National Women & Infants Health Programme

National Clinical Practice Guideline

Reduced Fetal Movements



INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

Guideline Development Group

Dr Tamara Kalisse, Specialist Registrar Obstetrics and Gynaecology

Ms Anne-Marie Farrell, Parent Advocate and MPH Student

Ms Anna Maria Verling, Clinical Midwife Specialist Bereavement and Loss

Dr Emily Rutherford, Registrar Obstetrics and Gynaecology

Dr Mareena Ravinder, Registrar Obstetrics and Gynaecology

Dr Azriny Khalid, Consultant Obstetrician Gynaecologist

Prof. Keelin O'Donoghue, Consultant Obstetrician Gynaecologist

Guideline Programme Team

Prof. Keelin O'Donoghue, Clinical Lead

Ms Nicolai Murphy, Programme Manager

Approved by

The National Women and Infants Health Programme (NWIHP) and the Institute of Obstetricians and Gynaecologists (IOG) Clinical Advisory Group (CAG) 2024

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Document Owner name:	Prof Keelin O'Donoghue
Document Owner email:	NWIHP.Corporate@hse.ie
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Document Approved by:	Dr Cliona Murphy Clinical Director, NWIHP Chair, NWIHP/IOG Clinical Advisory Group
Document Approver Sign-off:	Cliona Murphy.
Document Approver Registration number:	17256
Development Group Name:	Dr Tamara Kalisse, Ms Anne-Marie Farrell, Ms Anna Maria Verling, Dr Emily Rutherford, Dr Mareena Ravinder, Dr Azriny Khalid, Prof. Keelin O'Donoghue.
Development Group Chairperson:	Prof. Keelin O'Donoghue

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This Guideline aims to provide evidence-based recommendations for the care of women reporting reduced fetal movements in the antenatal period, as well as promoting a standardised approach nationally across all maternity units/hospitals and primary care settings.
Description:
This National Clinical Practice Guideline provides an evidence-based, nationally standardised framework for the assessment and management of reduced fetal movements in pregnancy. It promotes maternal awareness and timely reporting of altered fetal movement patterns, recognising their association with fetal growth restriction, placental dysfunction and stillbirth. Recommendations address risk stratification, clinical assessment, cardiotocography, ultrasonography, management of recurrent presentations, and individualised shared decision-making regarding surveillance and timing of birth.

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Algorithm

Management of Reduced Fetal Movements (RFM) ≥ 28 Weeks' Gestation

Initial Response

- Ask all women reporting reduced fetal movements to attend their maternity unit/ hospital immediately for review.
- Do not delay assessment for any reason, including with non-evidence-based advice on methods to stimulate movements such as consuming certain foods or drinks or concentrating on movements for a period of time prior to attending for review.

Fetal Death Suspected

- Urgent review by senior Obstetrician
- Confirm intrauterine fetal death with ultrasound scan
- Management in line with National Guideline for Stillbirth.

Initial Assessment

- **Detailed history** including details of change in fetal movement pattern, prior presentation with reduced fetal movements, other associated symptoms (e.g. pain, bleeding), pre-existing medical conditions and risk factors for fetal growth restriction/placental insufficiency and stillbirth*.
- **Clinical examination** including vital signs and symphysial fundal height measurement.
- **Confirmation of fetal viability:** Auscultate fetal heart using hand-held Doppler or Pinard Stethoscope

Initial Investigations

- **CTG:** exclude acute fetal compromise. If abnormal, seek urgent senior obstetric review.
- **Bedside ultrasound:** Assess liquor volume and presence/absence of fetal movements.

Further Investigations

If concerns raised at initial assessment or discharge criteria not met, senior obstetric review is recommended, and consideration given to admission and further investigations:

Departmental Ultrasound: Fetal biometry (if not done in preceding 2 weeks), liquor volume and umbilical artery Doppler. Timeframe will depend on clinical urgency.

FMH testing: If there is a high index of suspicion of FMH and in the absence of other causes of RFM, then testing for it could be considered following review by a Consultant Obstetrician, and in discussion with laboratory/Haematology services.

Discharge Criteria

Consider discharge to routine antenatal care if **ALL** the following criteria are met:

- First presentation with RFM.
- No identified risk factors for stillbirth*
- Normal assessment, CTG and liquor volume.
- Maternal concerns regarding fetal movements have resolved.

Ensure appropriate advice given regarding further RFM.

Birth Planning and Recurrent RFM

Consider increased antenatal surveillance if recurrent RFM especially in presence of risk factors for stillbirth.

Individualised and shared decision making between women and clinicians with regard to the timing of birth.

Reasonable to consider expediting birth/delivery in women with RFM who are ≥ 39 weeks.

An assessment of risk versus benefit should be adopted if considering expediting birth/delivery <39/40.

*Stillbirth Risk Factors

- Previous stillbirth
- Maternal age
- Maternal tobacco use
- Assisted reproduction
- Obesity
- Nulliparity
- Recurrent presentations with reduced fetal movements
- Pre-existing conditions (e.g. diabetes, hypertension)
- Pre-eclampsia
- Small for gestational age
- Alcohol and other illicit substances
- Low socioeconomic status
- Gestational age: Post-term pregnancy

Key Recommendations

1. Reduced fetal movements (RFM) is defined as any alteration in maternal perception of fetal movements including change in pattern (strength and/or frequency), reduction or cessation of movements. *Best Practice*
2. Clinicians and pregnant women should be aware that fetal movements tend to increase in strength throughout pregnancy and normally follow a diurnal pattern with a stronger more active period observed in the evenings. *Grade 2B*
3. Clinicians should be aware of the outcomes associated with RFM including the increased risk of stillbirth and/or fetal growth restriction (FGR). *Grade 1C*
4. Women reporting RFM should undergo a comprehensive assessment of fetal wellbeing. *Best Practice*
5. Clinicians should be aware that fetal growth restriction (FGR) is associated with adverse pregnancy outcomes in women with RFM. *Grade 1C*
6. Clinicians should be aware of the risk factors for stillbirth and be vigilant in their assessment of women with RFM when any of these risk factors are identified. *(Best Practice*
7. Women should be provided with verbal and written information about fetal movements by 24 weeks' gestation. They should also be provided with contact information to facilitate reporting of concerns about fetal movements. *Best Practice*
8. Clinicians should take the opportunity to remind women about the importance of maternal awareness of fetal movement at each scheduled and unscheduled contact. *Best Practice*
9. Healthcare staff should advise women reporting RFM to attend their maternity unit/hospital for further evaluation without delay. *Best Practice*
10. Assessment of women reporting RFM should not be delayed for any reason, including with non-evidence-based advice on methods to stimulate movements such as consuming certain foods or drinks or concentrating on movements for a period of time prior to attending for review. *Best Practice*
11. The use of "kick-charts" or pre-set alarm limits for monitoring fetal movements is not recommended in routine antenatal care. *Grade 1B*
12. Maternal reports of altered fetal movements should be used as a trigger to evaluate fetal wellbeing. *Best Practice*
13. The initial assessment of women with RFM should include a detailed history, examination and a thorough assessment of risk factors for fetal growth restriction and/or stillbirth. *Grade 1C*
14. The evaluation should include a comprehensive assessment of changes in fetal movement pattern (strength and frequency), along with any associated symptoms such as bleeding and abdominal pain. *Best Practice*

15. The fetal heart should be auscultated using hand-held Doppler or Pinard Stethoscope to confirm viability. If an intrauterine fetal death (IUFD) is suspected, urgent senior obstetric review is warranted and IUFD confirmed using real-time ultrasound. *Best Practice*
16. A CTG should be performed on all women reporting RFM who are ≥ 28 weeks' gestation to exclude acute fetal compromise. *Best Practice*
17. All women with RFM should have a bedside ultrasound, by an appropriately trained healthcare professional, at the initial presentation to assess liquor volume and the presence/absence of fetal movements. *Best Practice*
18. Women can be discharged to routine antenatal care if all the following criteria is met: first presentation with RFM, normal initial assessment including normal CTG and bedside ultrasound, no risk factors for fetal growth restriction and/or stillbirth identified, and maternal concerns regarding fetal movements have resolved. *Best Practice*
19. Where the discharge criteria are not met, discussion with a senior Obstetrician is recommended and consideration given for admission and further investigations. *Best Practice*
20. A Departmental ultrasound assessment of fetal biometry (if not done in the preceding 2 weeks), liquor volume and umbilical artery Doppler should be considered for all women with RFM, especially those with persistent RFM, risk factors for fetal growth restriction and/or stillbirth and those with concerns raised at their initial assessment. *Grade 1C*
21. Routine testing for feto-maternal haemorrhage (FMH) in cases of RFM is not currently recommended. However, if there is a high index of suspicion of FMH, then testing for it could be considered following review by a Consultant Obstetrician. *Best Practice*
22. Given the limitations of the Kleihauer-Betke test in this setting and lack of availability outside routine working hours, discussion with the hospital laboratory and/or Consultant Haematologist is required prior to the test being requested. Best Practice
23. Clinicians should be aware that pregnancies complicated by recurrent presentations of RFM (more than one) are at increased risk of adverse pregnancy outcomes. *Grade 2C*
24. Women with recurrent presentations of RFM should undergo a Departmental ultrasound examination to assess fetal biometry (if not done in the preceding 2 weeks), liquor volume and umbilical artery Doppler. *Best Practice*
25. In the absence of other identifiable causes of recurrent RFM, further investigations for FMH should be considered following review by a Consultant Obstetrician, depending on the expertise available. These tests include assessing Middle Cerebral Artery Peak Systolic Velocity (MCA-PSV) on ultrasound and the Kleihauer-Betke test. *Best Practice*
26. If all investigations are normal and following discussion with the woman, it is reasonable to consider increased antenatal surveillance in women with recurrent RFM, especially in the presence of risk factors for placental dysfunction. *Best Practice*
27. Care should be individualised and shared decision making between the woman and the clinician with regard to the timing of birth should be encouraged. We recommend that clinicians discuss with women the risks and benefits of expediting birth/delivery, and consider the woman's preferences, gestational age, clinical assessment and risk factors for stillbirth. *Best Practice*
28. It is reasonable to consider expediting birth/delivery in women with RFM who are ≥ 39 weeks' gestation, especially women with recurrent presentations of RFM and those with risk factors for stillbirth. *Best Practice*

29. Consideration should be given to sending the placenta for histopathological examination if the birth occurs as a result of a clinical complication associated with RFM. *Best Practice*
30. In cases of RFM <28 weeks' gestation, the initial assessment should include a detailed history, clinical examination and confirmation of fetal viability through auscultation of the fetal heart. *Best Practice*
31. The decision to perform a CTG between 26-27^{+6}/40 gestation should be made by a senior Obstetrician on a case-by-case basis. It is reasonable to consider a CTG assessment at this gestation in those with risk factors for stillbirth and/or placental insufficiency. However, caution should be adopted in the interpretation of the CTG at this early gestation. *Best Practice*
32. An anatomy ultrasound is recommended for women RFM < 28 weeks' gestation, if not performed earlier in the pregnancy. *Best Practice*
33. For women with RFM <28 weeks' gestation, a Departmental ultrasound scan for fetal biometry (if not done in the preceding two weeks), liquor volume and umbilical artery Doppler should be considered in those with risk factors for stillbirth. *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

The purpose of this Guideline was to develop and provide a comprehensive evidence-based guidance for the assessment and management of pregnant women reporting reduced fetal movement (RFM) in the Republic of Ireland.

We acknowledge that RFM can be associated with adverse pregnancy outcomes such as stillbirth and fetal growth restriction (FGR). However, we recognise the limitations of currently described or available interventions in improving outcomes in all cases of RFM. This document provides advice for healthcare professionals and pregnant women about the importance of antenatal awareness and education surrounding fetal movements. It also aims to provide a standardised, evidence-based approach to the investigation and management of women reporting RFM. These guidelines are designed to guide clinical judgment but not to replace it.

1.2 Scope

Target Users

The Guideline is a resource for all clinicians working in maternity units/hospitals and primary care in Ireland. This includes healthcare staff, doctors, advanced midwifery practitioners[2], midwives, nurses, health and social care professionals involved in the care of pregnant women.

Throughout this guideline, the term Clinicians is used to describe Doctors, Obstetricians and Midwives involved in the care of pregnant women. Where the term Senior Obstetrician is used, this is intended to refer to a Consultant or Specialist Registrar, unless otherwise stated.

Target Population

The target population for this guideline is all pregnant women during the antenatal period.

Objective

To provide evidence-based recommendations for the care of women reporting reduced fetal movements in the antenatal period, as well as promoting a standardised approach nationally across all maternity units/hospitals and primary care settings.

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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. www.nmbi.ie/NMBI/media/NMBI/Advanced-Practice-(Midwifery)-Standards-and-Requirements-2018-final.pdf

1.4 Guideline development process

The Guideline Developers agreed to undertake this work under the direction of the Guideline Programme Team (GPT). An Expert Advisory Group (EAG) was commissioned by the GPT. 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 the Guideline programme process.

The Guideline Developers group is as follows:

- Dr Tamara Kalisse, Obstetrics & Gynaecology Specialist Registrar, CUMH
- Ms Anne-Marie Farrell, Parent Advocate and MPH Student, University College Cork
- Ms Anna Maria Verling, Former Clinical Midwife Specialist in Bereavement and Loss
- Dr Emily Rutherford, Obstetrics & Gynaecology Registrar, CUMH
- Dr Mareena Ravinder, Obstetrics & Gynaecology Registrar, CUMH and UHW
- Dr Azriny Khalid, Consultant Obstetrician & Gynaecologist, UHW
- Prof. Keelin O'Donoghue, Consultant Obstetrician & Gynaecologist and Maternal-Fetal Medicine Subspecialist, CUMH

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 Obstetricians, Midwives and a parent advocate with a special interest in RFM. Consultant Haematologists nationally were asked to contribute to the wording on recommendations for feto-maternal haemorrhage.

The PPI contributor/author, Anne-Marie Farrell, reviewed and provided feedback on the clinical guidelines and wrote the patient information leaflet (PIL). Anne-Marie based the PIL on the evidence and recommendations collated as part of the development of the guideline, feedback from the working group, discussions with women who have presented with reduced fetal movements, and educational material developed by the NHS and Tommy's in the United Kingdom and the Stillbirth Centre of Research Excellence in Australia. Anne-Marie leveraged her experience as a bereaved parent, as well as her behavioural economics expertise, which explains how and why humans make decisions, to ensure the PIL shares the evidence in a manner which is easy to understand and provides clear next steps to empower expectant parents to seek help if needed.

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]

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.

Professor Keelin O'Donoghue is Clinical Lead for Guideline Development in Maternity and Gynaecology at the National Women and Infants Health Programme (NWIHP), HSE (2021-) and leads implementation for the HSE's National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death (2017-). In the last five years, she has received research funding for projects related to pregnancy loss, perinatal death and maternal-fetal medicine from Science Foundation Ireland, the Health Research Board, the Irish Research Council, the Department of Children and Youth Affairs, the Irish Hospice Foundation, the MPS Foundation and Féileacáin. Prof O'Donoghue served/serves on the following Committees/Groups (in non-remunerated roles): Institute of Obstetricians and Gynaecologists (IOG) Speciality Training Committee (2014-); IOG Executive Council (2018-2022); Royal Irish Academy Life and Health Sciences Multidisciplinary Committee (2022-); Department of Health National Screening Advisory Committee (2019-2023); Termination of Pregnancy (Review Recommendations National Implementation Group (2023-); Perinatal Mortality National Clinical Audit Governance Committee (2014-); Clinical Advisory Group, NWIHP (2017-); International Stillbirth Alliance Advocacy Working Group (2022-).

Anne-Marie volunteers with the following organizations:

- PUSH for Empowered Pregnancy (US based) - https://www.pushpregnancy.org/
- Measure the Placenta (US based) - https://www.measuretheplacenta.org
- A Little Lifetime (Ireland) - https://www.alittlelifetime.ie/

and is as member of ISA (https://www.stillbirthalliance.org/)

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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 Traversy G, Barnieh L, Akl EA, Allan GM, Brouwers M, Ganache I, Grundy Q, Guyatt GH, Kelsall D, Leng G, Moore A, Persaud N, Schünemann HJ, Straus S, Thombs BD, Rodin R, Tonelli M. CMAJ. 2021, 193(2):E49-E54. DOI: 10.1503/cmaj.200651 https://www.cmaj.ca/content/193/2/E49

5 Holger J. Schünemann, Lubna A. Al-Ansary, Frode Forland, *et al.*; for the Board of Trustees of the Guidelines International Network. Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines. Ann Intern Med. 2015;163:548-553. doi:10.7326/M14-1885. https://www.acpjournals.org/doi/10.7326/m14-1885

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 within 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

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.

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

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.

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

Chapter 2: Clinical Practice Guideline

Background

Fetal movement has been regarded as one of the early signs of fetal life and is perceived to be a part of a healthy pregnancy.[1, 2] Maternal perception of fetal movements usually begins between 16-20 weeks' gestation.[3] Movements are initially described as "flutters" or "butterflies" and go on to increase in strength and frequency reflecting the neural development and maturation of the fetus.[4, 5]

Reduced fetal movements (RFM) is a common reason for unscheduled presentations to maternity services. Up to 15% of pregnancies will have at least one episode of RFM.[6] The majority of women, 74%, presenting with RFM will go on to have an uncomplicated pregnancy.[7] However, pregnancies complicated by RFM are at increased risk of adverse perinatal outcomes such as stillbirth, fetal growth restriction and preterm delivery.[7-9] It has been reported that 30-55% of women who experienced a stillbirth reported perceiving RFM in the week preceding fetal death.[10, 11]

The MBRRACE-UK 2015 Perinatal Confidential Enquiry report highlighted the importance of standardising the care of women presenting with RFM in order to reduce the risk of stillbirth.[8] However, two Cochrane reviews in 2012 and 2015 highlighted the lack of good quality evidence regarding the best approach to managing pregnancies complicated by RFM.[12, 13] This guideline evaluates the evidence available to date and takes into account consensus advice from other international bodies.

Recommendations relevant to this guideline can also be found in:

- National Clinical Guideline: Stillbirth: Prevention, Investigation, Management and Care[10]
- National Clinical Practice Guideline: Induction of Labour[11]
- National Clinical Guideline: Fetal Growth Restriction (expected in 2024)
- National Clinical Guideline: Fetal Monitoring (expected in 2024)

10 McDonnell A, Butler M, White J, Escañuela Sánchez T, Cullen S, Cotter R, Murphy M, O'Donoghue K. National Clinical Practice Guideline: Stillbirth: Prevention, Investigation, Management and Care. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. 2023.

11 Mitchell J.M, Nolan C, El Shaikh M, Cullinane, S, Borlase D. National Clinical Practice Guideline: Induction of Labour. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. 2023.

Clinical Question 2.1: What is reduced fetal movement?

Introduction

There have been several attempts made at defining "normal" fetal movements, which is difficult as every pregnancy is individual and different. Even within the Obstetric and Midwifery professional community it has been challenging to agree a universal definition for RFM. It should be noted that the lack of a consensus definition of both "normal" and "reduced" fetal movements is a limitation when reviewing the existing literature.

Evidence Statement

International expert bodies, including the Royal College of Obstetricians and Gynaecologists (RCOG) and Perinatal Society of Australia and New Zealand (PSANZ) have reached a consensus that no absolute definition of RFM is of greater value than the reported maternal perception of alteration, reduction or cessation of fetal movements.[2, 6, 14] However, the positive predictive value of maternal perception of reduced movements in identifying fetal compromise remains limited, ranging from 2-7%.[15]

Perceived fetal movements are defined as the maternal sensation of any discrete kick, flutter, swish or roll.[16] In most pregnancies, fetal movements can vary from 4 up to 100 movements per hour.[13] Studies have demonstrated that fetal movements increase in strength and frequency from 20 weeks until 32 weeks' gestation.[17] As a pregnancy approaches term, fetal movements have been described as becoming more smooth rather than discrete jerks and kicks.[5, 17] Fetal movements are usually absent during fetal sleep cycles. These cycles usually range between 20 to 40 minutes, and rarely exceed 90 minutes.[18, 19] Some studies have suggested that fetal movements follow a circadian rhythm, with "strong" or more prominent movements felt during evening times throughout the third trimester.[17, 20] As such, there is a proposed association between reduction in fetal movements in the evening and the occurrence of stillbirth. Bradford *et al.* demonstrated that a reduction in maternal perception of fetal movements in the evening is associated with a four-fold increase in the risk of stillbirth.[21]

Maternal perception of fetal movements varies significantly and can range from 4-94% of movements visualised during ultrasound scans.[6] Women tend to perceive synchronous movements of the trunk and limbs more readily than isolated short movements.[22-24] Various factors have been implicated in the reduction of maternal perception of fetal movements including intrauterine fetal death (IUFD), increased maternal physical activity levels, fetal size, fetal sleep, fetal anaemia, congenital fetal anomalies including neurological and musculo-skeletal disorders, amniotic fluid volume, maternal sedating medications (e.g. narcotics and benzodiazepines), anterior placentation, smoking, increased maternal BMI and parity.[25] However, the evidence regarding the association of these factors with reduced maternal perception of fetal movements is conflicting.

Maternal tobacco use has been shown to be associated with increased RFM presentations, with adjusted OR of 1.4 (95% CI 1.0-2.0).[26] There has been limited research on the effect of maternal physical activity on perception of fetal movements. However, available data to date suggest that heightened levels of maternal physical activity can be associated with reduced perception of fetal movements.[17, 27]

Sasson *et al.* reported that anterior placentation and nulliparity were significant factors in increased admissions with RFM (odds ratios (OR) of 1.44 and 2.28 respectively), whereas increased BMI was not.[28] Similarly, an Irish study described increased presentations to maternity services with RFM in primiparous women.[29] On the other hand, Brown *et al.* demonstrated that neither placental site, parity, amniotic fluid volume, nor BMI had statistically significant association with reduced maternal perception of fetal movements.[22]

A systematic review by Bradford *et al.* indicated that women with an increased body size were more likely to present with RFM. However, increased maternal body habitus does not seem to impair actual maternal perception of fetal movements.[30] This study also highlighted that women presenting with RFM are at higher risk of adverse pregnancy outcomes such as stillbirth and/or fetal growth restriction (FGR) if they were overweight or obese.[30]

Clinical Practice

For the purpose of antenatal surveillance and management, RFM is defined as any alteration in maternal perception of fetal movements, including a change in pattern (strength and/or frequency), reduction or cessation of movements.

Clinicians and pregnant women should be aware that fetal movements often increase in frequency up until 32 weeks and can increase in strength throughout the pregnancy until delivery. They should also be aware that fetal movements can follow a diurnal pattern, with stronger movements felt during evening times.

Clinicians should be aware of the various factors that may influence maternal perception of fetal movements (Table 1).

Table 1: Conditions that may be associated with reduced maternal perception of fetal movements.

Fetal factors	Maternal factors	Other Factors
Fetal death	Maternal physical activity levels (e.g. busy woman who is not concentrating on fetal movements/activity)	Amniotic fluid volume (oligohydramnios and polyhydramnios)
Fetal sleep	Smoking	Anterior placenta
Fetal anaemia	Primiparous	
Fetal size and growth (including fetal growth restriction)	BMI >30	
Fetal congenital anomalies (e.g. CNS and Musculo-skeletal disorders)	Medications (e.g. Sedating drugs: benzodiazepines, narcotics)	

Recommendations

1. **Reduced fetal movements (RFM) is defined as any alteration in maternal perception of fetal movements including change in pattern (strength and/or frequency), reduction or cessation of movements.**
2. **Clinicians and pregnant women should be aware that fetal movements tend to increase in strength throughout pregnancy and normally follow a diurnal pattern with stronger more active period observed in the evenings.**

Clinical Question 2.2: What is the clinical significance of reduced fetal movements?

Introduction

There are numerous complications and clinical outcomes, of varying clinical significance, associated with RFM.

Evidence Statement

The most important clinical significance of RFM is the link to an increased risk of stillbirth. A 2023 systematic review and meta-analysis by Carroll *et al.* looked at 39 non-randomised studies involving women beyond 24 weeks pregnant who presented with RFM compared to those who did not have RFM. This systematic review demonstrated an increased risk of stillbirth (OR 3.44, 95% CI 2.02-5.88) in women reporting reduced fetal movements.[31] Heazell *et al.* published an international internet-based case control study involving 153 women who had a third-trimester stillbirth and 480 women with an ongoing pregnancy or liveborn child. This study showed that in cases of stillbirth, there was a significant reduction in perceived fetal movement in the two weeks period preceding the occurrence of stillbirth with an adjusted odds ratio (aOR) of 14.1 (95% CI 7.27-27.45).[32]

Another case control study from the UK, looking at the perception of fetal movement in 291 women across 41 maternity units who had a third trimester stillbirth, showed similar findings. A reduction in the perceived strength or frequency of fetal movements was associated with an increased risk of stillbirth with OR of 2.36 (95% CI 1.69-3.30), increasing to 5.11 (95% CI3.22-8.10) if there were recurrent presentations with RFM.[33] Bradford *et al.* concurred with the above findings, and also suggested an association between RFM in the evening and an increased risk of late stillbirth (³ 28 weeks' gestation) with an aOR of 3.82 (95% CI 1.57-9.31)[21] in a multicentre case-control study. It is worth noting that, as shown above, the majority of published studies investigating a relationship between RFM and stillbirth are non-randomised observational studies, which are at higher risk of confounding factors compared to randomised controlled trials. Moreover, a causal relationship between RFM and stillbirth cannot be established based on these observational studies.

Fetal growth restriction (FGR) and small for gestational age (SGA) babies are also more prevalent in women who report RFM. Carroll *et al.* described an increased risk of the pregnancy being complicated by SGA (OR of 1.37, 95% CI 1.16-1.61) if women described reduced fetal movements.[31] This was also illustrated in several other studies by Saatad *et al.* and Tveit *et al.*[26, 34, 35] However, the direction and degree of causality, if any, is not definitive. For example, a potential explanation is that a reduction in fetal movements is an adaptive fetal response to a suboptimal uterine environment, such as that seen in placental insufficiency manifesting as FGR.[6]

The recently published report pertaining to RFM from International Stillbirth Alliance conference workshop further highlighted the link between RFM and placental dysfunction based on three studies.[36] A case-control study by Warrender *et al.* looked at the structural and functional differences in placentas of 36 women ≥ 28 weeks with RFM delivered within 7 days of presentation compared to 36 other placentas from women without RFM.[37] Macroscopically, placentas from pregnancies complicated by RFM were more likely to be smaller with an off-centre cord insertion.[36, 37] Microscopically, placentas from women with RFM had significantly excessive syncytial knots and infarctions compared to controls.[37] While another study by Winje *et al.* did not link RFM to placental pathology (OR 1.3, 95% CI: 0.8-2.2), it showed an association with maternal vascular malperfusion (OR 3.5, 95% CI: 1.1-11.3).[36, 38]

Oligohydramnios, preterm birth, neurodevelopmental problems, fetal musculoskeletal anomalies and congenital malformations are also seen more commonly in women presenting with RFM.[6, 26, 39-45] Several case reports have demonstrated that pregnancies complicated by feto-maternal haemorrhage (FMH) can present with RFM; in some instances, RFM can be the only complaint.[46-48]

Clinical Practice

Clinicians should be aware of the association between RFM and the increased risk of stillbirth, FGR, placental insufficiency, oligohydramnios, fetal congenital anomalies and FMH. As such, all women reporting RFM should have a comprehensive assessment of fetal wellbeing. This is set out in detail in Clinical Question 2.6.

Recommendations

3. **Clinicians should be aware of the outcomes associated with RFM including the increased risk of stillbirth and/ or fetal growth restriction (FGR).**
4. **Women reporting RFM should undergo a comprehensive assessment of fetal wellbeing.**

Clinical Question 2.3: What are the risk factors associated with poor perinatal outcomes and stillbirth in women with reduced fetal movements?

Introduction

The majority of women who experience RFM go on to have an uncomplicated pregnancy but 1 in 4 pregnancies will have a poor perinatal outcome. There are factors that increase the risk of adverse pregnancy outcomes, especially when combined with maternal perception of RFM.

Evidence Statement

The National Clinical Guideline *Stillbirth – Prevention, Investigation, Management and Care* outlines an in-depth analysis of the various risk factors for stillbirth.[49] These risk factors are summarised in Appendix 4. Some of these factors have been studied independently in the context of RFM.

A retrospective review by O'Sullivan *et al.* looked at 203 pregnancies who presented with RFM and compared their outcome to the general obstetric population in the same time period.[7] Of those with RFM, 74% had a normal pregnancy outcome and 26% had a poor perinatal outcome defined as IUFD, SGA <10th centile for birth weight or preterm birth <37/40.[7]

Significant risk factors for poor perinatal outcome in that cohort were:

- Symphysial fundal height (SFH) measuring small for gestational age (OR 15.43, 95% CI 4.20-56.75)[7]
- Significant past medical history (OR 3.02, 95% CI 1.01-9.06)[7]
- Significant past obstetric history (OR 2.2, 95% CI 1.17-4.14)[7]
- Two or more presentations with RFM (OR 1.6, 95% CI 1.05-2.44)[7]

Another prospective study by Dutton *et al.* of 305 women presenting with RFM showed a similar link between SGA and adverse pregnancy outcome in this cohort.[50] However, it did not show an association between poor perinatal outcomes and past obstetric history or recurrent presentations with RFM.[50] The authors acknowledge that there was limited power to detect these effects in this small study.[50] A larger retrospective Swedish cohort study of over 4000 women with RFM similarly showed that SGA was associated with adverse neonatal outcomes in both primiparous and multiparous women.[51] A wide variety of "adverse" outcomes are reported in the above studies; however, stillbirth, the most clinically relevant outcome, is relatively rare and thus adequate powering of studies is challenging.

Clinical Practice

Clinicians should be aware that certain factors increase the risk of adverse pregnancy outcomes in women with RFM (Table 2).

It is acknowledged that there are numerous risk factors for stillbirth, and not all of these have been individually studied in the context of RFM. However, clinicians are urged to be vigilant in their assessment of women with RFM, especially when any risk factor for stillbirth is identified.

Table 2: Risk factors associated with adverse outcomes in women with RFM[7]

Risk Factor	Odds ratio (OR)	95% Confidence Interval	p value
Small for gestational age (SGA)**	15.43	4.20-56.75	<0.001
Significant medical comorbidities	3.02	1.01-9.06	0.048
Significant obstetric history	2.20	1.17-4.14	0.015
Recurrent presentations with RFM (≥2 presentations)	1.60	1.05-2.44	0.030

***Diagnosed based on symphysial fundal height measurement*

Recommendations

5. Clinicians should be aware that fetal growth restriction is associated with adverse pregnancy outcomes in women with RFM.
6. Clinicians should be aware of the risk factors for stillbirth and be vigilant in their assessment of women with RFM when any of these factors are identified.

Clinical Question 2.4: What is the role of antenatal education for women with reduced fetal movements?

Introduction

Antenatal education plays an important role in ensuring that pregnant women are aware of fetal movements, as well as the appropriate course of action in cases where movements are reduced or different from their normal pattern. It also ensures that clinicians are aware of the importance of RFM, and current best practice in the management of women presenting with RFM. The importance of antenatal education for both pregnant women and clinicians lies in the association between RFM and the risk of stillbirth and other adverse perinatal outcomes.

Evidence Statement

Several studies have highlighted areas for improvement pertaining to antenatal education, specifically regarding fetal movement awareness. Two studies from Australia and New Zealand concluded that 30-40% of women do not recall receiving antenatal education or advice on fetal activity during their pregnancy.[52, 53] The majority of women in the studied population preferred to get their information from their midwife or obstetrician.[53] A qualitative descriptive study from Sweden demonstrated that pregnant women requested better provision and consistent information on RFM during the antenatal period including what constitutes normal movement patterns and how to pay attention to their baby's decreased movements.[54] This was echoed in a recently published qualitative evidence synthesis on women's views regarding assessing fetal movements.[55] Women prefer to receive information from a healthcare professional, especially from midwives. They also prefer to receive information in a printed document format which they can refer to again rather than just verbal information.[55]

Several studies have investigated the impact of improved maternal awareness of fetal movements on perinatal outcomes. A systematic review by Winje *et al.* evaluating interventions to improve maternal awareness of RFM included 16 randomised and non-randomised studies of fair to poor quality.[56] It concluded that there is insufficient evidence to recommend interventions to enhance maternal awareness of RFM as means to assess fetal well-being.[56] However, the authors suggested that clinicians should inform women about the importance of fetal movement awareness and the need to report perceived RFM to their healthcare provider.[56] This conclusion was based on evidence from limited-quality non-randomised studies showing promising results in terms of stillbirth reduction, and the authors acknowledge the need to confirm these findings in more robust large-scale randomised trials.[56] A more recent systematic review and meta-analysis by Hayes *et al.* was equivocal regarding the efficacy of encouraging awareness of RFM on stillbirth reduction compared to standard care.[57] However, studies included in that systematic review may not have been adequately powered to measure the effect of intervention on the rate of stillbirth. The review did, however, demonstrate that improved maternal awareness may be associated with reduced admission to NICU and Apgar scores <7 at 5 minutes.[57]

A quality improvement prospective study in Norway in 2009 showed that improved maternal awareness of RFM was associated with a reduction in the rate of stillbirth.[58] It evaluated the role of combining improved maternal awareness of RFM (via increased information provision to antenatal women), and providing clinicians with standardised clinical guidelines on the management of RFM. The combined intervention was associated with reduction in stillbirth in the overall studied population (OR 0.67, 95% CI 0.49-0.94), and in those with RFM (OR 0.51, 95% CI 0.32-0.81).[58] In the same Norwegian population, primiparous women who had received antenatal education and were provided with written information on reduced fetal activity in the second trimester had a significant reduction in the delayed reporting of RFM longer than/equal to 48 hours (OR 0.61, 95% CI 0.47-0.81).[59]

Similar to the Norwegian study above, the largest RCT on the management of women with RFM, the AFFIRM trial, published in 2018, included a care package involving combing improved antenatal education to increased maternal awareness of RFM and a standardised management protocol for women reporting RFM from 24 weeks onwards. Unlike the Norwegian population-based cohort study above, this RCT did not demonstrate a reduction in the risk of stillbirth when adopting the study care package. The AFFIRM trial is discussed in more detail in Clinical Question 2.6.

The "My Baby's Movements" (MBM) trial was a large stepped-wedge cluster randomised control trial (RCT) in Australia and New Zealand published in 2022 evaluating the effect of a multifaceted approach to antenatal education regarding fetal movements on the rate of stillbirth. It evaluated improving women's awareness of fetal movement through the use of a smartphone app, and improving maternity staff awareness through an online educational programme on the rate of stillbirth beyond 28 weeks' gestation.[60] The stillbirth rate was lower in the intervention group compared to the control group, however it did not reach statistical significance (2.2/1000 versus 2.4/1000 births; aOR 1.18, 95% CI 0.93-1.50; p-value 0.18).[61] The reduction in stillbirth rate was greater over time. The authors concluded that the specific intervention did not reduce the rate of stillbirth beyond the downtrend seen over time, and have suggested that the importance of fetal movement awareness had reached pregnant women and maternity staff prior to intervention implementation.[61] The intervention did not result in an increase in obstetric intervention or adverse neonatal outcomes.[61]

The recent report from the International Stillbirth Alliance conference workshop on decreased fetal movements highlighted that despite the recent publication of relatively large scale trials on fetal movement awareness interventions, these trials have to yet to show a significant impact of any intervention on the rates of stillbirth.[36] The authors acknowledged the difficulties associated with large scale trials of complex educational interventions.[36] They also highlighted that all trials to date on fetal movement awareness interventions have compared it with routine care, which invariably also involves a degree of fetal movement awareness and education, making it difficult to measure the effect of any intervention.[36]

There remains a lack of consistency in the information provided to women, which in turn has the potential for future mismanagement of the pregnancy.[62] Women with RFM are often advised to try and stimulate the baby with "sugary" drinks or snacks prior to attending their maternity unit/hospital for assessment. However, studies have not shown that intravenous glucose administration or an oral meal or fluids alter fetal movements.[63,64] Another study highlighted that women themselves request that doctors and midwives encourage those experiencing RFM to consult their maternity unit/hospital immediately without delay.[54]

When discussing antenatal education, it is important to take into account women's viewpoints, perspectives and behaviours regarding fetal movements awareness. A multicentre RCT in 1,013 women evaluated pregnant women's experiences when instructed to monitor fetal movements.[65] Women who were randomised to count/monitor fetal movements in the third trimester reported significantly less pregnancy-related concerns than those in the control group. The frequency of maternally reported reduced fetal activity was similar between both groups.[65]

The previously-mentioned qualitative evidence synthesis highlighted that women in pregnancy have a subconscious informal engagement with fetal movements.[55] However, it also highlighted some of the drawbacks associated with increasing fetal movement awareness. Some women have reported experiencing worry and increased anxiety with formal fetal movement monitoring, and others considered it to be inconvenient (formal fetal movement monitoring is discussed in depth in Clinical Question 2.5).[55] Moreover, this qualitative study highlighted some of the interactions between women and healthcare professionals regarding fetal movements. Some women were reluctant to contact their healthcare professional when concerned about fetal movements out of fear of ridicule, not being taken seriously or listened to, or merely not wanting to waste the healthcare professional's time with their concerns.[55]

Both the RCOG and PSANZ guidelines agree that women should be advised to develop an awareness of their baby's movements.[2, 14] PSANZ recommends giving women written and verbal information on fetal movements by 28 weeks' gestation.[14] Both organisations also agree that women should not delay seeking advice when they perceive RFM.[2, 14]

Clinical Practice

Antenatal education on normal and reduced fetal movements should constitute an important aspect of routine antenatal care.

Antenatal education:

Women should receive accurate and evidence-based information on what constitutes "normal" and "reduced" fetal movements throughout pregnancy. However, as discussed in Clinical Question 2.1 above, the definition of RFM can be challenging. All pregnant women should be advised that fetal movements continue to increase in strength throughout pregnancy until delivery. They should also be made aware that fetal movements normally follow a diurnal pattern with stronger and more frequent movements felt during the evening time.

As part of antenatal education, women should be informed that feeling their baby move is a sign they are well and that when a baby slows down it can be a signal that the baby is unwell. RFM can be associated with adverse pregnancy outcomes such as stillbirth and FGR, however women should also be made aware that most women who experience an episode of RFM go on to have an uncomplicated pregnancy. Women should be informed to present at their maternity unit/hospital immediately if they feel any changes in the strength (weaker movements), frequency (less movements), a cessation in movements or a rapid increase in movements. They should be advised to not delay until the following day, especially if they feel a change in the evening, and not to wait until their next appointment.

We recommend that verbal advice along with written information about fetal movements is given to women by 24 weeks' gestation during their scheduled antenatal visits. This should include the Patient Information Leaflet (PIL) included in Appendix 3 in this Guideline. We recommend that this PIL is used in each maternity unit/hospital and formatted to include specific contact information, including 24-hour contact numbers, for women to report their concerns. Thereafter, clinicians should take the opportunity to remind women about the importance of fetal movement awareness at each scheduled and unscheduled antenatal visit.

The following can be used a prompt to facilitate a discussion about fetal movements:

- Tell me about your baby's movements?
- What do the movements feel like to you?
- How strong are your baby's movements?
- How often does your baby move?
- Does baby have quiet times and busy times?

Each maternity unit/hospital should ensure that women are provided with contact information to facilitate reporting concerns about fetal movement and seeking further advice.

Maternity staff education

The multidisciplinary team, including Midwives, Obstetricians as well as primary care providers/GPs, should be familiar with up-to-date evidence on fetal movements and current recommendations on the management of women presenting with RFM. This can be facilitated through ensuring regular educational sessions at a local level in each maternity unit/hospital, with appropriate links to Primary care teams.

Inaccurate information, such as "babies run out of room to move" in the third trimester, should not be given to women. Clinicians should be aware that the assessment of women with RFM should not be delayed with advice on methods to stimulate the baby such as eating or drinking a "fizzy" or "sugary" drink/meal or concentrating on feeling movements for a specified time period prior to attending the maternity unit/hospital for evaluation. Clinicians should also instruct women reporting RFM to attend their maternity unit/hospital without delay for further evaluation.

Recommendations

7. **Women should be provided with verbal and written information about fetal movements by 24 weeks' gestation. They should also be provided with contact information to facilitate reporting of concerns about fetal movements.**
8. **Clinicians should take the opportunity to remind women about the importance of maternal awareness of fetal movement at each scheduled and unscheduled contact.**
9. **Healthcare staff should advise women reporting RFM to attend their maternity unit/hospital for further evaluation without delay.**
10. **Assessment of women reporting RFM should not be delayed for any reason, including with non-evidence-based advice on methods to stimulate movements such as consuming certain foods or drinks or concentrating on movements for a period of time prior to attending for review.**

Clinical Question 2.5: What is the role of formal fetal movement counting and use of "kick-charts" in clinical practice?

Introduction

Numerous studies have attempted to set arbitrary alarm limits to what should be considered "normal" and "abnormal" fetal movements warranting additional interventions and investigations.

Evidence Statement

A Cochrane review published in 2015 evaluated the role of fetal movement counting in the assessment of fetal wellbeing. It assessed the effect of formal fetal movement counting (done routinely, selectively or not at all) on several pregnancy outcomes including perinatal death or severe morbidity, caesarean section, maternal satisfaction and anxiety levels, antenatal interventions and other adverse pregnancy outcomes. Five randomised control trials were included involving 71,258 women. Four of those studies included low/normal risk pregnancies and one included high-risk participants. The authors concluded that there was insufficient evidence that formal fetal movement counting, whether for all pregnancies or for those at higher risk of adverse outcomes, is beneficial and recommended further research in this matter.[13]

The largest trial on formal fetal movement counting in the review above was published in 1989 by Grant *et al.* which included 68,654 women randomised in thirty three pairs of clusters of around 1000 women.[66] It compared the "Cardiff Count to 10" method in all pregnancies vs controls where women were either not asked or selectively asked to formally count movements. There was no statistically significant reduction in the rate of stillbirth for those in the formal counting group when compared to the control group.[66] There was however a trend towards increased antenatal admission in those in the formal fetal

movement counting group compared to the control group but this did not reach statistical significance.[66] The authors also noted that formal routine counting would represent a significant additional demand on healthcare system resources.

More recently, in 2020 Bellussi *et al.* published a systematic review and meta-analysis looking at the association between fetal movement counting and perinatal mortality.[67] They included five randomised control trials in which women were instructed on fetal movement monitoring in one arm and given no instructions in the other arm. Of those five studies, three studies were not included in the 2015 Cochrane review mentioned earlier.[13, 67] This systematic review did not show a difference in perinatal mortality in women instructed on fetal movement counting compared to those who did not receive instructions. The incidence of perinatal death was 0.54% in the fetal movement counting group vs 0.59% in the control group (RR 0.92, 95% CI 0.85-1.00). There were no statistically significant differences between the two groups for other perinatal outcomes including stillbirths, neonatal deaths, birth weight less than 10th percentile, 5-minute Apgar score less than 7, neonatal intensive care unit admission or perinatal morbidity. There were slight increases in preterm delivery (7.6% vs 7.1%; RR 1.07, 95% CI 1.05-1.10), induction of labour (36.6% vs 31.6%; RR 1.15, 95% CI 1.09-1.22), and caesarean delivery (28.2% vs 25.3%; RR 1.11, 95% CI 1.10-1.12) in the fetal movement counting group.[67]

One of the randomised controlled trials included in the most recent systematic review was a Norwegian trial, published in 2011, involving 1076 pregnancies where women were randomised to either formal fetal movement counting using the "Modified Count to 10" kick-charts or given no instruction on fetal movement counting from 28 weeks' gestation. There was a significantly higher rate of antenatal detection of fetal growth restriction in the intervention arm vs the control (87% vs 60% respectively).[34] However, there was no difference between the two groups in their primary outcome, which was a compound measure of FGR, emergency caesarean section for fetal indication, oligohydramnios, pathological umbilical artery Doppler indices, maternal perception of absent fetal movement >24 hours before hospital admission and perinatal death. In keeping with other studies cited here, stillbirth remains a rare outcome; there were no fetal deaths reported in either arm of this study.[34]

In addition to perinatal outcomes, it is also worth noting the potential effect formal fetal movement counting might have on maternal psychological outcomes. A systematic review and meta-analysis published by Alamri *et al.* in 2022 evaluated the effect of formal fetal movement counting on maternal worry, anxiety or concern and maternal-fetal attachment.[68] It included 9 studies with a total of 70824 pregnant women. This review demonstrated a significantly higher maternal-fetal attachment in those women who undertook formal fetal movement counting compared to those who did not adopt formal counting methods (standardised mean difference=0.72; 95% CI: 0.10-1.33, five studies, 1565 women).[68] However, there were no differences in maternal concern or anxiety levels between the two groups.[68]

Clinical Practice

The above evidence suggests that formal fetal movement counting using any form of "kick-chart" has not been shown to reduce adverse perinatal outcomes, especially stillbirth. Therefore, the use of "kick-charts" or setting of specific alarm limits on expected fetal movement over a specified time period should not be routinely recommended in current obstetric practice.

However, as discussed earlier in this Guideline, maternal perception of RFM can be associated with significant adverse perinatal outcomes. As such, we recommend that maternal concerns regarding altered perception of fetal movement should be used as a trigger for further evaluation rather than setting arbitrary numbers on expected "normal" fetal movements in a specified time period.

Recommendations

11. The use of "kick-charts" or pre-set alarm limits for monitoring fetal movements is not recommended in routine antenatal care.
12. Maternal reports of altered fetal movements should be used as a trigger to evaluate fetal wellbeing.

Clinical Question 2.6: What is the optimum management of women presenting with reduced fetal movements at ≥ 28/40 weeks' gestation?

Introduction

It is important to standardise the approach to the management of women presenting with RFM. This will facilitate the identification of the "at risk" pregnant woman and provide comprehensive assessment and further management, in an attempt to reduce the occurrence of stillbirth.

Evidence Statement

Despite a recent revived interest in optimising the management of women with RFM, good quality evidence on the best approach to managing this cohort remains lacking. Most clinical trials and international guidelines to date are based on expert consensus opinion rather than robust clinical evidence. It is worth noting that both The RCOG and PSANZ guidelines suggest 28 weeks' gestation as a cut off at which women reporting RFM should undergo an in-depth assessment.

Initial assessment:

The RCOG and PSANZ, along with a significant proportion of clinical trials conducted on the management of women presenting with RFM, suggest an initial evaluation that includes a detailed clinical history and examination.[2, 14, 58, 60, 69] Some studies advocate for the use of symphysial fundal height (SFH) measurement as an initial assessment for fetal growth.[60] A small case-note retrospective review of 92 singleton pregnancies with RFM showed that SFH measurement had a 60% positive predictive value (PPV) and 76.8% negative predictive value (NPV) for the detection of fetal growth restriction.[9] However, recent evidence on the usefulness of serial SFH measurement in the low risk population within a structured antenatal assessment protocol, GAP: Growth Assessment Protocol, did not show an effect on the antenatal detection of small for gestation fetuses compared to standard care.[70]

Studies with management protocols for RFM:

A prospective population-based quality improvement programme in Norway combined uniform information provision to women with a standardised staff guideline for the management of women presenting with RFM who were at least 28 weeks' gestation.[58] This practice guideline consisted of the use of both cardiotocograph (CTG) and ultrasound assessment at presentation to ascertain fetal viability and wellbeing within a set timeframe; within 2 hours in cases of absent fetal movement and within 12 hours if movements were reduced.[71] Ultrasound assessment included an assessment of fetal movements, estimation of fetal weight and amniotic fluid volume. In this study, the rate of stillbirth during the intervention period fell from 4.2% to 2.4%, (OR 0.51 95% CI 0.32-0.81).[58] There was no increase in preterm birth, fetal growth restriction or neonatal admission. The use of ultrasound scans more than doubled (OR 2.64; 95% CI 2.02-3.45); however this was ameliorated by the reduction in follow up

consultations and admission for induction of labour.[58] The strengths of this study lie in the large number of women included and relatively low risk of recruitment bias by outcome, as women reporting RFM were included in the trial registry and information on stillbirths during the study period were collected separately, while those without RFM were subsequently excluded from analysis.[58] The exact effect size of each intervention cannot be calculated due to the non-randomised nature of the study. Moreover, given that this was a population quality improvement project base on clinical shortcomings in a specific population, the results of this study might not be transferable to other populations.[58]

The largest RCT on the management of pregnancies complicated by RFM was the AFFIRM trial. This trial was conducted across 37 maternity units in the UK and Ireland and included 409,175 pregnancies.[72] The investigators assessed whether the introduction of a standardised care package including increased maternal awareness of fetal movement through the provision of a patient information leaflet and the adoption of a standardised management approach to those presenting with RFM from 24 weeks' gestation would reduce the rate of stillbirth. The management protocol for pregnancies at or beyond 27 weeks' gestation presenting with RFM included performing a CTG within 2 hours of presentation, a liquor volume assessment within 12 hours of presentation, a fetal growth scan to calculate an estimated fetal weight and abdominal circumference on the next working day, if not done within the preceding 3 weeks, and encouraged the use of umbilical artery Doppler assessment if available.[72,73] The intervention protocol included recommendations on whether delivery or return to original care was indicated based on gestation, CTG and ultrasound findings.[73] There was no difference in the rate of stillbirths between the control and intervention group in the AFFIRM trial, with the incidence of stillbirth at 4.40 per 1000 births in the control arm versus 4.06 per 1000 births in the intervention group (aOR 0·90, 95% CI 0·75-1·07; p=0·23).[72]

Some of the strengths of the AFFIRM study lie in its large population encompassing >400,00 pregnant women and the generalisability of the study to UK and Ireland depicted by similar stillbirth incidence in participating hospitals to that of the UK as a whole as presented by the MBRRACE report.[72] However, it is worth noting that the study results might have been influenced by the imperfect adherence of participating hospitals to the study protocol where over a third of participating hospitals (39.4%) adhered to four or less of the five intervention components.[72]

Role of CTG:

Antenatal CTG is a commonly used and widely acceptable tool for the initial assessment of fetal wellbeing.[74, 75] A normal fetal heart rate pattern depicted by a normal CTG suggests a normally functioning fetal autonomic nervous system.[76, 77] Changes to the fetal heart rate pattern depends on vagal and sympathetic stimuli, and therefore varies with gestational age as the nervous and autonomic systems mature. Electronic fetal monitoring through the use of CTG is recommended from 28 weeks' gestation onwards as the fetal organs are relatively mature at that gestation.[78] Accelerations are seen in 92-97% of gross fetal body movements felt by mothers.[79,80] However, a Cochrane review on the use of an antenatal CTG did not confirm or refute any benefit to the routine use of antenatal CTG assessment in the "at risk" pregnancies.[74] The authors, however, acknowledged several limitations to this review including the small number of women studied (1588 women) and the fact that the trials included were conducted in the early 1980s when CTG monitoring was being introduced into routine obstetric care.

Non-randomised trials have shown a benefit for the use of CTG assessment in those presenting with RFM. An Irish population-based cohort study of 524 women presenting with RFM in the third trimester showed that the use of CTG in this cohort was a reliable screening tool for fetal wellbeing.[81] Abnormal pregnancy outcomes were more commonly seen in those with an initial abnormal CTG or when the CTG was persistently non-reassuring.[81] In a Norwegian population-based cohort study, a CTG was performed in 97.5% of cases and anomalies were detected in 3.2%.[71] In an observational study in which CTG and ultrasound were used for the initial assessment of women with RFM who were otherwise deemed "low-risk," 21% of pregnant women had anomalies requiring further testing and follow up, and 4.4% required admission for immediate intervention and delivery.[69] Another study, albeit in the early 1980s, showed that the rate of stillbirth (corrected for lethal congenital anomalies) after a normal and abnormal CTG was 1.9 and 26 per 1000 births, respectively.[82]

Role of ultrasound:

The use of ultrasound in the setting of RFM lies in its potential ability to identify conditions that could contribute to a perceived reduction in fetal movement, as well as conditions that are associated with poorer perinatal outcomes and increased risk of stillbirth in this cohort. A prospective cohort study in the UK of 305 women presenting with RFM showed that of the 67 pregnancies with poor perinatal outcomes, 20 cases were identified by ultrasound assessment of fetal growth, liquor volume and umbilical artery Doppler and 4 cases were identified using CTG. In the prospective Norwegian cohort study of over 3000 women presenting with RFM, anomalies (fetal growth restriction, oligohydramnios, or fetal abnormalities) were identified on ultrasound in 11.6% of cases, and umbilical artery Doppler studies were abnormal in 1.9% of cases.[71]

Current evidence on the usefulness of umbilical artery Doppler studies is limited to "high-risk" pregnancies. A 2013 Cochrane concluded that the use of umbilical artery Doppler studies in "high-risk" pregnancies is associated with a reduced risk of perinatal death and can result in fewer obstetric interventions.[83] In that review, the authors considered pregnancies to be at "high risk" for fetal compromise if they were complicated by fetal growth restriction, post-term pregnancies, previous pregnancy loss, hypertension, diabetes, or other maternal pathology such as thrombophilias.[83] However, the authors cautioned that further studies are required, as the current evidence is not of high quality. In the aforementioned Norwegian quality improvement programme, the addition of umbilical artery Doppler evaluation to the study protocol did not show any further benefit.[58]

The CEPRA trial is currently ongoing and might be helpful in highlighting the role of fetal Doppler studies in identifying the "at risk pregnancies" in the RFM cohort.[36, 84] It is investigating whether expedited delivery due to an abnormal cerebroplacental ratio (calculated using measurement of umbilical artery Doppler and middle cerebral artery Doppler) in term pregnancies with RFM and estimated fetal weight >10th centile might be helpful in reducing adverse outcomes in this cohort.[36, 84]

The role of Biophysical Profile (BPP) score in the assessment of fetal wellbeing remains uncertain. A 2008 Cochrane review reviewing 5 trials involving 2974 women concluded that there is insufficient evidence to support the use of Biophysical Profile (BPP) score as a test of fetal wellbeing in high-risk pregnancies.[85] However, non-randomised observational studies have shown that the value of BPP lies in its high negative predictive value; meaning that fetal death is rare in the presence of a normal BPP score.[86]

Role of other investigations:

Reduced fetal movement can, in an otherwise uncomplicated pregnancy, be the only apparent symptom of a clinically relevant/massive feto-maternal haemorrhage (FMH).[87, 88] A retrospective analysis from the USA showed that a perception of reduced or absent fetal movements was the most common presenting symptom reported by 54% of women whose pregnancies were complicated by FMH.[89] Various studies have demonstrated that massive FMH occurred in 4% of stillbirths and 0.04% of neonatal deaths,[88, 90] while moderate-to severe FMH occurs in 0.3% of all live births.[87] However, clinically insignificant FMH is common and usually unrecognised.[87] The classic CTG description indicating underlying fetal anaemia is a sinusoidal fetal heart rate pattern, however, this is not present in all cases of clinically significant FMH.[88] One study showed that only 12.5% of cases with severe fetal anaemia had a sinusoidal pattern on CTG.[89]

The PSANZ guideline recommends testing for FMH and fetal anaemia in the preliminary assessment of women with reduced fetal movement if there is clinical suspicion of FMH, particularly in the setting of sustained or recurrent RFM.[14] It suggests using the Kleihauer-Betke test, flow cytometry and/or Doppler assessment of the Middle Cerebral Artery Peak Systolic Velocity (MCA-PSV), the latter if appropriate ultrasound expertise is available.

The diagnostic utility of the Kleihauer-Betke test, however, in the prediction of poor perinatal outcomes remains questionable with some studies supporting its universal use[91, 92] and others refuting it, particularly in Rhesus-positive women in the setting of suspected trauma or placenta abruption[93-95]. A recent retrospective Canadian Cohort study of 641 women found that the Kleihauer-Betke test offered no diagnostic precision in the emergency evaluation of women with suspected FMH.[96] Interestingly, there were 22 cases of positive Kleihauer-Betke tests in this cohort, however on further evaluation with flow cytometry the majority of these tests were negative, giving the Kleihauer-Betke a false positive rate of 94% in that study. There were 34 cases of RFM in this study; the Kleihauer-Betke test had a high specificity of 94.4% for composite outcomes however, the sensitivity was very low at 6.3%, with both negative and positive predictive value of less than 55. A French retrospective review on the utility of the Kleihauer-Betke test in women presenting with RFM showed that of the 338 women analysed, 3 had a positive test (0.9%).[97] In two of these cases, there were abnormalities in their CTG and/or MCA Doppler and fetal anaemia was confirmed on umbilical cord sample at delivery. In the sole case with a positive Kleihauer-Betke test and normal ultrasound and CTG, there was no documented fetal anaemia at delivery.[97]

The recent (2023) consensus report from the International Stillbirth Alliance conference workshop acknowledged that while RFM can be a presentation of feto-maternal haemorrhage, most women reporting RFM do not have FMH.[36] The consensus group also highlighted that testing for FMH using Kleihauer-Betke test, which can be costly and an unreliable indicator of fetal anaemia, can result in unnecessary interventions when small haemorrhages are detected.[36] Overall, any use of FMH testing must be understood in the wider clinical context of the individual pregnant woman and other clinical investigations.

Clinical Practice

There is lack of consistent evidence to support a particular gestation at which a comprehensive evaluation of all women with RFM should commence. As such, we suggest a threshold ≥ 28/40, marking the beginning of the third trimester and at which stage a CTG can be used to reflect the fetal status. This is in keeping with other international guidelines including those from the PSANZ and RCOG.

At each encounter in antenatal care, clinicians should ensure that women are listened to and that their concerns about their baby's wellbeing are adequately addressed. Consideration should be given to the environment in which the assessment of women reporting RFM should take place, ideally allowing for privacy in the event of a poor outcome.

Initial Assessment:

The initial assessment of women presenting with RFM at ≥ 28/40 should encompass a comprehensive clinical evaluation including:

- History:
  - Detailed history of the change in fetal movements including: change in pattern, including strength and frequency, of fetal movements (reduced/absent/loss of diurnal prominence of fetal movements) and duration of the change in fetal movements.
  - Any associated symptoms including, but not limited to: vaginal bleeding, abdominal pain, nausea and vomiting and symptoms of pre-eclampsia.
  - Presence of risk factors for fetal growth restriction/placental insufficiency and stillbirth (refer to Clinical Questions 2.2 and 2.3 above).
- Clinical examination:
  - Assessment of vital signs including blood pressure, maternal heart rate and temperature and urinalysis.
  - Abdominal examination including assessment of symphysial fundal height (SFH).
  - Assessment of maternal hydration status.
  - Assessment of fetal viability.
  - Auscultation of fetal heart using a hand-held Doppler or Pinard Stethoscope.
  - If intrauterine fetal death (IUFD) is suspected, urgent review by senior Obstetrician and confirmation of IUFD with ultrasound scan is recommended.

Initial Investigations:

- CTG: This should be performed on all women presenting with RFM who are ≥28/40 gestation to exclude acute fetal compromise.
- Bedside Ultrasound: All women with RFM who are ≥28/40 gestation should have initial ultrasound evaluation at the time of presentation to assess the liquor volume and presence/absence of fetal movements. This ultrasound assessment should be carried out by an appropriately-trained healthcare professional who has demonstrated competency in performing third trimester ultrasound scans.

Following the initial assessment and investigations, the woman can be discharged back to her routine antenatal care with **CLEAR** advice (i.e. the importance of seeking further advice if recurrence of RFM) if ***ALL*** the following criteria are met:

- First presentation with RFM
- No risk factors for FGR or stillbirth identified
- Normal clinical assessment, CTG and liquor volume
- Maternal concerns regarding fetal movement have resolved at the time of assessment.

If, after the initial review, any of the above criteria is not met and/or the woman continues to have concerns about fetal movements, discussion with a senior Obstetrician is recommended and consideration given for admission for further monitoring and investigations. Clinicians should be aware that a women's "gut instinct" that something is wrong should be taken seriously. In a retrospective case-control series, the risk of stillbirth was much higher in those who reported a "gut instinct" that something was wrong, either in association with RFM or throughout the pregnancy. Therefore, women should not be discharged home if they still have concerns.

Further Assessment/Investigations:

- Departmental ultrasound assessment
    - This includes measurement of fetal biometry/estimation of fetal weight (if not done in the preceding 2 weeks), liquor volume and umbilical artery Doppler.
    - This should be considered for all women with RFM, especially if:
        - Reduced perception of fetal movement persists.
        - Risk factors for stillbirth and/or FGR are present.
        - Concerns are raised at initial assessment (e.g. SGA on clinical examination or abnormal bedside ultrasound etc.).
    - The timeframe in which the ultrasound should be done will depend on the clinical urgency and service capabilities.
- Investigations for FMH
    - While RFM can be the only presenting symptom in cases of FMH, we acknowledge that clinically relevant FMH is an uncommon phenomenon and can be difficult to diagnose antenatally due to lack of robust diagnostic tools.
    - Therefore, routine testing for FMH in all cases of RFM is not recommended.
    - If there is a clinical suspicion of FMH in women presenting with RFM, in particular those with persistent or recurrent presentations, then testing for FMH, either using Kleihauer-Betke test and/or assessment of Middle Cerebral Artery Peak Systolic Velocity (MCA-PSV) can be considered following review by a Consultant Obstetrician.
    - Given limitations, lack of availability and potential for false-positive results, any request for the Kleihauer-Betke test in this setting must be discussed with the hospital laboratory and/or Consultant Haematologist. Ideally, this discussion should take place at Consultant level.
    - The use of either test will also depend on the expertise available in the maternity unit/hospital.

Recommendations

13. The initial assessment of women with RFM should include a detailed history, examination, and a thorough assessment of risk factors for FGR and/or stillbirth.
14. The evaluation should include a comprehensive assessment of changes in fetal movement pattern (strength and frequency), along with any associated symptoms such as bleeding and abdominal pain.
15. The fetal heart should be auscultated using hand-held Doppler or Pinard Stethoscope to confirm viability. If IUFD is suspected, urgent senior obstetric review is warranted and IUFD confirmed using real-time ultrasound.
16. A CTG should be performed on all women reporting RFM who are ≥ 28 weeks' gestation to exclude acute fetal compromise.
17. All women with RFM should have a bedside ultrasound, by an appropriately-trained healthcare professional, at the initial presentation to assess liquor volume and the presence/absence of fetal movements.
18. Women can be discharged to routine antenatal care if all the following criteria is met: first presentation with RFM, no risk factors for FGR and/or stillbirth identified, normal initial assessment including normal CTG and bedside ultrasound, and maternal concerns regarding fetal movements have resolved.
19. Where the discharge criteria is not met, discussion with a senior Obstetrician is recommended and consideration given for admission and further investigations.
20. A Departmental ultrasound assessment of fetal biometry (if not done in the preceding 2 weeks), liquor volume and umbilical artery Doppler should be considered for all women with RFM, especially those with persistent RFM, risk factors for FGR and/or stillbirth and those with concerns raised at their initial assessment.
21. Routine testing for feto-maternal haemorrhage (FMH) in cases of RFM is not currently recommended. However, if there is high index of suspicion of FMH, then testing for it could be considered following review by a Consultant Obstetrician.
22. Given the limitations of the Kleihauer-Betke test in this setting and lack of availability outside routine working hours, discussion with the hospital laboratory and/or Consultant Haematologist is required prior to the test being requested.

Clinical Question 2.7: What is the optimum management of women with recurrent presentations with reduced fetal movements?

Evidence Statement

A recent Irish prospective case-control study involving 2593 women with singleton pregnancies (850 women with RFM and 1743 controls) investigated potential risk factors for RFM and perinatal outcomes in women reporting RFM, and also included a subgroup analysis of women with a single vs recurrent RFM presentations.[98] Of those who reported RFM, 707 women had a single episode while 143 women had recurrent presentation with RFM. Compared to those without RFM, women with a single or recurrent RFM presentations had significantly higher BMIs and an anterior placenta.[98] Women with recurrent presentations of RFM were younger than those with a single presentation (32. 6 years vs 34.0 respectively, p=0.007) and younger than those without RFM (34.4 years, p<0.001).[98] Nulliparous women were more likely to have recurrent presentations with RFM than multiparous women (OR 2.07 95% CI 1.34-3.20, p=0.001). Women with recurrent RFM were more likely to present with their first episode of RFM at earlier gestations than those with a single presentation (mean 30.1 weeks (SD 3.94) vs 34.6 weeks (SD 4.92); p=<0.001).[98] Interestingly, there were no significant differences in the rates of stillbirth, preterm birth, gestational age at birth, birthweight or Apgar scores <7 at five minutes amongst women with single, recurrent or without RFM presentations.[98] However, those with a single RFM presentation had a significantly higher proportion of SGA infants at birth compared to women without RFM (62 vs 107 infants, p=0.02), but no difference was identified in the proportion of SGA infants when comparing single and recurrent RFM presentations.[98]

Several retrospective studies have demonstrated that women with recurrent presentations of RFM are at increased risk of poor perinatal outcomes.[7, 99] A retrospective study of 203 women with RFM showed that those with two or more presentations were nearly twice as likely to have a poor perinatal outcome (defined as either stillbirth, SGA or preterm birth) than those with one presentation (OR 1.92; 95% CI 1.21-3.02).[7] A retrospective cohort study of 1234 women presenting with RFM beyond 36 weeks' gestation showed that 16.6% had multiple presentations with RFM. Those with recurrent presentations were significantly more likely to have an SGA baby than those with a single presentation, 44.2% vs 9.8% respectively (OR 7.3; 95% confidence interval, 5.1-10.4; p-value < 0.05).[99] The authors concluded that women with repeated episodes of RFM should be regarded as being at high risk of placental dysfunction.

There is paucity of evidence on the best approach to the management of women with recurrent RFM. The AFFIRM trial included a specific management protocol for those with recurrent presentations of RFM. It entailed increased surveillance with twice weekly CTG and liquor volume assessment until their next growth scan for gestations between 27-37 weeks (provided their initial assessment was normal) and recommended offering delivery within 48 hours for gestations ≥37 weeks.[73] However, a limitation of this study was that the outcomes of this specific intervention in this subgroup was not analysed separately, but rather included in the overall study protocol analysis; ultimately this did not show a reduction in perinatal mortality.[72]

Clinical Practice

Clinicians should be aware that women with recurrent presentations of RFM are at increased risk of adverse pregnancy outcomes, especially those related to placental dysfunction, such as stillbirth and FGR. Any presentation with RFM should trigger an initial assessment to include detailed history, clinical examination, CTG and bedside ultrasound (refer to Clinical Question 2.6 for further guidance).

Women who have not undergone a Departmental ultrasound assessment (including fetal biometry, liquor volume and umbilical artery Doppler) should have this performed if they have recurrent presentations with RFM. If an FGR fetus is identified, further management should be in line with the National Guideline on Fetal Growth Restriction (expected in 2024).

The potential role for FMH in the aetiology of recurrent RFM should be explored, and investigations (either Kleihauer-Betke test and/or MCA-PSV on ultrasound) considered following review by a Consultant Obstetrician and depending on available expertise.

If the results of all investigations are normal, care should be individualised and, following discussion with the woman, it is reasonable to consider increased antenatal surveillance, particularly if risk factors for placental dysfunction are identified.

Recommendations

23. **Clinicians should be aware that pregnancies complicated by recurrent presentations of RFM are at increased risk of adverse pregnancy outcomes.**
24. **Women with recurrent presentations of RFM should undergo a Departmental ultrasound examination to assess fetal biometry (if not done in the preceding 2 weeks), liquor volume and umbilical artery Doppler.**
25. **In the absence of other identifiable causes of recurrent RFM, further investigations for FMH should be considered following review by a Consultant Obstetrician, depending on the expertise available. These tests include assessing Middle Cerebral Artery Peak Systolic Velocity (MCA-PSV) on ultrasound and the Kleihauer-Betke test. (Best Practice)**
26. **If all investigations are normal and following discussion with the woman, it is reasonable to consider increased antenatal surveillance in women with recurrent RFM, especially in the presence of risk factors for placental dysfunction.**

Clinical Question 2.8: What is the optimum timing of birth for women presenting with reduced fetal movements?

Evidence Statement

The decision to deliver in pregnancy, where there have been presentations with RFM, stems from the desire to reduce the risk of stillbirth. Numerous studies have focused on the association between the risk of stillbirth and gestational age. A UK-based cohort study of over 90,000 deliveries demonstrated that over half of all stillbirths (52%) occurred at >34 weeks' gestation.[100] Another recent systematic review showed that there is an increase in the trend of stillbirth from 37 to 43 weeks.[101]

One of the largest RCTs on the management of women with RFM, the AFFIRM trial, included recommendations for delivery in this cohort in whom the results of investigations were normal. They recommended offering induction of labour to all those with a single presentation of RFM ≥ 40 weeks and those with recurrent presentations ≥ 37 weeks.[73] However, this study showed a significantly increased rate of obstetric interventions (caesarean section aOR 1·09, 95% CI 1·06-1·12, induction of labour aOR 1·05, 95% CI 1·02-1·08) and increased neonatal admission longer than 48 hours (aOR 1·12, 95% CI 1·06-1·18) without demonstrating a reduction in perinatal mortality.[72]

On the other hand, the ARRIVE trial, a United States-based RCT investigating maternal and perinatal outcomes of induction of labour at 39 weeks versus expectant management in a low risk nulliparous population, did not demonstrate an increase in caesarean deliveries.[102] On the contrary, there was significant reduction in caesarean births from 22% to 18.6% (RR 0.84; 95% CI 0.76-0.93); however there was no significant reduction in composite adverse perinatal outcomes.[102] One limitation worth noting is that the study utilised an intention-to-treat analysis, meaning that women who laboured spontaneously in the induction group were included in the analysis, potentially confounding the study conclusions regarding interventions in the induction group.

Several population-based studies have demonstrated that early term delivery (37-38^{+6}/40) is linked to increased adverse outcomes for those infants that extend beyond the neonatal period.[103, 104] A national Swedish cohort study of over 600,000 singleton births demonstrated that early term deliveries between 37-38 weeks were independently associated with increased mortality in infancy, early childhood and young adulthood.[104] Similarly, an Australian study of over 150,000 births ≥ 32 weeks' gestation found that early term deliveries were associated with increased risk of poor child development at school age.[103] The risk of being "developmentally high risk" (scoring in the bottom 10% of ≥2 developmental domains) was inversely proportional to gestational age at delivery.[103] When compared to delivery at 40 weeks, the adjusted relative risk of being developmentally high risk was 1.17 (95% CI 1.10-1.25)at 37 weeks, 1.06 (95% CI 1.01-1.10) at 38 weeks and 0.98 (95% CI 0.94-1.02) at 39 weeks.[103]

Clinical Practice

Clinical assessment has abnormal findings:

In the event of an abnormal clinical assessment such as an abnormal CTG or fetal ultrasound, then senior obstetric review is warranted, and timing of delivery should be individualised. Where FGR is identified, management and timing of delivery should be in line with the National Guideline on Fetal Growth Restriction. If an IUFD is diagnosed, management and delivery should be in line with the National Guideline *Stillbirth – Prevention, Investigation, Management and Care.*

Clinical assessment is normal:

In cases where assessment and investigations are normal, care should be individualised and shared decision-making between clinicians and women should be encouraged. We recommend that clinicians have a discussion with women on the risks and benefits of delivery, including those of induction of labour and/or caesarean section, where appropriate, and take into consideration the woman's preferences, gestational age, clinical assessment and risk factors for stillbirth.

The risks of early term delivery (37-38^{+6}/40), including developmental and childhood problems, should be weighed against the risk of stillbirth with prolonging the pregnancy.

It is reasonable to consider and plan delivery in those with RFM who are ≥ 39 weeks' gestation, especially those with persistent or recurrent presentations and those with risk factors for stillbirth. We acknowledge that there are several factors and scenarios that need to be incorporated into the decision-making matrix that might influence the options for and timing of delivery (e.g., women with a previous caesarean section hoping for VBAC, unstable lie/high unengaged fetal head). As such, we encourage individualising decision making on a case-by-case basis. This involves balancing the risks of continuing on with the pregnancy with increased antenatal surveillance, against the risks associated with delivery.

If the birth occurs as a result of a clinical complication associated with RFM, then consideration should be given to sending the placenta for histopathological assessment. (Evidence regarding placental dysfunction in setting of RFM is set out in detail under Clinical Question 2.2 above).

Recommendations

27. **Care should be individualised and shared decision making between the woman and the clinician with regard to the timing of birth should be encouraged. We recommend that clinicians discuss with women the risks and benefits of expediting birth/delivery, and consider the woman's preferences, gestational age, clinical assessment and risk factors for stillbirth.**
28. **It is reasonable to consider expediting birth/delivery in women with RFM who are ≥ 39 weeks' gestation, especially women with recurrent presentations and those with risk factors for stillbirth.**
29. **Consideration should be given to sending the placenta for histopathological examination if the birth occurs as a result of a clinical complication associated with RFM.**

Clinical Question 2.9: What is the optimum management of women presenting with reduced fetal movements between 24-28/40 weeks' gestation?

Evidence Statement

At present, there is insufficient evidence to inform a standardised evidence-based approach to the management of women presenting with RFM under 28 weeks' gestation. As part of good clinical practice, both RCOG and PSANZ recommend auscultation of the fetal heart to confirm viability in those under 28 weeks' gestation.[2, 14] They also agree that routine CTG surveillance in pregnancies under 28 weeks' gestation is not recommended owing to fetal immaturity and difficulties in interpreting the results. The immaturity of the autonomic and nervous system in fetuses < 28 weeks' gestation can result in physiological variation in the preterm CTG such as higher baseline, lower frequency and amplitude of accelerations, reduced variability and sporadic decelerations.[78, 105]

On the other hand, as part of their standardised management protocol, the AFFIRM study protocol advised that a CTG be performed in all pregnancies at 26 weeks' gestation or more if they present with RFM, but did not elaborate on reasons why this gestation was chosen.[73] Several considerations need to be taken into account when deciding on whether to commence antenatal CTG monitoring in pregnancies <28 weeks' gestation. These include the prognosis for neonatal survival, the risk of fetal death, the severity of the maternal condition and the potential for iatrogenic prematurity complications arising from false-positive test results.[106]

If there is a clinical suspicion of early onset FGR or other factors predisposing to reduced perception of fetal movements, such as fetal neuromuscular anomalies, the RCOG and PSANZ guidelines suggest that an ultrasound assessment is considered. The RCOG document stresses the importance of a comprehensive evaluation of risk factors for stillbirth,[2] while the PSANZ guideline suggests considering investigations for feto-maternal haemorrhage in cases where fetal anaemia is suspected.[14]

Clinical Practice

At each encounter, clinicians should ensure that women are listened to and that their concerns about their baby's wellbeing are adequately addressed. If there are concerns about fetal and/or maternal wellbeing at any stage during the assessment, or continued maternal concern regarding fetal movements, consideration should be given for review by a senior Obstetrician.

Initial assessment:

- History:
    - Detailed history of presenting complaint including: change in pattern, including strength and frequency, of fetal movements (reduced/absent/loss of diurnal prominence of fetal movements) and duration of the change in fetal movements.
    - Any associated symptoms including, but not limited to: vaginal bleeding, abdominal pain, nausea and vomiting and symptoms of pre-eclampsia.
    - Presence of risk factors for fetal growth restriction/placental insufficiency and stillbirth (refer to questions 2.2 and 2.3 above)

- Clinical examination:
  - Assessment of vital signs including blood pressure, maternal heart rate and temperature and urinalysis.
  - Abdominal examination including assessment of symphysial fundal height (SFH).
  - Assessment of maternal hydration status.
- Assessment of fetal viability:
  - Auscultation of fetal heart using a hand-held Doppler or Pinard Stethoscope.
  - If intrauterine fetal death (IUFD) suspected, urgent review by senior Obstetrician and confirmation of IUFD with ultrasound scan is recommended.

Investigations:

- CTG:
  - The decision to perform a CTG on fetuses between 26-27^{+6} weeks' gestation should be made by a senior Obstetrician on a case-by-case basis.
  - It is reasonable to consider a CTG assessment in those with risk factors for stillbirth/placental insufficiency who are between 26-27^{+6} weeks' gestation. However, caution should be adopted in the interpretation of CTGs at this early gestation as the fetal heart rate pattern that is normally expected at a later gestation might not be present.
  - Senior obstetric input should be sought if there are any concerns and consideration given to a more detailed ultrasound assessment.
- Ultrasound:
  - It is reasonable to perform a bedside ultrasound to assess the liquor volume and presence/absence of fetal movements at the time of initial assessment.
  - An anatomy ultrasound should be organised in women presenting with reduced or absent fetal movements <28 weeks if this has not been already performed earlier in pregnancy.
  - It is reasonable to perform a detailed ultrasound assessment of fetal biometry, liquor volume and umbilical artery Doppler in those with risk factors for fetal growth restriction and/or stillbirth, especially in women with continued/recurrent perception of RFM, < 28 weeks.

Recommendations

30. In cases of RFM <28 weeks' gestation, the initial assessment should include a detailed history, clinical examination and confirmation of fetal viability through auscultation of the fetal heart.
31. The decision to perform a CTG between 26-27+6/40 gestation should be made by a senior Obstetrician on a case-by-case basis. It is reasonable to consider a CTG assessment at this gestation in those with risk factors for stillbirth and/ or placental insufficiency. However, caution should be adopted in the interpretation of the CTG at this early gestation.
32. An anatomy ultrasound is recommended for women RFM < 28 weeks' gestation, if not performed earlier in the pregnancy.
33. For women with RFM <28 weeks' gestation, a Departmental ultrasound scan for fetal biometry (if not done in the preceding 2 weeks), liquor volume and umbilical artery Doppler should be considered in those with risk factors for stillbirth and/or growth restriction.

Chapter 3: Development Of Clinical Practice Guideline

3.1 Literature search strategy

A comprehensive search of electronic databases Cochrane Library, PUBMED and Google Scholar were undertaken. These databases were searched using relevant medical subject headings and keywords. The main keywords used were “fetal movements” and “reduced fetal movements” in combination with “antenatal management”, “stillbirth”, “small for gestational age”, “maternal perception”, “fetal movement counting” and “pregnancy outcome”. Searches were limited to humans and articles published between 1960 – April 2023. Reference lists for key papers were searched by hand. The results yielded from these searches included relevant meta-analyses, systematic reviews, and interventional and observational studies. A detailed literature review was subsequently carried out.

International guidelines were also reviewed with a focus on those from the Royal College of Obstetricians and Gynaecologist (RCOG) and the Perinatal Society of Australia and New Zealand (PSANZ) guidelines. The UK, Australia and New Zealand have an obstetric and antenatal care structure similar to that in Ireland where Obstetricians, Midwives and General Practitioners are involved in delivering antenatal care.

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 women with RFM 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 assessed using the AGREE II checklist (Appendix 7) as recommended by the Department of Health in the 'How to Develop a National Clinical Guideline: a manual for guideline developers', 2019.[12]

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

3.4 Literature review

Details of supportive evidence-based literature for this Guideline are reported in chapter two. The following steps were undertaken to ensure a comprehensive literature review of the available evidence on the management of RFM. A list of clinical questions was devised by the Guideline Development Group early in the creation process. The literature review was carried out by Dr Tamara Kalisse between January-April 2023 and the evidence reviewed with Prof. Keelin O'Donoghue. The guideline was drafted by the lead developer, Dr Kalisse, while the Patient Information Leaflet (PIL) was drafted by Ms Anne-Marie Farrell. Both the guideline and PIL were reviewed by the Guideline Development Group at regular intervals.

There was evidence available to answer the majority of the clinical questions proposed. The quality of the evidence available was, for the most part, moderate evidence consisting of a mixture of case control studies, a small number of recent large RCTs and systematic reviews. Where strong evidence was not available, recommendations were made based on group consensus. 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.[13]

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.[14] (Appendix 6)

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12 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/

13 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.

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3.6 Future research

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

The research questions of relevance to this Guideline include but are not limited to these suggestions from the Guideline Development Group:

1. What is the current level of knowledge among the general public regarding the causes of reduced fetal movements (including myths) and appropriate responses to this condition during pregnancy.
2. What is the current level of knowledge among the healthcare professionals regarding the causes of reduced fetal movements (including myths) and appropriate responses to this condition during pregnancy.
3. What is the role and clinical implications of testing for fetomaternal haemorrhage (FMH) in the setting for RFM.
4. What is the optimum management of women with RFM who are <28 weeks' gestation.
5. What is the best approach to managing women with recurrent RFM presentations where clinical investigations are within expected ranges.
6. What novel investigative methods (eg pathology, biochemistry and/or genetics) can be used to evaluate if and how RFM is caused by placental insufficiency.
7. What language is best used when counselling or giving information to women about RFM.
8. What is the accuracy, quality, readability, and credibility of the information regarding reduced fetal movements on web pages and/or in current patient information on RFM.
9. What are the histopathological differences between placentas from cases of reduced fetal movements (RFM) with livebirth induced by medical intervention, stillbirth, and livebirth with spontaneous labour.
10. How effective have the RFM guidelines and educational material been in improving knowledge (among pregnant women and healthcare professionals) about reduced fetal movements.

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 (GPT). 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 overall template of the HSE National Framework[15] for developing Policies, Procedures, Protocols and Guidelines (2016) (Appendix 8) and under supervision of the Guideline Programme Team.

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 5 for list of CAG members.

15 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.[16]

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 standard 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 websites (https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/) 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.

16 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 Guideline 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
- Patient information leaflet (PIL) (Appendix 3)

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. Multidisciplinary education for Clinicians on implementation of this Guideline should be provided both locally and nationally.

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 for the implementation of recommendations in this Guideline include:

- Structural factors – design of hospital/unit emergency departments and/or fetal assessment units, access to unscheduled care especially out-of-hours care
- Organisational factors – availability of ultrasound in hospital/unit emergency departments and/or fetal assessment units,
- Individual factors – knowledge and education of healthcare professionals about RFM
- Woman's perceptions and the role of disinformation and/or misinformation about RFM through peer, online and professional networks

In the case of this Guideline, it will be necessary to examine 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. Another example of an implementation strategy is a national public health campaign about the importance of fetal movements, which would require investment.

6.4 Resources necessary to implement recommendations

The implementation of this Guideline should be undertaken as part of the quality improvement programme of work in each maternity hospital/unit. Hospitals should review existing service provision against this Guideline, identifying both the key areas for staff education and training as well as necessary resources required to implement the recommendations in this Guideline.

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. The number of women documented to have received verbal and written information (PIL) on RFM with contact details for each maternity unit/hospital between 20-28 weeks' gestation.
2. The number of women reporting RFM who are asked to attend their maternity unit/hospital for assessment, in accordance with the Guideline recommendations.
3. The number of women reporting RFM ≥ 28 weeks who undergo a CTG and bedside ultrasound assessment as part of their initial evaluation.
4. The number of women with RFM not meeting the discharge criteria (i.e. have risk factors for stillbirth and/or FGR, persistent/recurrent RFM, abnormal initial investigations) who have a departmental ultrasound scan within the next working day.
5. The number of women with recurrent RFM or who do not meet the discharge criteria who are reviewed by a senior clinician.
6. The number of women with RFM for whom intervention is planned (induction of labour or caesarean section) before and after 39 weeks' gestation.

In addition, Maternity units/hospitals should consider auditing the outcomes for all women presenting to emergency services with RFM, and whether the management steps outlined in this Guideline were adhered to.

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.[17]

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.

17 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.[18]

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 clinical 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.

18 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
(for the Purpose of this Guideline)

AGREE Appraisal of Guidelines for Research and Evaluation

ACOG American College of Obstetricians and Gynaecologists

BMI Body Mass Index

BPP Biophysical Profile

CAG Clinical Advisory Group

CNS Central Nervous System

CTG Cardiotocograph

EAG Expert Advisory Group

FGR Fetal Growth Restriction

FIGO International Federation of Gynaecology and Obstetrics

FMH Fetomaternal Haemorrhage

GPT Guideline Programme Team

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

HIQA Health Information and Quality Authority

HSE Health Service Executive

IOG Institute of Obstetricians and Gynaecologists

IUFD Intrauterine Fetal Death

MCA-PSV Middle Cerebral Artery Peak Systolic Velocity

NCEC National Clinical Effectiveness Committee

NICE The National Institute for Health and Care Excellence

NPV Negative Predictive Value

NWIHP National Women and Infants Health Programme

OR Odds Ratio

aOR Adjusted Odds Ratio

PIL Patient Information Leaflet

PPPG Policy, Procedures, Protocols and Guidelines

PPV Positive Predictive Value

PSANZ Perinatal Society of Australia and New Zealand

RCOG Royal College of Obstetricians and Gynaecologists

RCT Randomised Controlled Trial

RCPI Royal College of Physicians of Ireland

RFM Reduced Fetal Movement

RR Relative Risk

SFH Symphysial Fundal Height

SGA Small for Gestational Age

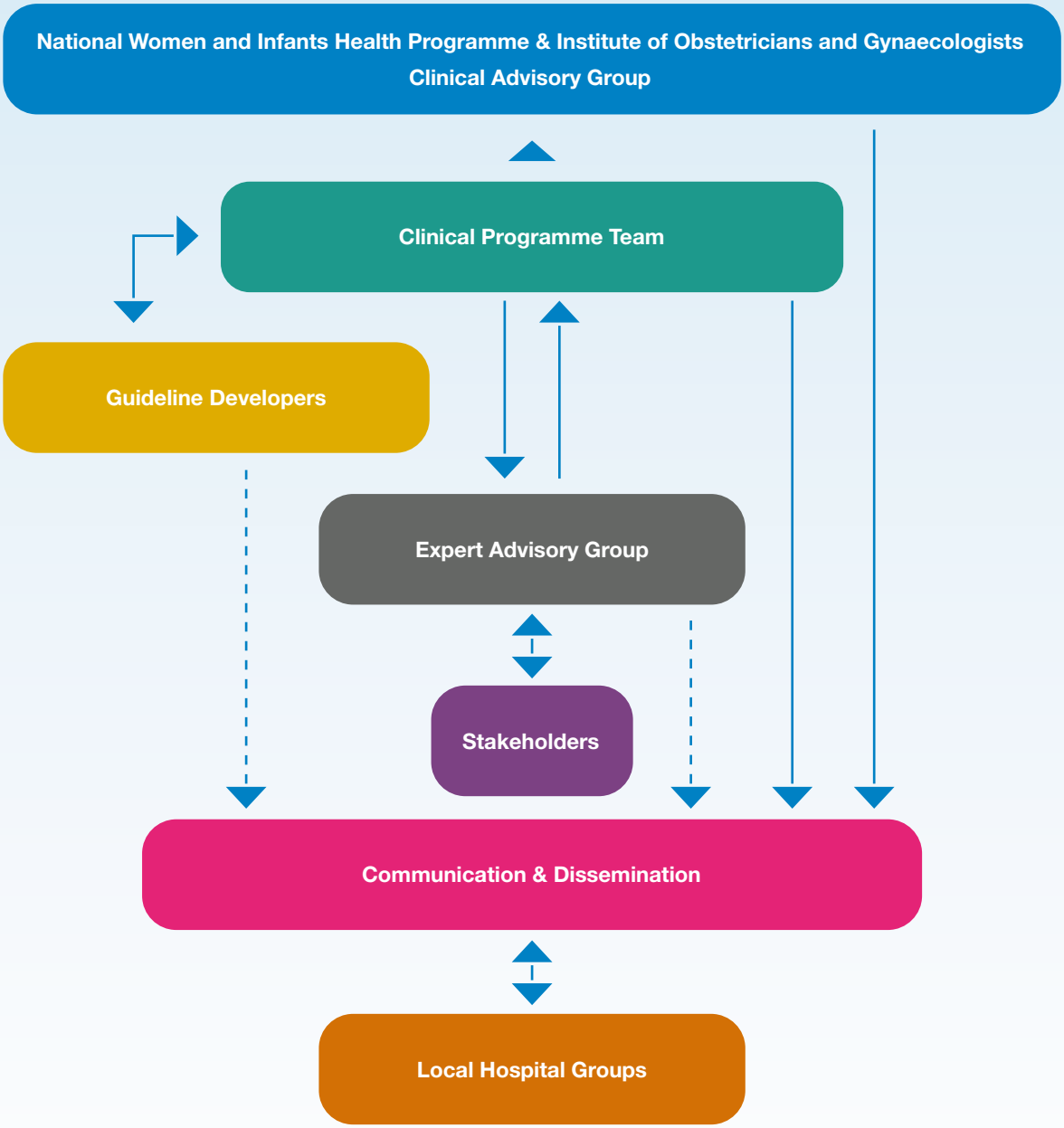
Appendix 1: **Expert Advisory Group Members 2021-**

Attendee	Profession	Location (2021)
Dr Fergus McCarthy	Consultant Obstetrician, Gynaecologist, Senior Lecturer and Maternal-Fetal Medicine Sub-specialist	Cork University Maternity Maternity unit, University College Cork
Dr Mairead Butler	Consultant Obstetrician and Gynaecologist	University Maternity unit Waterford
Prof. Declan Keane	Professor of Obstetrics and Gynaecology	National Maternity Maternity unit Dublin, Royal College of Surgeons in Ireland
Dr Katherine Astbury	Consultant Obstetrician and Gynaecologist Gynaecology Oncology Sub-specialist	University Maternity unit Galway
Dr Cathy Monteith	Consultant Obstetrician and Gynaecologist	Our Lady of Lourdes Hospital Drogheda
Dr Sarah Petch	Specialist Registrar, Obstetrics and Gynaecology	National Maternity Maternity unit Dublin
Dr Orla Donohoe	Specialist Registrar, Obstetrics and Gynaecology	Sligo University Maternity unit
Dr Aisling McDonnell	Specialist Registrar, Obstetrics and Gynaecology	Mater Misericordiae University Hospital Dublin
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 Maternity unit 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 Maternity unit

Attendee	Profession	Location (2021)
Ms Janet Murphy	Advanced Midwifery Practitioner	University Maternity unit Waterford
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 Maternity unit Dublin Royal College of Surgeons in Ireland
Ms Marie Finn	Medical Social Work Counsellor	Saolta University Health Care Group
Ms Marie Culliton	Scientific Lead	National Clinical Programme for Pathology
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 Maternity unit University College Cork
Dr Richard Duffy	Consultant Perinatal Psychiatrist	Rotunda Maternity unit Dublin
Ms Áine Kelly	Physiotherapy Manager	Coombe Women & Infants University Hospital, Dublin
Ms Sinéad Curran	Dietician Manager	National Maternity Maternity unit
Dr Nicholas Barrett	Lead for Obstetric Anaesthesiology services	Limerick University Maternity unit
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist	Cork University Maternity unit
Dr Niamh Conlon	Consultant Histopathologist	Cork University Maternity unit
Ms Georgina Cruise	National Manager	Patient Advocacy Service

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3:
Patient Information Leaflet (PIL)

My Baby's Movements

Feeling your baby move is a sign that they are well. When babies are unwell, they sometimes slow down their movements. This is to save energy. Call your maternity unit/hospital immediately if you have any concerns about your baby's movements and tell them you are coming in now for a check-up.

How often should my baby move?

You should start to feel your baby move around 16 to 20 weeks of pregnancy. A baby's movements can be described as anything from a kick, flutter, swish, or roll.

There's no set number of movements you should feel each day – every baby is different. Babies move all day with movements usually increasing in the evening. It's important to get to know what's normal for your baby (this is your baby's pattern of movement).

Babies do not run out of room or slow down towards the end of pregnancy.

Why are my baby's movements important?

No movement, less movement or kicks, weaker movements or kicks, or an unusual rapid increase in movement can be an early sign and sometimes the only warning sign that your baby needs to be checked at hospital. Most women who had a stillbirth noticed their baby's movements had changed. If your baby is unwell, there is a chance to save their life, if reported promptly.

Trust your gut instincts.

What should I do if my baby's movements stop, slow down, or are weaker?

Call and go to your maternity unit/hospital immediately if you notice any changes or feel concerned. You are not wasting their time. Don't wait until the next day, especially if you notice a change in movements in the evening. Don't wait until your next appointment.

What happens when I come into the maternity unit/hospital?

When you come in for a check-up (staff are available 24 hours, 7 days a week) investigations may include:

- Checking and monitoring your baby's heartbeat
- Ultrasound scan to measure your baby's growth and wellbeing
- Urine and blood tests

In most cases, the results will show that your baby is fine, and you will go home. If the results show that your baby needs extra monitoring, you will be admitted.

Do not leave until you are happy with your baby's movements. Do not go home if you are not feeling reassured or have any concerns. You know your baby best.

Common questions

Can I make my baby move?

No. Call and go to your maternity unit/hospital immediately. Do not delay getting checked by drinking cold water or eating something sugary to get your baby moving.

Can I use a home Doppler to check my baby's heartbeat?

No. Call and go to your maternity unit/hospital immediately. Do not use handheld monitors, Dopplers, or phone apps to check your baby's heartbeat. Even if you detect a heartbeat, this does not mean your baby is well.

What if I notice a change in my baby's movements again?

Call and go to your maternity unit/hospital immediately. You're always doing the right thing by getting your baby checked. Even if everything was fine last time, your baby must be checked again. Your baby might require additional monitoring, or you might be admitted.

Where can I get more information?

- https://m.youtube.com/watch?v=YQUHSXvGQ30
- https://www.tommys.org/pregnancy-information/pregnancy-symptom-checker/baby-fetal-movements

Appendix 4: **Risk Factors for Stillbirth**

Maternal	Fetal	Pregnancy related
Non-modifiable • Maternal age • Parity • Ethnicity • Socioeconomic background • Obstetric History • Medical History • Assisted reproduction	• Gestational age • Fetal growth restriction • Multiple gestation • Male sex • Congenital anomalies	• Gestational diabetes • Preeclampsia • Intrahepatic cholestasis of pregnancy
Modifiable • Antenatal care • BMI • Smoking • Substance use • Sleeping positions		

McDonnell A, Butler M, White J, Escañuela Sánchez T, Cullen S, Cotter R, Murphy M, O'Donoghue K. National Clinical Practice Guideline: Stillbirth: Prevention, Investigation, Management and Care. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023.

Appendix 5: **NWIHP/IOG CAG (2023-)**

Dr Cliona Murphy (Chair, 2023-). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Director, National Women and Infants Health Programme.

Dr Sam Coulter-Smith (2023-). Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Chair, Institute of Obstetricians and Gynaecologists.

Dr Venita Broderick (2024-). Clinical Lead Gynaecology, National Women and Infants Health Programme.

Dr Brian Cleary (2023-). Chief Pharmacist, Rotunda Hospital. Medications Lead, Maternal and Newborn Clinical Management System Project.

Angela Dunne (2023-). Director of Midwifery, National Women and Infants Health Programme.

Prof. Seán Daly (2023-). Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

Prof. Maeve Eogan (2023-). Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Clinical Lead, Sexual Assault Treatment Units, National Women and Infants Health Programme.

Prof. Richard Greene (2023-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, National Perinatal Epidemiology Centre, University College Cork.

Prof. John Higgins (2023-). Cork University Maternity Hospital, Consultant Obstetrician and Gynaecologist, Clinical Director, Ireland South Women and Infants Directorate.

Prof. Shane Higgins (2023-). Master, Consultant Obstetrician and Gynaecologist, National Maternity Hospital.

Dr Mendinaro Imcha (2023-). Clinical Director, Consultant Obstetrician and Gynaecologist, University Maternity Hospital Limerick.

Prof. John Murphy (2023-). Clinical Lead Neonatology, National Women and Infants Health Programme.

Dr Aoife Mullaly (2023-). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Lead, Termination of Pregnancy Services, National Women and Infants Health Programme.

Prof. John Morrison (2023-). Consultant Obstetrician and Gynaecologist, University Hospital Galway. Clinical Director, Saolta Maternity Directorate.

Kilian McGrane (2023-). Director, National Women and Infants Health Programme.

Dr Peter McKenna (2023-). Clinical Lead, Obstetric Event Support Team, National Women and Infants Health Programme.

Prof. Keelin O'Donoghue (2023-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Lead, National Guidelines, National Women and Infants Health Programme.

Dr Suzanne O'Sullivan (2023-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Director of Education and Training, Obstetrics and Gynaecology, Institute of Obstetricians and Gynaecologists.

Prof. Mike O'Connell (2023-). Master, Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital.

Dr Vicky O'Dwyer (2023-). Consultant Obstetrician and Director of Gynaecology, Rotunda Hospital.

Prof. Nóirín Russell (2023-). Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, Cervical Check.

Dr Carmen Regan (April 2024). Clinical Lead Obstetrics, National Women and Infants Health Programme.

Dr Orla Shiel (2024-). Consultant Obstetrician and Gynaecologist, National Maternity Hospital

Ms Clare Thompson (2023-). Consultant Gynaecological Oncologist, The Mater, Dublin.

Prof. Mary Wingfield (2024-). Clinical Lead Fertility, National Women and Infants Health Programme.

Appendix 6: **Grades of Recommendations**[19]

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….
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…

19 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. https://pubmed.ncbi.nlm.nih.gov/23978245/

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
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…
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…

Grade of recommendation	Clarity of risk/ benefit	Quality of supporting evidence	Implications	Suggested Language
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 7: **AGREE II Checklist**[20]

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	

20 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 8: **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/