National Women & Infants Health Programme

National Clinical Practice Guideline

Induction of Labour

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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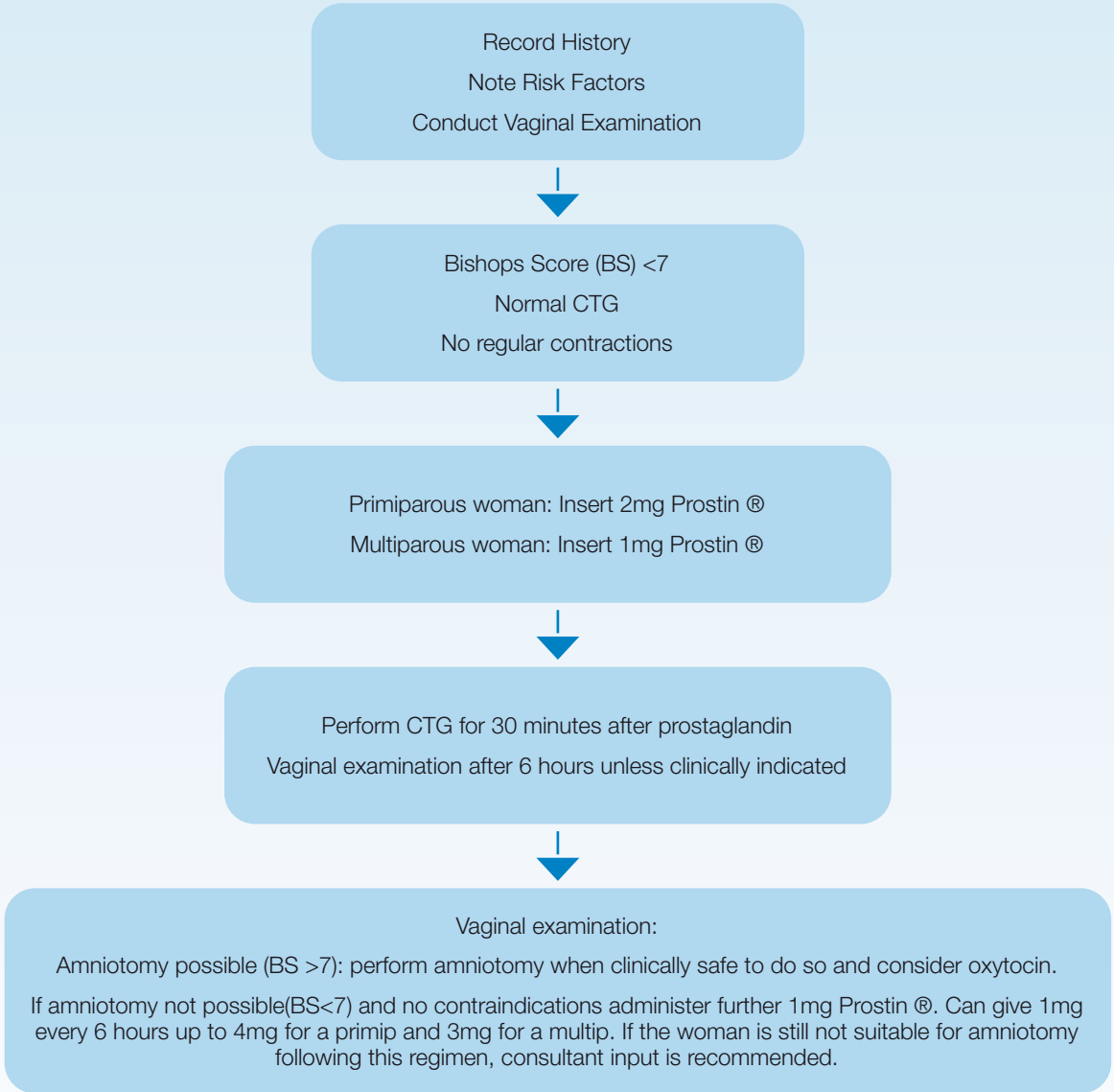

Key: CTG = Cardiotocograph
BS = Bishops score

Algorithm 2: Induction of labour pathway for women with intact membranes using Propess® 10mg vaginal delivery system

Key: CTG = Cardiotocograph
BS = Bishops score

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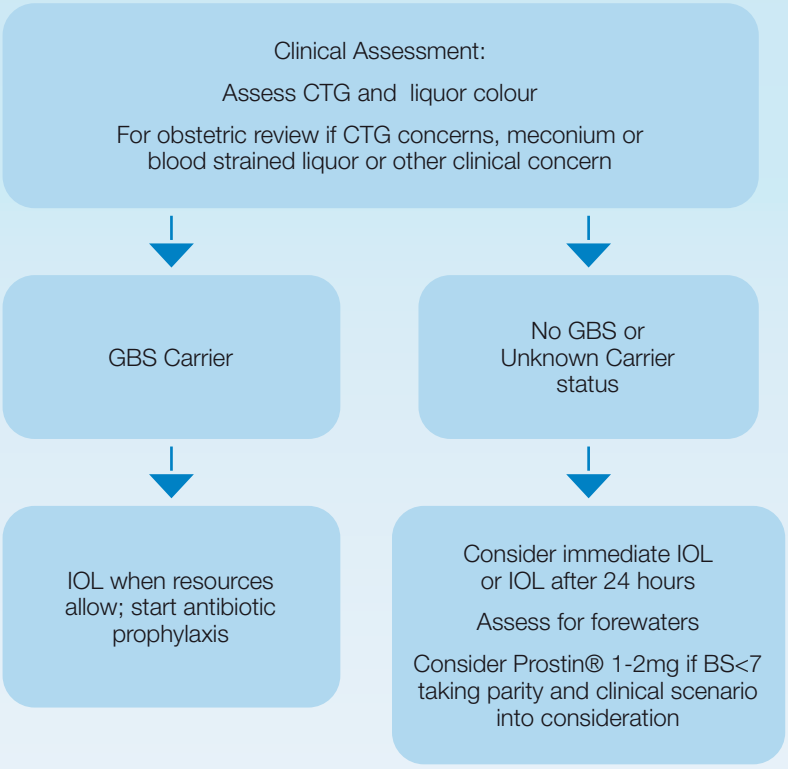
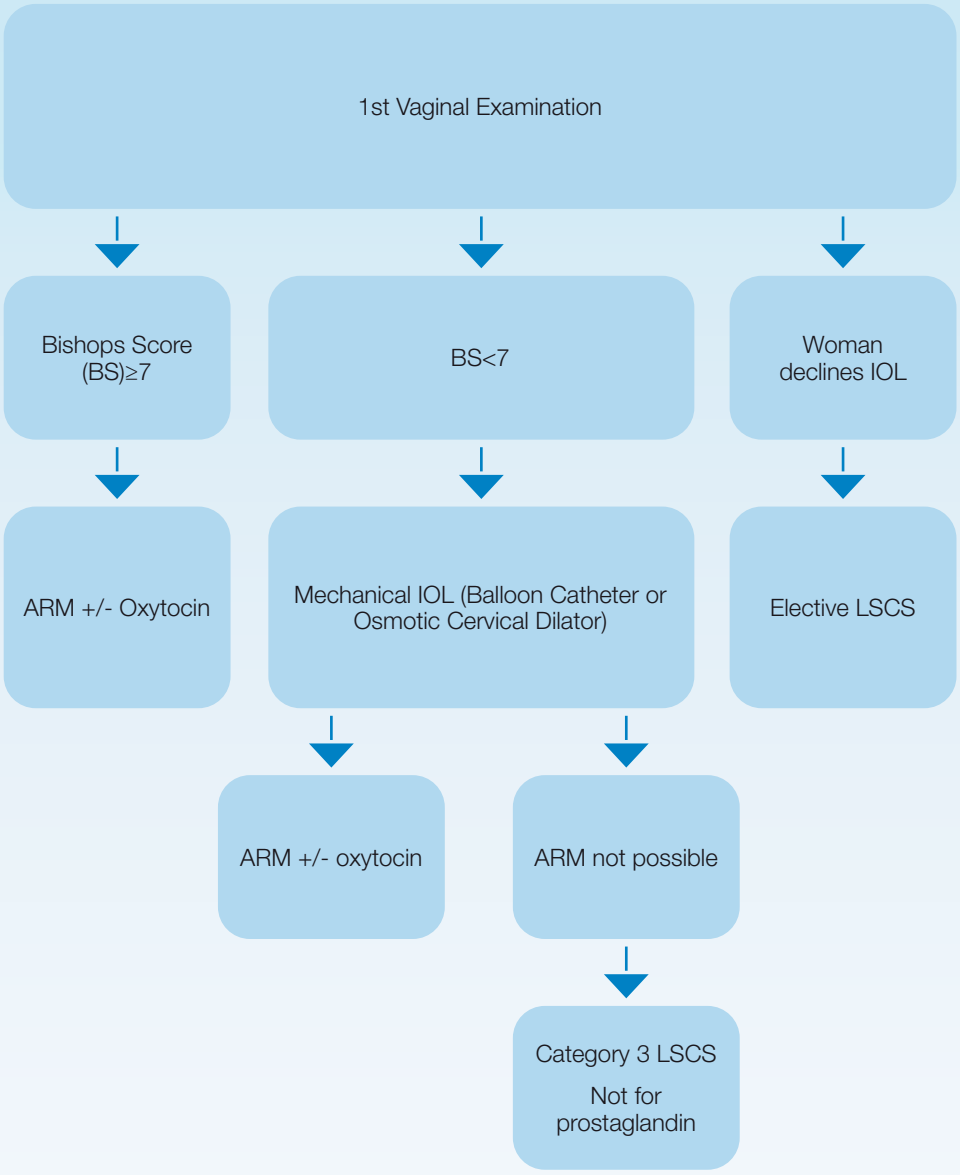


Key: CTG = Cardiotocograph
GBS = Group B Streptococcus
IOL = Induction of Labour
ARM = Artificial Rupture of Membranes

Algorithm 4: Induction of labour pathway for women with one previous lower segment Caesarean section



Key: BS= Bishops Score
IOL=Induction of Labour
LSCS=Lower Segment Caesarean Section
ARM= Artificial Rupture of Membrane

Key Recommendations

Indications for Induction of Labour

1. We recommend women with uncomplicated pregnancies should be offered induction of labour (IOL) at 41+0 weeks. A full discussion with the woman should occur and include discussion of the benefits and risks of induction. The benefits, risks and alternative monitoring options must be accurately presented using a shared decision-making approach so that women and their partners, families and carers can understand the likely or potential outcomes of induction, taking into account their individual circumstances and preferences. (Level 2A)
2. We recommend that women who decide not to have their labour induced at 41+0 weeks for the prevention of prolonged pregnancy should meet with a senior clinician (Midwife or Obstetrician) where an individualised management plan can be made and documented in the maternity notes. This plan may include Caesarean birth or expectant management and/or commencing induction at a date agreeable to the woman. We recommend that an ultrasound estimation of amniotic fluid single deepest pool depth be undertaken at this visit at 41+0 weeks. (Best Practice)
3. We recommend that all pregnant women (Supported, Assisted and Specialised care pathways) meet with a Consultant Obstetrician at 42+0 weeks or as close as practically possible where an individualised management plan can be made and documented in the maternity notes. This discussion should include options from this point and should outline the increased and unpredictable risk of stillbirth. Ideally for women planning a Homebirth they should meet the Consultant Obstetrician linked to the HSE home birth services, or their nominated deputy in their absence. (Best Practice)
4. Increased fetal monitoring in the form of twice weekly cardiotocographs and twice weekly ultrasound estimations of amniotic fluid single deepest pool depths should be offered from 42+0 weeks until the baby is born. (Best Practice)
5. We recommend that women who decide not to have an induction are advised to contact their maternity provider by telephone or other means if they change their mind or if they have any concerns regarding fetal wellbeing e.g. reduced fetal movements. Women should be provided with verbal and written information on what to monitor for and when to seek urgent assistance and should have a clear point of contact with the maternity hospital/unit. (Best Practice)
6. Each maternity hospital/unit should create a designated pathway for women who change their mind regarding their induction or want to have an additional conversation before the next appointment. (Best Practice)
7. Women with pre-labour rupture of membranes at term (at or over 37 weeks), who do not have known Group-B Streptococcus (GBS) colonisation, should be offered either expectant management for up to 24 hours, or immediate IOL. We recommend a shared decision-making approach between the woman and her care provider. (Level 1C)
8. We recommend that women with pre-labour rupture of membranes who are known GBS carriers should be offered prompt intrapartum antibiotic prophylaxis and IOL as soon as reasonably possible. (Level 1A)

9. We suggest that in the setting of pre-labour rupture of membranes and an unfavourable cervix (Bishops Score <7) labour can either be induced in the first instance with an oxytocin infusion or with a single 1 to 2mg dose of Prostin® gel placed into the posterior fornix, using a shared decision-making approach between the woman and her clinician. (Level 2B)
10. We recommend that, in the setting of pre-labour rupture of membranes, a vaginal examination should be performed to confirm the forewaters are absent or an amniotomy should be performed if forewaters are still present before commencing an oxytocin infusion. (Best practice)
11. We recommend the decision for IOL and for commencing oxytocin on a woman with a previous Caesarean birth should be made by a Consultant Obstetrician in consultation with the woman and clearly documented in the maternity notes, alongside relevant risks and accounting for the woman's preferences. (Best practice)
12. We recommend that the increased risk of uterine rupture associated with any induction of labour and the potential decreased possibility of achieving a vaginal birth after Caesarean section (VBAC) should be considered and discussed with the woman. (Level 1C)
13. We recommend that IOL in women who have had uterine surgery, such as myomectomy or uterine perforation, should be discussed with a Consultant Obstetrician. Operation notes from the procedure previously undertaken should be reviewed, where possible. (Best practice)
14. Induction of labour in a woman with a previous single Caesarean birth may be undertaken with amniotomy, balloon catheter or with the Dilapan-S® cervical dilator. We recommend that a review of women aiming for vaginal birth after Caesarean section (VBAC) should be undertaken prior to 41+0 weeks to assess the cervix and reconsider the options. (Best Practice)
15. Prostaglandins for planned VBAC are not recommended as they significantly increase the risk of uterine rupture. (Level 1C)
16. It is reasonable to offer induction of labour at 39+0-40+0 weeks' gestation for women aged 40 and above. Benefits and risks of IOL should be discussed with the woman, taking into account her individual circumstances and preferences. (Level 2C)
17. In the setting of suspected fetal macrosomia in the absence of gestational diabetes mellitus, women should be provided with information about the benefits and risks of expectant management versus IOL so they can make an informed decision. (Level 2B)
18. Requests for IOL from 39 weeks should be considered, after discussing the benefits and risks with the woman, and taking into account the woman's circumstances and preferences as well as the maternity hospital/unit's resources and established care pathways. (Level 2B)
19. Induction of labour for maternal request is not recommended prior to 39 weeks due to the increased risk of maternal and neonatal morbidity. (Level 2B)
20. There is insufficient evidence to recommend IOL at 39 weeks in normal risk pregnancies for the prevention of stillbirth. (Level 2C)
21. Women with a history of precipitous labour should not routinely be induced in order to avoid a birth unattended by healthcare professionals. However, should a woman request IOL, each case should be considered individually with a review by their healthcare provider taking into account the woman's individual preferences and circumstances (including distance from maternity hospital/unit) using a shared decision-making approach. (Best Practice)

Birth Experience

22. Communicating the indication, intended benefits, possible risks, and methods available for IOL allows informed decisions, and women should be supported in their choice. (Level 2B)
23. The use of non-pharmacological pain management such as breathing techniques, massage, hydrotherapy and one-to-one support should be optimised as well as pharmacological pain relief (e.g. IM pethidine or epidural anaesthesia) as required. (Level 1C)
24. Continuous emotional support during labour should be facilitated, this includes one to one midwifery care. (Level 1B)

Methods of Induction of Labour

25. We recommend membrane sweeping should be offered from 39 weeks. (Level 2A)
26. We recommend that abdominal palpation, including a measurement of the symphysial fundal height (SFH), assessment of the lie and presentation of the baby and auscultation of the fetal heart should be performed prior to carrying out a membrane sweep. (Best practice)
27. Informed consent should always be obtained prior to carrying out a membrane sweep. (Best practice)
28. We recommend that prior to membrane sweeping and IOL, the fetal anatomy ultrasound scan report and the most recent ultrasound scan should be reviewed to ensure the placenta is not low lying. (Best practice)
29. We recommend membrane sweeping and IOL should be performed by a suitably trained healthcare professional. (Best practice)
30. Healthcare professionals should be aware of the contraindications and precautions to using all methods of IOL. (Best practice)
31. We recommend the use of prostaglandins, oral misoprostol or mechanical methods of induction of labour as safe and effective induction agents. (Level 2A)
32. Amniotomy alone followed by oxytocin infusion can be considered for a woman with a favourable cervix (Bishop's Score of 7 or more) (Level 2C). It is reasonable to commence an intravenous oxytocin infusion soon after amniotomy in order to establish labour. (Level 2B)
33. Women should have one to one midwifery care and continuous fetal monitoring via cardiotocography while receiving an oxytocin infusion. (Level 1C)

Setting of Induction of Labour

34. Women with a high-risk pregnancy undergoing IOL should be part of the handover process to the incoming obstetric and midwifery teams (including the Consultant Obstetrician on call and the Assistant Director of Midwifery) at clinical handover times. (Best Practice)
35. Outpatient induction of labour should be considered in women who wish to return home, have no co-existing medical conditions or obstetric complications, have good social support and have good accessibility to the maternity hospital/unit. (Grade 1C)
36. Safety and support procedures should be in place for an outpatient IOL. Women should receive written information detailing the maternity hospital/unit's contact details, red flag symptoms and instructions on when to return to the maternity hospital/unit for review. Staff should confirm that women have access to a telephone, transport to the maternity hospital/unit and that there is a support person at home. (Best Practice)

37. We recommend that women are asked to contact their Midwife, maternity hospital/unit or Obstetrician:
    a. when no contractions within an agreed timeframe, depending on IOL method used
    b. when contractions begin
    c. if her membranes rupture
    d. if she develops bleeding
    e. if she has any other concerns, such as reduced or altered fetal movements, excessive pain, side effects or loss of the pessary/mechanical induction agent. (Best Practice)

Complications of Induction of Labour

38. We recommend that when labour has not started after one cycle of IOL treatment, the full clinical picture should be reassessed and discussed with a senior clinician, taking into account the individual clinical scenario, the original indication for IOL, maternal and fetal wellbeing, and the woman's preferences. (Best practice)
39. A second dose of Propess®, immediately after the first dose, is not recommended as the effects have not been studied. (Level 2C)
40. Additional doses of Prostin® gel (1mg) can be administered when Propess® has been unsuccessful. (Best Practice)
41. After a period of 24-hour rest, a full cycle of Dinoprostone (Propess® or Prostin®) can be restarted from the beginning. (Best Practice)
42. Both prostaglandins and mechanical methods of induction of labour are as effective as each other in induction of labour. They can be considered in sequence if one method has been unsuccessful in rendering the cervix suitable for amniotomy. (Best Practice)
43. It is reasonable to offer Caesarean birth when induction has been unsuccessful at starting labour. (Best Practice)
44. In the event of hyperstimulation, any form of ongoing induction agent in situ should be removed such as Propess®, osmotic dilators or balloon catheter. (Best practice)
45. In the event of hyperstimulation consider tocolysis with betamimetics. The preferred drug of choice is terbutaline 250 micrograms injection administered subcutaneously. (Level 2C)
46. In the setting of hyperstimulation we recommend expediting birth of the baby if the CTG is pathological, despite tocolysis. (Best practice)
47. We advise against the administration of tocolysis to a woman who is bleeding at the time of uterine hyperstimulation. (Best practice)
48. Before IOL is started, we recommend assessing the engagement of the presenting part, and ruling out umbilical cord presentation on vaginal examination to reduce the likelihood of a cord prolapse. (Best practice)
49. We recommend that women with a previous Caesarean birth should have antenatal counselling regarding decision for mode of birth. This process needs to be clearly documented in the notes. (Best practice)

50. We recommend that women who are planning a VBAC should be cared for in a setting where continuous electronic fetal heart rate monitoring, one to one midwifery care and the other resources for emergency Caesarean birth are available. (Best practice)
51. Continuous CTG (using oxytocin, at the onset of contractions, at the diagnosis of labour) is recommended for women who are planning a VBAC as abnormal fetal heart rate patterns are the most consistent finding in uterine rupture. (Level 1C)
52. There is no role for attempted induction of labour for women with a previous classical Caesarean section. (Level 1B)
53. We recommend mechanical methods of IOL over pharmacological methods in a woman with a previous Caesarean birth. (Level 1C)

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 indications, methods, and complications of induction of labour (IOL).

1.2 Scope

Target Users

The Guideline is a resource for all clinicians working in maternity care. This includes healthcare staff, students, Doctors, Advanced Midwife Practitioners[2], Midwives, Nurses, health and social care professionals involved in the care of pregnant women.

Target Population

Pregnant women and their partners, families, and carers.

1.3 Objective

To provide evidence based recommendations for the care of women undergoing IOL, including methods, risks and criteria, as well as promoting a standardised approach nationally across all maternity hospital/ units.

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 Guideline Programme Process.

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

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

The following were involved in the development of this Guideline:

1. Jill Mitchell (Specialist Registrar)
2. Ciara Nolan (Specialist Registrar)
3. Mohamed El Shaikh (Registrar)
4. Sandra Cullinane (Assistant Director of Midwifery)
5. Daniel Borlase (Consultant Obstetrician and Gynaecologist)

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 Expert Advisory Group has representatives from a broad range of professional backgrounds. It includes representatives from Patient Advocacy Ireland and the Irish Neonatal Health Alliance. Also included in the membership are professionals from the areas of neonatology, obstetrics and midwifery.

The Guideline Development Group is grateful to Dr Cliona Murphy (Clinical Director, National Women and Infants Health Programme), Ms Angela Dunne (Midwifery lead, National Women and Infants Health Programme), Ms Clare Kennedy (Project Co-Ordinator for HSE Baby Friendly Initiative, National Women and Infants Health Programme), Prof Keelin O'Donoghue (Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital) and Prof Maeve Eogan (Consultant Obstetrician and Gynaecologist, Rotunda Hospital) for their review and feedback on this Guideline.

1.6 Disclosure of interest

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]

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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

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

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

1.7 Disclaimer

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

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

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

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

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

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

5 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

1.8 Use of language

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

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

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

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

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

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

Chapter 2:
Clinical Practice Guideline

Background

Induction of labour (IOL) is a medical intervention aimed at initiating or augmenting uterine contractions and cervical ripening in order to facilitate birth of a fetus[1].

Induction of labour (IOL) is a frequently undertaken intervention and is recommended when giving birth confers a benefit to the woman or her baby/babies, greater than if the pregnancy were to continue[1-3]. However, many women subscribe to different philosophies, ideologies and understanding about their pregnancy and its management, so it is important that healthcare professionals adopt an individualised and women centred approach when considering IOL [2, 4-6].

The importance of respecting women's autonomy in childbirth has long been understood and includes encouraging women to participate in their health care decisions[4-7]. The information that women receive about the IOL process can have a significant impact on the decisions they make. Supporting women and their partners to be involved in the decision making may facilitate autonomy and control of labour which will impact on their overall experience of the procedure[4, 7].

IOL can be a challenging experience for women[4]. It is important that they receive clear, concise, unbiased, appropriately timed individualised information about the procedure[2, 4]. This will allow women and their partners the opportunity to make the appropriate decision regarding the IOL process.

The information women receive should outline the indication, intended benefits, possible risks, and methods of IOL available[2, 4, 8, 9].

- Women should be informed that IOL is a medical intervention that may affect their birth options and their experience.
- They should be aware that it will impact on their place of birth and may affect the duration of their hospital stay.
- It may impact on the need for pain relief as induced labour may be more painful than spontaneous labour.
- It results in an increased number of vaginal examinations, as this is required to assess the cervix and monitor progress.
- It results in an increased level of fetal monitoring.
- Inducing labour can allow planning for both the mother and the healthcare team. It may facilitate scheduling of hospital resources and support, which can be particularly helpful in situations where logistical factors need to be considered.
- Induction of labour can accommodate the preferences of the pregnant woman. If a woman prefers to have a planned birth or wants to avoid going past her due date, induction can provide the opportunity to align with her preferences and create a personalised birth plan.
- Inducing labour in post-dates pregnancies (41 weeks) can help reduce the risk of stillbirth.

When receiving this information, women and their partners should be allowed ample time to discuss the procedure which should be supported with written information[2, 4].

Particular care should be taken to ensure that women who do not speak English as a first language understand any information given to them regarding induction of labour.

Relevant recommendations can also be found in:

- National Clinical Practice Guideline: Stillbirth: Prevention, Investigation, Management and Care [10]
- National Clinical Practice Guideline: Prevention of Early Onset Group B Streptococcal Disease in Term Infants [11]
- National Clinical Practice Guideline: Vaginal Birth After Caesarean Section[12]
- National Clinical Guideline for Intrapartum Fetal Heart Rate Monitoring [13]
- National Clinical Practice Guideline: Reduced Fetal Movements[14]

Section 1: Clinical Indications For Induction Of Labour

Introduction

In this section, we will discuss the clinical indications for IOL. These include prolonged pregnancy, term pre-labour rupture of membranes, previous lower segment Caesarean section and/or previous uterine surgery, advanced maternal age, large-for-gestational age and maternal request.

This guideline will not address IOL for small for gestational age/growth restricted fetuses, preterm pre-labour rupture of membranes, twin pregnancies, cases of stillbirth or maternal medical conditions, as these are beyond the scope of this guideline. A non-exhaustive list of medical complications of pregnancy which may require IOL include gestational hypertensive diseases, gestational and pre-existing diabetes mellitus and intrahepatic cholestasis of pregnancy. It is anticipated these topics will be covered in upcoming/future national clinical guidelines.

Shared decision making and autonomy in childbirth represent integral dimensions of a quality modern health service. The benefits, risks and alternative treatment options must be accurately presented so that women and their partners, families and carers can understand the likely or potential outcomes of treatment taking into account their individual circumstances and preferences[10].

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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. January 2023

11 Dakin A., Loughlin L., Ferguson W., Babu S., Power L., Dempsey G., Meehan M., Knowles S., Drew R., Eogan M., National Clinical Practice Guideline: Prevention of Early Onset Group B Streptococcal Disease in Term Infants. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023.

12 Ryan G, Duggan J, Finnegan C, Morrison JJ. National Clinical Practice Guideline: Vaginal Birth After Caesarean Section. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023

13 Fetal Heart Rate Monitoring Working Group, National Women and Infants Health Programme, HSE. National Clinical Guideline for Fetal Heart Rate Monitoring: Ireland. Dublin: Health Service Executive. 2019.

14 Kalisse T, Farrell AM, Verling AM, Rutherford E, Ravinder M, Khalid A, O'Donoghue K. National Clinical Practice Guideline: Reduced Fetal Movements. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. 2023

The relevant national clinical guidelines should be consulted for further information on timing of IOL in specific maternal or fetal situations. [15,16]

Clinical Question 2.1: When is induction of labour indicated for prolonged pregnancy?

Evidence Statement

A Cochrane review compared maternal and neonatal outcomes of IOL at or beyond term compared with a policy of awaiting spontaneous labour (or until planned birth is deemed necessary) [11]. This review included 34 RCTs (reporting on over 21,000 women and infants). The trials compared a policy to induce labour usually after 41 completed weeks of gestation with waiting for labour to start and/or waiting for a period before inducing labour.

Compared with a policy of expectant management, a policy of labour induction was associated with fewer perinatal deaths (risk ratio (RR) 0.31, 95% confidence interval (CI) 0.15 to 0.64; 22 trials, 18,795 infants; high-certainty evidence). There were four perinatal deaths in the labour induction policy group compared with 25 perinatal deaths in the expectant management group. The number needed to treat in order to prevent one perinatal death, was 544 (95% CI 441 to 1042). There were fewer stillbirths in the IOL group (RR 0.30, 95% CI 0.12 to 0.75; 22 trials, 18,795 infants; high-certainty evidence); two in the induction policy group and 16 in the expectant management group.

There were fewer Caesarean sections in the induction policy group compared with expectant management (RR 0.90, 95% CI 0.85 to 0.95; 31 trials, 21,030 women; moderate-certainty evidence); and no difference in operative vaginal births with induction (RR 1.03, 95% CI 0.96 to 1.10; 22 trials, 18,584 women; moderate-certainty evidence). There was no significant differences in perineal trauma (severe perineal tear: RR 1.04, 95% CI 0.85 to 1.26; 5 trials; 11,589 women; low-certainty evidence), postpartum haemorrhage (RR 1.02, 95% CI 0.91 to 1.15, 9 trials; 12,609 women; moderate-certainty evidence), or breastfeeding at discharge (RR 1.00, 95% CI 0.96 to 1.04; 2 trials, 7487 women; moderate-certainty evidence).

Rates of neonatal intensive care unit (NICU) admission were lower (RR 0.88, 95% CI 0.80 to 0.96; 17 trials, 17,826 infants; high-certainty evidence), and fewer babies had Apgar scores less than seven at five minutes in the induction groups compared with expectant management (RR 0.73, 95% CI 0.56 to 0.96; 20 trials, 18,345 infants; moderate-certainty evidence). There was no difference in rates of neonatal encephalopathy (RR 0.69, 95% CI 0.37 to 1.31; 2 trials, 8851 infants; low-certainty evidence) or neonatal trauma (RR 0.97, 95% CI 0.63 to 1.49; 5 trials, 13,106 infants; moderate-certainty evidence) between the induction and expectant management groups.

In subgroup analyses, no differences were seen for timing of induction (< 40 versus 40-41 versus ≥ 41+0 weeks' gestation), by parity (primiparous versus multiparous) or state of cervix for any of the main outcomes (perinatal death, stillbirth, NICU admission, Caesarean section, operative vaginal birth, or perineal trauma).

15 https://www.hse.ie/eng/about/who/acute-maternity units-division/woman-infants/clinical-guidelines/

16 https://www.rcpi.ie/Faculties-Institutes/Institute-of-Obstetricians-and-Gynaecologists/National-Clinical-Guidelines-in-Obstetrics-and-Gynaecology

A large, multi-centred RCT (n= 2762 women) not included in the Cohcrane review compared induction of labour at 41+0 weeks with expectant management and induction of labour at 42 weeks in terms of perinatal outcome in healthy women with a normal risk pregnancy. This trial found that IOL after 41+0 weeks was associated with a lower perinatal mortality rate[12]. No perinatal deaths occurred in the induction group but six (five stillbirths and one early neonatal death) occurred in the expectant management group (P=0.03). The number needed to treat with IOL at 41+0 weeks to prevent one perinatal death was 230. There was no significant difference in the primary composite adverse perinatal outcome (2.4% in the induction group and 2.2% in the expectant management group, RR 1.06, 95% confidence interval 0.65 to 1.73, P=0.90). Adverse perinatal outcome was defined as one or more of several outcomes: Apgar score less than 7 at five minutes, pH less than 7.00 or metabolic acidosis (pH <7.05 and base deficit >12 mmol/L) in the umbilical artery, hypoxic ischaemic encephalopathy grades 1-3, intracranial haemorrhage, convulsions, meconium aspiration syndrome, mechanical ventilation within 72 hours, or obstetric brachial plexus injury.

Similarly, another RCT comparing IOL at 41+0 weeks with expectant management until 42 weeks found that IOL was associated with reduced adverse perinatal outcomes (1.7% vs 3.1%, absolute risk difference, -1.4%, 95% CI -2.9 to 0.0), however, this study was underpowered to demonstrate superiority of IOL at 41+0 weeks. [13]

Most women will labour spontaneously by 42 weeks (see Table 1).

Table 1. Gestational age at which labour started, as a proportion of labours which started spontaneously

Gestational age (weeks)	Proportion of spontaneous labours that started at this gestational age	Cumulative proportion of spontaneous labours that started by this gestational age
31 weeks and under	2.4%	2.4%
32+0 to 36+6 weeks	5.3%	7.7%
37+0 to 37+6 weeks	5.1%	12.8%
38+0 to 38+6 weeks	12.1%	24.9%
39+0 to 39+6 weeks	25.4%	50.3%
40+0 to 40+6 weeks	32.5%	82.8%
41+0 to 41+6 weeks	16.2%	99.0%
42+0 weeks and over	0.9%	100%

Data from NHS Maternity unit/hospital Episode Statistics/Maternity Services Data set 2019-20[14].

Clinical Practice

Women with uncomplicated pregnancies should be offered induction at 41+0 weeks. The timing should consider the woman's preferences and local circumstances. This is in keeping with the Inducing Labour, NICE Guideline [2].

Women should be advised that most will labour spontaneously by 42 weeks.

Recommendations

1. **We recommend women with uncomplicated pregnancies should be offered induction of labour (IOL) at 41+0 weeks. A full discussion with the woman should occur and include discussion of the benefits and risks of induction. The benefits, risks and alternative monitoring options must be accurately presented using a shared decision-making approach so that women and their partners, families and carers can understand the likely or potential outcomes of induction, taking into account their individual circumstances and preferences.**

Clinical Question 2.2: How should a woman who has not given birth at 41+0 weeks be monitored?

Evidence Statement

The NICE Guideline on Inducing Labour recommends offering women twice weekly cardiotocographs (CTGs) and ultrasound estimations of maximum amniotic pool depths from 42+0 weeks if a woman declines postdates IOL [2]. NICE recommends advising women that monitoring only informs about the current situation and cannot reliably predict any changes after monitoring ends.

The SAFE trial found that measuring amniotic fluid index (AFI) rather the single deepest pocket (SDP) technique resulted in increased rates of diagnosis of oligohydramnios (9.8% (n = 49) vs 2.2% (n = 11); RR, 4.51 (95% CI, 2.2-8.57); P < 0.01) and labour induction for oligohydramnios (12.7% (n = 33) vs 3.6% (n = 10); RR, 3.50 (95% CI, 1.76-6.96); P<0.01) without improving perinatal outcome compared to single deepest pocket (SDP) technique for estimating amniotic fluid volume [15]. NICU admission rates were similar between groups (4.2% (n = 21) vs 5.0% (n = 25); relative risk (RR), 0.85 (95% CI, 0.48-1.50); P=0.57). This is congruent with the results of a Cochrane review which included five trials (3226 women)[16]. It compared AFI to SDP and found no difference in adverse perinatal outcomes, including NICU admission (RR 1.04; 95% CI 0.85 to 1.26); an umbilical artery pH of less than 7.1; the presence of meconium; an Apgar score of less than 7 at five minutes; or Caesarean birth. When the AFI was used, significantly more cases of oligohydramnios were diagnosed (RR 2.39, 95% CI 1.73 to 3.28), and more women had IOLs (RR 1.92; 95% CI 1.50 to 2.46) and Caesarean sections for fetal distress (RR 1.46; 95% CI 1.08 to 1.96).

Clinical Practice

Where women have not given birth at 41+0 weeks, this should be discussed with a senior clinician (senior Midwife or Obstetrician), where an individualised management plan can be made and documented in the maternity notes.

This plan may include the option of Caesarean birth at this point, or expectant management for a period of time. We recommend that an ultrasound estimation of amniotic fluid single deepest pool depth be undertaken at this visit at 41+0 weeks, as this will inform the consultation and may inform decision-making around fetal wellbeing.

Women (all women, whether on Supported, Assisted or Specialised care pathways) should meet with a Consultant Obstetrician at 42+0 weeks where an individualised management plan can be made and documented in the maternity notes. This discussion should include options from this point (including Caesarean birth and/or expectant management) and should outline the increased risk of stillbirth. Ideally the Consultant Obstetrician involved in this discussion would be linked to the home birth services or be their nominated deputy in their absence. Women planning a Homebirth should meet the Consultant Obstetrician linked to the HSE home birth services, or their nominated deputy in their absence.

Management should be overseen by a Consultant Obstetrician if the pregnancy exceeds the gestation of 42+0 weeks.

Women who decide to not have their labour induced at any stage should contact their maternity provider if they change their mind or if they have any concerns regarding fetal wellbeing e.g. reduced fetal movements.

Women should be provided with verbal and written information on what to monitor for in terms of their own wellbeing as well as fetal wellbeing and when to seek urgent assistance and should have a clear point of contact with the maternity hospital/unit.

Increased fetal monitoring should be offered from 42+0 weeks. This includes ultrasound estimation of amniotic fluid and cardiotocography.

Women should be advised that:

- monitoring only gives a snapshot of the current situation, and cannot reliably predict any changes after monitoring ends, but provides information on how their baby is at the moment and so may help them make a decision on options for birth
- adverse effects on the baby (including stillbirth), and when these events might happen, cannot be predicted reliably or prevented even with monitoring
- fetal monitoring might consist of twice-weekly cardiotocography and ultrasound estimation of single deepest pool depth until the woman is delivered[2].
- The Chamberlain classification of amniotic fluid is a widely accepted method used to define oligohydramnios. This uses a single deepest pocket depth smaller than 2 cm in depth x 1 cm wide; however, we recommend checking local protocols where they are defined [17].
- The recommendation to induce labour at 41+0 weeks may increase the number of women who undergo induction. The recommendations on monitoring may also increase the number of women who chose not to undergo induction and then choose to have additional monitoring. Both of these factors may increase resource use in maternity hospital/units.

Recommendations

2. We recommend that women who decide not to have their labour induced at 41+0 weeks for the prevention of prolonged pregnancy should meet with a senior clinician (Midwife or Obstetrician) where an individualised management plan can be made and documented in the maternity notes. This plan may include Caesarean birth or expectant management and/or commencing induction at a date agreeable to the woman. We recommend that an ultrasound estimation of amniotic fluid single deepest pocket depth be undertaken at this visit at 41+0 weeks.
3. We recommend that all pregnant women (Supported, Assisted and Specialised care pathways) meet with a Consultant Obstetrician at 42+0 weeks or as close as practically possible where an individualised management plan can be made and documented in the maternity notes. This discussion should include options from this point and should outline the increased and unpredictable risk of stillbirth. Ideally for women planning a Homebirth they should meet the Consultant Obstetrician linked to the HSE home birth services, or their nominated deputy in their absence.
4. Increased fetal monitoring in the form of twice weekly cardiotocographs and twice weekly ultrasound estimations of amniotic fluid single deepest pool depths should be offered from 42+0 weeks until the baby is born.
5. We recommend that women who decide not to have an induction are advised to contact their maternity provider by telephone or other means if they change their mind or if they have any concerns regarding fetal wellbeing e.g. reduced fetal movements. Women should be provided with verbal and written information on what to monitor for and when to seek urgent assistance and should have a clear point of contact for the maternity hospital/unit.
6. Each maternity hospital/unit should create a designated pathway for women who change their mind regarding their induction or want to have an additional conversation before the next appointment.

Clinical Question 2.3: Should women be induced immediately following term pre-labour rupture of membranes or be managed expectantly?

Evidence Statement

A Cochrane review examined the maternal and fetal outcomes of immediate intervention or intervention within 24 hours of diagnosis of term prelabour rupture of membranes (PROM) versus expectant management (no planned intervention within 24 hours).

Twenty-three trials involving 8615 women and their babies were included in this review. Planned early birth (with induction methods such as oxytocin or prostaglandins) was found to reduce the risk of maternal infectious morbidity such as chorioamnionitis or endometritis (RR 0.49; 95% CI 0.33 to 0.72; eight trials, 6864 women), and their neonates were less likely to have definite or probable early-onset neonatal sepsis (RR 0.73; 95% CI 0.58 to 0.92; 16 trials, 7314 infants) compared with expectant management for PROM at 37 weeks' gestation or later, without an apparent increased risk of Caesarean section

(RR 0.84; 95% CI 0.69 to 1.04; 23 trials, 8576 women). Two included trials reported on measures of maternal satisfaction. Both trials found that women in the planned early birth group had more positive experiences compared with women in the expectant management group.

It should be noted that the evidence included in this review was regarded as low quality and that a subgroup analysis was not performed for maternal group B streptococcus (GBS) colonisation[18]. The Term PROM Study found that maternal GBS colonisation was an independent risk factor for neonatal infection in the setting of term pre-labour rupture of membranes[19].

Clinical Practice

Women with pre-labour rupture of membranes at term (at or over 37 weeks) who do not have known GBS colonisation should be offered either expectant management for up to 24 hours or immediate IOL. The healthcare provider should discuss the benefits and risks of these options with the woman and take into account her individual circumstances and preferences. This is in keeping with NICE clinical guidelines [NG207] and the RCOG green-top Guideline no. 36[2, 20]. Immediate IOL may help reduce maternal and neonatal infections without increasing Caesarean section rates.

Women who are known GBS carriers should be offered immediate intrapartum antibiotic prophylaxis and induction of labour as soon as reasonably possible[2, 20]. Each maternity hospital/unit should choose one of the suggested screening options as set out in the National Clinical Practice Guideline: Prevention of Early Onset Group B Streptococcal Disease in Term Infants.[17]

Recommendations

7. **Women with pre-labour rupture of membranes at term (at or over 37 weeks) who do not have known Group-B Streptococcus (GBS) colonisation, should be offered either expectant management for up to 24 hours, or immediate induction of labour. We recommend a shared decision-making approach between the woman and her care provider.**
8. **We recommend that women with pre-labour rupture of membranes who are known GBS carriers should be offered prompt intrapartum antibiotic prophylaxis and induction of labour as soon as reasonably possible.**

17 Dakin A., Loughlin L., Ferguson W., Babu S., Power L., Dempsey G., Meehan M., Knowles S., Drew R., Eogan M., National Clinical Practice Guideline: Prevention of Early Onset Group B Streptococcal Disease in Term Infants. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023.

Clinical Question 2.4: Is there a role for administering prostaglandins prior to oxytocin in the setting of pre-labour rupture of membranes?

Evidence Statement

The TERMPROM Study showed no difference in neonatal infection rates or Caesarean section rates with oxytocin versus prostaglandin for stimulation of labour. However, induction with oxytocin was associated with less risk of maternal pyrexia [21]. In view of this, oxytocin can be used as the primary method of induction after discussion with the woman and in accordance with her wishes.

A small single centre RCT (n=184) compared the fetal and maternal outcomes of vaginal prostaglandins versus oxytocin post term prelabour rupture of membranes[22]. They reported a statistically significant lower incidence of fetal heart rate abnormalities in the prostaglandin group, 4.4% versus 12.8%. There was no difference in epidural use, Caesarean section, maternal infection, admission to special care nursery or neonatal sepsis. Time to onset of labour was significantly longer in the prostaglandin group (25.7h versus 19.7h) but with no difference in the length of first stage. Maternal satisfaction was high in both groups.

Clinical Practice

In the setting of prelabour rupture of membranes with no indication to expedite birth, a vaginal examination is not required and should be limited.

A vaginal examination to assess Bishops score and rule out intact forewaters if the woman does not labour spontaneously after 24 hours should be offered. If the cervix is unfavourable (Bishops Score <7) then labour can either be induced in the first instance with an oxytocin infusion or with a single 1 to 2mg dose of Prostin® gel placed into the posterior fornix beforehand for multiparous or nulliparous women respectively. The woman's preferences and parity should be considered.

A vaginal examination should be performed 6 hours after administering Prostin® to confirm the forewaters are absent or to perform an amniotomy before transferring the woman to the labour ward/ birthing suite for an oxytocin infusion[23].

Recommendations

9. **We suggest that in the setting of pre-labour rupture of membranes and an unfavourable cervix (Bishops Score <7) labour can either be induced in the first instance with an oxytocin infusion or with a single 1 to 2mg dose of Prostin® gel placed into the posterior fornix using a shared decision-making approach between the woman and her clinician.**
10. **We recommend that, in the setting of pre-labour rupture of membranes a vaginal examination be performed to confirm the forewaters are absent or an amniotomy should be performed if forewaters are still present before commencing an oxytocin infusion.**

Clinical Question 2.5: Can labour be induced in a woman who has had a previous Caesarean section and/or previous uterine surgery?

Evidence Statement

In the setting of a large Irish maternity hospital with strict guidelines for women undergoing planned vaginal birth after Caesarean section (VBAC), the rate of uterine rupture was 2 per 1000 overall, and 1 per 1000 for women in spontaneous labour who did not receive oxytocin augmentation[24].

A metanalysis including 14 studies (48,457 women) found that the pooled rate of VBAC and rate of uterine rupture in spontaneous labour group were 74.3% (95%CI: 0.679 to 0.807; p = 0.001) and 0.7% (95%CI: 0.004 to 0.009; p < 0.001), respectively; while rates in women in the induced labour group were 60.7% (95%CI: 0.532 to 0.682; p < 0.001) and 2.2% (95%CI: 0.012 to 0.033; p = 0.0001) respectively[25]. These results suggested that the women with spontaneous labour had significantly higher rate of VBAC (Z = 3.43; p = 0.001), and lower rate of uterine rupture (Z = 2.96; p = 0.003) than those who underwent induced labour.

The same metanalysis also found that the pooled rates of uterine rupture in women using oxytocin and women not using oxytocin in women undergoing labour after a previous Caesarean birth were 1.4% and 0.5% (p=0.0002), respectively. The rate of uterine rupture in oxytocin augmentation among women with spontaneous labour and women who had a successful IOL were not significantly different (1.7% and 2.2%, respectively, p=0.443).

There is a paucity of RCTs investigating the effects of prostaglandins on uterine rupture in the setting of planned VBAC with one previous Caesarean section. A meta-analysis including 69 studies (53 retrospective cohort studies, 4 prospective cohort studies, and 12 RCTs) found that prostaglandins did not increase the incidence of uterine rupture in term, singleton, cephalic pregnancies who had one previous lower segment Caesarean section compared to other methods of IOL[26]. However, this review does not detail what methods of induction they are using as a comparison making it difficult to interpret the results. There is large heterogeneity among included studies.

This review should be interpreted with caution as the included studies were mostly observational in nature. Subgroup analyses on prostaglandin formulation (gel, pessary, or tablet), dose, and route of administration (cervical, vaginal, or oral) were not performed and the potential additional risk from oxytocin was not addressed.

Conversely, the NICHD study found that that the risk of uterine rupture with prostaglandin methods of IOL is 0.87% and 0.29% with the use of a balloon catheter or ARM. It also reported that the use of prostaglandins when inducing women with one previous Caesarean section was associated with a higher risk of perinatal death due to uterine rupture ([0.11% – prostaglandins] versus [0.045% – mechanical methods of IOL])[27].

A Cochrane review investigating methods of induction of labour in the setting of one previous Caesarean section found that RCT evidence was lacking in this area[28]. The review included one trial (42 women) which compared vaginal PGE2 versus intravenous oxytocin. No clear difference was noted for Caesarean section (risk ratio (RR) 0.67, 95% confidence interval (CI) 0.22 to 2.03, evidence graded low), serious neonatal morbidity or perinatal death (RR 3.00, 95% CI 0.13 to 69.70, evidence graded low) or serious maternal morbidity or death (RR 3.00, 95% CI 0.13 to 69.70, evidence graded low). The study did not comment on vaginal birth not achieved within 24 hours, or uterine hyperstimulation with fetal heart rate changes.

The review included one small study comparing double-balloon catheter versus vaginal PGE2 (26 women). This reported no difference in Caesarean section rates (RR 0.97, 95% CI 0.41 to 2.32, evidence graded very low). Vaginal birth not achieved within 24 hours, uterine hyperstimulation with fetal heart rate changes, serious neonatal morbidity or perinatal death, and serious maternal morbidity or death were not reported.

The Cochrane review included one trial (53 women) which compared foley catheter versus intravenous oxytocin, which found no clear difference between groups for vaginal birth not achieved within 24 hours (RR 1.47, 95% CI 0.89 to 2.44, evidence graded low), uterine hyperstimulation with fetal heart rate changes (RR 3.11, 95% CI 0.13 to 73.09, evidence graded low), and Caesarean section (RR 0.93, 95% CI 0.45 to 1.92, evidence graded low). The trial did not comment on serious neonatal morbidity or perinatal death, and serious maternal morbidity or death.

The incidence of uterine rupture during labour post myomectomy is estimated to be 0.47% and the majority of uterine ruptures post myomectomy occurred prior to the onset of labour [29, 30]. Women with a previous myomectomy are a heterogenous group due to differences in surgical technique and fibroid type. Further studies are needed to evaluate how these influence risk of uterine rupture[29].

For further discussion around the care of a woman aiming for a VBAC refer to the National Clinical Practice Guideline. [18]

Clinical Practice

The decision for IOL and for commencing oxytocin when a woman has had one previous Caesarean section should be made following discussion with a Consultant Obstetrician in consultation with the woman and clearly documented in the maternity notes, alongside relevant risks and accounting for the woman's preferences. Where English is not the woman's first language, interpreter services may be required.

The potential increased risk of uterine rupture associated with any induction and the potential decreased possibility of achieving a VBAC should be considered.

A history of Caesarean section is not in itself an indication for IOL. IOL in women who have had uterine surgery, such as myomectomy, or who have had a uterine perforation should be discussed with a Consultant Obstetrician. The operation and medical maternity notes from the procedure previously undertaken should be reviewed.

Women with a previous Caesarean section/uterine surgery should have a birth plan made prior to 41+0 weeks using a shared decision model taking into account the woman's individual circumstances and preferences. IOL in a woman with a previous single Caesarean section may be undertaken with ARM or with a balloon catheter or with the Dilapan-S® cervical dilator. If prostaglandins are being considered for use in a woman attempting a VBAC this must be following a review by a senior Obstetrician due to the increased risk of uterine rupture.

18 Ryan G, Duggan J, Finnegan C, Morrison JJ. National Clinical Practice Guideline: Vaginal Birth After Caesarean Section. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023

Recommendations

11. We recommend the decision for IOL and for commencing oxytocin on a woman with a previous Caesarean birth should be made by a Consultant Obstetrician in consultation with the woman and clearly documented in the maternity notes, alongside relevant risks and accounting for the woman's preferences.
12. We recommend that the increased risk of uterine rupture associated with any induction of labour and the potential decreased possibility of achieving a vaginal birth after Caesarean section (VBAC) should be considered and discussed with the woman.
13. We recommend that IOL in women who have had uterine surgery, such as myomectomy or uterine perforation should be discussed with a Consultant Obstetrician. Operation notes from the procedure previously undertaken should also be reviewed, where possible.
14. IOL in a woman with a previous single Caesarean birth may be undertaken with amniotomy, balloon catheter or with the Dilapan-S® cervical dilator. We recommend that a review of women aiming for a VBAC should be undertaken prior to 41+0 weeks to assess the cervix and reconsider the options.
15. Prostaglandins for planned VBAC are not recommended as they significantly increase the risk of uterine rupture.

Clinical Question 2.6: Is advanced maternal age an indication for induction of labour?

Evidence Statement

The incidence of stillbirth at term in women is low. It is higher in women of advanced maternal age[31]. At 39-40 weeks of gestation the incidence of stillbirth is 2 in 1000 for women aged 40 years of age or older compared to 1 in 1000 for women aged less than 35 years of age[31].

Women ≥40 years of age have a similar stillbirth risk at 39 weeks of gestation to women aged in their mid-20s at 41+0 weeks of gestation [31-33]. Reddy et al reported cumulative rates for stillbirth per 1000 pregnancies through 41+0 weeks' gestation for women younger than 35 years, 35 to 39 years, and older than 40 years as 6.2, 7.9, and 12.8, respectively[32]. They found that the risk of stillbirth for women 35 to 39 years at 37 to 41+0 weeks' gestation was approximately 1 in 382 ongoing pregnancies, RR being 1.32-fold greater (95% CI 1.22, 1.43) when compared with women younger than 35 years. The risk of stillbirth for women 40 years old or older at 37 to 41+0 weeks' gestation was approximately 1 in 267 ongoing pregnancies, RR being 1.88-fold greater (95% CI 1.64, 2.16) when compared with women younger than 35 years. The relative risk was 3-fold higher for women 40 years old or older than women younger than 35 years at 41+0 weeks[32]. At 41+0 weeks of gestation the risk of stillbirth is 0.75 in 1000 women under the age of 35 years old, and 2.5 in 1000 women aged ≥40 years old[31]. The effect of maternal age persisted despite accounting for medical disease, parity, race and ethnicity[32]. Nulliparous women and women of Black African, Black Caribbean, Pakistani and Bangladeshi ethnicity have a higher rate of stillbirth compared to multiparous, Caucasian women, independent of maternal age[32 34]. These factors should be incorporated into shared decision-making consultations.

Clinical Practice

It is reasonable to consider IOL for women aged 40 and above at 39+0-40+0 weeks' gestation. Evidence suggests a slight increase in the risk of stillbirth after 40 weeks[31]. It is reasonable to offer women aged over 40 with other co-morbidities induction of labour before 40 weeks. In light of the lack of robust evidence, this requires shared decision making between the woman and her healthcare provider, taking into account her individual preferences and circumstances and respecting her decision.

Recommendations

16. **It is reasonable to offer IOL at 39+0-40+0 weeks' gestation for women aged 40 and above. Benefits and risks of IOL should be discussed with the woman, taking into account her individual circumstances and preferences.**

Clinical Question 2.7: Is suspected large for gestational age an indication for induction of labour?

Evidence Statement

A Cochrane review reported that IOL between 37+0 and 38+6 in the setting of suspected macrosomia significantly reduced the risk of shoulder dystocia (RR 0.60, 95% CI 0.37 to 0.98; 1190 women; four trials, moderate-quality evidence) and neonatal fractures (RR 0.20, 95% CI 0.05 to 0.79; 1190 women; four studies, high-quality evidence) compared to expectant management; without increasing the risk of Caesarean section (risk ratio (RR) 0.91, 95% confidence interval (CI) 0.76 to 1.09; 1190 women; four trials, moderate-quality evidence) or instrumental birth (RR 0.86, 95% CI 0.65 to 1.13; 1190 women; four trials, low-quality evidence)[35].

There were no clear differences between groups for brachial plexus injury (low-quality evidence). There was no difference in five minute Apgar scores or arterial cord blood pH (RR 1.51, 95% CI 0.25 to 9.02; 858 infants; two trials, low-quality evidence; and, RR 1.01, 95% CI 0.46 to 2.22; 818 infants; one trial, moderate-quality evidence, respectively). One study (n=818 women) reported an increased incidence of obstetric anal sphincter injury among the induction group (RR 3.70, 95% CI 1.04 to 13.17)[36].

While the risk of shoulder dystocia in a low-risk population is expected to be approximately 1%, there are a number of studies that suggest that in pregnancies complicated by macrosomia, this risk can be 20 times as high[37]. In a large population-based study of 175, 886 pregnancies, the prevalence of shoulder dystocia showed an exponential increase with birthweight: 5.2% in the group with birthweight 4000-4250 g; 9.1% in those with birthweight of 4250-4500 g; 14.3% in those with birthweight of 4500-4750 g and 21.0% in those with birthweight of 4750-5000g[37]. Women with diabetes treated with insulin were excluded from this trial, although 10% of included participants had gestational diabetes mellitus controlled by diet.

The American College of Obstetricians and Gynaecologists have stated that although the prediction of fetal macrosomia is imprecise, planned Caesarean birth may confer benefits for newborns suspected to have macrosomia with estimated fetal weight of at least 5,000 g in women without diabetes[38]. However, the decision to offer planned Caesarean birth in these cases remains controversial due to the absence of randomised clinical trials, and it is largely based on expert opinion.

Neonatal risks associated with early term birth include an increased risk of respiratory distress syndrome (RDS), hypoglycaemia, hyperbilirubinemia, and admission to the neonatal intensive care unit (NICU) [39, 40].

A prospective observational study of 17,794 deliveries reported a 15.2% (*P=0*.003) NICU admission rate among elective IOLs at 37 weeks, a 7.0% (*P=0*.001) rate at 38 weeks and a 6.0% rate at 39 weeks[41]. A large retrospective study (n= 46,329,018) reported increased neonatal mortality rates at 37 weeks compared to 40 weeks of gestation: Hispanics: RR= 2.6 (95% CI 2.0-3.3); non-Hispanic whites: RR= 2.6 (95% CI 2.2-3.1); and non-Hispanic blacks: RR= 2.9 (2.2-3.8).[42]. In a large prospective cohort study examining repeat elective Caesarean births in normal risk pregnancies (n=28,867 women), the composite risk of neonatal death and any of several adverse events, including respiratory complications, treated hypoglycaemia, newborn sepsis, and admission to the neonatal intensive care unit was found to be significantly higher for infants born at 37 weeks and 38 weeks compared to those born at 39 weeks (aOR for births at 37 weeks, 2.1; CI 1.7 to 2.5; aOR for births at 38 weeks, 1.5; 95% CI, 1.3 to 1.7; P for trend <0.001). [43]

The Consortium on Safe Labor reported that giving birth at 37 weeks' gestation compared to birth at 39-40 weeks' gestation resulted in an adjusted odds ratio of 3.1 for RDS, 2.5 for transient tachypnoea of the newborn (TTN), 1.7 for pneumonia, and 2.8 for respiratory failure. Furthermore, 11.8% of infants born at 37 weeks' gestation compared to 6.1% at 39 weeks' gestation were admitted to a NICU[44]. Ghartey et al evaluated neonatal respiratory morbidity in infants born at 37-38 weeks' gestation compared to those born at 39 weeks' gestation. Early-term infants had a 2-fold higher risk of composite respiratory morbidity (TTN, RDS, oxygen usage, continuous positive airway pressure (CPAP), and tracheal intubation) [45].

An observational study (n=4765 sonographic weight estimations) compared sonographic fetal weight-estimation models and abdominal circumference (AC) as predictors of macrosomia (>4000 g birth weight)[46]. Using a fixed threshold, models varied in sensitivity (range: 13.6% to 98.5%) and specificity (range: 63.6% to 99.8%). However, deriving thresholds from the ROC curve's inflection point reduced intermodel variation, improving sensitivity (range: 84.4% to 91.4%) and specificity (range: 79.5% to 86.3%). Models with three to four biometric indices outperformed those with two or AC alone (p = 0.03). Ultrasound predictions of macrosomia can be inaccurate, and therefore it is recommended to include three to four biometric indices for improved accuracy.

Clinical Practice

Women should be informed that there is uncertainty about the benefits and risks of IOL compared to expectant management in the setting of suspected macrosomia in the absence of gestational diabetes mellitus, but:

- with IOL the risk of shoulder dystocia is reduced compared with expectant management
- with IOL the risk of third- or fourth-degree perineal tears is increased compared with expectant management
- there is evidence that the risk of perinatal death, brachial plexus injuries in the baby, or the need for emergency Caesarean birth is the same between the two options
- that early-term birth (>37 and <39 weeks) is associated with increased neonatal and maternal morbidity

However, women will also need to consider the impact of induction on their birth experience (see section 2, birth experience).

Discuss the options for birth with the woman, taking into account her individual circumstances and her preferences, and respect her decision.

Recommendations regarding timing of IOL in the setting of gestational diabetes mellitus is beyond the scope of this guideline. Please see HSE Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus from Pre-conception to the Postnatal period[47].

Ultrasound predictions of macrosomia can be inaccurate, and it is recommended to include three to four biometric indices for improved accuracy.

Recommendations

17. **In the setting of suspected fetal macrosomia in the absence of gestational diabetes mellitus, women should be provided with information about the benefits and risks of expectant management versus IOL so that they can make an informed decision.**

Clinical Question 2.8: Should elective induction after 39 weeks be facilitated?

Evidence Statement

A recent systematic review comparing elective IOL <41+0 weeks versus expectant management where spontaneous labour occurred or intervention at a future gestation was required did not find a statistically significant increase in risk of Caesarean section (OR 1.73, 95% CI 0.67-4.5)[48].

The ARRIVE trial[49] compared outcomes for low-risk nulliparous women associated with IOL at 39 weeks (between 39+0 and 39+4) versus expectant management. While this trial did not find any differences between perinatal death and severe neonatal complications, it did find that IOL was associated with a reduction in Caesarean section rate by 4%.

This is in keeping with the results of a large retrospective population-based study (n= 1,271,549 women) that compared women of all ages undergoing elective IOL without medical indication at weekly gestations from 37-41+0 weeks of gestation versus women managed expectantly[50]. Elective IOL was associated with decreased perinatal mortality with an adjusted odds ratio (aOR) of 0.15 (95% CI 0.03-0.68) at 37 weeks of gestation increasing to 0.31 (95% CI 0.19-0.49) at 41+0 weeks of gestation, without an increase in operative vaginal births or Caesarean sections. Operative vaginal birth was actually reduced in women electively induced at 40 weeks of gestation with an aOR of 0.85 (95% CI 0.82-0.89) for operative vaginal births and an aOR of 0.82 (95% CI 0.79-0.88) for Caesarean sections. They did however find an increase in neonatal admissions to the special care facilities.

Similarly, a large retrospective cohort study (n=55,694 births) compared 4002 elective inductions at 39 weeks gestation and 51,692 births at 39+0 to 42+6 weeks gestation that were not electively induced[51]. In nulliparous women, elective induction at 39 weeks gestation was associated with a decreased likelihood of Caesarean birth (14.7% vs 23.2%; aOR, 0.61; 95% CI, 0.41-0.89) and an increased rate of operative vaginal birth (18.5% vs 10.8%; aOR, 1.8; 95% CI, 1.28-2.54) compared with on-going pregnancies. In multiparous women, Caesarean birth rates were similar in the elective inductions and on-going pregnancies.

A large observational study (n=115,502 mother-infant dyads) compared outcomes among low-risk parous women who underwent elective IOL at 39 weeks versus expectant management[95]. Caesarean birth was lower among women who underwent elective induction at 39 weeks than those who did not (2.4 vs. 4.6%, aOR: 0.70, CI: 0.53-0.92). The frequency of the composite maternal adverse outcome was significantly lower for the elective induction cohort as well (1.6 vs. 3.1%, aOR: 0.66, 95% CI: 0.47-0.93). The composite neonatal adverse outcome was not significantly different between the two groups (0.3 vs. 0.6%; aOR: 0.60, 95% CI: 0.29-1.23).

A meta-analysis of six cohort studies found that elective IOL at 39 weeks, compared with expectant management beyond that gestational age, was associated with a significantly lower risk of Caesarean birth, maternal peripartum infection, and perinatal adverse outcomes, including respiratory morbidity, intensive care unit admission, and mortality[52].

An economic analysis of elective labour induction at 39 weeks versus expectant management in low-risk nulliparous women (n= 1,201) found that the total cost of elective induction was no different than expectant management (mean difference +4.7%; 95% CI –2.1% to +12.0%) [53].

Shared decision making and autonomy in childbirth represent integral dimensions of a quality modern health service. The benefits, risks and alternative options to IOL must be accurately presented so that women can understand the likely or potential outcomes of IOL[10].

There is a body of evidence which has recently suggested that elective IOL as early as 39 weeks' gestation in low risk women, reduces the incidence of perinatal morbidity and mortality, fewer caesarean sections and fewer episodes of hypertensive disorders associated with pregnancy[49, 52].

Clinical Practice

Based on evidence, it is reasonable to offer IOL from 39 weeks at the request of the woman and if available resources permit within the maternity hospital/unit.

Recommendations

18. **Requests for IOL from 39 weeks should be considered, after discussing the benefits and risks with the woman, and taking into account the woman's circumstances and preferences as well as the maternity hospital/unit's resources and established care pathways.**

Clinical Question 2.9: At what gestation should IOL for maternal request be considered?

Evidence Statement

Neonatal risks associated with early term birth include an increased risk of respiratory distress syndrome (RDS), hypoglycaemia, hyperbilirubinemia, and admission to the neonatal intensive care unit (NICU) [39, 40].

A prospective observational study of 17,794 deliveries reported a 15.2% (*P=0*.003) NICU admission rate among elective IOLs at 37 weeks, a 7.0% (*P=0*.001) rate at 38 weeks and a 6.0% rate at 39 weeks [41]. A large retrospective study (n= 46,329,018) reported increased neonatal mortality rates at 37

weeks compared to 40 weeks of gestation: Hispanics: RR= 2.6 (95% CI 2.0-3.3); non-Hispanic whites: RR= 2.6 (95% CI 2.2-3.1); and non-Hispanic blacks: RR= 2.9 (2.2-3.8)[42]. In a large prospective cohort study examining repeat elective Caesarean births in normal risk pregnancies (n=28,867 women), the composite risk of neonatal death and any of several adverse events, including respiratory complications, treated hypoglycemia, newborn sepsis, and admission to the neonatal intensive care unit was found to be significantly higher for infants born at 37 weeks and 38 weeks compared to those born at 39 weeks (aOR for births at 37 weeks, 2.1; CI 1.7 to 2.5; aOR for births at 38 weeks, 1.5; 95% CI, 1.3 to 1.7; P for trend <0.001). [43]

The Consortium on Safe Labor reported that giving birth at 37 weeks' gestation compared to birth at 39-40 weeks' gestation resulted in an adjusted odds ratio of 3.1 for RDS, 2.5 for transient tachypnoea of the newborn (TTN), 1.7 for pneumonia, and 2.8 for respiratory failure. Furthermore, 11.8% of infants born at 37 weeks' gestation compared to 6.1% at 39 weeks' gestation were admitted to a NICU[44]. Ghartey et al evaluated neonatal respiratory morbidity in infants born at 37-38 weeks' gestation compared to those born at 39 weeks' gestation. Early-term infants had a 2-fold higher risk of composite respiratory morbidity (TTN, RDS, oxygen usage, continuous positive airway pressure (CPAP), and tracheal intubation) [45].

Clinical Practice

Induction of labour for maternal request should be considered from 39 weeks' gestation due to the increased risk of neonatal and maternal morbidity seen in early-term births (37-38 weeks).

Induction of labour for maternal request is not recommended prior to 39 weeks due to the increased risk of morbidity.

Recommendations

19. **Induction of labour for maternal request is not recommended prior to 39 weeks due to the increased risk of maternal and neonatal morbidity.**

Clinical Question 2.10: Should Induction of Labour be offered at 39 weeks to reduce Stillbirth rates?

Evidence Statement

Recent studies and meta-analyses have examined the effectiveness of elective IOL at 39 weeks for the prevention of stillbirth. The ARRIVE trial, a large randomised controlled trial, found that IOL at 39 weeks for low-risk, nulliparous women led to a lower rate of Caesarean section and did not increase the risk of adverse maternal or neonatal outcomes (18.6% versus 22.2%, p=0.04) [49]. Although the trial did not find a statistically significant difference in stillbirth rates between the induction and expectant management groups, there was a trend towards a lower rate of stillbirth in the induction group (0.3% vs 0.6%, p=0.06).

A Cochrane review compared maternal and neonatal outcomes of IOL at or beyond term compared with a policy of expectant management[11]. This review included 34 RCTs (reporting on over 21,000 women and infants). The trials compared a policy to induce labour after 41 completed weeks of gestation with waiting for labour to start and/or waiting for a period before inducing labour. Compared with a policy of expectant management, a policy of labour induction was associated with less perinatal deaths (risk ratio

(RR) 0.31, 95% confidence interval (CI) 0.15 to 0.64; 22 trials, 18,795 infants; high-certainty evidence). This review reported no differences for timing of induction (< 40 versus 40-41 versus ≥ 41+0 weeks' gestation) for perinatal death, stillbirth, NICU admission, Caesarean section, operative vaginal birth, or perineal trauma.

A large retrospective study compared elective IOL at 39 weeks to expectant management in singleton, low-risk pregnancies with a non-anomalous fetus delivered at 39-42 weeks' gestation (n= 5,017,524)[54]. They reported a lower stillbirth rate (aRR 0.195; 95% CI [0.153-0.249]; *p* value <.01), 5-min Apgar ≤3 (aRR 0.684; 95% CI [0.647-0.723]; *p* value <.01), prolonged ventilation (aRR 0.840; 95% CI [0.800-0.883]; *p* value <.01) and NICU admission (aRR 0.862; 95% CI [0.849-0.875]; *p* value < 0.01) in the 39 week IOL cohort compared with the expectant management cohort. They found no differences in risk for neonatal seizures (aRR 0.848; 95% CI [0.718-1.003]; *p* value 0.011) or death (aRR 1.070; 95% CI [0.722-1.586]; *p*value 0.660). There were 1,178,430 women in the 39-week IOL group, with 520 neonatal deaths, and 120 intrapartum stillbirths. Among those managed expectantly, there were 3,839,094 births, among which there were 1659 subsequent neonatal deaths and 2250 stillbirths. They reported no statistically significant difference between the IOL group and the expectant management group. A systematic review and meta-analysis evaluated the safety and efficacy IOL at term (37-42 weeks of gestation) in uncomplicated singleton pregnancies[55]. The authors identified 31 RCTs with a total of 12,819 women comparing IOL with expectant management. There was no difference in stillbirth risk among the IOL or expectant management groups. The pooled RR for stillbirth was 1.02 (95% CI, 0.33-3.12) with low statistical heterogeneity (I2 = 0%).

A meta-analysis of six cohort studies found that elective IOL at 39 weeks, compared with expectant management beyond that gestational age, was associated with a significantly lower risk of perinatal adverse outcomes, including respiratory morbidity, intensive care unit admission, and mortality[52].

Clinical Practice

Further research is needed to fully understand the benefits and risks of elective induction of labour at 39 weeks for the prevention of stillbirth, particularly in different populations and settings.

Ultimately, the decision to induce labour for this indication should be made on a case-by-case basis, taking into account the individual woman's circumstances and preferences.

Recommendations

20. **There is insufficient evidence to recommend IOL at 39 weeks in normal risk pregnancies for the prevention of stillbirth.**

Clinical Question 2.11: Is history of precipitous labour an indication for induction of labour?

Evidence Statement

The NICE guideline: Inducing Labour does not recommend offering routine IOL in the setting of previous precipitous labour in order to avoid a birth unattended by healthcare professionals[2]. There is a paucity of evidence on this subject. To the best of our knowledge there are no RCTs or systematic reviews on the subject.

Clinical Practice

Women with a history of precipitate labour should not routinely be induced in order to avoid a birth unattended by healthcare professionals. However, should a woman request IOL, each case should be considered individually with a review by their healthcare provider taking into account the woman's individual preferences and circumstances (including distance from maternity unit/hospital) using a shared decision-making approach. The maternity hospital/unit's resources and established care pathways will also need to be considered.

Recommendations

21. **Women with a history of precipitous labour should not routinely be induced in order to avoid a birth unattended by healthcare professionals. However, should a woman request IOL, each case should be considered individually with a review by their healthcare provider taking into account the woman's individual preferences and circumstances (including distance from maternity hospital/unit) using a shared decision-making approach.**

Section 2: Birth Experience

Introduction

In this section we discuss how IOL affects birth experience and give suggestions on how to improve maternal satisfaction with IOL.

Clinical Question 2.12: How can a woman's birth experience in the setting of IOL be enhanced?

Evidence Statement

Communication and informed decision-making

In a survey study published in Women Birth in 2021, Coates et al. examined women's experiences of decision-making and attitudes in relation to IOL. A total of 503 women completed the survey, and 87% reported that they were involved in the decision-making process regarding IOL. Of those who were involved, 60% reported that they were given information and felt they had a choice in the decision,

while 18% reported feeling pressured or coerced into having an induction. In addition, 22% of women reported feeling inadequately informed about the risks and benefits of induction.

A systematic review and thematic synthesis of qualitative studies explored women's experiences of IOL (n=22 studies)[56]. The authors identified four main themes that emerged from women's experiences of IOL:

i. The decision-making process: Women described feeling pressure from healthcare professionals to accept induction, but also reported feeling empowered when they were involved in the decision-making process.

ii. The induction process: Women described a range of experiences with the induction process, including discomfort, pain, and frustration. Some women also reported feeling unsupported during the process.

iii. The impact of induction on the birth experience: Women reported feeling that induction had a negative impact on their birth experience, with some describing it as traumatic.

iv. Coping with the experience: Women reported using a range of coping mechanisms during the induction process, including seeking support from their partner or a doula, using relaxation techniques, and focusing on the end goal of having a healthy baby.

The authors concluded that IOL is a complex and multifaceted experience for women, and that healthcare professionals should strive to involve women in the decision-making process and provide support throughout the induction process to minimise negative experiences. These findings highlight the importance of providing women with comprehensive information and involving them in the decision-making process regarding IOL.

The NICE Guideline Inducing Labour [NG 207] recommends discussing the following with women being offered induction of labour[2]:

- the reasons for induction being offered
- when, where and how induction could be carried out
- the arrangements for support and pain relief
- the alternative options if the woman chooses not to have induction of labour, or decides at a later stage that she no longer wishes to proceed with the induction process
- the risks and benefits of induction of labour in specific circumstances, and the proposed induction methods
- that induction may not be successful, and how this would affect the woman's options

Non-pharmacological pain management

A systematic review and meta-analysis evaluated the effectiveness of nonpharmacologic approaches for pain management during labour, comparing these approaches to usual care[57]. The authors included 53 randomised controlled trials (RCTs) in their analysis, involving a total of 5,961 women. The nonpharmacologic approaches for pain management were grouped into four main categories: (i) Cognitive-behavioural strategies (e.g., relaxation, breathing techniques, and childbirth education) (ii) Alternative therapies (e.g., acupuncture, acupressure, and hypnosis) (iii) Sensory stimulation (e.g., massage, water immersion, and thermal stimulation) (iv) Supportive care (e.g., continuous support from a caregiver, emotional support, and encouragement). Women receiving nonpharmacologic pain management were less likely to report dissatisfaction with their birth experience (RR = 0.54; 95% CI, 0.41-0.72).

Continuous emotional support during labour

In a Cochrane review of 26 studies, continuous support during childbirth was associated with reduced use of analgesia (RR 0.93, 95% CI 0.88 to 0.99), a lower likelihood of Caesarean birth (RR 0.78, 95% CI 0.67 to 0.91), and greater maternal satisfaction with the birth experience (RR 1.23, 95% CI 1.11 to 1.37) [58].

Clinical Practice

Women themselves should be at the centre of the decision-making regarding their care, and clear information should be given. Good communication with the woman and her family regarding the indication, intended benefits, possible risks, and methods available allows informed decisions, and women should be supported in their decision.

Antenatal educators should prepare women and their partners for required changes in their birthing plan when induction is deemed necessary, as well as helping women to adapt their birth plans during the induction process. Women can decide not to have IOL, and appropriate care should then be offered to optimise the outcome of the pregnancy while respecting the woman's wishes[59].

There are several ways in which a woman's birth experience in the setting of IOL can be enhanced.

1. Communication and informed decision-making: It is important to involve the woman in decision-making regarding the induction process, explaining the rationale, benefits, and risks of induction, and addressing any concerns or questions she may have. This can help to empower the woman and reduce anxiety and fear associated with the induction process.
2. Non-pharmacological pain management: Non-pharmacological pain management techniques such as breathing techniques, massage, hydrotherapy and one-to-one support have been found to be effective in reducing pain and anxiety during labour induction, and can enhance the woman's overall birth experience. Every endeavour should be made to keep the woman as comfortable as possible through non-pharmacological and/or pharmacological methods.
3. Continuous support during labour: Providing emotional support to the woman during labour, such as through the presence of a doula or a supportive birth partner and one to one midwifery care can help to reduce anxiety and improve the overall birth experience.

Recommendations

22. **Communicating the indication, intended benefits, possible risks, and methods available for IOL allows informed decisions, and women should be supported in their choice.**
23. **The use of non-pharmacological pain management such as breathing techniques, massage, hydrotherapy and one-to-one support should be optimised as well as pharmacological pain relief (e.g. pethidine or epidural) as required.**
24. **Facilitate continuous emotional support during labour, this includes one to one midwifery care.**

Section 3: Methods of Induction of Labour

Introduction

In this section we will discuss the hormonal and mechanical methods of induction of labour (IOL). We discuss the contraindications and insertion techniques of each method. Staff must receive training on all induction agents i.e. Prostin®, Propess®, Balloon Catheters, Dilapan-S® and Misoprostol. Each hospital should develop local protocols on how this will be facilitated, who will be responsible for the training and how staff will be deemed competent. Staff should receive training in outpatient induction of labour, namely who it should be offered to, the contraindications of outpatient IOL and when women should be advised to return to the maternity hospital/unit.

The method being used to induce labour should be discussed with the woman. The woman should be informed that the method used is dependent on a number of factors: including their clinical status, the team's obstetric experience and the evidence supporting IOL based on clinical circumstances.

It is important to clearly document all discussions and examinations in the woman's chart as well as prescribing any induction agents used and documenting the times they were administered in the medication chart.

Clinical Question 2.13: What are the methods of induction of labour?

1. Membrane sweeping

Evidence Statement

Evidence relating to membrane sweeping was available from a systematic review[60]. The review which includes 21 studies involving 3443 women summarizes the evidence on membranes sweeping and IOL. Comparison of sweeping membranes and expectant management found that membrane sweeping was associated with a 33% reduction in the risk of formal IOL (14 trials, 2446 women, RR 0.67, 95% CI 0.59-0.76). There was a 23% lower risk of not being in labour or not giving birth within 48 hours (5 trials, 726 women, RR 0.77, 95% CI 0.7-0.84). Expectant management was not associated with an increased risk of Caesarean section, Apgar score less than seven at 5 minutes of life, serious maternal morbidity or death, admission to neonatal intensive care unit, or perinatal death.

Clinical Practice

Women may be offered a vaginal examination for membrane sweeping. This is usually offered to women at antenatal visits from 39+0 weeks[2]. Repeat membrane sweeps can be offered if labour does not start spontaneously. Membrane sweeps should be conducted by qualified Midwives or Obstetricians, or under the supervision of a trained Midwife or Obstetrician, including students undergoing appropriate clinical training.

To support women in their decision to have a membrane sweep, they should be informed:

- What a membrane sweep is and how it is performed.
- Membrane sweeps may be associated with discomfort, pain and vaginal spotting at the time and immediately after the sweep.
- Membrane sweeps may be associated with rupture of the membranes both during the procedure or immediately after or before the onset of labour.
- Membrane sweeps are associated with an increased rate of spontaneous labour
- Membrane sweeps reduce the need for induction of labour, especially in multiparous women.

Abdominal palpation, including a measurement of the symphysial fundal height (SFH), assessment of the lie and presentation of the baby and auscultation of the fetal heart should be performed prior to carrying out a membrane sweep. Informed consent must be obtained by the clinician from the woman prior to carrying out a membrane sweep. The most recent scan should also be reviewed to ensure the placenta is not low lying.

2. Prostaglandins for Induction of Labour

Evidence Statement

A Cochrane systematic review summarising the evidence relating to the use of prostaglandins for the IOL found that prostaglandins are effective at inducing labour[61]. Thirty-nine trials (with 6761 women) compared prostaglandin E2 (PGE2) versus placebo or no treatment. Two trials with 159 women compared different PGE2 preparations: gel with pessary or suppository. Two trials (384 women) compared vaginal prostaglandins to expectant management of placebo in terms of 'Vaginal birth not achieved within 24 hours'.

The review reported that it is likely that vaginal prostaglandin E2 compared with placebo or no treatment reduces the likelihood of vaginal birth not being achieved within 24 hours (RR 0.19, 95% CI 0.14-0.25). Prostaglandins were found to increase the risk of uterine hyperstimulation with fetal heart rate changes but without additional adverse maternal or perinatal outcomes (4.8% versus 1.0%, risk ratio (RR) 3.16, 95% confidence interval (CI) 1.67 to 5.98, 15 trials, 1359 women). Evidence suggests that the use of prostaglandins is associated with a reduced risk of requiring a Caesarean section. (13.5% versus 14.8%, RR 0.91, 95% CI 0.81 to 1.02, 36 trials, 6599 women).

There was no increase in the use of epidural anaesthesia when prostaglandins were used (49.6% versus 45.5%, average RR 1.16, 95% CI 0.85 to 1.60, seven trials, 3555 women) There was no evidence on an effect of instrumental vaginal birth when compared to placebo (RR 0.77, 95% CI 0.58 to 1.02, three trials, 565 women). Two trials with 159 women compared different PGE2 preparations: gel with pessary or suppository and no differences in the effectiveness between the gel and sustained release pessary forms of PGE2 were detected.

Clinical Practice

Dinoprostone Vaginal Delivery System (Propess®)

For contraindications for the use of the Dinoprostone Vaginal Pessary (Propess®), please see the Health Products Regulatory Authority's (HPRA) Summary of Product Characteristics[62].

Propess® should not be used or left in place in the following circumstances:

- When the woman is experiencing regular uterine contractions
- When oxytocic drugs and/or other labour induction agents are being given
- Previous major uterine surgery e.g. Caesarean section, Myomectomy
- Fetal malpresentation
- Suspicion or evidence of fetal distress
- Current pelvic inflammatory disease, unless the woman has had adequate prior treatment
- Hypersensitivity to dinoprostone or to any or the excipients
- Placenta praevia or unexplained vaginal bleeding during the current pregnancy.

Precautions for use include [62]**:**

- Ensure facilities are available for cardiotocography wherever induction of labour is started[2].
- Propess® may not be advisable where the woman is experiencing irregular uterine contractions
- After insertion, uterine activity and fetal heartrate must be monitored 4 hourly unless clinical concern prior.
- Propess® must be removed from the vagina if there is evidence of fetal or maternal complications.
- A second Propess® is not currently licenced for use when the first Propess® has not rendered the cervix favourable for amniotomy, however there is a multicentre, randomised superiority trial (RE-DINO) underway at present comparing rates of vaginal birth with sequential doses of Propess® versus oxytocin in the setting of an unfavourable cervix[63].

Preparing the woman before administering Dinoprostone Vaginal Pessary (Propess®):

- The benefits and risks associated with Propess® administration should be fully discussed with the woman and informed consent should be obtained and documented. The woman should be offered the presence of a chaperone during examination and administration.
- Before IOL an abdominal examination should be undertaken to confirm a longitudinal lie, cephalic presentation, degree of engagement, and the fetal heart should be auscultated. This should be documented in the healthcare record. If in doubt an ultrasound scan to confirm cephalic presentation should be offered and performed.
- Confirm a normal fetal heart rate pattern using antenatal cardiotocography (CTG) interpretation.

Administration of Dinoprostone Vaginal Pessary (Propess®):

- The Dinoprostone Vaginal Delivery System (Propess®) may be administered by a Midwife or doctor who has received the appropriate training in its administration.
- It should be prescribed on the drug chart by an Obstetrician or Midwife prescriber along with appropriate analgesia.
- Remove Dinoprostone Propess® from the freezer shortly before administration.

- Assess the cervix using the Modified Bishop's score to determine how to proceed with the induction.
- Proceed with the insertion of the Propess® pessary (see figure 1) high into the posterior fornix using a water-soluble lubricant.
- The pessary should lie transversely in the posterior fornix. The retrieval tape will be visible just outside the vagina (See Appendix 7, Figure 1).
- The findings from the vaginal examination, including the Bishops score should be documented in the woman's notes.

The woman should be advised that the Propess® will usually be removed after 24 hours if labour has not already established.

Removal of Dinoprostone Propess® is not required until 24 hours after insertion unless:

- Onset of labour (the presence of regular painful uterine contractions occurring every 3 minutes irrespective of any cervical change)
- Spontaneous rupture of membranes or amniotomy
- Evidence of changes to fetal heart rate indicative of fetal distress
- Uterine hyperstimulation or hypertonic uterine contractions. This is over activity of the uterus as a result of induction of labour. It is variously defined as uterine tachysystole (more than 5 contractions per 10 minutes for at least 20 minutes) and uterine hypersystole/hypertonicity (a contraction lasting at least 2 minutes)[2]
- At the woman's request
- Adverse reactions to Dinoprostone Propess® e.g. nausea, vomiting, hypotension or tachycardia.

In the event of the Propess® inadvertently falling out during the induction process, the woman should be assessed clinically for the progress made since the commencement of her induction of labour. If the Bishops Score remains <7 the administration of a new Propess® can be repeated once a CTG has confirmed a normal fetal heart rate pattern. As this will be a new Propess®, it will need to be prescribed in the medication chart. All the alternative methods of induction of labour should be offered and a senior clinician should be informed.

Women should be provided with a call bell and told to inform a Midwife if contractions become painful, if their membranes rupture or if they experience bleeding. A cardiotocograph should be performed for 30 minutes post prostaglandin insertion/administration.

Prostaglandin E2 1mg and 2mg Vaginal Gels (Prostin®)

Contraindications for the use of the Dinoprostone (Prostin®) gels are detailed in the HPRA's Summary of Product Characteristics [64]:

- Women with a known allergy or sensitivity to Dinoprostone
- Clinical suspicion or definite evidence of pre-existing fetal distress
- Fetal malpresentation
- Obstetric conditions where either maternal or fetal benefit:risk ratio favours surgical intervention
- Current pelvic inflammatory disease, unless adequate prior treatment has been instituted
- Clinical suspicion or definite evidence of placenta praevia.

While uterine scars and grand multiparity are not absolute contraindications to the use of Dinoprostone (Prostin®) gels, they should be used with caution in these cases and the lowest possible dose should be used after discussion with a Consultant Obstetrician. The response to oxytocin may be accentuated in the presence of exogenous prostaglandin therapy. A dosing interval of at least six hours is recommended in cases where oxytocin use is considered necessary following dinoprostone administration[64].

Preparing the woman before administering Dinoprostone (Prostin®):

- The benefits and risks associated with Prostin® administration should be fully discussed with the woman and informed consent should be obtained and documented.
- The woman should be offered the presence of a chaperone during examination and administration.
- Before IOL an abdominal examination should be undertaken to confirm a longitudinal lie, cephalic presentation, degree of engagement and auscultation of the fetal heart. This should be documented in the maternity notes.
- If any doubt about presentation an ultrasound scan should be offered and performed.
- Confirm a normal fetal heart rate pattern using antenatal cardiotocography (CTG) interpretation prior to commencing IOL.

Administration of Dinoprostone (Prostin®) gels:

- Administration of Dinoprostone (Prostin®) gel can be carried out by a Midwife or doctor trained in its administration.
- Prostaglandin E2 (Prostin®) gels are available in 1mg and 2mg preparations.
- Prostaglandin E2 (Prostin®) gels should be prescribed on the drug chart by an Obstetrician or Midwife prescriber along with appropriate analgesia as requested.
- The administration time should be documented on the drug chart.
- The dose of Prostaglandin E2 (Prostin®) gel to be given is dependent on the clinical status of the woman. Parity, Bishop's score, the risk of hyperstimulation and/or fetal compromise should all be considered when deciding on the dose to be given.
- Dinoprostone (Prostin®) gels are to be inserted high into the posterior fornix of the vagina. (Not into the cervical canal – the intracervical placement of dinoprostone gel may result in inadvertent disruption and subsequent embolization of antigenic tissue causing in rare circumstances an Amniotic Fluid Embolism)[64].

Women should be provided with a call bell and told to inform a Midwife if contractions become painful, if their membranes rupture or if they experience bleeding. A cardiotocograph should be performed for 30 minutes post prostaglandin insertion/administration.

3. Misoprostol for Induction of labour

Evidence Statement

A meta-analysis of 61 trials involving over 20,000 women identified that compared to vaginal dinoprostone, oral misoprostol results in a reduced risk of requiring Caesarean birth (RR 0.84, 95% CI 0.78 to 0.90) and also reduces the risk of hyperstimulation and fetal heart rate abnormalities in labour (RR 0.49, 95% CI 0.40 to 0.59) [65]. The meta-analysis also found that using oral misoprostol might reduce the risk of hyperstimulation and fetal heart rate changes in labour compared to vaginal misoprostol (RR 0.69, 95% CI 0.53 to 0.92) but may result in fewer vaginal births within 24 hours (RR 0.81, 95% CI 0.68 to 0.95).

Clinical Practice

Oral misoprostol use appears to be as safe and have comparable effectiveness compared to other forms of induction of labour, including dinoprostone and mechanical methods; however vaginal misoprostol is associated with a higher incidence of hyperstimulation. The doses of misoprostol being used for induction of labour are dependent on the route of administration. Twenty-five micrograms of oral misoprostol (Angusta®, Norgine Pharmaceuticals Ltd) every 2 hours to a maximum dose of 200 micrograms appears to be safe.

Women should be provided with a call bell and told to inform a Midwife if contractions become painful, if their membranes rupture or if they experience bleeding.

A cardiotocograph should be performed for 30 minutes post prostaglandin insertion/administration.

4. Intravenous Oxytocin

Evidence Statement

A Cochrane review involving sixty-one trials (12,819 women) comparing oxytocin with either intravaginal or intracervical PGE2 reveals that the prostaglandin agents probably increase the chances of achieving vaginal birth within 24 hours. Oxytocin induction may increase the rate of interventions in labour[66]. The review found that compared to placebo or expectant management, the use of oxytocin alone was associated with fewer vaginal births not achieved within 24 hours of induction of labour (three trials, 399 participants, RR 0.16, 95% CI 0.1-0.25), fewer admissions to the neonatal intensive care unit (seven trials, 4387 participants, RR 0.79, 95% CI 0.68-0.92), and increased risk of Caesarean section (24 trials, 6620 participants, RR 1.17, 95% CI 1.01-1.35). Most of the studies comparing the use of oxytocin with expectant management specifically recruited women with ruptured membranes (i.e. 20 of the 25 studies reported outcomes for women with ruptured membranes). The TERMPROM Study showed no difference in neonatal infection rates or Caesarean section rates with oxytocin versus prostaglandin for stimulation of labour. However, induction with oxytocin was associated with less risk of maternal pyrexia[21].

A small single centre RCT (n=184) compared the fetal and maternal outcomes of vaginal prostaglandins versus oxytocin post term prelabour rupture of membranes[22]. They reported statistically significant lower incidence of fetal heart rate abnormalities in the prostaglandin group, 4.4% versus 12.8%. There was no difference in epidural use, Caesarean section, maternal infection, admission to special care nursery or neonatal sepsis. Time to onset of labour was significantly longer in the prostaglandin group (25.7h versus 19.7h) but with no difference in the length of first stage. Maternal satisfaction was high in both groups.

An RCT compared augmentation of labour with oxytocin, amniotomy or a combination of both[67]. Inclusion criteria included women at term with intact membranes and a singleton fetus in cephalic presentation, who had a spontaneous onset of labour, a cervical dilatation between two and four cm, vertex level of no more than two cm above the pelvic inlet and had a prolonged latent phase of labour The combined use of oxytocin and amniotomy resulted in a mean reduction of 120 minutes in labour duration compared to amniotomy alone ($p = 0.08$). Women in the combined augmentation group (oxytocin and amniotomy) had a shorter length of time from augmentation until the beginning of the active phase and a shorter first stage of labour compared to the amniotomy alone group ($p = 0.03$), or the oxytocin alone group ($p = 0.001$). Women in the combined augmentation group reported greater satisfaction compared to the amniotomy alone group and the oxytocin alone group ($p = 0.01$). Mode of birth and neonatal outcomes were comparable between the groups.

Clinical Practice

We recommend that an amniotomy should be performed before commencing an oxytocin infusion.

We suggest that in the setting of prelabour term rupture of membranes and an unfavourable cervix (Bishops Score <7) labour can either be induced in the first instance with an oxytocin infusion or with a single 1 to 2mg dose of Prostin® gel placed into the posterior fornix beforehand using a shared decision-making approach between the woman and her clinician.

Women should have one to one midwifery care and continuous fetal monitoring via cardiotocography while receiving an oxytocin infusion.

The use of oxytocin for acceleration for augmentation of labour is beyond the scope of this guideline.

5. Mechanical Methods of Induction of Labour

Evidence Statement

Mechanical methods of IOL appear to be as effective as pharmacological methods and appear to have a better safety profile. They are associated with less adverse events such as uterine hyperstimulation. There appears to be no difference in rates of Caesarean section [46-49].

Mechanical options of cervical ripening include balloon devices that apply pressure directly on the internal os of the cervix to release local prostaglandins and osmotic cervical dilators that soften and ripen the cervix. Simplicity of use, potential for reversibility, reduction in certain side effects such as excessive uterine activity, and low cost are advantages of these methods[68].

A Cochrane review found that mechanical methods reduced the risk of hyperstimulation with fetal heart rate changes when compared with vaginal prostaglandins: vaginal PGE2 (eight studies; 1203 women, RR 0.16; 95% CI 0.06 to 0.39) and misoprostol (3% versus 9%) (nine studies; 1615 women, RR 0.37; 95% CI 0.25 to 0.54)[69]. Risk of Caesarean section between mechanical methods and prostaglandins was comparable. Serious neonatal and maternal morbidity were infrequently reported and did not differ between the groups.

Osmotic Cervical Dilators (e.g. Dilapan-S®)

Evidence Statement

Dilapan-S® is a fast acting synthetic osmotic cervical dilator made of a hydrogel specifically developed for cervical ripening[70]. It works by absorbing fluid from around the cervix, allowing it to soften. This process also allows for the release of endogenous prostaglandin secretions allowing for further cervical ripening.

Studies have shown that use of Dilapan-S® significantly increases the Bishop's score with cervical ripening being achieved in 90% of cases. Dilapan-S® is suitable and licenced for all women requiring IOL. The majority of women who receive Dilapan-S® do not contract during the IOL process and this improves women's satisfaction while allowing the cervix to ripen prior to ARM[71].

Clinical Practice

Cervical osmotic dilators such as Dilapan-S® can be used as the primary method of IOL for any reason. However, it is typically used for women who:

1. Have had 1 previous Caesarean section
2. When prostaglandins have not rendered the cervix suitable for amniotomy
3. In some cases where there is a high risk of fetal compromise (e.g. Intrauterine growth restriction).

Contraindications for the use of cervical osmotic dilators include:

- Women with a known allergy or sensitivity to cervical osmotic dilators such as Dilapan-S®
- Abnormal CTG
- Fetal malpresentation
- Clinical suspicion or confirmed placenta praevia
- Bishops score ≥ 7
- Women who decline a cervical osmotic dilator.

Preparing the woman for application of osmotic dilators (e.g. Dilapan-S®):

- The benefits and risks associated with the use of osmotic dilators should be fully discussed with the woman and informed consent should be obtained and documented.
- The woman should be offered the presence of a chaperone during examination and administration.
- Before induction of labour an abdominal examination should be undertaken to confirm a longitudinal lie, cephalic presentation, degree of engagement and auscultation of the fetal heart. This should be documented in the maternity notes.
- If in any doubt an ultrasound scan should be performed to confirm presentation.
- Confirming a normal fetal heart rate pattern using antenatal cardiotocography (CTG) interpretation prior to commencing IOL.

Insertion of Dilapan-S®[70]: See Appendix 7, Fig 2 and 3.

- Dilapan-S® should be inserted by an Obstetrician or Midwife trained in its application.
- (Figures provide images depicting the instructions for the insertion of Dilapan-S®)
- Equipment required for the insertion of Dilapan-S® include:
    1. A sponge holding forceps
    2. Cusco's Speculum
    3. Lubricating gel, saline or sterile water
    4. Light source
    5. Dilapan-S® 4mm x 55mm sized rods
- A sterile speculum should be used to visualise the cervix. If the cervix is unfavourable or posterior, a sponge holding forceps can be used to stabilise the cervix, straighten the cervical canal to allow for easier insertion of the rods.
- Dilapan-S® rods can be moistened or lubricated with sterile water, saline, or water-soluble gel prior to insertion.

- Using a sponge holding forceps, the rod is inserted through the external cervical os gradually without force. It is essential for the tip of the rod to pass through the internal os. Do not insert the Dilapan-S® rod beyond the handle.
- Between 3 and 5 Dilapan-S® rods are usually inserted. The number of rods inserted is dependent on the favourability of the cervix and the number of rods that can fit within the cervical canal.
- Once inserted, care should be taken not to dislodge the Dilapan-S® rods on removal of the speculum.
- The procedure of insertion, including the number of rods applied must be documented in the maternity notes.

Removal of Dilapan-S® and subsequent care instructions:

- Dilapan-S® should be removed immediately prior to ARM. This is because the osmotic changes achieved may regress soon after its removal.
- Dilapan-S® rods are usually left in place for 12 hours and should not be left in situ for longer than 24 hours.
- To remove the rods, pull gently on the retrieval strings. A sponge holding forceps may be needed for this step.
- Rarely, forceps may be required to grasp the handle of the Dilapan-S® if the strings do not successfully remove the rods.
- Ensure that the number of rods removed coincides with the number of rods documented on insertion.
- Onward care of labour with oxytocin is usually required unless labour starts spontaneously.
- If ARM is not possible, onward care and plans for IOL or birth should be made by a Consultant Obstetrician.
- Dilapan-S® is not radiopaque but can usually be identified on ultrasound scan in the very rare event of it migrating.

Balloon Catheter Induction of Labour

Evidence Statement

A Cochrane review involving twenty-eight trials (6619 women) showed mechanical induction with a balloon is as effective as vaginal PGE2 as there may be little or no difference in vaginal births within 24 hours (RR 1.01, 95% CI 0.82 to 1.26; 7 studies; 1685 women; low-quality evidence) or in the rates of Caesarean sections (RR 1.00, 95% CI 0.92 to 1.09; 28 studies; 6619 women; moderate-quality evidence) between groups[68]. However, a balloon reduces the risk of uterine hyperstimulation with fetal heart rate abnormalities (RR 0.35, 95% CI 0.18 to 0.67; 6 studies; 1966 women; moderate-quality evidence), serious fetal morbidity and mortality (RR 0.48, 95% CI 0.25 to 0.93; 8 studies; 2757 women; moderate-quality evidence) and may slightly reduce the risk of a NICU admission (RR 0.82, 95% CI 0.65 to 1.04; 3647 women; 12 studies; low-quality evidence). IOL is accepted as a recognised method of IOL by the World Health Organisation[1].

Clinical Practice

IOL can be used as the primary method of IOL for any reason; however, it is typically used for women who:

1. Have had one previous Caesarean section
2. When prostaglandins have not rendered the cervix suitable for amniotomy
3. In some cases where there is a high risk of fetal compromise (e.g. Intrauterine growth restriction).

Contraindications to the use of balloon catheters for IOL include:

- Abnormal CTG
- Fetal malpresentation
- Clinical suspicion or confirmed placenta praevia
- Bishops score ≥ 7
- Women who decline mechanical IOL.
- Rupture of membranes.

Preparing the woman before balloon catheter for IOL

- The benefits and risks associated with the use of balloon catheter induction of labour should be fully discussed with the woman and informed consent should be obtained and documented.
- The woman should be offered the presence of a chaperone during examination and administration.
- Before induction of labour an abdominal examination should be undertaken to confirm a longitudinal lie, cephalic presentation, degree of engagement and auscultation of the fetal heart. This should be documented in the maternity notes.
- If in any doubt an ultrasound scan to confirm cephalic presentation should be offered and performed.
- Confirm a normal fetal heart rate pattern using antenatal cardiotocography interpretation for twenty minutes.

Insertion of a balloon catheter for IOL:

Balloon Catheter insertion should be performed by an Obstetrician or Midwife trained in this method of Induction of labour. (See Appendix 7, Figure 4)

The equipment required for the insertion of a urinary catheter for IOL includes:

1. 1 x sponge holding forceps
2. Sterile cotton wool
3. 1 x Cusco's Speculum
4. Lubricating gel
5. Saline, sterile water or cleaning solution.
6. Light source
7. 1 x size 16 urinary catheter (with 30ml balloon)
8. 1 x cord clamp
9. 1 x 50ml sterile syringe
10. 30mls sterile water (not Saline).

- A lubricated sterile speculum should be used to visualise the cervix. If the cervix is unfavourable or posterior, a sponge holding forceps can be used to stabilise the cervix, straighten the cervical canal to allow for easier insertion of the catheter.
- Sterile cotton wool should be soaked in cleaning solution or saline and used to clean the entrance of the cervical canal with the sponge holding forceps.
- Using the sponge holding forceps, the catheter is placed through the external os and past the internal cervical os.
- Sterile water should be drawn up into the syringe and used to inflate the catheter. The amount of water varies with different balloons and should be confirmed via the user instructions prior to inflation.
- Once inserted, care should be taken not to dislodge the catheter on removal of the speculum.
- The end of the catheter should be clamped with a cord clamp and the catheter taped to the woman's inner thigh
- The procedure of insertion must be documented in the maternity notes.

Removal of Balloon Catheters and subsequent care:

- The balloon catheter can remain in situ for up to 24 hours, by which time ARM is usually possible. It is common for the catheter to self-expel within that time.
- Earlier removal of the catheter is warranted when:
    1. There has been spontaneous rupture of the membranes
    2. Established labour
    3. Ongoing bleeding (heavier than a show)
    4. Uterine Hyperstimulation (Rare in catheter IOL)
    5. Continuous pain or the catheter is not tolerated
    6. Request of the woman
- Onward care of labour with oxytocin is usual following ARM, unless labour starts spontaneously.
- If ARM is not possible, onward care and plans for IOL or birth should be made by a Consultant Obstetrician.
- Removal of the balloon catheter should be documented in the woman's notes.

6. Amniotomy

Evidence Statement

A Cochrane systematic review of amniotomy alone for IOL included two studies with 310 total participants[72]. One included study compared women receiving amniotomy with those receiving either oxytocin alone or no intervention. This study was underpowered to detect differences in any outcome of interest and the review concluded that no meaningful results could be drawn from these comparisons. The second included study compared amniotomy alone to a single dose of vaginal prostaglandin for women with a favourable cervix and found a significant increase in the need for oxytocin augmentation in the amniotomy alone group compared with the women receiving prostaglandin (260 women, 57/130 versus 20/130; RR 2.85, 95% CI 1.82 to 4.46).

A randomised control trial of amniotomy and immediate oxytocin infusion versus amniotomy and delayed oxytocin infusion for induction of labour in 123 women at term found that women in the immediate group were more likely to be in established labour 4 hours post amniotomy, have a shorter amniotomy to birth interval ($P < 0.001$), and achieve vaginal birth within 12 hours (RR 1.5; 95% CI 1.2 to 12.6).There was no difference between the groups with regard to mode of birth or incidence of uterine tachysystole with abnormal fetal heart rate recording [72].

Further research is needed regarding the value of amniotomy alone for IOL.

Clinical Practice

Amniotomy alone followed by oxytocin infusion may be considered for women with a favourable cervix (Bishop's Score of 7 or more). An intravenous oxytocin infusion can be commenced immediately following amniotomy if the woman has no uterine activity (ie. stimulation of labour) or 6 hours after the last dose of prostaglandin. However, stimulation and augmentation of labour with oxytocin following amniotomy may be left for up to 24 hours after amniotomy (unless contraindications such as GBS carriage or meconium-stained liquor) in an attempt to allow labour to start without oxytocin.

Contraindications to Amniotomy include:

- Vasa Praevia
- Placenta Praevia
- Suspected or confirmed fetal distress.

Recommendations

25. **We recommend membrane sweeping should be offered from 39 weeks.**
26. **We recommend that abdominal palpation, including a measurement of the symphysial fundal height (SFH), assessment of the lie and presentation of the baby and auscultation of the fetal heart should be performed prior to carrying out a membrane sweep.**
27. **Informed consent should always be obtained prior to carrying out a membrane sweep.**
28. **We recommend that prior to membrane sweeping and IOL the fetal anatomy ultrasound scan report and the most recent ultrasound scan should be reviewed to ensure the placenta is not low lying.**
29. **We recommend membrane sweeping and IOL should be performed by a suitably trained healthcare professional.**
30. **Healthcare professionals should be aware of the contraindications and precautions discussed above to using all methods of induction of labour.**
31. **We recommend the use of prostaglandins, oral misoprostol or mechanical methods of induction of labour as safe and effective induction agents.**
32. **Amniotomy alone followed by oxytocin infusion can be considered for a woman with favourable cervix (Bishop's Score of 7 or more). It is reasonable to commence an intravenous oxytocin infusion soon after amniotomy in order to establish labour.**
33. **Women should have one to one midwifery care and continuous fetal monitoring via cardiotocography while receiving an oxytocin infusion.**

Section 4: Setting Of Induction Of Labour

Clinical Question 2.14: What is the appropriate setting for induction of labour?

Introduction

In this section we discuss the literature surrounding outpatient IOL and make recommendations on who is suitable for outpatient IOL, how to assess the woman prior to outpatient IOL and when to advise her to return to the maternity hospital/unit for assessment.

Evidence Statement

A systematic review including twelve publications, representing nine RCTs, found that outpatient IOL is at least as safe and effective as inpatient IOL in terms of maternal, neonatal and resource-related outcomes[73]. The review included 2615 cases of labour induction (1320 outpatients versus 1295 inpatients). The included RCTs compared outcomes in normal risk pregnancies in high resource settings (Europe, Australia, and America) and included both pharmacological and mechanical methods of IOL. Overall, apart from a higher number of suspicious fetal heart rate tracings [RR = 1.43 (1.10, 1.86)] and a shorter mean length of maternity hospital/unit stay [MD = 282.48 min (160.23, 404.73) shorter] in the outpatient group, there were no differences in mode of birth, adverse outcomes or resource-use between the two groups.

One of the trials included in this review was the OPRA study (n=827 women), which compared inpatient and outpatient IOL in normal risk women using vaginal PGE2[74]. No significant differences in oxytocin use (2.5% difference, CI4.3 to 9.4), Caesarean sections (0.59% difference, CI6.3 to 5.1), epidural use (1.5% difference, CI5.1 to 8.2), vaginal birth within 24 hours (8.2% difference, CI17.6 to 1.3) or labour complications were reported.

A recent Cochrane Review comparing outpatient and inpatient IOLs did not report any significant differences in adverse outcomes[75]. They noted that when using intracervical balloons or foley catheters that outpatient inductions may reduce the number of Caesarean births (RR 0.64, 95% CI 0.41 to 1.01, two studies, 159 women). However, the review noted that the data on the effectiveness, safety and women's experiences of outpatient versus inpatient IOL are limited and of very low-certainty. Current evidence reports overnight return to maternity hospital/unit rates in outpatient IOL as 10-38.1% [74, 76, 77]. The NICE Guideline Inducing Labour discusses best practice for outpatient IOL[2].

Clinical Practice

Ideally, women undergoing inpatient IOL should be cared for in a designated clinical area rather than being located in different clinical areas around the maternity hospital/unit. We acknowledge that this may not always be feasible given available resources in maternity hospital/units.

Women with high-risk pregnancy undergoing induction of labour should be handed over to the incoming obstetric and midwifery teams including the Consultant Obstetrician on call and the Assistant Director of Midwifery at clinical handovers.

Outpatient induction of labour with vaginal dinoprostone preparations or mechanical methods can be considered in women who wish to return home, have no co-existing medical conditions or obstetric complications, have good social support, good understanding and ability to communicate in the English language, and who have easy accessibility to the maternity hospital/unit.

A full clinical assessment of the woman and baby will need to be carried out.

This assessment should include:

- An abdominal examination to assess the level and stability of the fetal head in the lower part of the uterus at or near the pelvic brim
- Confirming fetal presentation with ultrasound if there are any concerns about the position of the baby
- Performing a vaginal examination to assess and record the Bishop score
- Confirming a normal fetal heart rate pattern using antenatal cardiotocography (CTG) interpretation
- Clinically assessing the women to confirm the absence of significant uterine contractions (not Braxton-Hicks).

It is necessary to ensure safety and support procedures are in place. The women should receive written information detailing the maternity hospital/unit's contact details, red flag symptoms and instructions on when to return to the maternity hospital/hospital for review. Staff must ensure that the women has access to a telephone, transport to the maternity unit/hospital and that she has a support person with her at home.

Women are requested to contact their Midwife, maternity hospital/unit or Obstetrician if any of the following occur:

- contractions begin
- membranes rupture
- she develops bleeding
- she has any other concerns, such as reduced or altered fetal movements, excessive pain, side-effects or loss of the pessary/mechanical induction agent.

Each unit should create their own local policies on outpatient IOL, and take into account their own facilities, staffing resources and geographical location.

Recommendations

34. Women with a high-risk pregnancy undergoing IOL should be part of the handover process to the incoming obstetric and midwifery teams (including the Consultant Obstetrician on call and the Assistant Director of Midwifery) at clinical handover times.
35. Outpatient induction of labour should be considered in women who wish to return home, have no co-existing medical conditions or obstetric complications, have good social support and have easy accessibility to the maternity hospital/unit.
36. Safety and support procedures should be in place for an outpatient IOL. Women should receive written information detailing the maternity unit/hospital's contact details, red flag symptoms and instructions on when to return to the maternity unit/hospital for review. Staff should confirm that women have access to a telephone, transport to the maternity hospital/unit and that there is a support person at home.
37. We recommend that women are asked to contact their Midwife, maternity hospital/unit or Obstetrician:
    a. when no contractions within an agreed timeframe, depending on IOL method used
    b. when contractions begin, or
    c. if her membranes rupture, or
    d. if she develops bleeding, or
    e. if she has any other concerns, such as reduced or altered fetal movements, excessive pain, side-effects or loss of the pessary/mechanical induction agent.

Section 5: Complications of Induction of Labour

Introduction

In this section, we outline the best practice advice for the on-going care of women in the case that labour has not started, or if complications arise because of the induction process.

Clinical Question 2.15: What are the options if labour has not started after a full cycle of treatment?

Introduction

An "unsuccessful induction" is when labour has not started after one full cycle of treatment, as described in Section 3. Decisions regarding further management options when IOL has been unsuccessful should be made with a senior clinician, and after discussion with the woman and her partner. The woman's preferences should be supported, as well as taking the overall maternal and fetal condition into account. The original indication for IOL should also be considered, together with parity and cervical status.

Evidence Statement

Evidence for the safety of repeated cycles of prostaglandin is derived from the Health Products Regulatory Authority (HPRA) advice on Dinoprostone products and Propess®[62, 64]. Both NICE and WHO agree that an unsuccessful IOL does not necessarily mean Caesarean section. It is recommended that the full clinical picture is taken into account, and that the woman's preferences are supported going forward[1, 59]. Preclinical studies have demonstrated that dinoprostone is a locally acting substance that is rapidly inactivated. It is metabolised primarily in the tissue, and any which escapes local inactivation is rapidly cleared from the circulation with a half-life estimated as 1-3 minutes[62].

Clinical Practice

In the event of an 'unsuccessful induction', the individual clinical scenario should be considered and the woman's preferences taken into account. The woman's condition and the pregnancy in general should be fully reassessed, and fetal wellbeing evaluated using antenatal cardiotocography interpretation.

Management options include; considering a rest period prior to attempting further induction of labour (if clinically appropriate) or further attempts to induce labour with pharmacological or mechanical methods. A second dose of Propess® is not recommended immediately after the first dose, as the dosing effects have not been studied. Additional doses of Prostin® gel can be considered when Propess® has not rendered the cervix suitable for amniotomy, although the safety of this practice has not been studied.

After a full period of 24-hour rest, restarting a full cycle of dinoprostone (Propess® or Prostin ®) can be considered. However, repeated cycles are not recommended by the HPRA and should be considered with caution. Alternative mechanical methods, such as osmotic cervical dilators or balloon catheters, can be considered when pharmacological methods of induction have not rendered the cervix suitable for amniotomy. Similarly, pharmacological methods can be considered when mechanical methods have been unsuccessful. The decision on whether to continue to pursue a vaginal birth and repeated attempts at IOL, versus a decision to undergo Caesarean section, should be made by a senior Obstetrician on an individual basis after clear discussion of the risks and benefits.

Recommendations

38. **We recommend that when labour has not started after one cycle of IOL treatment, the full clinical picture should be reassessed and discussed with a senior clinician, taking into account the individual clinical scenario, the original indication for IOL, maternal and fetal wellbeing, and the woman's preferences.**
39. **A second dose of Propess® immediately after the first dose, is not recommended as the effects have not been studied.**
40. **Additional doses of Prostin® gel (1mg) can be administered when Propess® has been unsuccessful.**
41. **After a period of 24-hour rest, a full cycle of dinoprostone (Propess® or Prostin®) can be restarted from the beginning.**
42. **Both prostaglandins and mechanical methods of induction of labour are as effective as each other in induction of labour. They can be considered in sequence if one method has been unsuccessful in rendering the cervix suitable for amniotomy.**
43. **It is reasonable to offer Caesarean birth when induction has been unsuccessful at starting labour.**

Clinical Question 2.16: What is the preferred management of uterine hyperstimulation?

Introduction

Uterine hyperstimulation is over activity of the uterus as a result of induction of labour it is defined as uterine contractions lasting more than 120 seconds (hypertonus), or more than 5 contractions in 10 minutes over a 20 minute period (tachysystole), regardless of the state of the fetus[59]. It has the potential to cause abnormal fetal heart rate patterns, and also increases the risk of abruption and rupture[78].

Any form of induction, stimulation, or augmentation of labour, including the use of oxytocin, has the potential to cause uterine hyperstimulation. The recommended dose of dinoprostone should not be exceeded (see Section 3 above), and the dosing interval should not be shortened to sooner than 6 hourly as this may increase the risk of hyperstimulation. Once regular painful uterine activity is established, a Propess® should be removed if still in situ, irrespective of cervical state, to avoid the risk of uterine hyperstimulation. Similarly, oxytocin should not be started sooner than 6 hours after the last dose of dinoprostone[64].

Evidence Statement

The advice for management of uterine hyperstimulation was derived from the WHO clinical guideline on induction of labour, with reference to the 2018 Cochrane systematic review on the use of tocolytics[1,79]. Betamimetics are the recommended tocolytics for uterine hyperstimulation, but only weak evidence exists to show their benefit in improving fetal heart rate changes over no intervention in the context of uterine hyperstimulation. Cochrane examined selective ß2-adrenergic agonists versus no tocolytic agent, whilst awaiting emergency delivery. They found that abnormal CTGs are probably lower with tocolytic treatment (RR 0.28, 95% CI 0.08 to 0.95; moderate-quality evidence), but the effects on Apgar scores at birth were uncertain (low-quality evidence).

The report concluded that there is insufficient evidence to determine the effects of tocolytics for uterine hyperstimulation or suspected fetal distress during labour. The sample sizes were too small to detect effects on neonatal morbidity, mortality, or serious adverse effects. It is also important to note that caution should be exercised with their use because of side effects such as palpitations, tremor, tachycardia, hyperglycaemia, pulmonary oedema and myocardial ischaemia[80-82]. In 2011 the FDA issued a warning against the prolonged use of betamimetics (>42-72 hours) due to their association with maternal pulmonary oedema and cardiac arrhythmias. However, prolonged use like this is usually in the context of preterm birth prevention; their use in the acute setting of uterine hyperstimulation may confer benefits that outweigh the risks. However, it is important to note that the use of betamimetics is off-licence for obstetric purposes and an individual assessment of risk is needed.

Clinical Practice

In the event of hyperstimulation, the woman should be advised to lie in the left lateral position and the CTG commenced to assess fetal status. The woman's abdomen should be palpated to assess for strength and duration of contractions.

Urgent obstetric review should be requested if contractions are lasting greater than 2 minutes or have a frequency of more than 5 contractions in 10 minutes. IV access should be secured with urgent bloods sent for FBC and blood group if these have not already been taken.

Any form of ongoing induction agent in situ should be removed such as Dinoprostone Vaginal Pessary (Propess®), osmotic dilators or balloon catheter.

Consider tocolysis with betamimetics in the case of uterine hyperstimulation. The drug of choice is:

- Terbutaline 250 micrograms injection given subcutaneously (SC)
- This dose can be repeated at 5-minute intervals to a maximum of 3 doses
- Second line is salbutamol 1-2 puffs via spacer (if available)
- Contraindications for terbutaline and salbutamol include severe cardiac disease and cardiac arrhythmias.

Analgesia may be required if the woman is distressed. If the CTG remains pathological despite tocolysis, delivery should be expedited.

Tocolysis should not be given to a woman who is bleeding at the time of uterine hyperstimulation. This would raise suspicion for a placental abruption or rupture, and delivery should be expedited according to local emergency protocols.

Recommendations

44. In the event of hyperstimulation, any form of ongoing induction agent in situ should be removed such as Propess®, osmotic dilators or balloon catheter.

45. In the event of hyperstimulation consider tocolysis with betamimetics. The preferred drug of choice is terbutaline 250 micrograms injection administered subcutaneously.

46. In the setting of hyperstimulation we recommend expediting birth of the baby if the CTG is pathological, despite tocolysis.

47. We advise against the administration of tocolysis to a woman who is bleeding at the time of uterine hyperstimulation.

Clinical Question 2.17: How can the risk of cord prolapse be reduced?

Introduction

The overall incidence of cord prolapse ranges from 0.1% to 0.6%, with a higher incidence in breech presentations (1%). The perinatal mortality rate is 91 per 1000, as cord compression and umbilical artery vasospasm are thought to contribute to fetal asphyxia. Prompt recognition and diagnosis allows delivery to be expedited, and management of cord prolapse should be practiced as part of multidisciplinary "skills and drills" [83].

Cord prolapse can occur at any stage of the induction process or labour when the membranes have ruptured. Antenatal ultrasound is not sufficiently sensitive or specific enough for the identification of cord presentation and is therefore not recommended as routine to predict the probability of cord prolapse. Obstetric interventions precede half of all cases of cord prolapse, with artificial rupture of membranes, external cephalic version, and internal podalic version the most commonly implicated procedures[84]. Certain precautions can be taken to reduce the likelihood of it happening at the time of amniotomy, as outlined below.

If cord presentation is felt on vaginal examination, amniotomy is contraindicated and birth should be by Caesarean section[83].

Evidence Statement

Advice for the recognition and management of cord prolapse is outlined in the RCPI National Clinical Guideline and the RCOG Green-Top Guideline on umbilical cord prolapse[83, 85]. Obstetric interventions precede half of the cases of cord prolapse, with artificial rupture of membranes amongst the commonly implicated procedures[84]. A 2013 Cochrane review of Artificial Rupture of Membranes (ARM) for augmentation of spontaneous labour versus no ARM showed no difference in the rate of cord prolapse (RR 1.0, 95% CI 0.14-7.1). This suggests that ARM in the context of spontaneous labour is low risk[86]. However, when performing ARM in the context of an induction, it is prudent to remember that the fetal head may be more loosely applied to the cervix, or may sit at a higher station, so the risk of a cord prolapse may be higher in these circumstances. Clinical judgement is needed to determine the safety of ARM on an individual basis. NICE recommends that before IOL is started, engagement of the presenting part should be assessed, and umbilical cord presentation should be out ruled on vaginal examination to reduce the likelihood of a cord prolapse[59].

Clinical Practice

Women with unstable, oblique or transverse lie should be considered for admission from 37-38 weeks to reduce the risk of a cord prolapse in the community. The exact gestation for admission should be based from a judgement made by the clinician taking into account factors such as distance from the hospital, parity and previous timing of birth.

Before starting the induction process, engagement of the presenting part should be assessed, and the fetal head confirmed fixed in the pelvis. The level and stability of the fetal head in the lower part of the uterus at or near the pelvic brim should be abdominally assessed. Obstetricians and midwives should palpate for umbilical cord presentation during each vaginal examination and avoid dislodging the baby's head upwards.

Amniotomy should be avoided if the baby's head is high, if the head is not fixed in the pelvis, or if the baby's lie is unstable. Consider waiting until the head is in a more favourable, fixed position (if the maternal and fetal condition allows), or a controlled amniotomy with stabilisation of the fetal head and mild fundal pressure may be considered after discussion with a Consultant Obstetrician. If it is necessary to rupture the membranes with a high presenting part, this should be performed in a suitable setting with arrangements available for quick recourse to Caesarean section if needed.

Cord prolapse should be suspected and excluded when there is an abnormal fetal heart rate pattern, particularly after a vaginal exam or rupture of membranes (artificial or spontaneous). The most commonly observed CTG abnormalities are variable decelerations (66%) and prolonged deceleration lasting >1 minute (34%)[87].

If cord prolapse is confirmed at any stage of the induction or labour, birth should be expedited according to local emergency protocols.

Recommendations

48. **Before IOL is started, we recommend assessing the engagement of the presenting part and ruling out umbilical cord presentation on vaginal examination to reduce the likelihood of a cord prolapse.**

Clinical Question 2.18: How can the risk of uterine rupture be reduced?

Introduction

Uterine rupture is a rare event with an incidence varying between 1:8,000-15,000 births [88]. It is most commonly seen in labour in the context of a scarred uterus. The use of prostaglandins in a scarred uterus significantly increases the rate of rupture when compared to non-pharmacological methods (0.87% versus 0.29%), and a higher risk of perinatal death from uterine rupture (0.11% vs 0.04%)[89]. The risk of rupture with one previous Caesarean section is 1:200 (0.5%), and IOL increases the chance of rupture by three-fold[90].

Clinicians should also be aware that spontaneous rupture can occur in an unscarred uterus, although this is very rare, occurring in 1:17,000-20,000 deliveries. This is most frequently associated with multiparous women, women with congenital uterine malformations, and the use of prostaglandins and oxytocin[88].

For women with one previous lower transverse Caesarean section, the rupture rates range from 0.2% to 0.7%. Spontaneous VBAC labour carries a rupture risk of 0.15% to 0.4%, while induction of labour increases the risk to 0.54% to 1.4%, and augmentation further raises it to 0.9% to 1.91%[91].

Evidence Statement

The National Clinical Practice Guideline Vaginal Birth After Caesarean Section outlines the antenatal counselling and intrapartum management of women with previous Caesarean sections[91]. Women should be reassured that planned VBAC is safe for the majority of women and babies with a single previous Caesarean section. Overall success rates are 72-75%. Women with a previous vaginal birth have a higher chance of success (85-90%) and this may help guide the decision of whether to induce or not. Specialist antenatal clinics and individual counselling have been shown to increase the rates of women attempting TOLAC. The woman's history that preceded the Caesarean section, intra-operative notes, success rates, risks and benefits, and information leaflets allow informed decision making with regards to mode of birth. Factors that may increase the risk of rupture are an unfavourable Bishops score, short inter-pregnancy interval (<12 months), post-dates pregnancy and maternal age over 40 years[90]. The plan for birth should be clearly documented in the maternity notes from 36 weeks.

Uterine rupture rates vary from 0.2-0.7% in those with one previous lower transverse CS. However, this risk of rupture varies depending on whether the VBAC labour is spontaneous (0.15-0.4%), induced (0.54-1.4%) or augmented (0.9-1.91%). For women who are induced, the risk of rupture with oxytocin use is approximately 1.1%, increasing to 2% with prostaglandin use, and close to 6% with the use of misoprostol for induction of labour. Further, induction of labour using mechanical methods (amniotomy or Foley catheter) appears to be associated with a lower risk of scar rupture compared with induction using prostaglandins[91].

Planning a VBAC is contraindicated in women with a previous classical Caesarean section. Women who have previously had a uterine rupture have a ten-fold risk of repeat rupture (5%)[90]. There is insufficient data to report on the safety of labour following classical Caesarean section in women with a previous "J" or "inverted T" incision, or where there was significant uterine angle extension. In these circumstances, the decision to aim for a VBAC should be made with a senior clinician on an individual basis. Similarly, there is paucity of evidence to comment on the safety of labour/planning a VBAC in women who have had a previous myomectomy, particularly if the endometrial cavity was breached. Several factors may predispose to higher rates of rupture after laparoscopic myomectomy versus open abdominal myomectomy, such as the use of electrocautery and the surrounding thermal damage, compared to the use of sutures for multilayer closure[92]. While rates of rupture after myomectomy appear to be rare, without clear conclusions to guide management in subsequent pregnancies and deliveries, these cases should be managed on a case-by-case basis with consultant input, and with a low threshold for Caesarean section. Women with two previous Caesarean sections should be counselled by a Consultant Obstetrician about the increased risk of rupture (circa 0.9-1.8%)[91].

Clinical Practice

Planned VBAC should be conducted in a setting capable of continuous electronic fetal heart rate monitoring, one to one midwifery care and the resources for emergency Caesarean section. The decision to induce, and the timing and method of IOL should be discussed with the woman and senior clinician. Women with a previous classical Caesarean section are recommended to have an elective repeat Caesarean birth.

Continuous CTG is recommended as abnormal fetal heart rate patterns are the most consistent finding in uterine rupture (55-87% cases). Women should be informed that IOL carries a 2- to 3-fold increased risk of uterine rupture, and a 1.5-fold increased risk of Caesarean section.

The use of prostaglandin to induce labour carries the greatest risk of rupture in women with a scarred uterus. Given the absence of robust evidence to guide dosing schedules in the context of a scarred uterus, there is no recommended safe dose of dinoprostone.

Oxytocin augmentation can be used and should be titrated so that it does not exceed a rate of contractions of 4 in 10 minutes.

Careful serial assessments of cervical progress and descent of the fetal head, as well as the overall clinical picture, should inform clinicians on whether to continue with the IOL process or whether to consider birth by Caesarean section. A low threshold for intervention should be adopted if there is suspicion of labour dystocia.

The diagnosis is not always clinically obvious, but morbidity and mortality are high for woman and baby. If uterine rupture is suspected during labour, the baby should be delivered immediately by emergency Caesarean section according to local protocols. Clinical signs can include cessation of contractions, a high presenting part, acute abdominal pain, vaginal bleeding and CTG abnormalities.

Recommendations

49. We recommend women with a previous Caesarean birth should have antenatal counselling regarding decision for mode of birth. This process needs to be clearly documented in the notes.
50. We recommend that women who are planning a VBAC should be cared for in a setting where continuous electronic fetal heart rate monitoring, one to one midwifery care and the other resources for emergency Caesarean birth are available.
51. Continuous CTG (using oxytocin, at the onset of contractions, at the diagnosis of labour) is recommended for women who are planning a VBAC as abnormal fetal heart rate patterns are the most consistent finding in uterine rupture.
52. There is no role for an attempted induction of labour for women with a previous classical Caesarean section.
53. We recommend mechanical methods of IOL over pharmacological methods in a woman with a previous Caesarean birth.

Chapter 3: Development Of Clinical Practice Guideline

3.1 Literature search strategy

A comprehensive literature review was undertaken which included national and international publications. Individual literature reviews were undertaken for each clinical question.

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 indications, methods and complications of induction of labour 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 3) as recommended by the Department of Health in the How to Develop a National Clinical Guideline manual, 2019[19].

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.

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

3.4 Literature review

Details of supportive evidence based literature for this Guideline are reported in chapter two. The following databases were searched as part of the literature review: The Cochrane Library (including the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects [DARE]), EMBASE, MEDLINE and PubMed (electronic databases).

Databases were searched for the following terms "induction of labour", "prostaglandin" and "mechanical methods of induction of labour" from September 2021 until February 2022 inclusive to include studies from 2000 until 2023.

The search was restricted to studies involving humans and those published in the English language. Relevant guidelines were also comprehensively reviewed as part of the guideline development process, with reference made to the following guidelines:

1. WHO recommendations for induction of labour 2018. World Health Organization, Dept. of Reproductive Health and Research[1]
2. Inducing Labour. NICE guideline [NG207][59].
3. Guideline No. 432c: Induction of Labour, 2023 [93].

The following steps were taken to ensure a comprehensive review of the literature with continuous input and discussion between committee members:

- The guideline committee met to consider the clinical questions to be addressed; these were divided into 3 parts as described in Chapter 2
- Committee members were divided into groups and performed literature reviews based on their area of expertise to address the questions for each area
- The guideline committee met regularly to discuss the recommendations for each area
- Where there was no evidence to support certain recommendations, these were made based on group consensus and committee expertise
- The final draft of the guideline was reviewed by all committee members, with a further meeting to discuss the final recommendations and evidence presented.

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 [94]. 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[20]. (Appendix 4)

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

3.6 Future research

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

The questions of relevance to this Guideline include:

1. If a woman declines postdates induction of labour, how should she be managed in order to optimise the outcome of the pregnancy while respecting the woman's wishes?
2. Is home induction of labour a safe, acceptable and cost-effective option? What are the advantages and disadvantages of this?
3. At what gestational age should induction of labour be offered in the subgroups of women who may be more likely to experience adverse outcomes if pregnancy continues? These groups include women of black, Asian and ethnic minority backgrounds, women with a BMI of 30 or over, and women aged over 35 years.

Chapter 4: Governance and Approval

4.1 Formal governance arrangements

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

4.2 Guideline development standards

This Guideline was developed by the Guideline Developer Group (GDG) within the overall template of the HSE National Framework[21] for developing Policies, Procedures, Protocols and Guidelines (2016) (Appendix 5) and under supervision of the Guideline Programme Team (GPT).

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

21 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: https://www.hse.ie/eng/about/who/qid/use-of-improvement-methods/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[22].

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 hospital/units are responsible for the appropriate dissemination of new and updated guidelines. Local maternity 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 and RCPI websites and other communication means can be used to maximise distribution. The NWIHP website will also provide a training webinar introducing each guideline and where relevant a downloadable version of the recommended algorithm will be available.

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

Chapter 6: **Implementation**

6.1 Implementation plan

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

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

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

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

6.2 Education plans required to implement the Guideline

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

6.3 Barriers and facilitators

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

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

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

Potential external barriers include:

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

Specifically, IOL from 39 weeks at the request of the woman may not be feasible if adequate resources to do so are not available within the maternity hospital/unit. Units will need individualised prioritisation/ resource plans surrounding this.

Furthermore, the recommendation to offer postdates IOL at 41+0 weeks decreases the gestational age at which induction of labour is offered and may increase the number of women who undergo induction. The recommendations on monitoring in the event that a woman is not delivered at 41+0 weeks may also increase the number of women who chose not to undergo induction and then choose to have additional monitoring. Both these factors may increase resource use in maternity hospital/units.

In the case of this Guideline, it will be necessary to examine possible barriers and consider implementation strategies to address them. Ideally, women undergoing inpatient IOL should be cared for in a designated clinical area rather than being located in different clinical areas around the maternity hospital/unit. We acknowledge that this may not always be feasible given the current available resources in maternity hospital/units.

Staff should receive training in outpatient induction of labour, namely who it should be offered to, the contraindications of outpatient IOL and when women should be advised to return to the maternity hospital/unit. Staff must receive training on all induction agents that are used (and mentioned in this guideline) i.e. Prostin®, Propess®, Balloon Catheters, Dilapan-S® and Misoprostol.

6.4 Resources necessary to implement recommendations.

The implementation of this guideline should be undertaken as part of the quality improvement of each maternity hospital/unit. Maternity hospitals/units should review existing service provision against this guideline, identifying necessary resources required to implement the recommendations in this Guideline. In the case of this Guideline, education around IOL and the associated complications is required. Given that only selected centres currently offer outpatient induction, and that different units may not use all forms of pharmacological and mechanical methods of induction, healthcare workers may not have the same experience and knowledge base, and thus local and national training is required.

Other resources to consider:

- The provision of training models for the insertion of Propess®, Dilapan-S® dilators and balloon catheters
- Pregnancies that continue past 41+0 weeks require increased fetal surveillance, and this will increase the workload in fetal assessment units
- Requests for elective induction at 39 weeks will increase workload and demands on bed capacity. Clinical activity may need to dictate which inductions are prioritised on a day-to-day and on an individual/indication basis
- The provision of information leaflets so that women can be informed and involved in decisions surrounding their care
- Each unit must consider their capacity to provide outpatient induction according to available staff and resources, and have a guideline/protocol around this

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 offered a membrane sweep prior to other methods of IOL.
2. The number of women being induced at 41+0 weeks.
3. The number of women receiving vaginal prostaglandin within two hours of being admitted for IOL.
4. The number of women in whom the Bishop score is recorded in the notes.
5. Maternal observations are carried out before and during IOL, prior to established labour.
6. Fetal heart rate monitoring is carried out before and during IOL, prior to established labour.
7. Mode of birth following IOL.
8. Women with a previous uterine scar have the decision for IOL made by a senior clinician and have an individual management plan recorded in their notes.

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[23].

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 maternity hospital/unit clinical management to support implementation.

23 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.[24]

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 because 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.

24 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)

AFI Amniotic Fluid Index

ARM Artificial Rupture of Membranes

AGREE Appraisal of Guidelines for Research and Evaluation

BS Bishops Score

CAG Clinical Advisory Group

CI Confidence Interval

CTG Cardiotocograph

EAG Expert Advisory Group

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

GPT Guideline Programme Team

HSE Health Service Executive

IOL Induction of Labour

PGE2 Prostaglandin E2

IOG Institute of Obstetricians and Gynaecologists

LSCS Lower Segment Caesarean Section

NICE The National Institute for Health and Care Excellence

NNT Number needed to treat

NWIHP National Women and Infants Health Programme

RCOG Royal College of Obstetricians and Gynaecologists

RCPI Royal College of Physicians Ireland

RCT Randomised Controlled Trial

RR Relative Risk

SDP Single Deepest Pocket

SROM Spontaneous Rupture of Membranes

TOLAC Trial of Labour after Caesarean Section

VBAC Vaginal birth after Caesarean

WHO World Health Organization

Definitions of Terms

Amniotomy	Artificial rupture of membranes to initiate or speed up labour.
Balloon Catheter	A flexible tube with an inflatable balloon at one end. This can be introduced through the cervix and the balloon inflated, holding the catheter in place
Expectant management	Allowing labour to develop and progress under supervision without intervention, unless clinically indicated.
Induction of labour	The process of artificially initiating labour.
Mechanical method	Non-pharmacological method of inducing labour.
Osmotic Cervical Dilator	Medical implements used to dilate the uterine cervix by swelling as they absorb fluid from surrounding tissue.
Membrane Sweep	Digital separation of the fetal membranes from the lower uterine segment during vaginal examination. This movement helps to separate the cervix from the membranes and stimulate the release of prostaglandins.

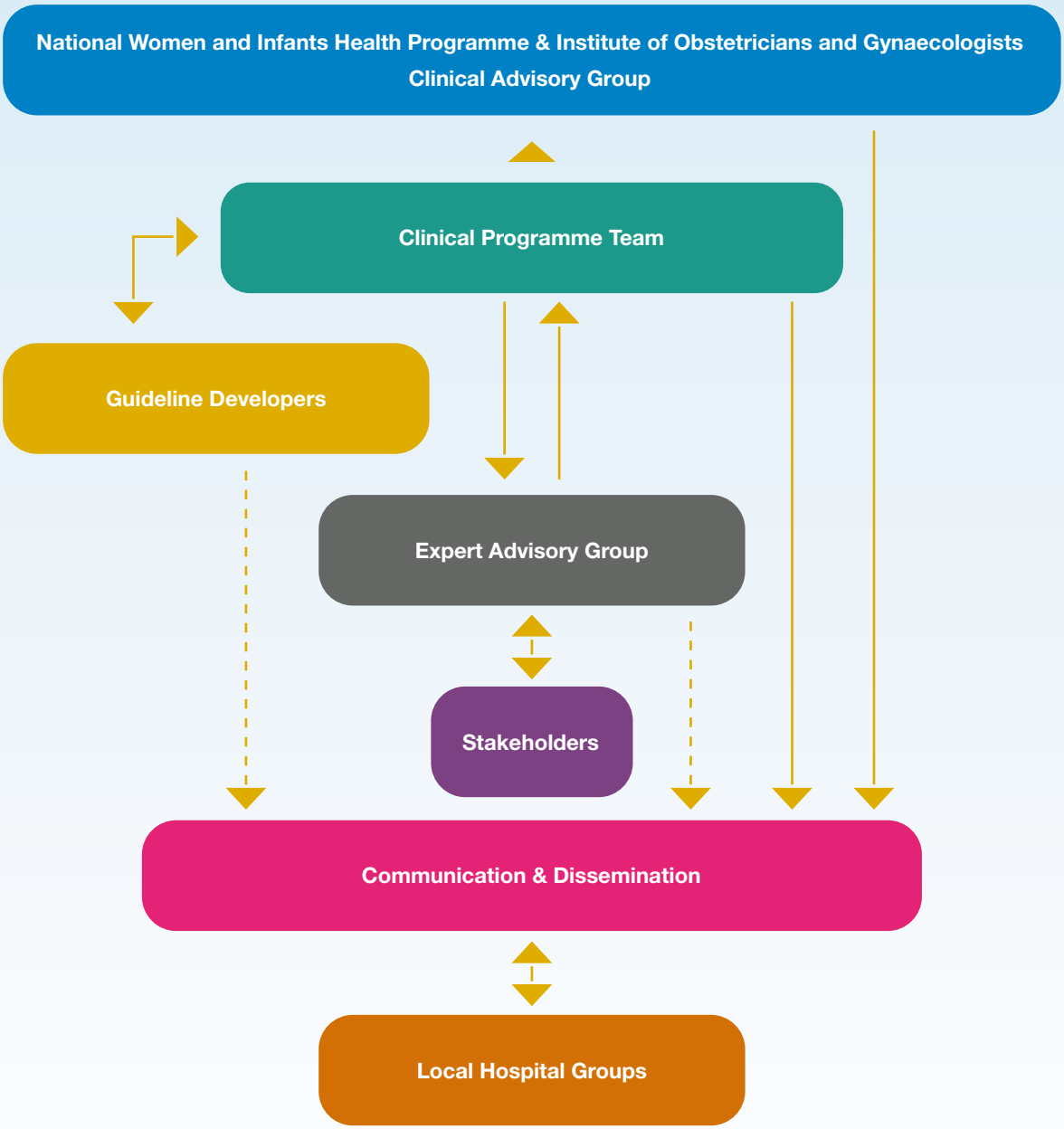
Appendix 1:
Expert Advisory Group Members 2021-

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 Sarah Petch	Specialist Registrar, Obstetrics and Gynaecology	National Maternity Maternity unit Dublin
Dr Orla Donohoe	Specialist Registrar, Obstetrics and Gynaecology	Sligo University Maternity unit
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
Ms Janet Murphy	Advanced Midwifery Practitioner	University Maternity unit Waterford

Attendee	Profession	Location (2021)
Dr Ciara McCarthy	General Practitioner and ICGP Women's Health Lead	Irish College of General Practitioners
Mr Fergal O' Shaughnessy *And* Dr Brian Cleary *(Shared nomination)*	Senior Pharmacist, Honorary Lecturer *And* Chief Pharmacist, Honorary Clinical Associate Professor and Medications Lead, Maternal & Newborn Clinical Management System	Rotunda 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 Clare Farrell	Physiotherapy Manager	Coombe Women & Infants University Maternity unit
Ms Fiona Dunlevy *And* Ms Sinéad Curran *(Shared nomination)*	Dietician Manager	Coombe Women & Infants University Maternity unit 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	Service Manager	Patient Advocacy Ireland

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3: **AGREE II Checklist**[25]

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	

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

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

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

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

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

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

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

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

Appendix 4: **Grades of Recommendation**[26]

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…

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

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 5
Policies, Procedures, Protocols and Guidelines Checklist

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

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

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

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

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

Appendix 6:
NWIHP/IOG CAG Membership list 2023

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

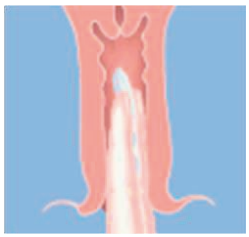
Prof Seán Daly. Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

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

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

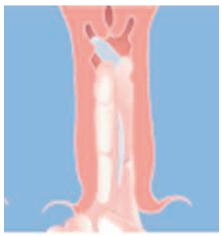
Appendix 7: **Propess®/Dilapan®/Balloon Catheter Administration**

Figure 1 Administration of Dinoprostone Vaginal Delivery System (Propess®)



1. Insertion

Holding the Propess® between the index and middle finger of the examining hand. Insert it high into the vagina towards the posterior vaginal fornix using only a small amount of water-soluble lubricant



2. Positioning

The index and middle finger should now be twisted a quarter turn clockwise, pushing the Propess® higher up into the posterior fornix and turning it through 90 so that it lies transversely in the posterior fornix.

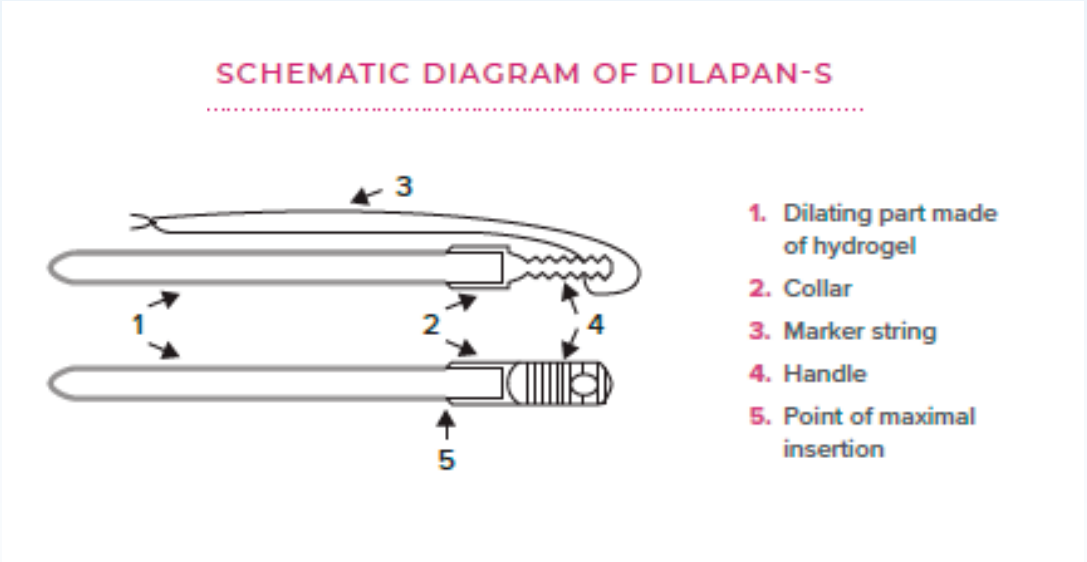
3. After positioning

Carefully withdraw the fingers leaving the Propess® in position. Women should remain recumbent for at least 30 minutes to allow the Propess® to swell. Allow for a small amount of tape to remain outside the vagina for easy removal.

4. Removal

To remove gently pull on the retrieval string. Ensure the whole Propess® pessary is removed.

Figure 2 Diagram of Dilapan-S®[27]



27 Permission granted from Medicem Group a.s. for use of images in Figure 2 and Figure 3.

Figure 3 Insertion of Dilapan-S

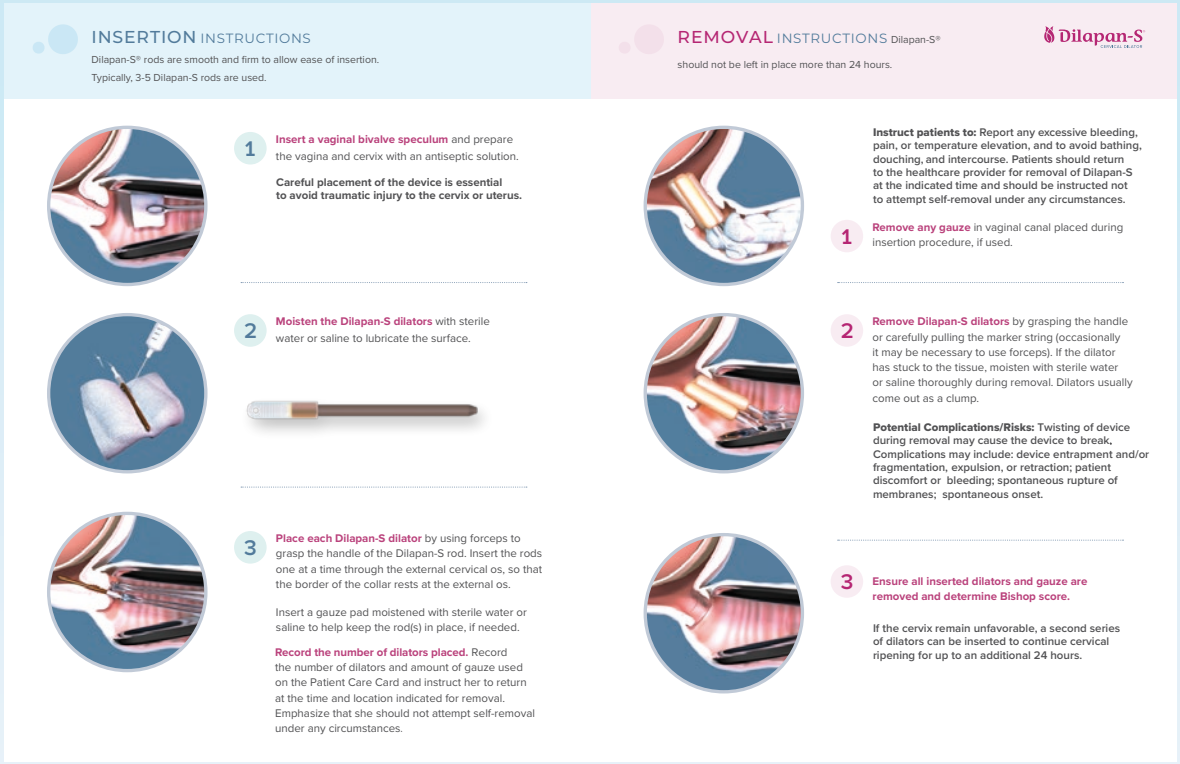
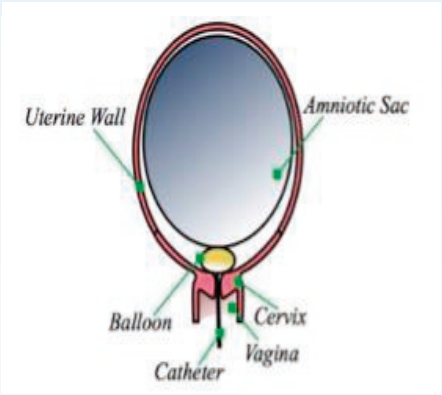


*Figure 4 Balloon Catheter Induction of Labour**



* Smith J. A simplified cervix model in response to induction balloon in pre-labour. *Theoretical biology & medical modelling* 2013; 10: 58. DOI: 10.1186/1742-4682-10-58.