National Women & Infants Health Programme

National Clinical Practice Guideline

Vaginal Birth After Caesarean Section

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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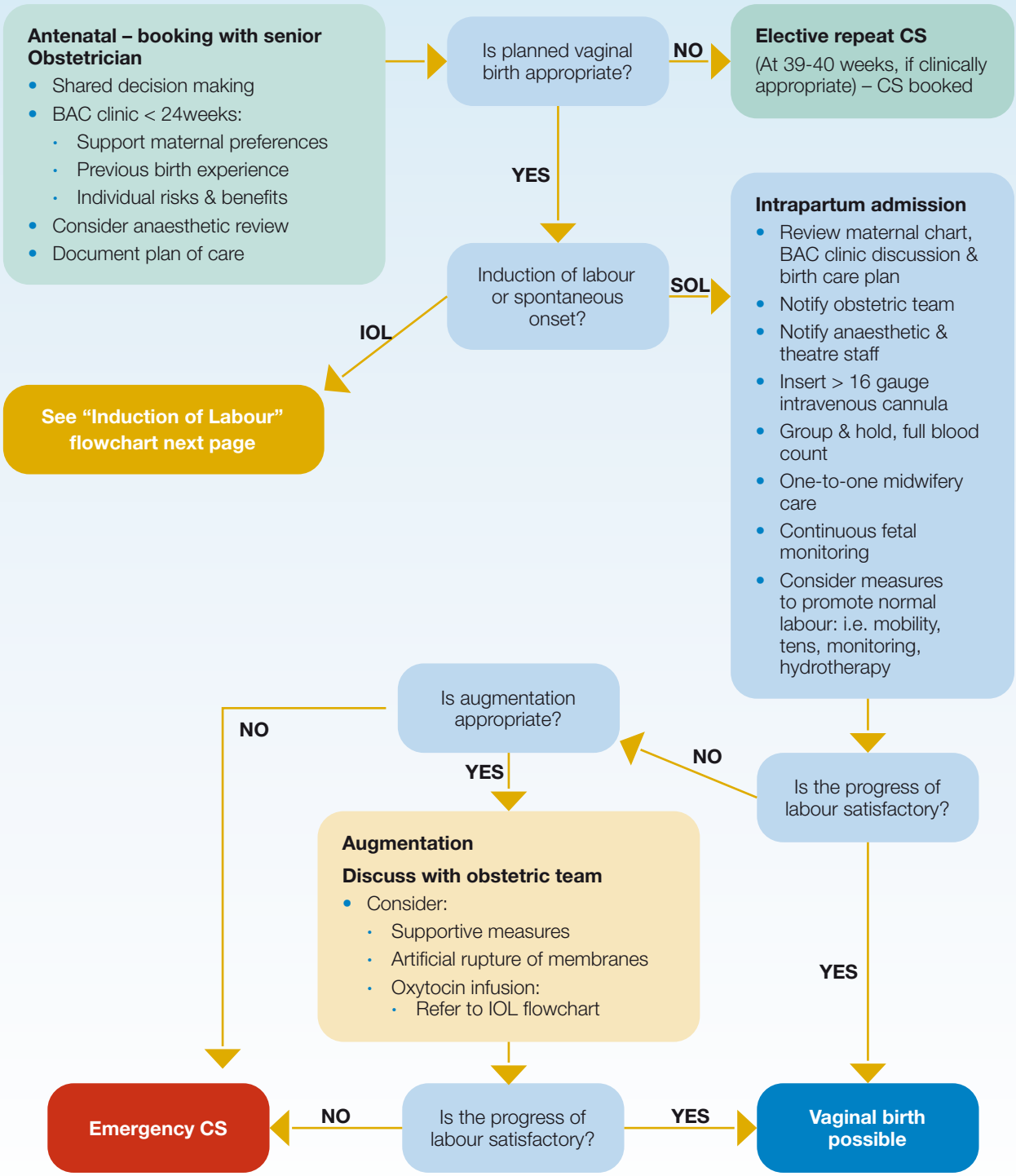
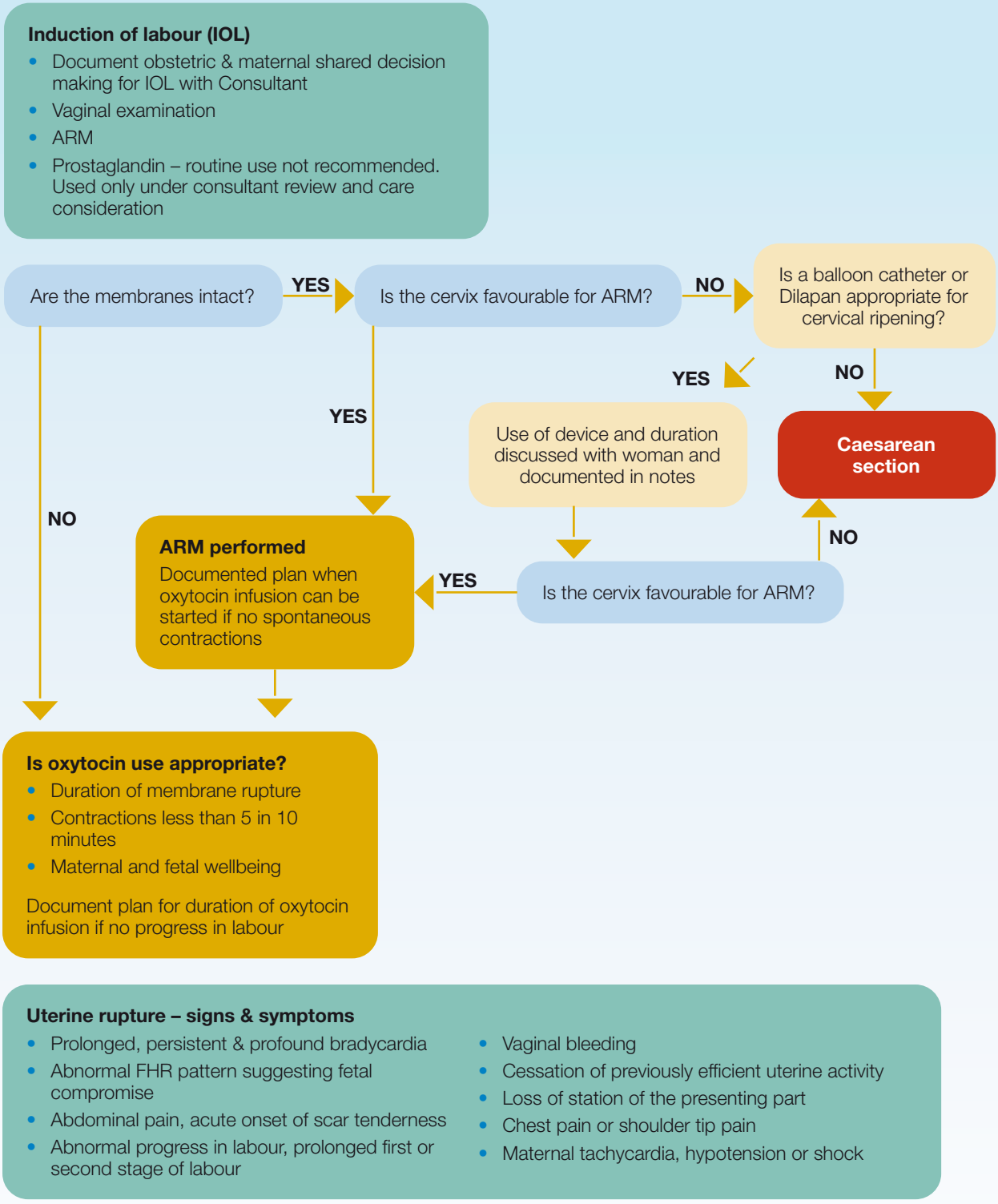
Algorithms

Algorithm 1: Birth After Caesarean Section (BAC)



Algorithm 2: Induction of labour (IOL) after Caesarean Section



Uterine rupture – signs & symptoms

- Prolonged, persistent & profound bradycardia
- Abnormal FHR pattern suggesting fetal compromise
- Abdominal pain, acute onset of scar tenderness
- Abnormal progress in labour, prolonged first or second stage of labour
- Vaginal bleeding
- Cessation of previously efficient uterine activity
- Loss of station of the presenting part
- Chest pain or shoulder tip pain
- Maternal tachycardia, hypotension or shock

Key Recommendations

Number	Recommendation	Grade
1	A woman with previous caesarean section(s) should be assessed by a senior Obstetrician at the booking antenatal visit.	*Best practice*
2	Previous maternity records should be available for review at the booking visit or sought for further review at the next visit.	*Best practice*
3	Women with a previous caesarean birth should be cared for through the Assisted Care Pathway.	*2B*
4	The decision for intended mode of birth should be agreed and documented in the maternity records in the second trimester.	*2B*
5	Placental location should be confirmed as per local/national guidelines.	*2C*
6	Planned Vaginal Birth After Caesarean (VBAC) is a safe and appropriate option for the majority of women with one previous transverse lower segment caesarean section, with a singleton term pregnancy and cephalic presentation.	*2C*
7	Absolute contraindications include previous classical caesarean birth, uterine rupture, placenta praevia and where a woman declines a planned VBAC.	*Best practice*
8	Women should be advised of the risks of VBAC versus Elective Repeat Caesarean Section (ERCS).	*Best practice*
9	The preferred mode of birth should be determined by the woman and her care provider after appropriate counselling.	*Best practice*
10	Women should be informed that a successful VBAC carries the lowest morbidity rates.	*2C*
11	Women should be informed that the most serious risk associated with a VBAC attempt is the risk of uterine rupture, in the region of 0.2-0.7%.	*2C*
12	Women should be informed that ERCS confers risk to both the current pregnancy and subsequent pregnancies, including the risk of placenta accreta and hysterectomy and these risks increase with each subsequent caesarean birth.	*2C*
13	Women should be informed of the increased risk of transient tachypnoea of the newborn (TTN) with ERCS.	*2C*
14	Women should be advised that the overall reported VBAC success rates are in the region of 72-75%.	*2C*

Number	Recommendation	Grade
15	Women should be informed that a history of one or more previous vaginal births is the best predictor for successful VBAC with success rates as high as 85-91%.	*2C*
16	If there is no contraindication to VBAC, maternal request for reversal of a prior plan for ERCS is acceptable after discussion with the Obstetrician and Midwife providing care.	*Best practice*
17	If the plan is for ERCS, and labour ensues before the assigned date, it is important to document the agreed plan of action, either a planned VBAC or caesarean birth, as per the woman's wishes and dependent on the clinical situation at the time.	*Best practice*
18	VBAC should be facilitated in a hospital with the capacity to provide a timely caesarean section if required and should have the necessary Obstetric, Anaesthetic, operating theatre staff and Neonatal expertise, as well as access to laboratory services and blood products.	*Best practice*
19	Women planning a VBAC should have one-to-one care in labour.	*2C*
20	The Obstetric Consultant on call should be made aware of the woman's admission to delivery suite.	*Best practice*
21	Continuous electronic fetal monitoring (CEFM) should be commenced from the diagnosis of labour.	*2C*
22	Recognition of the clinical features of uterine rupture and prompt escalation to senior Obstetric review and laparotomy is vital to ensure the best outcome for the woman and infant.	*2C*
23	Otherwise unexplained post-partum haemorrhage should be considered uterine rupture until out ruled.	*Best practice*
24	Women should be informed that the risk of uterine rupture is higher for a VBAC labour that is either induced or augmented versus a spontaneous VBAC labour.	*2C*
25	Women should be informed that there is an increased risk of unplanned caesarean birth if a VBAC labour is induced or augmented.	*2C*
26	The decision to induce or augment VBAC labour should be determined following careful Obstetric assessment and be made by senior Obstetricians in consultation with the woman.	*Best practice*
27	The option of VBAC for the woman with two previous caesarean births may be considered. This decision requires senior Obstetric input.	*Best practice*
28	Routine debriefing should occur with the woman after caesarean birth, this should outline both the reasons for the caesarean section and the implications for future pregnancies and births.	*Best practice*
29	There are several clinical situations for which careful individual consideration of the benefits and risks of VBAC versus ERCS should be considered by the woman and her Obstetrician and these include macrosomia, twin pregnancy, postdates pregnancy, as well as preterm gestation and other possible clinical scenarios.	*Grade 2C*

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 comprehensive evidence-based guidance for the antenatal and intrapartum periods for a woman who is considering a vaginal birth after a caesarean section. The document provides advice for healthcare professionals around the provision of safe, evidence-based care to women who have had a previous caesarean birth. These guidelines are designed to guide clinical judgement but not replace it.

1.2 Scope

Target Users

The Guideline is a resource for all clinicians working in Maternity hospital/units. Healthcare staff, Doctors, Midwives, Nurses, Health and Social Care Professionals involved in the antenatal and intrapartum care of the woman hoping to achieve vaginal birth after a previous caesarean section.

Target Population

Women planning a vaginal birth after a previous caesarean section.

1.3 Objective

To provide evidence-based recommendations for the care of women planning a vaginal birth after a caesarean section, as well as promoting a standardised approach nationally across all maternity 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.

The clinical practice Guideline writing group members were Dr Gillian Ryan, Jennifer Duggan, Dr Catherine Finnegan and Prof John Morrison.

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

1.5 Stakeholder involvement

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

The Guideline Development Group was made up of Obstetricians and Midwives with a special interest in vaginal birth following caesarean section.

1.6 Disclosure of interests

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

All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the clinical practice Guideline in question.[2] 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 patients 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.[3]

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.[4]

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.

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2 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

3 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

4 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

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 patient 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 ensuring 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

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[5]. We also appreciate that there are risks to desexing language when describing female reproduction[6 7]. 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[8]. 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.

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5 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/

6 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

7 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

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

Chapter 2:
Clinical Practice Guideline

Background

For women who have had one previous caesarean section the optimum mode of birth in a subsequent pregnancy remains a controversial topic and an area where clinical practice varies somewhat worldwide. The vaginal birth after caesarean section (VBAC) rates vary significantly from country to country and range from 9.6% - 52.2% [1-3] in the developed world. At a time when general caesarean section (CS) rates are deemed to be disproportionately high at 25-50% in many countries [4-8], and rising, it must be borne in mind that one of the largest contributions to such rates in a population arises from the cohort of women who have had one previous caesarean section [6, 9]. In approximately 28% of caesarean births in the UK [10], and in 30-50% in the USA a previous caesarean section has been cited as the primary indication [11-13].

For women who have had one previous caesarean section (CS) there are two options for childbirth in a subsequent pregnancy, either VBAC or elective repeat caesarean section (ERCS). It is well established that both options confer a degree of additional maternal and perinatal morbidity, and rarely mortality [4, 11, 14, 15] While the risks are lowest with successful VBAC, none of the existing VBAC screening tools are consistently able to identify women who may achieve this. [16-18]

The reasons for the declining rates of VBAC are multiple and complex and often include a combination of the following: patient and clinician factors, variation in the management of VBAC at local, national, and international levels and the fear of litigation. Multiple studies have found that women are most influenced in their decision-making by their care providers. [19, 20] A Swiss study concluded that caregivers' recommendations about mode of birth after CS, and women's preferences during the third trimester, were the most important predictors for women preferring a VBAC at term. [19] However it is known that women sometimes receive unclear and conflicting advice. [21] One Australian study reported a 10% improvement in VBAC uptake rates by instituting a dedicated next birth after caesarean clinic for counselling and support, aiming to provide a more consistent approach to care during the antenatal period and in labour [22].

A recent randomised trial, OptiBIRTH, was performed in Italy, Ireland and Germany with the aim of increasing VBAC rates through increased women-centred care. This included specially designed antenatal classes for these women and education for care providers [23]. However, while there was no statistically significant difference in the change in the proportion of women having a VBAC between intervention and control sites, at an individual site level the results did appear to show that the OptiBIRTH intervention may assist in supporting VBAC in sites with very low VBAC rates [9]. Studies have shown that women want to receive information from supportive care providers and professional support from a calm and confident Midwife or Obstetrician during childbirth [24]. Care providers should also be aware that when caring for women who are pregnant after previous CS, they should be observant of their needs on an individual level [24].

The data pertaining to the optimal mode of birth in a subsequent pregnancy is limited. Additionally, we acknowledge that are limited studies in recent years on this topic. While the consensus in the literature is that a randomised trial on mode of birth is necessary to accurately compare both options, the question remains as to whether women would agree to be involved when previous attempts internationally at recruitment have been unsuccessful. [11, 25]

Recommendations relevant to this Guideline can also be found in:

- National Clinical Practice Guideline: Induction of labour (2023)
- National Clinical Practice Guideline: Prevention and Management of Primary Postpartum Haemorrhage (2023)[9]
- National Clinical Practice Guideline: Stillbirth: Prevention, Investigation, Management and Care. (2023)[10]
- National Clinical Practice Guideline: Prevention of Early-Onset Group B Streptoccocal Disease in Term Infants (2023)[11]
- National Clinical Practice Guideline: Diagnosis and Management of Placenta Accreta Spectrum (2023)[12]

Introduction

The purpose of this Guideline is to provide evidence-based recommendations on best practice for the antenatal and intra-partum care and management of women undergoing planned VBAC. It also provides guidance on counselling women after an index caesarean birth, as well as supportive counselling to enable women to make an informed decision on VBAC versus ERCS. This Guideline replaces a previous Guideline on birth after previous caesarean birth produced by the RCPI in 2013 [26].

Clinical Question 2.1: **Who should assess the woman and what clinical information should be available at the booking visit?**

Evidence Statement

Best practice recommends that a woman with a previous caesarean section(s) be assessed by a senior Obstetrician to ascertain any contraindication to VBAC [4]. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), 2019 best practice statement, recommends review of the previous caesarean section records to identify the indication(s) and post-operative recovery [27].

9 Byrne B, Spring A, Barrett N, Power J, McKernan J, Brophy, D, Houston C, Faryal R, McMahon E, Manning C, Murphy P, Ni Ainle F. National Clinical Practice Guideline: Prevention and Management of Primary Postpartum Haemorrhage. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists, December 2022.

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. December 2022.

12 Bartels H.C, Walsh J.M, Ní Mhuircheartaigh R, Brophy D, Moriarty J, Geoghegan T, O'Leary M, Donnelly J. C, Colleran, G.C, Thompson, C, Cooney, N, Byrne, B, Downey, P, Greene, R, Higgins, S, Brennan, D.J. National Clinical Practice Guideline: Diagnosis and Management of Placenta Accreta Spectrum. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. December 2022.

The use of standardised proformas can aide in collaborative decision making and clinical documentation for women with a previous caesarean section [13].

Referral to a Birth after Caesarean clinic has been shown to be beneficial in increasing planned VBAC rates [22].

Clinical Practice

Each woman's care should be individualised and adapted to her needs as her pregnancy progresses. A woman should be assessed by the Consultant/Senior Obstetrician at the booking visit, to consider suitability for subsequent vaginal birth. This decision should be made with the aid of her previous maternity and gynaecology records as applicable, as well as any relevant medical or surgical records. Records should be requested from other hospitals where possible.

The use of a proforma/checklist can assist in streamlining this process. (Appendix 3)

Where vaginal birth is an option, the women should be given verbal and written information as to the benefits and risks of both VBAC and ERCS to inform decision making.

Recommendations

1. **A woman with previous caesarean section(s) should be assessed by a senior Obstetrician at the booking antenatal visit.**
2. **Previous maternity records should be available for review at the booking visit or sought for further review at the next visit.**

Clinical Question 2.2: **What model of antenatal care should be offered to women with a previous caesarean section?**

Evidence Statement

The following recommendations are based on the HSE (2018) Home Birth Service, Clinical Guidelines [28], the Stratification of Clinical Risk in Pregnancy (2020) [29] and the HSE (2016) National Maternity Strategy 2016-2026 [30].

The National Maternity Strategy [30] has identified three care pathways based on the woman's risk profile. The *Stratification of Clinical Risk in Pregnancy* [29] recommends that women with a previous caesarean section(s) should be offered the Assisted Pathway of Care; this pathway is intended for mothers and babies considered to be at medium risk. Care in this pathway is led by a named Obstetrician and delivered by Obstetricians and Midwives, as part of a multidisciplinary team. Women with a previous caesarean section are considered ineligible for a home birth according to the criteria set out in the HSE Home Birth Service, clinical guidelines [28]. A decision for intended mode of birth should be confirmed and documented in the maternity records in the second trimester [26].

Women have found the issue of VBAC is like "being in a fog", where decision-making and information from the health care system and professionals, both during pregnancy and the birth, is unclear and contrasting [21].

Clinical Practice

Birth After Caesarean section (BAC) clinics allow the opportunity to provide information on VBAC and ERCS and support women in the decision-making process.

Women need evidence-based information not only about the risks involved but also positive aspects of VBAC.

Placenta location must be confirmed to out rule placenta praevia and/or possible placenta accreta spectrum (PAS) as per national guidelines.

Recommendations

3. **Women with a previous caesarean birth should be cared for through the Assisted Care Pathway.**
4. **The decision for intended mode of birth should be agreed and documented in the maternity records in the second trimester.**
5. **Placental location should be confirmed as per routine local/national guidelines.**

Clinical Question 2.3: **For women with one previous caesarean section, who is suitable for a VBAC?**

Evidence Statement

For the majority of women with one previous transverse lower segment caesarean section, with a singleton term pregnancy (>37+0 weeks gestation), of cephalic presentation, planned VBAC is an appropriate option and may be offered [4, 31]. However, there are absolute contraindications to VBAC which include previous classical caesarean birth or inverted 'T' incision, a previous uterine rupture and other contraindications to labour including placenta praevia and malpresentation [4, 6, 15, 31]. Women with a previous hysterotomy or myomectomy entering the uterine cavity should be assessed by a consultant and suitability for VBAC considered on an individualised basis. Furthermore, any woman who declines a planned VBAC should also be offered a planned ERCS birth [15]. Other relative contraindications to VBAC include breech presentation, fetal macrosomia and twin pregnancy [6] while those with two previous transverse lower segment caesarean sections should be considered on an individualised basis [4, 6].

Clinical Practice

All women after a previous caesarean birth should be assessed by a senior obstetrician at their booking visit and their suitability for planned VBAC determined.

The previous maternity notes should be reviewed with the woman at this visit.

The reason for a woman's previous caesarean birth should be elicited, and the type of uterine incision confirmed. If a woman has had a previous classical caesarean birth, an inverted 'T' incision or a previous uterine rupture they should be advised that a planned VBAC is contraindicated.

Women with a previous hysterotomy or myomectomy entering the uterine cavity should be assessed by a Consultant and suitability for VBAC considered on an individualised basis.

Women should be reviewed at subsequent visits for other contra-indications to VBAC which may arise during the pregnancy. These include absolute contra-indications (placenta praevia and accreta and malpresentation) and relative contra-indications (breech presentation, macrosomia and twin pregnancy).

Any woman who declines a planned VBAC, at any time in the antenatal period, should be offered a planned ERCS.

Recommendations

6. **Planned Vaginal Birth After Caesarean (VBAC) is a safe and appropriate option for the majority of women with one previous transverse lower segment caesarean section, with a singleton term pregnancy and cephalic presentation.**
7. **Absolute contraindications include previous classical caesarean birth, uterine rupture, placenta praevia and where a woman declines a planned VBAC.**

Clinical Question 2.4: **How should women be counselled about the risks and benefits of VBAC and ERCS?**

Evidence Statement

A decision about a subsequent birth following a previous CS will be influenced by several factors. These include whether a woman has had a previous vaginal birth, the risks, and benefits of each mode of birth, clinical factors in the current pregnancy, a woman's desire to achieve a vaginal birth and other social factors, as well as medical influences. The preferred mode of birth should be determined by the mother and her care provider after appropriate counselling. The woman should be made aware that both VBAC and ERCS are associated with risks of maternal and fetal morbidity, and occasionally mortality [6].

Unfortunately, there are no robust trials comparing the outcomes of these groups and the data available are derived primarily from observational studies [6].

Maternal risks of both ERCS and planned VBAC include hysterectomy, transfusion, thromboembolism, operative birth/injury, uterine rupture/dehiscence, chorioamnionitis/endometritis, shoulder dystocia and death [2, 11, 32-34]. Fetal/neonatal risk factors include neonatal respiratory complications, hypoxic ischaemic encephalopathy, NICU admission, reduced Apgar scores, injury sustained during vaginal/caesarean birth including fracture or trauma to the face or scalp, intrapartum fetal demise, and neonatal death [2, 3].

Women should be informed that a successful VBAC carries the lowest morbidity rates [4]. A 2010 systematic review and meta-analysis of 203 studies concluded that VBAC was a reasonable option for the majority of women and the overall risk of serious adverse outcomes was rare [35]. They observed that although rare in both ERCS and trial of labour, maternal mortality was significantly increased for ERCS at 0.013% compared with 0.004% for trial of labour [35]. Furthermore, they also observed that perinatal mortality was significantly increased for trial of labour (0.13% compared with 0.05% for ERCS), however the absolute rates were deemed to be relatively low [35]. The rates of maternal hysterectomy, haemorrhage, and transfusions did not differ significantly between trial of labour and elective repeat caesarean delivery [35]. This review also reported a uterine rupture rate for all women with prior caesarean birth as 0.30%, also reporting that the risk was significantly higher for those undergoing a trial of labour (0.47% compared with 0.03% for ERCS) [35].

A Canadian study by McMahon *et al* of 6138 women compared the outcomes of women with a previous CS in a subsequent pregnancy [32]. They observed no maternal deaths in either group. Furthermore, while they observed no significant difference in the overall maternal complications between the groups they found that women undergoing a planned VBAC were nearly twice as likely to have a major complication (defined as the need for hysterectomy, uterine rupture or operative injury) [32]. While the risks are lowest with a successful VBAC, unfortunately none of the existing VBAC screening tools have been consistently able to identify women most at risk of successfully achieving a planned VBAC [16].

Clinical Practice

Women should be counselled at their booking visit about the risks of both VBAC and ERCS. This should be clearly documented in the antenatal notes.

The preferred mode of birth should be determined by the mother and her care provider after appropriate counselling at both the antenatal booking visit and subsequent antenatal visit.

Where possible written information on both VBAC and ERCS should be provided to the woman to aide in decision making and referral should be organised to a dedicated Birth After Caesarean Clinic where available.

Recommendations

8. **Women should be advised of the risks of VBAC versus Elective Repeat Caesarean Section (ERCS).**
9. **The preferred mode of birth should be determined by the woman and her care provider after appropriate counselling.**
10. **Women should be informed that a successful VBAC carries the lowest morbidity rates.**

Clinical Question 2.5: **What are the risks of VBAC?**

Evidence Statement

Uterine rupture is the most serious risk associated with a VBAC attempt. Uterine rupture is associated with a high rate of both maternal and fetal morbidity and sometimes mortality. Rupture rates vary from 0.2-0.7% [4, 36, 37] in those with one previous lower transverse CS [4, 15, 34, 36], and from 0.9-1.8% in those with two lower transverse previous CS. [38-40] Uterine rupture is both difficult to predict, and prevent, and adverse effects can be catastrophic to both the mother and to the fetus. Therefore, it is of critical importance that care providers are aware of this potential risk and are trained in recognition of early clinical signs. For those with a previous classical CS the risk of uterine rupture is in the rate of 3-6% and is therefore an absolute contraindication to VBAC. [41, 42]

VBAC has also been associated with an increased risk of obstetric anal sphincter injury (OASI). A recently published systematic review found an increased prevalence of OASI in women undergoing VBAC (8.18%) compared with primiparous women (6.59%) [43].

There is an increased risk to infants of hypoxic ischaemic injury (HIE) in those undergoing a planned VBAC (0.08%), when compared to those undergoing planned ERCS (<0.01%) [4] though the absolute rates remain low.

Clinical Practice

Women should be clearly informed at their antenatal booking visit that the most serious risk associated with a VBAC attempt is the risk of uterine rupture.

Women should be informed that this risk is in the region of 0.2-0.7% and this should be clearly documented in the antenatal notes.

Recommendations

11. **Women should be informed that the most serious risk associated with a VBAC attempt is the risk of uterine rupture, in the region of 0.2-0.7%.**

Clinical Question 2.6: **What are the risks of ERCS at or after 39 weeks?**

Evidence Statement

ERCS, particularly multiple CS procedures, is associated with increased risks of haemorrhage, transfusion, surgical injury, placenta praevia, placenta accreta, and hysterectomy, with the risks increasing for each subsequent CS [33, 44, 45]. Previous studies have found that the absolute risk of praevia associated with any number of caesareans is 12 per 1000 (95% CI 8, 15 per 1000; *P*<.001) [35]. The incidence with each additional prior caesarean delivery increased from 10 per 1000 with 1 prior caesarean delivery (95% CI 6, 13 per 1000) to 28 per 1000 (95% CI 18, 37 per 1000) with 3 or more caesarean deliveries [33]. Women with no prior caesarean birth and previa required hysterectomy in 0.7% to 4% of cases compared with 50% to 67% in women with 3 or more prior caesarean deliveries [46-48].

A Finnish study of 16 938 women who had undergone a caesarean birth also observed that previous CS is associated with an increased risk of ectopic pregnancy (RR, 1.28), placenta previa (RR, 3.89), and placental abruption (RR, 2.41) [15, 49]. Women should be informed that hysterectomy rates are increased with each additional CS [15, 16, 33, 35, 49]. Women with 1 prior caesarean have a 0.19% risk of hysterectomy, those with 2 prior caesareans have a 0.56% risk of hysterectomy [50].

Women should also be informed that the risk of a morbidly adherent placenta is also increased with increasing number of caesarean births [15, 44, 45]. A US study concluded in the context of a confirmed placenta praevia, the risk of placenta accreta was 3%, 11%, 40%, 61%, and 67% for the first, second, third, fourth, and fifth or greater repeat caesarean births, respectively [44]. While still relatively uncommon the risk of placenta accreta spectrum in a subsequent pregnancy should be borne in mind when deciding on ERCS and discussing a woman's wish for further children should also be part of the counselling and discussion.

With ERCS neonates are at increased risk of breathing difficulties after birth, including transient tachypnoea of the newborn (TTN) and respiratory distress syndrome (RDS), which may result in increased admission rates to neonatal special care units. The risk of neonatal respiratory morbidity for term infants born by CS before the onset of labour is higher than for those born by other means [51, 52]. Long-term follow up studies of children born by CS are emerging which show increased rates of several childhood issues, particularly asthma, atopy, childhood obesity and behavioural problems [6, 53-56], although further research is required to clarify some of these associations [6].

Clinical Practice

Women should be clearly counselled at their antenatal booking visit about the risks of ERCS, not only in the current pregnancy, but also any increased risk in a subsequent pregnancy.

Women should be informed of the increased risk of morbidly adherent placenta with each subsequent CS.

Women should also be informed of the increased risk of transient tachypnoea of the newborn with ERCS.

Recommendations

12. **Women should be informed that ERCS confers risk to both the current pregnancy and subsequent pregnancies, including the risk of placenta accreta and hysterectomy and these risks increase with each subsequent caesarean birth.**
13. **Women should be informed of the increased risk of transient tachypnoea of the newborn (TTN) with ERCS.**

Clinical Question 2.7: **What is the likelihood of having a successful VBAC?**

Evidence Statement

Women should be counselled that an attempt at VBAC may result in either a "successful" VBAC or an "unsuccessful" planned VBAC resulting in a repeat caesarean birth. VBAC success (achieving a vaginal birth) rates vary in the literature but are generally quoted as somewhere between 54-85%, with an average rate of approximately 72-75% [4], with the highest rates in those with a history of previous vaginal birth [4, 27, 33, 34].

What factors are associated with an increased likelihood of a successful VBAC?

Women should be informed that a history of one or more previous vaginal births is the 'single best predictor of successful VBAC' and carries with it success rates of 85-91% and is associated with a lower risk of uterine rupture [4, 27, 33]. A meta-analysis by Eden *et al* indicated that a history of prior vaginal birth increased the chance of successful VBAC by 3-4 fold [16]. Data from the National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network found that an increasing number of prior successful VBAC attempts was associated with improved success rates for subsequent attempts [33, 57]; women with 0-4 VBACs had progressively increasing success rates of achieving a VBAC in a subsequent pregnancy, 63-91.6% respectively [33, 57].

There are other obstetric factors which appear to exert a favourable outcome on a successful VBAC. Having had a previous CS for malpresentation, including breech presentation, is associated with a better chance of a successful VBAC [4, 33]. Furthermore, women who present in spontaneous labour have a two-fold increase in the likelihood of a successful VBAC, in comparison to women who require induction of labour [4, 33].

What factors are associated with a decreased likelihood of a successful VBAC?

Women should also be informed of additional factors which are associated with reduced VBAC success including non-white ethnicity, higher infant birth weight, induced labour, no previous vaginal birth, BMI greater than 30, and previous caesarean birth for dystocia [1, 4, 16, 26, 58]. If a number of these factors are present success rates can be as low as 40% [1, 4]. Women who's BMI was >30kg/m^2 have been found to have lower rates of successful VBAC (54.6%) vs BMI 25-29.9kg/m^2 (65.5%) and women with BMI 19.8-24.9kg/m^2 (70.5%) [59]. However, given the difficulties the patients with higher BMI pose both practically during surgery in addition to the extra risk conveyed by wound infection, VTE risk etc the risks of successful VBAC must be balanced against this. Other factors that potentially reduce successful VBAC included maternal age >40 years [16] and the presence of maternal medical conditions including hypertension, gestational diabetes and renal disease [58].

Clinical Practice

Women should be counselled at the antenatal booking visit and at subsequent visits about their individual chance of having either a 'successful' VBAC versus or 'unsuccessful' planned VBAC. These factors may change over the course of the pregnancy and the counselling should be tailored accordingly.

Women should be informed that the overall success rates for VBAC are in the region of 72-75%.

Women should also be informed that there is a higher chance of a successful VBAC in the event of spontaneous onset or labour and a lower chance of a successful VBAC where labour is induced.

Recommendations

14. **Women should be advised that the overall reported VBAC success rates are in the region of 72-75%.**
15. **Women should be informed that a history of one or more previous vaginal births is the best predictor for successful VBAC with success rates as high as 85-91%.**

Clinical Question 2.8: **How to manage change of mind regarding mode of birth later in pregnancy?**

Evidence Statement

It is recommended that the antenatal counselling provided to a woman during pregnancy regarding mode of birth should be adequately documented [4]. It is also recommended that a final decision for mode of birth should be agreed upon by the woman and her professional team prior to the estimated date of birth, and ideally in the second trimester [4]. However, it is well recognised that a significant proportion of women who have had one previous caesarean section will express further uncertainty, or request a change of plan, in relation to the previously decided mode of birth [6].

This change of mind potentially falls into three main categories as follows:

1. Change of mind from planned VBAC to planned ERCS.
2. Change of mind from planned ERCS to planned VBAC.
3. Uncertainty on how to proceed if spontaneous labour ensues before a planned ERCS (which occurs in approximately 10% of cases when ERCS is planned for 39 weeks' gestation).

Clinical Practice

Women should be made aware of the need for a planned approach as distinct from continuing uncertainty and/or reliance on discussion with the on-call team at the time of unplanned presentations. Discussion, which may need to be repeated, should be individualised to the woman's clinical circumstances and views. If there is no contraindication to VBAC, reversal of a prior plan for ERCS is reasonable after discussion with the Obstetrician and Midwife providing care. Similarly, reversal of a prior plan for VBAC may be appropriate after careful consideration of the woman's wishes.

It is imperative that such discussions, and the revised plan agreed, are clearly documented in the woman's case notes. If the plan is for ERCS, and labour ensues before the assigned date, it is important to document the agreed plan of action. Such a plan of action reasonably includes the option to continue with attempted VBAC, or have the planned ERCS after presentation in labour. Whichever of these plans is agreed, it is important that it is clearly documented.

Women also need to be advised that clinical circumstances may change after presentation in labour (e.g. concerns regarding fetal wellbeing, advanced labour on admission) and that the agreed plan may be open to some revision by the team providing care on call, in consultation with women, as medically necessary.

Recommendations

16. **If there is no contraindication to VBAC, maternal request for reversal of a prior plan for ERCS is acceptable after discussion with the Obstetrician and Midwife providing care.**
17. **If the plan is for ERCS, and labour ensues before the assigned date, it is important to document the agreed plan of action, either a planned VBAC or caesarean birth, as per the woman's wishes and dependent on the clinical situation at the time.**

Clinical Question 2.9: **What birth setting should be facilitated for a woman planning a VBAC?**

Evidence Statement

The following recommendations are primarily consensus based from the RCOG (2015) Birth After Caesarean Section [8], ACOG (2019) Vaginal Birth After Caesarean Delivery [7], SOGC (2018) No.155 – Guidelines For Vaginal Birth After Previous Caesarean Birth [15], and RANZCOG (2019) Birth after previous caesarean section [29]. International best practice guidelines agree that VBAC is a 'safe and appropriate' option for most women who have had a prior caesarean birth [4, 27, 31]. They do, however, caution that labour should be planned in a hospital setting, with an appropriately staffed and equipped delivery suite, with appropriate facilities for monitoring throughout labour, and the resources to progress to a timely and safe emergency CS if required [3, 4]. The facility should have access to an operating theatre to perform a timely caesarean section, with Category 1 (immediate threat to the life of the woman or fetus) urgency if required. [60]

Clinical Practice

It is recommended that VBAC should be offered in a hospital setting, with an appropriately staffed and equipped delivery suite. This includes timely access to an operating theatre, including for category 1 scenarios, along with appropriate anaesthetic and operating theatre staff.

It is also recommended that the hospital have access to laboratory services, including blood and blood products.

Women planning a VBAC should have continuous one-to-one care; including continuous electronic fetal monitoring (CEFM) and support in labour by midwifery and obstetric staff.

It is also recommended that neonatal resuscitation, if required, should also be available and staffed by neonatal trained staff.

Recommendations

18. **VBAC should be facilitated in a hospital with the capacity to provide a timely caesarean section if required and should have the necessary Obstetric, Anaesthetic, operating theatre staff and Neonatal expertise, as well as access to laboratory services and blood products.**

Clinical Question 2.10: **What are the aspects of care that should be recommended in labour and birth for women planning a VBAC?**

Evidence Statement

Women planning a VBAC have the additional risk factor of the potential for uterine rupture during labour. As uterine rupture is diagnosed at caesarean section or postpartum laparotomy, the focus of maternity care during labour is monitoring for the signs and symptoms of uterine rupture [4, 27].

Possible signs and symptoms of uterine rupture include:

- Cardiotocograph (CTG) Abnormalities
- Per vaginam blood loss/ blood-stained liquor
- Haematuria
- Severe abdominal pain particularly between contractions
- Scar pain – (or previously effective epidural)
- Maternal tachycardia, hypotension, fainting or shock
- Cessation of previously regular contraction pattern
- Change in the fetal station and/or position and site of fetal heart auscultation. [4, 15, 27]

Women should also be informed that there is no contraindication to epidural anaesthesia in labour. One study reported a significantly lower caesarean rate for women who had an epidural in labour 8.7% vs. no epidural 11.8%, P<0.0001, with a parallel increased rate of assisted vaginal birth. They observed no increased risk of uterine rupture [61]. Other studies have also reported that epidural analgesia is safe and effective in women undergoing a trial of labour with and no increased risk of postpartum bleeding or uterine rupture [62, 63].

Clinical Practice

The following measures aim to assist in recognition of potential or actual uterine rupture:

- Continuous one-to-one care throughout labour and birth
- The Obstetric Consultant on call should be made aware of the woman's admission to delivery suite and of the relevant clinical factors
- Continuous Electronic Fetal Monitoring (CEFM) with the diagnosis of labour onset [64]
- Fresh eyes/second eyes approach with CTG assessment [65, 66]
- Prompt and appropriate escalation of abnormal findings using the ISBAR communication tool (HSE)
- IV cannulation, Full Blood Count and Group and Hold/Save (if additional risk factors for caesarean birth)
- Cervical dilatation should be assessed no less than 2-4 hourly up to 7cm and no less than 2 hourly during transition (from 6-10cm cervical dilatation) to assess for evidence of delay in labour Diagnosis of delay should trigger clinical reassessment by an experienced Obstetrician [4, 27]
- Epidural analgesia is appropriate during labour if the woman requests it
- Recognition of the signs and symptoms of uterine rupture and prompt escalation to laparotomy is vital to ensure the best outcome for the women and infant
- Otherwise unexplained post-partum haemorrhage should be considered uterine rupture until excluded.

*Fetal blood sampling should only be used in consultation with the Consultant Obstetrician as its use may detract from other signs and/or delay birth of the infant.

Recommendations

19. **Women planning a VBAC should have one-to-one care in labour.**
20. **The Obstetric Consultant on call should be made aware of the woman's admission to delivery suite.**
21. **Continuous electronic fetal monitoring (CEFM) should be commenced from the diagnosis of labour.**
22. **Recognition of the clinical features of uterine rupture and prompt escalation to senior Obstetric review and laparotomy is vital to ensure the best outcome for the woman and infant.**
23. **Otherwise unexplained post-partum haemorrhage should be considered uterine rupture until out ruled.**

Clinical Question 2.11: **What information should be provided to the woman considering induction or augmentation of labour?**

Evidence Statement

As alluded to above, the most serious risk associated with a VBAC attempt is the risk of uterine rupture and rupture rates vary from 0.2-0.7% [4] in those with one previous lower transverse CS [4, 34, 36]. 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%) [4]. 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 [15, 33, 67]. Furthermore, 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 [4, 15, 27].

An NICHD study reported a higher rate of uterine rupture risk with prostaglandin induction (0.87%) compared with non-prostaglandin induction (0.29%) (e.g. amniotomy or intracervical Foley catheter) [4, 36]. A further study by Bujold *et al* also reported no increased rate of uterine rupture in women induced using a Foley catheter for cervical ripening compared with those in spontaneous labour [15, 68]. However, one further study reported an increased risk of uterine rupture in those induced with a Foley catheter [27, 69]. These data on the effectiveness and safety of transcervical catheters are limited due to their small sample size and as such it is difficult to draw robust clinical conclusions on their use.

Women should also be informed of the increased risk of caesarean birth in induced and/or augmented labour compared with spontaneous VBAC labour [4]. They should also be informed that induced and/or augmented labour is associated with a higher rate of 'unsuccessful VBAC', resulting in a caesarean birth, compared with spontaneous VBAC labour [4, 27].

Any decision to induce or augment a VBAC labour should be made jointly between a woman and her care provider following careful obstetric assessment. Women should be counselled by a senior Obstetrician and should be informed of the increased risks of failed induction, uterine rupture and emergency caesarean birth associated with induction and/or augmentation of a VBAC labour [4, 15, 27]. Women should also be informed of the alternative option of a caesarean birth [4]. The proposed method of induction should be discussed and any decision to augment with oxytocin should be discussed with each woman and the decision to augment labour thereafter clearly documented. Furthermore, a plan should be made to determine the most appropriate time intervals for serial vaginal examinations during labour along with parameters of progress determined, that if not met, would necessitate discontinuing the trial of VBAC [4, 27].

Clinical Practice

Women should be counselled that the risk of uterine rupture is higher for a VBAC labour that is induced or augmented versus a VBAC labour of spontaneous onset.

Women should also be clearly informed that there is an increased risk of emergency CS when a VBAC labour is either induced or augmented.

Any decision to induce or augment a VBAC labour should be made jointly between a woman and her care provider following careful obstetric assessment by a senior Obstetrician.

Recommendations

24. Women should be informed that the risk of uterine rupture is higher for a VBAC labour that is either induced or augmented versus a spontaneous VBAC labour.
25. Women should be informed that there is an increased risk of caesarean birth if a VBAC labour is induced or augmented.
26. The decision to induce or augment VBAC labour should be determined following careful obstetric assessment and be made by senior Obstetricians in consultation with the woman.

Clinical Question 2.12: **How should women with two previous caesarean sections, requesting a VBAC, be counselled?**

Evidence Statement

Women who have previously had two lower segment caesarean sections, and for whom there is no other contraindication to VBAC, may be facilitated with an option for VBAC if that is what their preference is. They should be counselled by a senior Obstetrician about the increased risk of rupture (circa 0.9 – 1.8%) [4, 27]. They should also be offered ERCS, and it should be documented that they know that this option is also available. The counselling should include all the other aspects outlined for the woman who has had one previous caesarean section, i.e., individualised risk of success, a plan for change of mind, and the risks and benefits of VBAC versus ERCS. The labour should be planned to take place with all the necessary expertise and where there is immediate access to operative facilities should the need for CS arise. The success rates reported for planned VBAC for women with two previous caesarean sections are in the of region of 60-70% in general [4, 27], however there may be confounding individualised factors for each particular woman.

Clinical Practice

Any woman with two previous caesarean births requesting a VBAC should be counselled by a senior Obstetrician. The woman should be offered the option of ERCS as an alternative.

The risks and benefits of VBAC versus ERCS should be outlined clearly to the woman and documented in the antenatal notes and this should include the increased risk of rupture (approx. 0.9 – 1.8%), its associated risks of morbidity and mortality, the likelihood of a successful VBAC and a plan for the woman changing her mind.

Recommendations

27. The option of VBAC for the woman with two previous caesarean births may be considered. This decision requires senior Obstetric input.

Clinical Question 2.13: **What debriefing should occur following caesarean section?**

Evidence Statement

All women who have had a caesarean birth should have the opportunity to discuss and be debriefed about their birth in the postnatal period, preferably prior to discharge. Ideally, this should be carried out by the Obstetrician who performed the surgery or senior obstetric member of the team, and, if possible, the midwife who cared for the woman in labour [27], and, it may also be helpful if the midwife who provided intrapartum care reviews/meets with/debriefs the woman postnatally as well.

Clinical Practice

This discussion should be individualised and include the following, where applicable:

- reasons that led to the caesarean birth
- implications for future pregnancies and births and
- possible suitability (or not) for VBAC as an option for future births
- ideally the Obstetrician who performed the surgery should indicate the suitability for VBAC in a subsequent pregnancy either in the operative notes or in the postnatal notes at the time of the debrief.

It can also be an opportunity to inform the women of measures that may enhance the success of VBAC in the future.

This information can be given with the aid of a proforma/checklist as a written record. (Appendix 4)

If the woman is not ready, this discussion/ debrief may require a follow up appointment, as appropriate.

This information should also be communicated to the PHN and the GP to ensure continuity of care for the woman.

Recommendations

28. **Routine debriefing should occur after caesarean birth. This should outline both the reasons for the caesarean section and the implications for future pregnancies and births.**

Guiding statements on special considerations

There are several clinical situations for which individual consideration of the benefits and risks of VBAC versus ERCS may require consideration by a senior Obstetrician and discussion with the woman regarding her preferences. For management of routine post-dates care for the woman with a previous caesarean section who is aiming for VBAC, a reasonable approach for such review is that it should take place by 41+0 weeks. This allows for full obstetric assessment and a review of the total clinical picture [4]. It is reasonable to book a provisional CS at or around 41+0 weeks and any plan for induction of labour should be clearly discussed and documented at this time.

For twin pregnancies, there are reports outlining the safety of VBAC, but many studies included small numbers [4, 15]. However, twin pregnancy is not a contraindication to VBAC. There are limited data pertaining to the safety and efficacy of planned VBAC in a twin pregnancy. The VBAC success rates have been reported ranging from 45% to 76% [27, 70-73], with a uterine rupture rated reported as 0.9% [73]. There was no increase in perinatal morbidity in three of the studies [70-72], however in the largest study the neonatal outcome data was not provided [73]. Multiple pregnancy is therefore not a contraindication to a trial of VBAC labour [4, 15], however a cautious approach is advocated [27], with each case to be considered on an individualised basis, after review by a senior Obstetrician.

For women with suspected fetal macrosomia (birth weight > 4kg) there are reported findings of a reduced success rate of VBAC and a possible association with an increased risk of uterine rupture [4, 15]. Further reported risks of VBAC for the infant with a birthweight greater than 4000g include an increased risk of shoulder dystocia, perineal lacerations and third- and fourth-degree perineal tears [4]. Furthermore, the woman who had a previous caesarean birth for dystocia, or no previous vaginal birth, with a birthweight greater than 4000g in a subsequent pregnancy, has a decreased likelihood of a successful VBAC, less than 50% [4, 74, 75]. Peaceman *et al* reported a VBAC success rate of only 38% if the planned VBAC birth weight exceeded the initial pregnancy birth weight by more than 500g [74]. Furthermore there has been an increased uterine rupture rate of up to 3.6% reported in one study where the birth rate was 4000g or greater [75].

For some of the above clinical scenarios the decision of VBAC versus ERCS may be further complicated by a need for induction of labour.

Finally, VBAC at a preterm period of gestation may be associated with a lower rate of uterine dehiscence or rupture, and an NICHD study in the US reported that perinatal outcomes were similar for preterm VBAC and preterm ERCS [4, 76]. Preterm gestation is not a contraindication to VBAC [53].

Recommendations

29. **There are a several clinical situations for which careful individual consideration of the benefits and risks of VBAC versus ERCS should be considered by the woman and her Obstetrician and these include macrosomia, twin pregnancy, postdates pregnancy, as well as preterm gestation and other possible clinical scenarios.**

Chapter 3: Development of Clinical Practice Guideline

3.1 Literature search strategy

A comprehensive search of the electronic databases PUBMED (Jan 2022 – April 2022) and the Cochrane Library were undertaken. These databases were searched using relevant medical subject headings and keywords. The main key words used were "vaginal birth after caesarean", "TOLAC", "antenatal care", "intrapartum management" and "uterine rupture". There were no restrictions placed on the search terms. The results yielded from these searches were reviewed. A detailed literature review was subsequently carried out.

3.2 Appraisal of evidence

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

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

A number of evidence-based recommendations for management of vaginal birth after caesarean section 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 5) as recommended by the Department of Health in the 'How to develop a National Clinical Guideline: a manual for guideline developers', 2019[13].

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

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

3.4 Literature review

Details of supportive evidence based literature for this Guideline are reported in chapter two.

- The review of the literature was conducted by Dr Gillian Ryan and Jennifer Duggan between 01/2022 and 04/2022.
- The final documents selected were reviewed by Dr Gillian Ryan, Jennifer Duggan and Professor John Morrison
- There is substantial evidence available to answer the clinical questions proposed
- The quality of evidence available is, for the most part, strong evidence
- The evidence reviewed comes from both national and international studies and has been adapted to fit the Irish context
- Literature was used when the evidence was relevant, strong and applicable to the Irish setting and omitted when this was not the case.

3.5 Grades of recommendation

GRADE offers a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations [54].

While we acknowledge that for this particular work an extensive GRADE approach is not possible, we have used the suggested language set out in the GRADE table when making recommendations.[14] (Appendix 6)

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. How many women aim for and successfully achieve vaginal birth after a previous caesarean section?
2. What are the rates of complications arising from vaginal birth after caesarean?
3. Examination of how best to approach the care and management of women hoping to achieve a vaginal birth after caesarean section.
4. Investigation of social and cultural barriers to progressing with vaginal birth after caesarean section.

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

Chapter 4: Governance and Approval

4.1 Formal governance arrangements

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

4.2 Guideline development standards

This Guideline was developed by the Guideline Developer Group (GDG) within the overall template of the HSE National Framework[15] for developing Policies, Procedures, Protocols and Guidelines (2016) (Appendix 7) 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 8 for list of CAG members.

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

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

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

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

This Guideline should also be distributed to other providers of women's healthcare in the community and private care settings in order to improve the cross-referral interface.

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

Chapter 6: **Implementation**

6.1 Implementation plan

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

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

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

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

6.2 Education plans required to implement the Guideline

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

6.3 Barriers and facilitators

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

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

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

Potential external barriers include:

- Structural factors (e.g. budget or service redesign)
    - Scalability of the service
- Organisational factors (e.g. lack of facilities or equipment)
    - Multifunctional rooms suitable for intimate gynaecological examination in addition to counselling
    - Prioritisation in terms of sharing resources eg extra clinical space and administration staff to facilitate VBAC clinics
- Individual factors (e.g. knowledge, skills, training)
- Patient perceptions

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

Internal barriers

- Staff knowledge and behaviour
- Evolving evidence required – we acknowledge that we cannot answer all the clinical pathways that intersect with the VBAC pathway due to the scope of the Guideline.

6.4 Resources necessary to implement recommendations

The implementation of this Guideline should be undertaken as part of the quality improvement of each hospital. Hospitals should review existing service provision against this Guideline, identifying necessary resources required to implement the recommendations in this Guideline.

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 patient care. Institutions and health professionals are encouraged to develop and undertake regular audits of Guideline implementation. Personnel tasked with the job of conducting the audit should be identified on receipt of the most recent version of the Guideline.

7.2 Auditable standards

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

Auditable standards for this Guideline include:

1. Number of women that have a documented booking visit with a senior Obstetrician
2. Number of women that have previous maternity records available for review at/after the booking visit
3. Number of women where the risks of VBAC vs ERCS are discussed as documented in maternity notes
4. Number of cases where a management plan is clearly documented if spontaneous labour should occur before a planned ERCS
5. Number of women where a debrief is documented in her notes following a caesarean birth and the inclusion of
    A. Reasons for the caesarean section
    B. Implications for future pregnancies and births.
    C. Possible suitability for VBAC as an option for future births

7.3 Evaluation

Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved[17].

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

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

Chapter 8: Revision Plan

8.1 Procedure for the update of the Guideline

It may be a requirement to amend, update or revise this Guideline as new evidence emerges. This Guideline will be reviewed at national level every three years, or earlier if circumstances require it, and updated accordingly.[18]

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

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

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

8.2 Method for amending the Guideline

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

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

1. 3 years since the Guideline was published
2. 3 years since last review was conducted
3. Update required as a result of new evidence

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

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

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Supporting Evidence

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

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

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

Glossary
(for the Purpose of this Guideline)

AGREE Appraisal of Guidelines for Research and Evaluation

ACOG American College of Obstetricians and Gynaecologists

BAC Birth After Caesarean Section

CAG Clinical Advisory Group

CEFM Continuous Electronic Fetal Monitoring

CS Caesarean Section

CTG Cardiotocograph

EAG Expert Advisory Group

ERCS Elective Repeat Caesarean Section

GPT Guideline Programme Team

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

HIQA Health Information and Quality Authority

HSE Health Service Executive

IOG Institute of Obstetricians and Gynaecologists

FIGO International Federation of Gynaecology and Obstetrics

NICE The National Institute for Health and Care Excellence

NCEC National Clinical Effectiveness Committee

NWIHP National Women and Infants Health Programme

PAS Placenta Accreta Spectrum

PPPG Policy, Procedures, Protocols and Guidelines

RCOG Royal College of Obstetricians and Gynaecologists

RCPI Royal College of Physicians of Ireland

VBAC Vaginal Birth After Caesarean Section

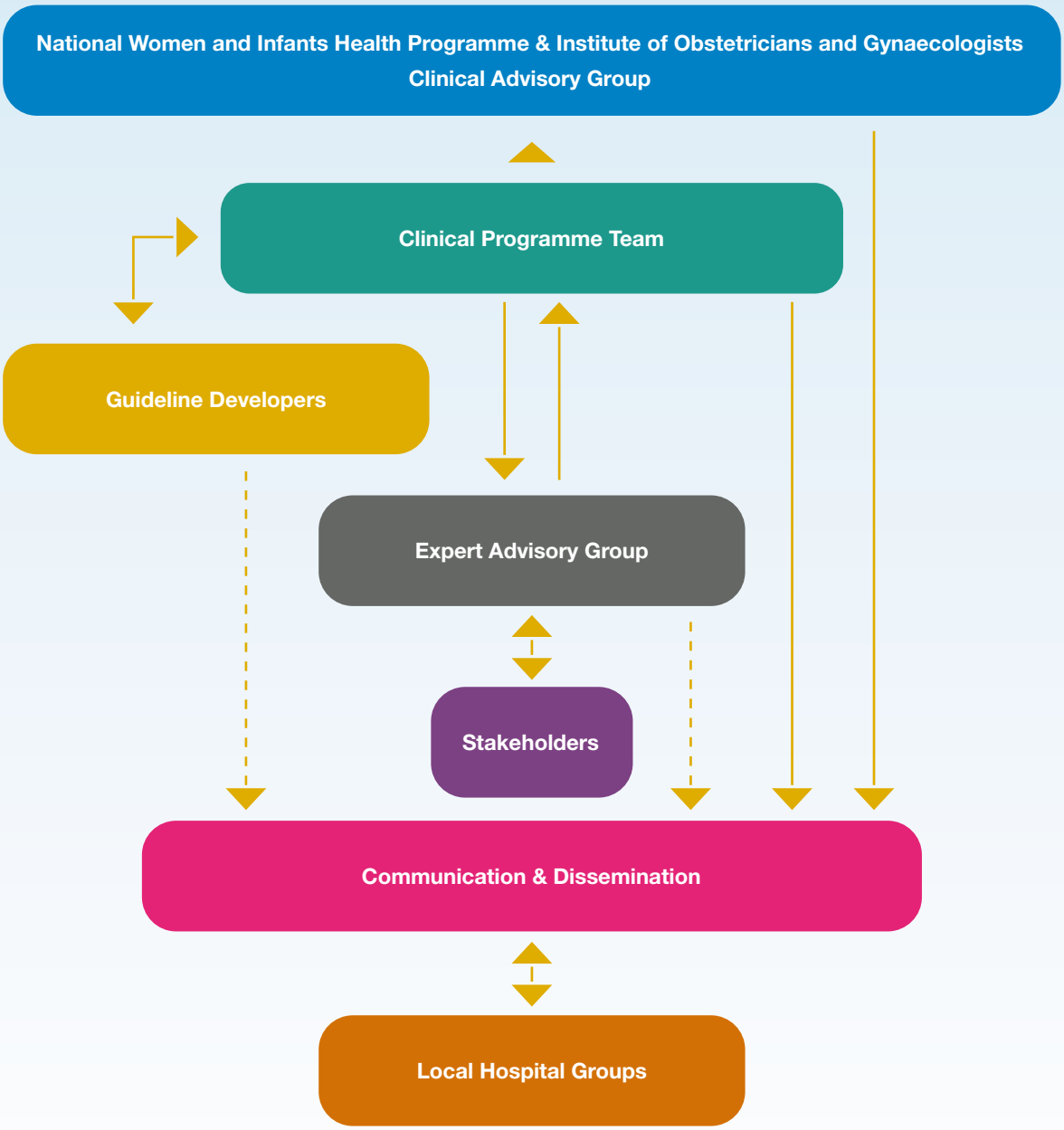
Appendix 1: **Expert Advisory Group Membership 2021-**

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

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

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3: **Clinical checklist for women with a previous caesarean birth**

Booking Appointment / Consultant Obstetrician			
Avoid making a decision regarding mode of birth until after BAC counselling			
Date:	Parity:	LMP:	EDD:
Gestation at booking visit:			/40
Formal dating scan performed:			☐ Yes ☐ No
Reason/s for previous CS:			
Notes from primary CS reviewed:	☐ Yes	☐ No	☐ Not Available ☐ Requested
Recurring medical risk factors:			
Refer to midwife BAC clinic:			☐ Yes ☐ No
Signature of obstetrician:			Date:
BAC Clinic Discussion 20/32 Weeks			
Discuss the following:			
Previous experience of birth:			☐ Yes ☐ No
Comments:			
Risks and benefits of VBAC:			☐ Yes ☐ No
Risks and benefits of ERCS:			☐ Yes ☐ No
Implications for future pregnancies:			☐ Yes ☐ No
BACS patient information leaflet discussed & given to woman:			☐ Yes ☐ No
Influencing factors on successful VBAC:			☐ Yes ☐ No
Signature of midwife:			Date:

Discussion for planned VBAC		
Care in labour:	☐ Yes	☐ No
Support in labour:	☐ Yes	☐ No
Mobility in labour:	☐ Yes	☐ No
Bloods and venous access:	☐ Yes	☐ No
Pain relief:	☐ Yes	☐ No
Continuous electronic fetal monitoring:	☐ Yes	☐ No
Use and benefits of telemetry CTG:	☐ Yes	☐ No
Maternal observations/monitoring of labour progress:	☐ Yes	☐ No
When to come to Hospital:	☐ Yes	☐ No
When to attend hospital information leaflet discussed:	☐ Yes	☐ No
Signs of labour:	☐ Yes	☐ No
Signature of midwife:	Date:	

Plan of Care 36/40			
Date:	Gestation:		
Woman wishes to have:	☐ VBAC	☐ ERCS	☐ Undecided
If spontaneous labour before ERCS plan for VBAC:	☐ Yes	☐ No	
Arrange appt at 40/40 in ANC to see Consultant:	☐ Yes	☐ No	
Date of appt:			
Book ERCS at 39 to 40/40:	☐ Yes	☐ No	
Date:	Clinic Area Informed:		
Midwife/Obstetrician Signature:			

Clinic appointment at 40/40 / Consultant Obstetrician				
Date:		Gestation:		
Is VBAC still recommended:			☐ Yes	☐ No
If No, why not?				
Woman wishes:	☐ Reassess at 41/40	☐ IOL		☐ ERCS
Sweep offered:			☐ Yes	☐ No
Sweep performed:			☐ Yes	☐ No
Bishop score:				
Plan and date for IOL:				
Method of IOL:		☐ Arm		☐ Oxytocin
Other:				
Book for ERCS:	☐ Yes	☐ No		☐ N/A
Clinic area informed:				
Consultant signature:				
Notes:				

Appendix 4: **Information checklist for women with a previous caesarean birth**

This document aims to explain some of the details of your caesarean section birth.

This information will be relevant for your next pregnancy and birth.

Information checklist for women with a previous caesarean section			
1.	**Date caesarean section preformed:**		
2.	**Clinical indication for caesarean section :**	☐ Uterine abnormality/surgery ☐ Placenta Praevia ☐ Malposition ☐ Malpresentation ☐ Induction not effective ☐ Slow progress in labour ☐ Non reassuring fetal heart rate ☐ Other	
3.	**Labour prior to CS :**	☐ Yes	☐ No
4.	Cervix was _____ cm dilated at the time of CS		
5.	Duration of first stage (established) of labour _____ hrs		
6.	Duration of second stage of labour _____ hrs		
7.	**Instrumental Vaginal Birth attempted :**	☐ Ventouse ☐ Forceps ☐ N/A Specify	

Information checklist for women with a previous caesarean section							
8.	**Position of baby's head at birth :**			☐ Occiput Anterior ☐ Occiput Posterior ☐ Occiput Transverse			
9.	**Level of baby's head in the pelvis:**	☐ -3 or above	☐ -2	☐ -1	☐ 0	☐ +1	☐ +2
10.	**Incision on the uterus:**			☐ Lower segment incision ☐ Vertical (Classical) incision ☐ T incision			
11.	**Is there a specific contraindication to VBAC for the next birth?**			☐ Yes		☐ No	
	Specify:						
	Signed:			Print:			
	Role:			Date:			

Appendix 5: AGREE II Checklist[19]

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	

19 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 6: **Grades of Recommendation**[20]

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….

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

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

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

Appendix 7: **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 8: **NWIHP/IOG CAG membership 2022**

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 Fergal Malone. Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

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.