping at conception	Severe disease if no alternatives	Severe disease if no alternatives	Potential toxicity***	Yes
Abatacept	Consider stopping at conception	Severe disease if no alternatives	Severe disease if no alternatives	Potential toxicity***	Yes
Il-17 inhibitors	Consider stopping at conception	Severe disease if no alternatives	Severe disease if no alternatives	Yes	Yes
Il-12/23 inhibitors	Consider stopping at conception	Severe disease if no alternatives	Severe disease if no alternatives	Potential toxicity****	Yes
JAK inhibitors	Stop ≥ 2 weeks pre conceptions	No	No	Potential toxicity****	Yes

* BSR guidelines recommend stopping 1 month prior to conception

** Inform the woman that infant live vaccines should not be administered for 12 months after birth if infliximab was used in pregnancy or during breastfeeding. Consideration may be given to administration of rotavirus vaccine if maternal infliximab did not extend beyond the first trimester in a non-breastfed infant.

*** Potential toxicity due to risk of immunosuppression in the new-born. If immunosuppression is anticipated to be moderate or severe, rotavirus vaccine should be deferred until the infant is four and six months of age. While BCG vaccine should be deferred for the first six months. Suggest refer to recommendations included in product literature/SmPC for each agent. If not specific recommendations made, the standard advice here could be considered.

**** Lack of human data in breast milk, therefore should be avoided in breastfeeding

Recommendations

11. **Drug therapy should be reviewed prior to conception and during pregnancy and again during breastfeeding. The risks and benefits of drug treatment to the woman and fetus should be discussed and documented by all healthcare professionals involved in the woman's care. A review of medication by a specialist pharmacist should be undertaken where available.**

Chapter 3: Development of Clinical Practice Guidelines

3.1 Literature search strategy

A comprehensive search of the electronic databases PUBMED (1970 – January 2021) and the Cochrane Library were undertaken. These databases were searched using relevant medical subject headings and keywords. The main keywords used were 'pregnancy' in combination with 'rheumatic disease', 'inflammatory arthritis', 'connective tissue' disease', 'vasculitis', and 'inflammatory myopathies. There were no restrictions placed on the searches. The results yielded from these searches were reviewed. A detailed literature review was subsequently carried out, this also included international clinical practice guidelines on relevant subject areas. This search did not include women's views of their healthcare needs in pregnancy.

3.2 Appraisal of evidence

Following a comprehensive literature review the quality, validity and relevance of the evidence gathered were critically appraised by the Guideline developers under the following headings:

- Study design
- Relevance of primary and secondary outcomes
- Consistency of results across studies
- Magnitude of benefit versus magnitude of harm
- Applicability to practice context

A number of evidence-based recommendations for management of rheumatic disease in pregnancy were agreed upon. They have been adapted to reflect care in the Irish healthcare setting.

3.3 AGREE II process

While being developed, the Guideline was continuously assessed using the AGREE II checklist (Appendix 3) as recommended by the Department of Health in the 'How to Develop a National Clinical Guideline: a manual for guideline developers', 2019.[10]

The purpose of AGREE II is to provide a framework to:

1. Assess the quality of guidelines;
2. Provide a methodological strategy for the development of guidelines; and
3. Inform what information and how information ought to be reported in guidelines.

10 Department of Health (2019). How to develop a National Clinical Guideline: a manual for guideline developers. Available at: https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/

3.4 Literature review

- The review of the literature was conducted by Dr Áine Gorman between January 2022 and April 2022
- The final documents selected were reviewed Dr Áine Gorman, Ms. Louise Moore, Celine O'Brien, Ms. Benedetta Soldati, Professor Fionnula McAulliffe, and Professor Douglas J. Veale.
- There is substantial evidence available to answer the clinical questions proposed
- The quality of evidence available is, for the most part, strong evidence
- The evidence reviewed comes from both national and international studies and has been adapted to fit the Irish context
- Literature was used when the evidence was relevant, strong, and applicable to the Irish setting and omitted when this was not the case.

3.5 Grades of recommendation

GRADE offers a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations.[11]

While we acknowledge that for this particular work an extensive GRADE approach is not possible, we have used the suggested language set out in the GRADE table when making recommendations.[12] (Appendix 4)

3.6 Future research

An important outcome of the guideline development process is in highlighting gaps in the evidence base.

The questions of relevance to this Guideline include.

1. Barriers to breastfeeding.
2. Further research examining pregnancy outcomes with combined rheumatology and obstetrics clinics vs standard obstetrics clinics.
3. Attitudes towards vaccination in pregnant women with RMD.
4. Maternal and fetal outcomes in women on biological agents.

11 Guyatt, Gordon, *et al.* "GRADE Guidelines: 1. Introduction – GRADE Evidence Profiles and Summary of Findings Tables." *Journal of Clinical Epidemiology*, vol. 64, no. 4, 2011, pp. 383-94, https://doi.org/10.1016/j.jclinepi.2010.04.026.

12 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 https://pubmed.ncbi.nlm.nih.gov/23978245/

Chapter 4: Governance and Approval

4.1 Formal governance arrangements

This guideline was written by the Guideline Developers under the direction of the Guideline Programme Team. An Expert Advisory Group was formed to review the Guideline prior to submission for final approval with the National Women and Infants Health Programme. The roles and responsibilities of the members of each group and their process were clearly outlined and agreed.

4.2 Guideline development standards

This Guideline was developed by the Guideline Developer Group (GDG) within the template of the HSE National Framework[13] for developing Policies, Procedures, Protocols and Guidelines (2016) (Appendix 5) and under supervision of the Guideline Programme Team (GPT).

A review was conducted by a group of experts, specialists, and advocates (the EAG) prior to approval by the Clinical Advisory Group (CAG) of the National Women and Infants Health Programme (NWIHP) with final sign off for publication by CAG Co-Chairs, the Clinical Director of NWIHP and the Chair of the IOG. See Appendix 6 for list of CAG members.

13 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Chapter 5: Communication and Dissemination

A communication and dissemination plan for this Guideline has been developed by the GPT and endorsed by NWIHP.

Effective ongoing clear communication is essential in explaining why the guideline is necessary and securing continued buy-in. It provides an opportunity to instil motivation within staff, helps overcome resistance to change and gives an opportunity for feedback.[14]

The Clinical Guideline will be circulated and disseminated through the Guideline Programme Team as well as through the professional networks who participated in developing and reviewing the document.

Senior management within the maternity units are responsible for the appropriate dissemination of new and updated guidelines. Local hospital groups including guideline committees are also instrumental in the circulation of new and updated Guidelines and promoting their use in the relevant clinical settings.

The HSE will make this guideline available to all employees through standards networks as well as storing it in the online PPPG repository. Electronic versions available on the NWIHP https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/clinical-guidelines/ and RCPI https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/ websites and other communication means can be used to maximise distribution. The NWIHP website will also provide a training webinar introducing each guideline and where relevant a downloadable version of the recommended algorithm will be available.

14 Department of Health (2018). NCEC Implementation Guide and Toolkit. Available at: https://health.gov.ie/national-patient-safety-office/ncec/

Chapter 6: **Implementation**

6.1 Implementation plan

Implementation was considered at the beginning, and throughout the Guideline development process. The local multidisciplinary clinical team, senior executive and clinical management in each maternity and gynaecology unit are ultimately responsible for the appropriate structured adoption and implementation of the Guidelines within their area of responsibility. They must ensure that all relevant personnel under their supervision have read and understood the Guideline and monitor both its effectiveness and adoption.

Within each site, local multidisciplinary teams are responsible for the clinical implementation of Guideline recommendations and ensuring that their local clinical practices and processes reflect and are aligned with the Guideline recommendations.

The following have been put in place to help facilitate the implementation of this Guideline.

- Quick Summary Document (QSD) for clinical staff (includes key recommendations, auditable standards, algorithms, and recommended reading)
- Clinical Guideline mobile application
- Plain language summary

6.2 Education plans required to implement the Guideline.

It is acknowledged that this Guideline should be complemented by ongoing education, training and assessment where required.

6.3 Barriers and facilitators

To ensure successful implementation of guidelines, it is first necessary to look at potential barriers and facilitators. Taking these into account when developing the implementation plan should improve levels of support from relevant users. (DOH 2018, 2019)

Barriers may be categorised as internal (specific to the Guideline itself) or external (specific to the clinical environment).

The Guideline Development Group has aimed to address any internal barriers during the development of this Guideline.

Potential external barriers include:

- Structural factors (e.g., budget or service redesign)
- Organisational factors (e.g., lack of facilities or equipment)
- Individual factors (e.g., knowledge, skills, training)
- Patient perceptions

In the case of this Guideline, it will be necessary to observe for any possible barriers and consider implementation strategies to address them. By example, this may include discussion with relevant management groups with regards budgetary impact or providing training to the relevant staff.

6.4 Resources necessary to implement recommendations.

The implementation of this Guideline should be undertaken as part of the quality improvement of each hospital. Hospitals should review existing service provision against this Guideline, identifying necessary resources required to implement the recommendations in this Guideline. A special interest group focusing on RMD in pregnancy is currently evaluating how care is structured at a local and national level.

Guideline education around pregnancy and RMD is required. Given that a joint rheumatology and obstetric clinic is only available in certain locations, healthcare workers' experiences and knowledge base may vary therefore local and national education training is required.

Chapter 7: Audit and Evaluation

7.1 Introduction to audit

It is important that both implementation of the guideline and its influence on outcomes are audited to ensure that this guideline positively impacts on the care of the woman. Institutions and health professionals are encouraged to develop and undertake regular audits of Guideline implementation. Personnel tasked with the job of conducting the audit should be identified on receipt of the most recent version of the guideline.

7.2 Auditable standards

Audit using the key recommendations as indicators should be undertaken to identify where improvements are required and to enable changes as necessary. Audit should also be undertaken to provide evidence of continuous quality improvement initiatives.

Auditable standards for this Guideline include:

1. Number of women with RMD who attend pre-pregnancy counselling
2. Number of women attending maternity services with RMD
3. Number of women with RMD accessing MDT services during pregnancy
4. Number of women having a rheumatology review during pregnancy
5. Number of antibody screening tests performed in pregnant women with RMD
6. Maternal complication rate (e.g infection after CS birth) in women with RMD
7. Disease flare rates in women with RMD during pregnancy and post-partum.

7.3 Evaluation

Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.[15]

Implementation of this Guideline will be audited periodically at national level, with standards for this set by the NWIHP. Evaluation of the auditable standards should also be undertaken locally by senior hospital clinical management to support implementation.

15 Health Information Quality Authority (2012). National Standards for Safer Better Healthcare [Internet]. Available from: https://www.hiqa.ie/reports-and-publications/standard/national-standards-safer-better-healthcare

Chapter 8: Revision Plan

8.1 Procedure for the update of the Guideline

It may be a requirement to amend, update or revise this Guideline as new evidence emerges. This Guideline will be reviewed at national level every three years, or earlier if circumstances require it, and updated accordingly.[16]

The Guideline Development Group will be asked to review the literature and recent evidence to determine if changes are to be made to the existing Guideline. If the Guideline Development Group are unavailable, the GPT along with the NWIHP senior management team will select a suitable expert to replace them.

If there are no amendments required to the Guideline following the revision date, the detail on the revision tracking box must still be updated which will be a new version number and date.

The recommendations set out in this Guideline remain valid until a review has been completed.

8.2 Method for amending the Guideline.

As new evidence become available it is inevitable that guideline recommendations will fall behind current evidence-based practice. It is essential that clinical guidelines are reviewed and updated with new evidence as it becomes available.

In order to request a review of this guideline one of the following criteria must be met:

a. 3 years since the guideline was published.

b. 3 years since last review was conducted.

c. Update required as a result of new evidence.

Correspondence requesting a review of the guideline should be submitted to the National Women and Infants Health. Any such requests should be dealt with in a timely manner.

16 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Chapter 9: **References**

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Supporting Evidence

GRADE: http://www.gradeworkinggroup.org/

AGREE: http://www.agreetrust.org/agree-ii/

HSE: https://www.hse.ie/eng/about/who/qid/use-of-improvement-methods/nationalframeworkdevelopingpolicies/

Glossary

AGREE Appraisal of Guidelines for Research and Evaluation
ACOG American College of Obstetricians and Gynaecologists
AS Ankylosing Spondylitis
CAG Clinical Advisory Group
CHB Congenital Heart Block
CRP C-reactive Protein
CNS Central Nervous System
DMARDS Disease-modifying antirheumatic drugs
EAG Expert Advisory Group
ENA Anti-extractable nuclear antibodies
ESR Erythrocyte sedimentation rate
GPT Guideline Programme Team
GRADE Grading of Recommendations, Assessments, Developments and Evaluations
HIQA Health Information and Quality Authority
HCP Health Care Providers
HSE Health Service Executive
IOG Institute of Obstetricians and Gynaecologists
JIA Juvenile Idiopathic Arthritis
FIGO International Federation of Gynaecology and Obstetrics
LMWH Low Molecular Weight Heparin
MTX Methotrexate
NICE The National Institute for Health and Care Excellence
NCEC National Clinical Effectiveness Committee
NWIHP National Women and Infants Health Programme
PPPG Policy, Procedures, Protocols and Guidelines
PSA Psoriatic Arthritis
RA Rheumatoid Arthritis
RCOG Royal College of Obstetricians and Gynaecologists
RCPI Royal College of Physicians of Ireland
RMD Rheumatic Musculoskeletal Disease
SLE Systemic Lupus Erythematosus
TFTs Thyroid function tests
VTE Venous Thromboembolism

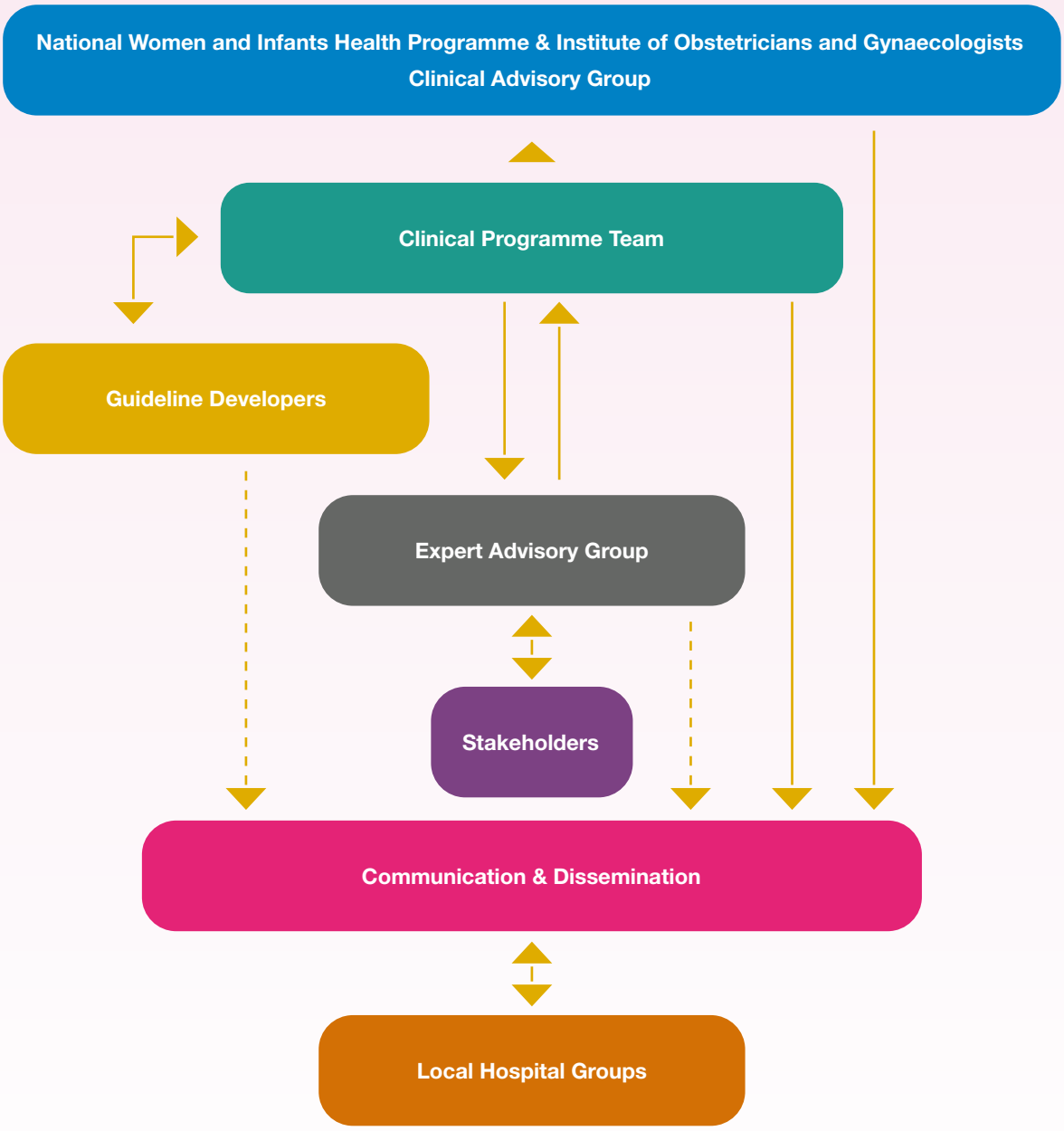
Appendix 1
Expert Advisory Group Members 2021-

Name	Profession	Location (2021)
Dr Fergus McCarthy	Consultant Obstetrician, Gynaecologist, Senior Lecturer and Maternal-Fetal Medicine Sub-specialist	Cork University Maternity Hospital, University College Cork
Dr Mairead Butler	Consultant Obstetrician and Gynaecologist	University Hospital Waterford
Prof Declan Keane	Professor of Obstetrics and Gynaecology	National Maternity Hospital Dublin, Royal College of Surgeons in Ireland
Dr Katherine Astbury	Consultant Obstetrician and Gynaecologist Gynaecology Oncology Sub-specialist	University Hospital Galway
Dr Sarah Petch	Specialist Registrar, Obstetrics and Gynaecology	National Maternity Hospital Dublin
Dr Orla Donohoe	Specialist Registrar, Obstetrics and Gynaecology	Sligo University Hospital
Prof John Murphy	Consultant Neonatologist and Clinical Lead for the National Clinical Programme for Paediatrics and Neonatology	National Women and Infants Health Programme
Ms Siobhan Canny	Group Director of Midwifery	Saolta University Health Care Group
Ms Fiona Hanrahan	Director of Midwifery and Nursing	Rotunda Hospital Dublin
Ms Margaret Quigley	National Lead for Midwifery	Office of Nursing and Midwifery Services Director
Prof Valerie Smith	Professor of Midwifery	School of Nursing and Midwifery, Trinity College Dublin
Ms Triona Cowman	Director of the Centre for Midwifery Education	Centre for Midwifery Education, Coombe Women & Infants University Hospital
Ms Janet Murphy	Advanced Midwifery Practitioner	University Hospital Waterford

Attendee	Profession	Location (2021)
Dr Ciara McCarthy	General Practitioner and ICGP Women's Health Lead	Irish College of General Practitioners
Mr Fergal O'Shaughnessy *And* Dr Brian Cleary *(Shared nomination)*	Senior Pharmacist, Honorary Lecturer *And* Chief Pharmacist, Honorary Clinical Associate Professor and Medications Lead, Maternal & Newborn Clinical Management System	Rotunda Hospital Dublin Royal College of Surgeons in Ireland
Ms Marie Finn	Medical Social Work Counsellor	Saolta University Health Care Group
Ms Marie Culliton	Lab Manager/Chief Medical Scientist	National Maternity Hospital Dublin
Ms Marita Hennessy	Post-Doctoral Researcher	Pregnancy Loss Research Group, INFANT Centre, University College Cork
Ms Niamh Connolly-Coyne *And* Ms Mandy Daly *(Shared nomination)*	Board of Directors	Irish Neonatal Health Alliance
Ms Caroline Joyce	Principal Clinical Biochemist PhD Candidate	Cork University Hospital University College Cork
Dr Richard Duffy	Consultant Perinatal Psychiatrist	Rotunda Hospital Dublin
Ms Clare Farrell	Physiotherapy Manager	Coombe Women & Infants University Hospital
Ms Fiona Dunlevy *And* Ms Sinéad Curran *(Shared nomination)*	Dietician Manager	Coombe Women & Infants University Hospital National Maternity Hospital
Dr Nicholas Barrett	Lead for Obstetric Anaesthesiology services	Limerick University Hospital
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist	Cork University Hospital
Dr Niamh Conlon	Consultant Histopathologist	Cork University Hospital
Ms Georgina Cruise	Service Manager	Patient Advocacy Ireland

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3
AGREE II Checklist[17]

AGREE Reporting Checklist 2016

This checklist is intended to guide the reporting of Clinical Practice Guidelines.

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
DOMAIN 1: SCOPE AND PURPOSE		
1. OBJECTIVES *Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.*	☐ Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) ☐ Expected benefit(s) or outcome(s) ☐ Target(s) (e.g., patient population, society)	
2. QUESTIONS *Report the health question(s) covered by the guideline, particularly for the key recommendations.*	☐ Target population ☐ Intervention(s) or exposure(s) ☐ Comparisons (if appropriate) ☐ Outcome(s) ☐ Health care setting or context	
3. POPULATION *Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.*	☐ Target population, sex and age ☐ Clinical condition (if relevant) ☐ Severity/stage of disease (if relevant) ☐ Comorbidities (if relevant) ☐ Excluded populations (if relevant)	
DOMAIN 2: STAKEHOLDER INVOLVEMENT		
4. GROUP MEMBERSHIP *Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/ rating the evidence and individuals involved in formulating the final recommendations.*	☐ Name of participant ☐ Discipline/content expertise (e.g., neurosurgeon, methodologist) ☐ Institution (e.g., St. Peter's hospital) ☐ Geographical location (e.g., Seattle, WA) ☐ A description of the member's role in the guideline development group	

17 AGREE Reporting Checklist is available on the AGREE Enterprise website, a free and open access resource to support the practice guideline field (www. agreetrust.org).

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	☐ Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐ Outcomes/information gathered on patient/public information ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
6. TARGET USERS *Report the target (or intended) users of the guideline.*	☐ The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) ☐ How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)	
DOMAIN 3: RIGOUR OF DEVELOPMENT		
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	☐ Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) ☐ Time periods searched (e.g., January 1, 2004 to March 31, 2008) ☐ Search terms used (e.g., text words, indexing terms, subheadings) ☐ Full search strategy included (e.g., possibly located in appendix)	
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	☐ Target population (patient, public, etc.) characteristics ☐ Study design ☐ Comparisons (if relevant) ☐ Outcomes ☐ Language (if relevant) ☐ Context (if relevant)	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	☐ Study design(s) included in body of evidence ☐ Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) ☐ Appropriateness/relevance of primary and secondary outcomes considered ☐ Consistency of results across studies ☐ Direction of results across studies ☐ Magnitude of benefit versus magnitude of harm ☐ Applicability to practice context	
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	☐ Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) ☐ Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) ☐ How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)	
11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	☐ Supporting data and report of benefits ☐ Supporting data and report of harms/side effects/risks ☐ Reporting of the balance/trade-off between benefits and harms/side effects/risks ☐ Recommendations reflect considerations of both benefits and harms/side effects/ risks	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	☐ How the guideline development group linked and used the evidence to inform recommendations ☐ Link between each recommendation and key evidence (text description and/or reference list) ☐ Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	☐ Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) ☐ Methods taken to undertake the external review (e.g., rating scale, open-ended questions) ☐ Description of the external reviewers (e.g., number, type of reviewers, affiliations) ☐ Outcomes/information gathered from the external review (e.g., summary of key findings) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)	
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	☐ A statement that the guideline will be updated ☐ Explicit time interval or explicit criteria to guide decisions about when an update will occur ☐ Methodology for the updating procedure	
DOMAIN 4: CLARITY OF PRESENTATION		
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	☐ A statement of the recommended action ☐ Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) ☐ Relevant population (e.g., patients, public) ☐ Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) ☐ If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline	
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	☐ Description of management options ☐ Population or clinical situation most appropriate to each option	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	
DOMAIN 5: APPLICABILITY		
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐ Types of facilitators and barriers that were considered ☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography) ☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐ Additional materials to support the implementation of the guideline in practice. For example: • Guideline summary documents • Links to check lists, algorithms • Links to how-to manuals • Solutions linked to barrier analysis (see Item 18) • Tools to capitalize on guideline facilitators (see Item 18) • Outcome of pilot test and lessons learned	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐ Criteria to assess guideline implementation or adherence to recommendations ☐ Criteria for assessing impact of implementing the recommendations ☐ Advice on the frequency and interval of measurement ☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐ Types of competing interests considered ☐ Methods by which potential competing interests were sought ☐ A description of the competing interests ☐ How the competing interests influenced the guideline process and development of recommendations	

From: Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. BMJ 2016;352:i1152. doi: 10.1136/bmj.i1152.

For more information about the AGREE Reporting Checklist, please visit the AGREE Enterprise website at http://www.agreetrust.org.

Appendix 4: Grades of Recommendation[18]

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Strong recommendations can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We strongly recommend… We recommend that …should be performed/ administered… We recommend that … is indicated/ beneficial/ effective….

18 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 https://pubmed.ncbi.nlm.nih.gov/23978245/

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
1 B. Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Strong recommendation and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We recommend… We recommend that … should be performed/ administered… We recommend that … is (usually) indicated/ beneficial/ effective…
1 C. Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Strong recommendation that applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality	We recommend… We recommend that … should be performed/ administered… We recommend that … Is (maybe) indicated/ beneficial/ effective…
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Weak recommendation: best action may differ depending on circumstances or patients or societal values	We suggest… We suggest that … may/might be reasonable…

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances	We suggest… We suggest that … may/might be reasonable…
2C. Weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Very weak recommendation: other alternatives may be equally reasonable.	We suggest… is an option We suggest that … may/might be reasonable.
Best practice	A recommendation that is sufficiently obvious that the desirable effects outweigh undesirable effects, despite the absence of direct evidence, such that the grading of evidence is unnecessary			We recommend… We recommend that … should be performed/ administered… We recommend that … Is usually) indicated/ beneficial/effective

Appendix 5: Policies, Procedures, Protocols and Guidelines Checklist

The PPPG Checklists were developed to assist staff to meet standards when developing Clinical PPPGs.

Standards for developing clinical PPPG	
Stage 1 initiation	**Checklist**
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	☐
Synergies/co-operations are maximised across departments/organisations (Hospitals/ Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	☐
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	☐
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	☐
The views and preferences of the target population have been sought and taken into consideration (as required).	☐
The overall objective(s) of the PPPGs are specifically described.	☐
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	☐
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	☐
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	☐
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	☐
There is service user/lay representation on PPPG Development Group (as required).	☐
Information and support is available for staff on the development of evidence-based clinical practice guidance.	☐

Stage 2 development	**Checklist**
The clinical question(s) covered by the PPPG are specifically described.	☐
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/ adopted from international guidance, their methodology is appraised and documented).	☐
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	☐
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	☐
There is an explicit link between the PPPG and the supporting evidence.	☐
PPPG guidance/recommendations are specific and unambiguous.	☐
The potential resource implications of developing and implementing the PPPG are Identified e.g. equipment, education/training, staff time and research.	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	☐
Budget impact is documented (resources required).	☐
Education and training is provided for staff on the development and implementation of evidence- based clinical practice guidance (as appropriate).	☐
Three additional standards are applicable for a small number of more complex PPPGs:	☐
Cost effectiveness analysis is documented.	☐
A systematic literature review has been undertaken.	☐
Health Technology Assessment (HTA) has been undertaken.	☐
Stage 3 governance and approval	**Checklist**
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	☐
The PPPG has been reviewed by independent experts prior to publication (as required).	☐
Copyright and permissions are sought and documented.	☐
Stage 4 communication and dissemination	**Checklist**
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	☐
Plan and procedure for dissemination of the PPPG is described.	☐
The PPPG is easily accessible by all users e.g. PPPG repository.	☐

Stage 5 implementation	**Checklist**
Written implementation plan is provided with timelines, identification of responsible persons/ units and integration into service planning process.	☐
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	☐
Education and training is provided for staff on the development and implementation of evidence- based PPPG (as required).	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	☐
Stage 6 monitoring, audit, evaluation	**Checklist**
Process for monitoring and continuous improvement is documented.	☐
Audit criteria and audit process/plan are specified.	☐
Process for evaluation of implementation and (clinical) effectiveness is specified.	☐
Stage 7 revision/update	**Checklist**
Documented process for revisions/updating and review, including timeframe is provided.	☐
Documented process for version control is provided.	☐

To view in full refer to website: https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/

Appendix 6:
NWIHP/IOG CAG Membership 2023

Dr Cliona Murphy (Chair). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Director, National Women and Infants Health Programme.

Dr Sam Coulter-Smith. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Chair, Institute of Obstetricians and Gynaecologists.

Angela Dunne. Director of Midwifery, National Women and Infants Health Programme.

Kilian McGrane. Director, National Women and Infants Health Programme.

Dr Peter McKenna. Clinical Lead, Obstetric Event Support Team, National Women and Infants Health Programme.

Prof John Murphy. Clinical Lead Neonatology, National Women and Infants Health Programme.

Prof Maeve Eogan. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Clinical Lead, Sexual Assault Treatment Units, National Women and Infants Health Programme.

Dr Aoife Mullaly. Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Lead, Termination of Pregnancy Services, National Women and Infants Health Programme.

Prof Keelin O'Donoghue. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Lead, National Guidelines, National Women and Infants Health Programme.

Prof Nóirín Russell. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, Cervical Check.

Prof Richard Greene. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, National Perinatal Epidemiology Centre, University College Cork.

Prof John Morrison. Consultant Obstetrician and Gynaecologist, University Hospital Galway. Clinical Director, Saolta Maternity Directorate.

Dr Suzanne O'Sullivan. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Director of Education and Training, Obstetrics and Gynaecology, Institute of Obstetricians and Gynaecologists.

Prof John Higgins. Cork University Maternity Hospital, Consultant Obstetrician and Gynaecologist, Clinical Director, Ireland South Women and Infants Directorate.

Dr Mendinaro Imcha. Clinical Director, Consultant Obstetrician and Gynaecologist, University Maternity Hospital Limerick.

Prof Shane Higgins. Master, Consultant Obstetrician and Gynaecologist, National Maternity Hospital.

Prof Mike O'Connell. Master, Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital.

Dr Brian Cleary. Chief Pharmacist, Rotunda Hospital. Medications Lead, Maternal and Newborn Clinical Management System Project.

Prof Seán Daly. Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

Ms Clare Thompson. Consultant Gynaecological Oncologist, The Mater, Dublin.

Dr Vicky O'Dwyer. Consultant Obstetrician and Director of Gynaecology, Rotunda Hospital.