Clinical Practice Guideline on Care in Normal Childbirth

NOTE:

More than 5 years have passed since the publication of this Clinical Practice Guideline, and **its validity has not been reviewed**.

Therefore, **it is unclear whether its recommendations remain valid**; they should therefore be treated with caution and applied in accordance with **clinical judgement and the individual circumstances of each patient**.

CLINICAL PRACTICE GUIDELINES IN SNHS
MINISTRY FOR HEALTH AND SOCIAL POLICY

MINISTERIO DE CIENCIA E INNOVACIÓN
MINISTERIO DE SANIDAD Y POLITICA SOCIAL
Plan de Calidad para el Sistema Nacional de Salud
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DEPARTAMENTO DE SANIDAD

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CLINICAL PRACTICE GUIDELINES IN THE SPANISH NATIONAL HEALTHCARE SYSTEM
MINISTRY FOR SCIENCE AND INNOVATION

MINISTERIO DE CIENCIA E INNOVACIÓN
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This CPG is an aid for healthcare decisions. It is not binding, and does not replace the clinical judgement of healthcare staff.

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Contents

Presentation 9

Authorship and Collaboration 11

Questions to Be Answered 15

Levels of Evidence and Grades of Recommendations 21

CPG Recommendations 23

1. Introduction 35

2. Scope and Aims 37

3. Methods 39

4. Care During Childbirth 43

4.1. Care by Professionals and Those Accompanying 43

4.2. Ingestion of Fluids and Solids 51

5. First Stage of Labour 57

5.1. Definition of the First Stage of Labour 57

5.2. Duration and Progress of the First Stage of Labour 59

5.3. Maternity Admission 62

5.4. Care on Admission 64

5.5. Possible Routine Interventions during the First Stage of Labour 68

6. Second Stage of Labour 101

6.1. Definition 101

6.2. Duration and Progress 103

6.3. Asepsis Measures 110

6.4. Position during the Second Stage of Labour 115

6.5. Maternal Pushing and Directed Pushing 120

6.6 Preventing Perineal Trauma 127

6.7. Episiotomy 133

6.8. Suturing Method and Materials for Perineal Repair 138

6.9. Kristeller Manoeuvre 147

7. Third stage of labour 149

7.1. Duration of theThird Stage of Labour 149

7.2. Managing the Third Stage of Labour 151

7.3. Use of Uterotonics 153

7.4. IV Dose of Oxytocin for Actively Managed Delivery 158

8. Care for Neonates 161

8.1. Clamping the Umbilical Cord 161

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.2. Skin-to-Skin Contact 165
8.3. Breastfeeding 167
8.4. Bathing the Neonate 170
8.5. Nasopharyngeal Aspiration and use of Gastric-Rectal tubes in Neonatal Period 171
8.6. Ophthalmic Prophylaxis 173
8.7. Haemorrhagic Disease Prophylaxis Using Vitamin K 178
9. Pain Relief During Labour 185
9.1. Pain, Analgesia and Maternal Satisfaction 186
9.2. Non-pharmacological Pain Relief Methods 190
9.3. Pharmacological Pain Relief Methods 202
9.4. Neuraxial Analgesia 211
10. Fetal Monitoring 243
11. Dissemination and Implementation 257
12. Future Lines of Research 265
Appendices 269
Appendix 1: Abbreviations 271
Appendix 2: Glossary 273
Appendix 3: Effective Communication Between Professionals and Women in Labour 279
Appendix 4: Partogram 281
Appendix 5: Algorithm for Diagnosing Delay in the First Stage of Labour 283
Appendix 6: Duration of Second Stage of Labour With and Without Neuraxial Analgesia 284
Appendix 7: Skin-to-Skin 285
Appendix 8: Technical Aspects of Nitrous Oxide utilisation 287
Appendix 9: Information for Women who Choose Neuraxial Analgesia 290
Appendix 10: Maternal supervision 291
Appendix 11: Intermittent Fetal Auscultation 292
Appendix 12: Flowchart for Decisions Based on Fetal pH Results 293
Appendix 13: Cardiotocographic Recordings 294
Appendix 14: Conflict of Interests Statement 297
Bibliography 299

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Presentation

Although scientific information is more accessible now than ever, the sheer volume of information leads to a need for certain tools which aim to support suitable, efficient, safe clinical decisions and to provide professionals with up-to-date knowledge and skills. Clinical Practice Guidelines (CPGs) answer the most important questions that may arise concerning the care that should be provided by the health services when a patient has a specific disorder, or, as in the case of childbirth, for a physiological process that requires a certain level of quality and sensitivity to provide an experience that is satisfactory for women, infants and families. They present scientific evidence in the form of recommendations which are weighted according to the quality of the studies which support them.

Realising that CPGs make thousands of clinical decisions easier every day in healthcare, and that they are a tool to improve healthcare outcomes, the Quality Agency supports their development, dissemination and use, and also monitors the quality of CPGs developed in Spain.

In 2003, the Inter-Regional Council of the Spanish National Healthcare System created a project known as GuíaSalud. This aims to improve clinical decisions based on scientific evidence via training activities and by establishing a register of Clinical Practice Guidelines (CPGs) within the Spanish National Healthcare System. Since then, the GuíaSalud project has evaluated dozens of CPGs according to explicit criteria established by its scientific committee, and it has registered them and disseminated them via the Internet.

In early 2006, the Quality Agency of the Spanish National Healthcare System developed a Quality Plan for the Spanish National Healthcare System, based on twelve strategies. The Quality Plan aims to increase cohesion within the Spanish National Healthcare System, and to help ensure that the healthcare received by all members of the public is of the utmost quality, regardless of where they live.

Strategy 10 of the Plan is designed to improve clinical practice. Its aims include reducing variability in clinical practice and stimulating the development and use of CPGs. The aims stated in the Quality Plan are being responded to by GuíaSalud by means of the creation of a register, training and consultancy, and by the CPG Development Programme by means of the creation of new guidelines.

Since 2006, CPGs such as this one on care during normal childbirth, presented today, have been developed with the participation of the scientific organisations involved.

The guideline presented below is a tool to accompany the Care Strategy for Normal Childbirth of the SNHS, in order to facilitate its implementation by midwives, obstetricians, paediatricians, nursing staff and other professionals involved in caring for women during labour. This Guideline is the result of the work of a large group of professionals from different autonomous regions who represent all the disciplines involved in care during normal labour. Women who belong to associations involved in promoting appropriate care during and after childbirth have also participated as full members. Professionals with good standing who belong to the scientific organisations in question, were involved in the revision process.

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The recommendations given in this guideline are based on the best scientific evidence available and are a good tool for improving care, promoting the participation of women in their birthing process and supporting initiatives for improvement in the obstetrics units of Spanish hospitals.

We believe that use of this guideline will contribute to improving the quality of care provided during normal childbirth in Spain and will increase the satisfaction of both professionals and women and their families.

PABLO RIVERO
Director of the Quality Agency of the Spanish National Healthcare System

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Authorship and Collaboration

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To the members of the team and colleagues who are mothers with experience of childbirth and who have provided their thoughts and opinions throughout guideline development.

Collaborating Societies

Spanish Federation of Midwives' Association (FAME)

Spanish Society of Gynaecology and Obstetrics (SEGO)

Perinatal Medicine Section (SEMPE) of SEGO

Spanish Paediatrics Association (AEP): Breastfeeding Committee Spanish Neonatology Society (SEN)

The *El Parto es Nuestro* (Childbirth is Ours) association

Members of these societies have participated in the writing and external review of the CPG.

Declaration of interest: The funding entity has not influenced the content or direction of the guideline's recommendations. All members of the working group have been asked to provide a disclosure of interests. (**Appendix 14**)

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Questions to Answer

I. Care during childbirth

Care by Professionals and Those Accompanying

1. How does the relationship between a woman and the professionals influence the progress of labour and her satisfaction with the labour experience?
2. How do professionals' profiles influence labour outcomes?
3. How effective is it for women to be accompanied during labour?

Fluid and Solid Intake

4. How effective is the restriction of fluids and solids during labour?
5. What can be recommended to prevent ketosis during labour?

II. First Stage of Labour

Definition of the First Stage

6. What is the definition of the latent phase of the first stage?
7. What is the definition of the active phase of the first stage?

Duration and Progress of the First Stage

8. What is the duration of the latent phase of the first stage of labour?
9. Do the duration and progress of the first stage of labour influence outcomes?

Maternity Admission

10. What is the ideal time for a woman in labour to be admitted to a maternity ward?

Care on Admission

11. What is the benefit of carrying out amnioscopy on all women with suspected labour arriving for admission?
12. What is the benefit of carrying out cardiotocography (CTG) on all women with suspected labour arriving for admission?

Possible Routine Interventions during the First Stage

13. How effective is routine enema during labour?
14. How effective is routine perineal shaving during labour?

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15. How effective is one-to-one care during labour?
16. What is the effect of mobility and adopting different positions on labour and its outcomes?
17. How effective is routine artificial amniorrhexis and routine perfusion of oxytocin?
18. Should antiseptics be used in vulvovaginal lavage prior to vaginal examination?
19. Does the use of a partogram improve outcomes?
20. What is the optimum frequency of vaginal examinations during the the first stage of labour?
21. What methods are effective in treating delays in the first stage of labour?

III. Second Stage of Labour

Definition

22. What is the definition of the latent phase of the second stage?
23. What is the definition of the active phase of the second stage?

Duration and Progress

24. Do the duration and progress of the second stage of labour influence outcomes?

Asepsis Measures

25. Do asepsis measures during labour influence outcomes?

Position During the Second Stage of Labour

26. What is the most appropriate position during the the second stage?

Position During the Second Stage of Labour

27. How effective are the different pushing techniques during the second stage on maternal and neonatal outcomes?
28. What is the optimum moment to recommend directed pushing?

Preventing Perineal Trauma

29. How effective are the following interventions in preventing genital trauma: perineal massage, application of heat to the perineum, use of local anaesthetics on the perineum, application of cold to the perineum, protection of the perineum, active deflection of the head and active extraction of shoulders versus doing nothing?

Episiotomy

30. How effective is episiotomy?

Suturing Method and Materials in Perineal Repair

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31. How effective is the suturing of first- and second-degree perineal tears?
32. What is the most effective suturing technique for episiotomy and/or first- and second-degree perineal tears?
33. Which synthetic material is most suitable for perineal repair?

Kristeller Manoeuvre

34. How effective is the Kristeller manoeuvre?

IV. Third Stage of Labour

Duration of the Third Stage

35. What is the duration of the third stage?

Managing the Third Stage

36. Does the management method of the third stage influence outcomes?

Use of Uterotonics

37. Which uterotonic is most suitable for the active management of the third stage? (oxytocin, ergotinic, prostaglandins and carbetocin)

Dose of Oxytocin (IV)

38. What is the most appropriate dose of intravenous (IV) oxytocin for the active management of the third stage of labour?

V. Care of Neonates

Clamping the Umbilical Cord

39. What is the most suitable time to champ the umbilical cord?

Skin-to-Skin Contact

40. What is the benefit of skin-to-skin contact?

Breastfeeding

41. Should the neonate take the breast spontaneously?

Bathing the Neonate

42. What is the effect of bathing the neonate?

Nasopharyngeal Aspiration and Gastro-Rectal Examination in Neonatal Period

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43. Does the use of gastro-rectal examinations and/or systematic nasopharyngeal aspiration in the immediate neonatal period improve neonatal prognosis?

Ophthalmic Prophylaxis

44. How effective is systematic ophthalmic prophylaxis in neonates?
45. What is the ideal time to carry out ophthalmic prophylaxis in neonates?
46. What is the most effective product for ophthalmic prophylaxis in neonates?

Haemorrhagic Disease Prophylaxis Using Vitamin K

47. What is the risk/benefit ratio of carrying out neonatal prophylaxis using vitamin K?
48. What is the most advisable route for prophylaxis using vitamin K?

VI. Pain Relief During Labour

Pain, Analgesia and Maternal Satisfaction

49 How do pain and pain relief during labour influence women's satisfaction?

Non-Pharmacological Pain Relief Methods

50. How effective is immersion in water as pain relief during the first stage of labour?
51. How effective is massage as pain relief during labour?
52. How effective is the use of birthing balls as pain relief during labour?
53. How effective are relaxation techniques as pain relief during labour?
54. How effective is the injection of sterile water as pain relief during labour?
55. How effective is transcutaneous electrical nerve stimulation (TENS) as pain relief during labour?

Pharmacological Pain Relief Methods

56. How effective is nitrous oxide as pain relief during labour?
57. How effective is pethidine as pain relief during labour?
58. How effective is pentazocine as pain relief during labour?
59. How effective is remifentanil as pain relief during labour?

Neuraxial Analgesia

60. How effective is neuraxial analgesia?
61. How effective are the following obstetric neuraxial analgesia techniques: traditional epidural vs low-dose epidural vs combined (intradural/epidural)?
62. Is it beneficial to carry out a systematic coagulation study before administering neuraxial analgesia?

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63. How effective is the perfusion of intravenous solutions (crystalloids, colloids) before performing an obstetric neuraxial analgesia technique?
64. Should the use of obstetric neuraxial analgesia be postponed until an advanced stage of labour?
65. How does the form of analgesia administration influence labour and its outcomes?
66. How effective is maternal monitoring during the establishment and maintenance of neuraxial analgesia?
67. How does the use of local anaesthetic influence obstetric neuraxial analgesia?
68. How does the use of opioids and neuraxial coadjuvants influence labour and its outcomes?
69. Should epidural anaesthesia be maintained during the second stage of labour?

VII. Fetal Monitoring

70. How effective are the following methods of fetal monitoring: continuous electronic fetal monitoring (CEFM) vs intermittent fetal auscultation (Pinard stethoscope or Doppler)?
71. How effective are the following methods of fetal monitoring: CEFM vs intermittent electronic fetal monitoring (IEFM)?
72. How effective are the following methods of fetal monitoring: CEFM with or without fetal pulse oximetry when there are alterations in fetal heart rate?
73. How effective are the following methods of fetal monitoring: CEFM with or without analysis of the ST (STAN) segment of the fetal ECG when there is an abnormal cardiotocography reading (CTGR)?
74. How effective are the following methods of fetal monitoring: CEFM with or without fetal scalp blood sampling (FBM)?
75. How effective are the following methods of fetal monitoring: CEFM with or without fetal stimulation test when there are alterations in fetal heart rate?
76. How does the use of a CEFM classification system influence neonatal outcomes?

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Levels of Evidence and Grades of Recommendations: SIGN

Levels of evidence and grades of recommendations according to SIGN (1; 2)

Levels of scientific evidence	
1++	High-quality meta-analyses, high-quality systematic reviews of clinical trials with very little risk of bias.
1+	Well-conducted meta-analyses, systematic review of clinical trials or well-conducted clinical trials with low risk of bias.
1-	Meta-analyses, systematic reviews of clinical trials or clinical trials with high risk of bias.
2++	High-quality systematic reviews of cohort or case and control studies; cohort or case and control studies with very low risk of bias and high probability of establishing a causal relationship.
2+	Well-conducted cohort or case and control studies with low risk of bias and moderate probability of establishing a causal relationship.
2-	Cohort or case and control studies with high risk of bias and significant risk that the relationship is not causal.
3	Non-analytical studies, such as case reports and case series.
4	Expert opinion.
Grades of recommendations	
A	At least one meta-analysis, systematic review or clinical trial classified as 1++ and directly applicable to the target population of the guideline, or a volume of scientific evidence comprising studies classified as 1+ and which are highly consistent with each other.
B	A body of scientific evidence comprising studies classified as 2++, directly applicable to the target population of the guideline and highly consistent with each other, or scientific evidence extrapolated from studies classified as 1++ or 1+.
C	A body of scientific evidence comprising studies classified as 2+, directly applicable to the target population of the guideline and highly consistent with each other, or scientific evidence extrapolated from studies classified as 2++.
D	Level 3 or 4 scientific evidence, or scientific evidence extrapolated from studies classified as 2+.

Due to their high risk of bias, studies classified as 1- or 2- should not be used in compiling recommendations

Good Clinical Practice

√[1]	Practice recommended on the basis of clinical experience and consensus by the drafting team

Occasionally the drafting group finds important practical issues that must be highlighted and for which no scientific evidence has been found. Generally, these cases are associated with an aspect of treatment that no one would usually question and that are valued as part of good clinical practice.

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Levels of Evidence and Grades of Recommendations for Diagnosis-Related Questions

NICE's Adaptation of the levels of evidence of the Oxford Centre for Evidence-Based Medicine and the Centre for Reviews and Dissemination (2; 3)

Levels of scientific evidence	Type of scientific evidence
Ia	Systematic review with homogeneous level 1 studies.
Ib	Level 1 studies.
II	Level 2 studies. Systematic review of level 2 studies
III.	Level 3 studies. Systematic review of level 3 studies.
IV	Consensus, expert opinions with no explicit critical evaluation.
Level 1 studies	Meet the following criteria: • Blinded comparison with a valid ("gold standard") comparator test. • Suitable range of patients.
Level 2 studies	Show only one of these biases: • Non-representative population (the sample does not reflect the population in which the test will be used). • Comparison with unsuitable comparator ("gold standard") (the test to be assessed is part of the gold standard or the result of the test affects the performance of the gold standard). • Non-blinded comparison. • Case and control studies.
Level 3 studies	Meet two or more of the criteria stated for level 2 studies.

Recommendation	Evidence
A	Ia or Ib
B	II
C	III
D	IV

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CPG Recommendations

Key Recommendations

Care During Childbirth

4.1. Care from professionals and those accompanying	
4.1.1. Women and professionals	
D	Women in labour should be treated with the utmost respect, and should be fully informed and involved in decision-making. To facilitate this, healthcare professionals and other staff caring for them should establish an empathetic relationship with women in labour and ask them about their expectations and needs, so that they can support and guide them, being aware at all times of the importance of their attitude, the tone of voice used, the words used and the manner in which care is provided.
4.1.2. Profile of professionals	
A	Care teams for hospital births should promote the use of midwife care for low-risk births.
4.1.3. Birth partner	
A	Women should have the option of being accompanied by the person of their choice during labour.
4.2. Restriction of fluids and solids	
4.2.1. Restriction of food	
A	Intake of clear liquids should be permitted during labour.
4.2.2. Prevention of ketosis	
A	Women should be informed that isotonic drinks are effective against ketosis, and are therefore preferable to water.

First Stage of Labour

5.1. Definition	
√	The definition of the **latent phase** that should be adopted is the period of labour between the start of labour and 4 cm dilatation. The definition of the **active phase** that should be adopted is the period of labour between 4 and 10 cm dilatation and accompanied by regular contractions.
5.2. Duration and progress	

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√	The duration of the latent phase of the first stage of labour cannot be established, due to the difficulty in determining the start of labour.
C	The duration of the active phase of labour varies between women and depends on parity. It does not necessarily progress in a linear fashion. • For first child: o The average duration is 8 hours. o It is unlikely to last for more than 18 hours. • For second and subsequent children: o The average duration is 5 hours. o It is unlikely to last for more than 12 hours.
√	The decision to intervene if the first stage of labour seems to be prolonged must be taken on the basis of the progress of dilatation and other obstetric factors, rather than on the basis of duration alone.
5.3. Maternity Admission	
√	Admission is recommended when the following criteria are met: regular uterine contractions, cervical effacement > 50% and dilatation of 3 4 cm.
√	Individualised support should be offered to women who arrive with painful contractions and are not in the active phase of labour. They should be encouraged to return home until the active phase of labour starts.
5.4. Care on admission: amnioscopy and CTG	
C	Amnioscopy is not recommended for initial assessment of women with low-risk labour.
A	Cardiotocography is not recommended when low-risk pregnant women are admitted.
5.5. Possible routine interventions during first stage of labour	
5.5.1 Enema	
A	Enemas should not be used routinely during labour.
5.5.2 Perineal shaving	
√	Systematic perineal shaving is not recommended for women in labour.
5.5.3 One-to-one care	
A	Women in labour should have one-to-one midwife care from admission onwards, at all times.
A	Women in the active phase of labour should not be left without professional care except for short periods of time or when they so request.
5.5.4. Mobility and adopting different positions	

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A	Women should be encouraged and helped, even when epidural anaesthesia is used, to adopt any position they find comfortable during the first stage and to be mobile if they wish, following a check of motor and proprioceptive block.
5.5.5. Amniorrhexis and use of oxytocin	
A	Artificial amniorrhexis and perfusion of oxytocin should not be used routinely in vaginal births that are progressing normally, as tests show that they do not improve outcomes.
5.5.6. Perineal lavage	
A	Running water should be used if lavage is required before a vaginal examination; the use of antiseptics is not necessary.
5.5.7. Use of a partogram	
A	If a partogram is used, a 4-hour action line is recommended.
5.5.8. Frequency of vaginal examinations	
√	In normal conditions, vaginal examinations should be carried out every 4 hours.
√	More frequent vaginal examinations should be carried out in women with slow labour progress, if there are complications or if the woman experiences a pushing sensation.
√	Before carrying out a vaginal examination, the following action should be taken: • Confirm that it is really necessary and that the information it provides will be relevant to decision-making. • Be aware that vaginal examination is uncomfortable and invasive, and associated with an increased risk of infection. • Guarantee the woman's privacy, dignity and comfort. • Sensitively explain the reason it is being carried out and the findings, especially if they are not as expected by the woman.
5.5.9. Treatment for delayed dilatation	
√	When a delay in the active phase of the first stage of labour is suspected, the following action should be taken: • Offer the woman support, hydration and an appropriate and effective method of pain relief. • If the membranes are intact, amniorrhexis should be carried out. • Vaginal examination 2 hours later; if dilatation is less than 1 cm, delayed dilatation is diagnosed. • Once delayed dilatation has been diagnosed, oxytocin stimulation should be offered. • Ongoing monitoring should be carried out and epidural anaesthesia should be offered before oxytocin is used. • Another vaginal examination should be carried out 4 hours after oxytocin perfusion is begun. If dilatation is less than 2 cm, the case should be reassessed, considering the option of a caesarean section. If dilatation is greater than 2 cm, another examination should be carried out 4 hours later.

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Second Stage of Labour

6.1. Definition	
√	The second stage of labour is the stage between full dilatation and fetal expulsion. It is subdivided in turn into two phases: • Passive period: full dilatation of cervix, before or without involuntary expulsion contractions. • Active period when: The foetus is visible, or There are expulsion contractions during full dilatation, or Maternal pushing during full dilatation without expulsion contractions.
6.2. Duration	
√	The normal duration of the passive phase of the second stage of labour in a nulliparous woman is up to 2 hours with or without epidural anaesthesia.
√	The normal duration of the passive phase of the second stage of labour in a multiparous woman is up to 1 hour without epidural anaesthesia and 2 hours with an epidural.
√	The normal duration of the active phase of the second stage of labour in a nulliparous woman is up to 1 hour without epidural anaesthesia and 2 hours with an epidural.
√	The normal duration of the active phase of the second stage of labour in a multiparous woman is up to 1 hour with or without epidural anaesthesia.
6.3. Asepsis measures	
Hand hygiene	
B	Hands should be washed immediately before any direct contact with the patient and after any activity or contact that might lead to potential contamination of the hands.
A	Visibly dirty hands or hands that are potentially highly contaminated with dirt or organic material must be washed with liquid soap and water.
A	Unless they are visibly dirty, hands should preferably be cleaned by rubbing in alcohol-based solution between caring for different patients or between different care activities for one person.
Clothing	
D	Choice of protective equipment should be based on assessment of the risk of transmission of microorganisms to the patient and the risk of contamination of healthcare professionals' clothing and skin with blood, bodily fluids and excretions or secretions.

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√	Full-body waterproof overalls should be used when there is a risk of frequent splashing of blood, bodily fluids, secretions or excretions other than sweat, on healthcare professionals' skin or clothing. This is the case when attending childbirth.
Use of gloves	
D	Gloves must be used for invasive procedures; contact with sterile locations, mucous membranes and non-intact skin; and all activities with a risk of exposure to blood, bodily fluids, secretions or excretions, or cutting or contaminated instruments.
D	Gloves must always be disposable. They must be put on immediately before an episode involving contact with a patient and removed as soon as the activity has ended. Gloves must always be changed between patients and between different activities for a single patient.
Use of masks	
D	Face masks and eye protection should be used when there is a risk of splashing of blood and bodily fluids in the face or eyes.
6.4. Position	
A	Women should adopt the position that is most comfortable for them during labour.
6.5. Maternal pushing and directed pushing	
A	Spontaneous pushing is recommended. If there is no pushing sensation, pushing should not be directed until the passive phase of the second stage of labour has ended.
A	For women with neuraxial analgesia, pushing should be directed once the passive phase of the second stage of labour has ended.
6.6. Preventing genital trauma	
A	***Perineal massage*** is not recommended during the second stage of labour.
A	The application of hot compresses should be made available during the second stage of labour.
B	The perineum should be actively protected using **controlled deflection of the fetal head**, asking the woman not to push.
A	***Local anaesthetic spray*** should not be used to reduce perineal pain during the second stage of labour.
6.7. Episiotomy	
A	Routine episiotomy should not be performed in spontaneous labour.
√	Episiotomy should be performed if there is a clinical need, such as an instrumental labour or suspected fetal compromise.
√	Before episiotomy an effective analgesia should be used, except in an emergency due to acute fetal compromise.

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D	When episiotomy is performed, the recommended technique is mediolateral episiotomy, starting at the posterior commissure of the labia minora and usually moving towards the right side. The episiotomy should be at an angle of 45-60 degrees from the vertical.
√	Episiotomy should not be performed routinely during a vaginal birth in women with third- or fourth-degree tears from previous births.
6.8. Suturing method and materials for perineal repair	
6.8.1. Suturing method and materials for perineal repair	
A	First-degree tears should be sutured in order to improve healing, unless the edges of the skin are close together.
A	Second-degree perineal tears should be repaired using continuous suturing.
A	If the edges of the skin are close together after muscle suturing of a second-degree tear, there is no need to suture the skin. If the skin needs to be closed, continuous intradermal suturing should be used.
6.8.2. Suturing materials for perineal repair	
A	Synthetic material with normal absorption should be used to suture perineal wounds.
√	A rectal examination must be performed after the repair has been completed, to ensure that no suturing material has accidentally been inserted through the rectal mucosa.
6.9. Kristeller manoeuvre	
A	The Kristeller manoeuvre is not recommended.

Third Stage of Labour

7.1. Duration of third stage	
D	The duration of the third stage of labour is considered to be dealyed if it is not complete within 30 minutes after birth of the neonate with active management, or within 60 minutes with a spontaneous third stage.
7.2. Managing the third stage	
A	Active management of delivery is recommended.
√	Women must be informed (preferably during pregnancy) that active management of the third stage of labour decreases its duration and reduces the risk of postpartum haemorrhage and the need for therapeutic oxytocin.
√	Spontaneous or physiological delivery is an option if the patient requests it.
7.3. Use of uterotonics	
A	Oxytocin should be used routinely in the third stage of labour.

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7.4. Dose of oxytocin for actively managed delivery	
√	10 IU slow IV should be administered as prophylaxis for postpartum haemorrhage.

Care of Neonates

8.1. Clamping the umbilical cord	
A	Delayed clamping of the umbilical cord is recommended.
B	One suggestion is to clamp the umbilical cord after the second minute or after it stops pulsing.
8.2. Skin-to-skin contact	
A	Women should have skin-to-skin contact with their babies immediately after birth.
√	To keep the baby warm, he or she should be covered and dried with a blanket or towel that has previously been warmed, whilst maintaining skin-to-skin contact with the mother.
√	The mother and baby should not be separated for the first hour or until the first feed has been given. During this period the midwife should remain vigilant and periodically observe, interfering as little as possible in the relationship between the mother and neonate, checking the neonate's vital signs (colour, respiratory movements, tone and if necessary heart rate). The midwife should inform the specialist of any cardiorespiratory change.
8.3. Breastfeeding	
A	Breastfeeding should be encouraged as soon as possible after birth, preferably within the first hour.
√	Women should be informed that if the neonate is not trying to feed, he or she can be placed in front of the breast to facilitate the reflexes necessary to obtain sufficient latch-on, but that this first feed should not be forced.
8.4. Bathing the neonate	
√	The neonate should not be bathed routinely in the first few hours after birth.
√	If the mother requests it, bathing is acceptable as long as the neonate has achieved thermal stability and it does not interfere with the recommended time for skin-to-skin contact.
8.5. Nasopharyngeal aspiration and gastro-rectal examination in neonatal period	
A	Systematic oropharyngeal and nasopharyngeal aspiration are not recommended for neonates.

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√	The systematic use of nasogastric and rectal examination should not be used to rule out atresia in healthy neonates.
8.6. Ophthalmic prophylaxis	
8.6.1. Systematic ophthalmic prophylaxis in neonates	
B	Ophthalmic prophylaxis should be performed as part of routine care for neonates.
8.6.2. Ideal time for ophthalmic prophylaxis	
√	The time for administration of ophthalmic prophylaxis may be extended to 4 hours after birth.
8.6.3. Most effective product for ophthalmic prophylaxis of neonates	
√	Erythromycin 0.5% ointment should be used as ophthalmic prophylaxis, or alternatively tetracycline 1%. Silver nitrate 1% should only be used if neither erythromycin nor tetracycline is available.
8.7. Haemorrhagic disease prophylaxis using vitamin K	
8.7.1. Neonatal prophylaxis using vitamin K	
A	Prophylaxis of neonates using vitamin K should be offered to prevent the rare but serious and sometimes fatal haemorrhagic syndrome due to vitamin K deficiency.
8.7.2. Route of administration of prophylaxis using vitamin K	
A	Vitamin K should be administered in a single IM dose (1 mg), as this is the route of administration that gives the best clinical results.
√	If parents refuse IM vitamin K, it may be offered orally as a second treatment option, and parents must be informed that a 1 mg dose will be required at birth, at one week and at one month. If the baby is exclusively breastfed, additional doses should be given.

Pain Relief During Labour

9.1. Pain, analgesia and maternal satisfaction	
B	The mother's expectations for pain relief during labour should be met as far as is possible.
9.2. Non-pharmacological pain relief methods	
9.2.1. Immersion in hot water	
A	Immersion in hot water is recommended as an effective pain relief method during the later phases of the first stage of labour.
9.2.2. Massage	

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B	Massage and calming physical contact are recommended as a pain relief method during the first and second stages of labour.
9.2.3. Use of birthing balls	
√	Women who choose to use birthing balls should be encouraged to do so, to seek more comfortable postures.
9.2.4. Relaxation techniques	
√	Women who choose to use breathing or relaxation techniques should be supported in their choice.
9.2.5. Injection of sterile water	
B	Injecting sterile water is recommended during labour as an effective method of relieving low-back pain; women should be informed that intradermal injection causes short-term stinging and intense pain.
9.2.6. TENS	
A	The TENS method should not be offered to women in established labour.
9.3. Pharmacological methods of pain relief	
9.3.1. Nitrous oxide	
B	Inhaling nitrous oxide is recommended during labour as a pain relief method; women should be informed that its analgesic effect is moderate and that it can cause nausea and vomiting, somnolence and altered memories.
9.3.2. Opioids: pethidine, pentazocine and remifentanil	
A	If parenteral opioids are chosen as analgesia, patients should be informed that they have a limited analgesic effect and can cause nausea and vomiting.
A	Anti-emetics should be administered when intravenous or intramuscular opioids are used.
A	In women who receive remifentanil, maternal SaO_2 should be monitored and extra oxygen should be administered.
9.4. Neuraxial analgesia	
9.4.1. Neuraxial analgesia vs no analgesia and vs analgesia with opioids	
A	Women should be informed that neuraxial analgesia is the most effective method of pain relief, but that it can cause hypotension, fetal heart rate alterations, urinary retention, pruritus and fever, and lengthens the second stage of labour, increasing the risk of instrumental birth.
√	Women should be informed of the risks, benefits and implications for the birth of neuraxial analgesia.
9.4.2. Traditional epidural anaesthesia vs low-dose epidural vs combined	
A	Any low-dose neuraxial technique is recommended: epidural or combined.

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A	If analgesia needs to be established quickly, combined epidural (epidural/intradural) should be used.
9.4.3. Coagulation study	
B	A routine coagulation study should not be carried out before neuraxial analgesia in healthy women in labour.
√	A routine intrapartum platelet count should not be carried out before neuraxial analgesia in healthy women in labour.
√	The decision to carry out a platelet count and a coagulation test should be tailored to each case and based on the patient's history, physical examination and clinical signs.
9.4.4. Preloading of intravenous solutions	
√	Intravenous access should be ensured before starting neuraxial analgesia.
A	Intravenous preloading need not be carried out routinely before low-dose epidural anaesthesia or with combined intradural/epidural anaesthesia.
9.4.5. Beginning analgesia	
A	Local analgesia can be provided when the woman requests it, even in early phases of the first stage of labour.
9.4.6. Maternal monitoring	
√	Blood pressure should be taken while neuraxial analgesia is becoming established and after each new dose is administered.
√	CEM of fetal heart rate should be carried out within 30 minutes of establishing neuraxial analgesia and after each bolus of 10 ml or more is administered.
9.4.7. Method of administering epidural anaesthesia	
A	PCEA should be administered. CP and bolus doses administered by hospital staff are valid alternatives, depending on the resources available.
9.4.8. Local anaesthetic in epidural anaesthesia	
A	There are no substantial differences that make it possible to recommend one local anaesthetic over another.
9.4.9. Opioids in epidural anaesthesia	
A	Low doses of local anaesthetic alongside opioids should be used for epidural anaesthesia.
9.4.10. Maintaining epidural anaesthesia during the the second stage	
A	Epidural anaesthesia should be maintained during the the second stage, delivery and during perineal repair if this is necessary.

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10. Fetal monitoring	
10.1. Continuous electronic fetal monitoring (CEFM) vs intermittent fetal auscultation (IA)	
B	Both CEFM and IA are valid and recommended methods for checking fetal well-being during labour.
√	IA can be performed using either Doppler ultrasound or a stethoscope.
10.2. CEFM vs intermittent electronic fetal monitoring (IEFM)	
A	Both CEFM and IEFM accompanied by IA are valid and recommended methods for checking fetal well-being during labour.
10.3. CEFM with pulse oximetry	
A	Fetal pulse oximetry should not be used routinely.
10.4. CEFM with ST segment analysis (STAN) of fetal ECG of an abnormal CTGR.	
A	Routine analysis of the ST segment of fetal ECG is not recommended for normal labour.
B	In hospital births when analysis of the ST segment of fetal ECG is available, it should only be used in women with an abnormal CTG.
10.5 CEFM with fetal scalp blood sampling (FBM)	
B	FBM should be performed when there is an abnormal CTG reading.
10.6. CEFM with fetalstimulation test when there are alterations in fetal heart rate	
√	Digital fetal stimulation test should be used as an additional diagnostic method when there is an abnormal CTG reading.
10.7. Use of a CEFM classification system	
√	The CTG classification system shown in Appendix 3.3.2. is recommended.

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1. Introduction

Labour and childbirth are profound and unique experiences, and at the same time complex physiological processes.

The desire for labour to culminate in the birth of a healthy child, with no harm to the mother's health, has led to childbirth being institutionalised and systematically managed medically, and to medical and surgical interventions being carried out without sufficient evidence of their safety and efficacy. Thus, in recent decades there has been rapid expansion in the development and use of a range of practices intended to initiate, increase, accelerate, regulate or monitor the birth process, with the aim of improving the outcome for women and their children. These have become usual, routine practices, even in births for healthy women with no complications.

This wish to guarantee the best outcomes has made it difficult to pay the necessary attention to the importance of the process of childbirth in a woman's life, emotional well-being and adaptation to motherhood, and to establishing a connection with her child, successful breastfeeding, parenting style and the later development of the children.

Fortunately, we now know that with appropriate care and support, most healthy woman can give birth with a minimum of medical procedures, without risking the safety of the process. This requires women to regain trust in their options for facing childbirth, and professionals to understand women's basic needs during this physiological process (safety, calm, privacy, etc.) and to offer a different kind of care that provides maternal satisfaction and guarantees the safety of mother and child.

We are also increasingly aware that childbirth is a defining event in women's lives and that the type of care provided to them has significant physical and emotional effects on them and their children, in the short and the long term, particularly if they consider it essential to play a leading role in their own labour.

With this in mind, a series of recommendations on the use of appropriate technology during labour was established at a 1985 meeting between the European Region of the WHO, the Regional Office for the Americas and the Pan American Health Organization held in Fortaleza, Brazil. Later, in 1996, the WHO drew up a Practice Guideline on care during normal childbirth (4).

Evidence-based medicine has also demonstrated that adopting a whole series of interventions that have been shown to be fruitless, inappropriate and/or unnecessary has been a serious error, made while trying to improve maternity services (4).

In Spain, the Care Strategy for Normal Childbirth of the Spanish National Healthcare System, approved by all autonomous regions, is leading a far-reaching change in the childbirth care model (5). This change, which could be called a paradigm shift, aims to be a new model whose guiding principles are a view of childbirth as a generally physiological process and the importance of offering customised, holistic care that covers biological, emotional and family issues, based on scientific evidence and respecting women's central role and right to receive information and take informed decisions as recognised by law.

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This guideline will examine the evidence for and against the most common practices connected with normal childbirth. It has been compiled in order to provide guidance on the best care to be given to healthy women and their babies during labour and birth, and to establish evidence-based recommendations and a reasoned evaluation of them. Under no circumstances should it replace the professionals' clinical judgement.

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2. Scope and Aims

The scope of this Guideline was given by the Care Strategy for Normal Childbirth of the Spanish National Healthcare System (SNHS) (5), compiled by the Ministry for Health and Consumer Affairs in collaboration with autonomous regions and scientific societies, and with the support of the Women's Health Observatory.

One of its principles was to create a scientific evidence-based Clinical Practice Guideline with the extensive involvement of professionals, scientific societies and women, through associations representing them.

In addition to this Strategy and within the context of the Quality Plan for the Spanish National Healthcare System of the Ministry for Health and Consumer Affairs, a programme was started in 2006 to develop evidence-based Clinical Practice Guidelines (GPC) to assist in clinical decisions within the SNHS. The Department of Health of the Basque Government, to which the Health Technology Assessment Agency of the Basque Country (Osteba) is attached, and the Health Technology Assessment Agency of Galicia (avalia t) signed a collaboration agreement to develop this guideline.

Consequently, the scope in terms of the medical condition addressed is limited to care for healthy women with normal labours. What we understand by *normal labour* and a *healthy woman* should therefore be defined.

Defining normal labour entails some difficulty, as the concept of normality in labour and childbirth has not been standardised. Together with other factors, the extremely widespread view that labour can only be considered normal retrospectively has led to care being provided for normal births that is very similar to that required for complicated births, turning a physiological event into a medical and surgical procedure.

For the purposes of this guideline, *normal labour* is defined as follows: *labour that begins spontaneously, and that presents a low risk at the outset that remains low until delivery. The child is born spontaneously in cephalic position between 37 and 42 full weeks. After birth, both the mother and the baby are in good health.*

A healthy woman is taken to be one who *is not suffering from a disease or presenting a pregnancy complication such as pre-term birth, hypertension during pregnancy, restricted intrauterine growth, multiple pregnancy, induced labour etc. that make it advisable to employ specific care or interventions.*

To summarise our position, in normal labour there should be a valid reason for any interference in the natural process.

However, as many women with health problems or complications during pregnancy experience normal labour and delivery, many recommendations in this study can be also applied to the care of these women.

The context in which this guideline should be applied is that of hospital births. This guideline does not aim to respond to the needs of home births or births in birth centres.

This Clinical Guideline endeavours to contribute to changing the model of care for

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childbirth in the Spanish healthcare system so that more effective, safe, customised care may be provided.

Its goal is to offer the guideline's users detailed, up-to-date information that allows decisions to be shared by professionals and women receiving care during childbirth.

This guideline is aimed principally at obstetricians, midwives, paediatricians, obstetric anaesthetists and healthcare staff responsible for care during childbirth and care for neonates in medical establishments. It is also intended for those in charge of planning and managing maternity services and for pregnant women and their families, for whom an adapted version of the guideline is available, to provide them with sufficient information and promote better communication with their care providers.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

3. Methods

To compile the CPG, the Methodology Manual for Developing Clinical Practice Guidelines of the Spanish National Healthcare System (2) was used. This can be consulted on the website of the SNHS's CPG library, GuíaSalud.

A mixture of methods was used, including strategies to update and adapt the questions addressed in the NICE guideline (10), which was selected in advance using the AGREE tool, due to its higher quality. Questions not covered by the NICE guideline were addressed from scratch (6;7)

The steps taken were as follows:

Creation of the Group to Develop the Guideline

The group consisted of professionals from various medical establishments and autonomous regions: obstetricians, midwives, paediatricians, obstetric anaesthetists, methodology specialists belonging to the Health Technology Assessment Agencies of the Basque Country and Galicia and women belonging to childbirth-related associations.

The SR (systematic review) involved several phases.

Formulation of Clinical Questions

This took place according to the PICO model: Patient, Intervention, Comparison, Outcomes.

Search of the Literature

A search of CPGs: search period 1998-2008. Languages: Spanish, English, French.

Specific guideline databases were searched: Tripdatabase, Pubgle, GuíaSalud, Fisterra. General databases were also searched: MEDLINE (PubMed) and EMBASE (Elsevier).

A search of SRs and RCTs: search period 2006 onwards (including alerts).

Once the CPGs had been identified and selected, a specific search of systematic reviews and meta-analyses was carried out for each clinical question in Cochrane Library Plus and the Centre for Reviews and Dissemination database of the UK's National Health Service (NHS), which includes both the HTA (Health Technology Assessment) database of assessment reports and the DARE database of efficacy reviews. General databases such as MEDLINE (PubMed) and EMBASE (Elsevier) were also used.

For the RCT search, the following databases were used: Cochrane Library Plus, MEDLINE, EMBASE.

To obtain references on the scope of the subject to be covered, ongoing unpublished

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RCTs were also sought in the HSRProj (Health Services Research Projects in Progress) database and at clinicaltrials.gov.

In addition to this process, a general Internet search was carried out (scientific societies and organisations) in order to locate other information of interest.

The literature search strategies are described in the document Methodology Materials, which is available in the Clinical Practice Guidelines of the Spanish National Healthcare System section of the GuíaSalud website: http://www.guiasalud.es/web/guest/gpc-sns.

Evaluation of Methodological Quality

The methodological quality of the CPGs located was evaluated using the AGREE (4) tool. The guideline with the highest score was selected to be used as a reference.

For questions not addressed either by the guideline selected or by the SRs located, or that did not reach the level of evidence (LE) 1+, a new search of randomised clinical trials (RCTs) was carried out. The system proposed by SIGN (1) was used to evaluate the methodological quality of the trials.

Extraction of data performed by two independent reviewers.

Preparation of tables of evidence.

The tables of evidence are included in the document Methodology Materials, which is available in the *Clinical Practice Guidelines of the Spanish National Healthcare System* section of the GuíaSalud website: http://www.guiasalud.es/web/guest/gpc-sns.

A detailed description of the methods used to perform the SR is provided in the report *Care of Healthy Women in Childbirth: Variability Study and Systematic Review* (8).

Classification of Study Quality

Classification of the levels of evidence and grading of recommendations was performed using the SIGN scale (1) for questions of efficacy and safety of interventions or treatments, and using the OXFORD scale (3;9) for diagnosis-related questions (see the section *Levels of Evidence and Grades of Recommendations*, pages 21-22).

Formulation of Recommendations

Recommendations were drawn up and formulated in working sessions attended by members of the group developing the guideline for each subgroup of questions and by methodology professionals.

The recommendations were drafted and graded on the basis of the evaluation of evidence quality.

In discussions, when evidence was analysed the importance of outcome variables for patients was taken into account, and when each recommendation was graded it was assessed whether its benefits outweighed its risks. This process was carried out according to

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the "Formal Assessment" or "Reasoned Opinion" system proposed by SIGN, which evaluates the following key aspects:

- Quantity, quality and consistency of scientific evidence
- Spread of results
- Applicability
- Clinical impact

Publication of the Guideline

This CPG contains recommendations based on publications of "expert opinion", classified with the letter D.

The symbol √ is also used, and is defined as "consensus of the group that developed the guideline". This grade of recommendation is used in cases where there are no publications or where there are studies but the evidence needs to be adapted due to the context in which it is to be applied.

Throughout the text, the type of study and level of evidence are indicated in the right-hand margin. These reflect the possibility of biases in the literature reviewed.

The text underwent external review by a multidisciplinary group of professionals. The final version of the guideline was reviewed and approved by the group compiling it.

The various scientific societies involved (the Federation of Midwives' Associations in Spain [FAME], the Spanish Society for Gynaecology and Obstetrics [SEGO], the Perinatal Medicine Section [SEMPE] of SEGO, the Spanish Paediatrics Association [APE], the Spanish Neonatology Society [SEN], the *El Parto es Nuestro* association, the Haurdun Association) were contacted. These societies are also represented by members of the group that compiled the CPG and by external reviewers.

This document is the full version of the CPG on Care in Normal Childbirth. It is divided into chapters that address the questions indicated at the beginning. A summary of the evidence and recommendations is given at the end of each chapter. There is also a summary version of the CPG, which is shorter and contains the main appendices of the full CPG, and a version with information for women.

All versions of the CPG and the methodology materials are available in Spanish at http://www.guiasalud.es/web/guest/gpc-sns, with detailed information on the process of CPG compilation, the search strategy for each clinical question and the tables of evidence.

It is intended that the CPG will be updated every five years. More frequent updating of the electronic version is not ruled out, should this prove necessary. The Methodology Manual for Updating Clinical Practice Guidelines of the Spanish National Healthcare System must be used for this purpose. The manual is available at http://www.guiasalud.es/emanuales/actualizacion/index.html.

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4. Care During Childbirth

4.1. Care by Professionals and Those Accompanying

4.1.1 Women and the Professionals Caring for Them

- How does the relationship between a woman and the professionals influence the progress of labour and her satisfaction with the labour experience?

Adequate communication between women and the professionals responsible for their care makes a decisive contribution to labour being a positive experience for women and their families. The following are aspects of care that are greatly appreciated by women and that make a great contribution to their satisfaction with the labour experience: dissipating fears and doubts, instilling security, providing extensive, detailed information, considering physical and emotional well-being, being available, showing understanding, support and respect, ensuring privacy and remaining in the background.

Meeting each woman's expectations, so that she feels involved, can take decisions and maintains control over the labour process, is connected with satisfaction. It is therefore important for professionals to be aware of these expectations, expressed verbally or in birth plans, so that they can meet them as far as possible and, through a process of communication and emotional support, contribute when necessary to limiting any discrepancy that may occur between expectations and the actual progress of each birth.

Scientific Evidence

The NICE guideline (10) addresses this point with the following question: What effect does communication have on the woman's perception of the birthing experience?

The guideline included 19 studies conducted in cultural contexts similar to that of the United Kingdom. Most were prospective, qualitative cohort studies conducted using surveys and interviews, and specially designed to describe the relationship between the behaviour of those caring for women during labour and women's psychosocial progress. Another of the studies was a systematic review (SR) (11) assessing this relationship (see table of evidence in the appendix to the avalia t report (8)).

The SR (11) included 137 studies that showed variations in both methods and the analysis used. Even so, it was determined that the relationship between a woman and the person providing care during labour has a significant influence on the woman's experience.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

To summarise, the most important factor for women was to be treated as an individual, with respect and warmth. Secondly, most required information and an interpretation of this information in order to feel guided and supported throughout the birth process. The studies presented their results in the form of a list of words used by women to describe both the midwives and the feelings involved in a positive experience of labour. These words were the following: warmth, consideration, understanding, professional competence, trust, empathy, tenderness, kindness, friendly/friendliness, calm, care, peaceful, professional specialisation and unhurried.

SR, observational studies 3

Women want to receive information and help, in order to be involved in the process and feel safe.

Update (2006 to April 2008)

Seven studies were found in the literature search but not ultimately selected, as they did not meet the inclusion criteria established.

The evidence, of which there was a large amount but which had a low level of evidence, is therefore supplied by the NICE guideline (10).

To summarise, descriptive studies were found that analyse women's perceptions and assessments of their relationships with professionals. No studies investigating how this influences their assessment of the birth process were found.

See Appendix 2

Summary of Evidence

The relationship between a woman and the person providing care during labour has a significant influence on her birth experience. The most important factors to women are to be treated as an individual, with respect and warmth (11).	3

Recommendations

D	Las mujeres en trabajo de parto deben ser tratadas con el máximo respeto, disponer de toda la información y estar implicadas en la toma de decisiones. Para facilitar esto, los profesionales sanitarios y el resto del personal que le atienden, deberán establecer una relación empática con las mujeres, preguntarles por sus expectativas y por sus necesidades, para poder apoyarlas y orientarlas, siendo en todo momento conscientes de la importancia de su actitud, del tono de voz empleado, de las palabras utilizadas y de la forma en que se proporcionan los cuidados.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

4.1.2.Profile of Professionals

- How do professionals' profiles influence labour outcomes?

There are various different models of care for women with low-risk labours: midwife care, obstetrician care and mixed models.

The midwife care model is based on the premise that pregnancy and labour are normal life events centred on women. The differences between the midwife care model and other care models often include differences in philosophy, approach, the relationship with the professional and the use of interventions during childbirth. It is assumed that the basic philosophy of a midwife care model is normality and women's natural capacity to experience childbirth with minimal intervention or no routine intervention, and so the goal of midwife care models is to provide care during labour for healthy women with complication-free, or "low-risk" pregnancies.

In other models, care is shared by midwives and obstetricians, with varying levels of involvement. In some countries (e.g. Canada and the Netherlands) the scope of midwives' work is limited to caring for women with complication-free pregnancies, while in other countries (e.g. the UK, France, Australia and New Zealand) midwives provide care to women with medical and obstetric complications, together with doctors. In addition, in some countries (e.g. the Republic of Ireland, Iran and Lebanon) medical maternity care is provided mainly by a midwife, but is directed by an obstetrician; a qualified midwife can provide real care, but the obstetrician assumes the responsibility for the care provided to a woman during labour.

Benefits of the midwife care model described include lower rates of intrapartum analgesia and accelerated labour, greater mobility during labour, higher rates of spontaneous vaginal delivery and lower rates of caesarean sections, episiotomies, serious perineal lesions and admissions to neonatal units.

However, a tendency towards higher levels of perinatal mortality and neonatal morbidity and mortality has also been observed. It has been suggested that this may be the result of a delay or failure in detecting complications or beginning appropriate interventions.

There is also a great deal of debate concerning the clinical cost and cost-effectiveness of the various models of medical maternity care. The debate as to which model is the best for childbirth care for healthy women is therefore ongoing.

Scientific Evidence

The NICE guideline (13) does not address this question.

Update (to February 2009)

In the search performed, a high-quality Cochrane SR, LE 1+, was selected. The goal of this SR, which was published in 2008 (12), was to compare midwife led care models for pregnancy, childbirth and puerperium with other care models.

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Of a total of 31 studies identified in the SR (12), 11 RCTs were selected. They included a total of 12,276 women. Of the 11 studies, seven compared a midwife-led model of care for pregnancy, childbirth and puerperium with a shared care model (midwives, obstetricians and primary care physicians), three compared a midwife-led model with doctor-led models and one compared midwife-led care with various standard care options, including a doctor-led model and a shared care model.

SR/MA of RCTs
1+

The results of the meta-analysis performed demonstrated that women who were cared for using midwife-led models, when compared with women cared for using other models, were less likely to be admitted to hospital during pregnancy: RR 0.90 [CI 95%, 0.81 to 0.99]; to receive local anaesthesia during labour: RR 0.81 [CI 95%, 0.73 to 0.91]; or to require an episiotomy: RR 0.82 [CI 95%, 0.77 to 0.88]. Women cared for using midwife-led models were more likely to have a spontaneous vaginal delivery: RR 1.04 [CI 95%, 01.02 to 01.06]; a greater feeling of control during labour: RR 1.74 [CI 95%, 1.32 to 2.30]; to be cared for by midwives they knew: RR 7.84 [CI 95%, 4.15 to 14.81]; and to initiate breastfeeding: RR 1.35 [CI 95%, 1.03 to 1.76]. Furthermore, women who received midwife-led care were less likely to miscarry before 24 weeks' gestation: RR 0.79 [CI 95%, 0.65 to 0.97] and had shorter hospital stays: WMD 2 days [CI 95%, -1.85 to -2.15]. There were no statistically significant differences between the models in question for fetal and overall neonatal death: RR 0.83 [CI 95%, 0.70 to 1.00].

To investigate the possible sources of variation, subgroup analyses were performed between the following: a) different midwife care models (models in which care is managed by 2-3 midwives and models involving teams of midwives), b) variations in maternal risk (low-risk versus mixed), and c) different environments (community care versus hospital care).

The three subgroup analyses did not explain the high statistical heterogeneity (I2 above 50%) found in some outcomes (admission to hospital during pregnancy, use of local anaesthesia, use of opioid analgesia, episiotomy, spontaneous vaginal delivery, care by midwives known to the mother, shorter hospital stay), except for use of opioid analgesia. This displays heterogeneity that may be affected by the different care environments.

Maternal Satisfaction

Nine studies assessed maternal satisfaction by measuring different aspects of the childbirth experience: information received, advice, explanations, place of birth, preparation for labour and birth, pain, perception of the choice of pain relief method and evaluation of the behaviour of the professional providing care during labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Due to the lack of consistency between the studies regarding the conceptualisation and measurement of a woman's experience and her satisfaction with care received, no meta-analysis was performed on maternal satisfaction outcomes. Despite this, the results of individual studies suggest that satisfaction seems to be greater in women cared for using midwife-led models.

SR of RCTs 1+

To summarise, it can be observed that care for pregnancy, birth and puerperium using midwife-led models provides greater benefits than other, doctor-led or shared care models, with no adverse effects: it reduces the use of local anaesthesia and episiotomy during the birth, increases the rate of spontaneous vaginal delivery, with a greater feeling of control for the woman and a higher probability of being cared for by midwives known to her, and a higher rate of initiating breastfeeding. The rate of caesarean sections and fetal and overall neonatal death is similar for all the care models examined; moreover, satisfaction appears to be greater.

It is important to remember that the benefits observed are for models in which midwives provide prenatal, intrapartum and postpartum care, both in primary care and in hospitals. With regard to the benefits observed with midwife care models in low-risk births, in the opinion of the group that developed the guideline obstetricians should provide supervision, and intervene only in the event of an abnormal complication.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Summary of Evidence

Care for pregnancy, birth and puerperium by midwives provides greater benefits than other, doctor-led or shared care models, with no adverse effects: it reduces the use of local anaesthesia and episiotomy during the birth, increases the rate of spontaneous vaginal delivery, with a greater feeling of control for the woman and a higher probability of being cared for by midwives known to her, and a higher rate of initiating breastfeeding. fetal and overall neonatal death rates are similar for all the care models examined; moreover satisfaction appears to be greater (12).	1+

Recommendations

A	Care teams for hospital births should promote the use of midwife care for low-risk births.

4.1.3. Birth partners

- How effective is it for women to be accompanied during labour?

In hospitals, during a normal birth a woman is cared for by midwives, although they are not present constantly as each member of staff may be responsible for more than one woman in labour. In some countries however, continuous support and one-to-one care are being promoted.

In Spain, woman have been encouraged to be accompanied by their partner, a relative or someone they have chosen. This is considered a factor that improves women's well-being and seems to improve birth outcomes.

Scientific Evidence

The evidence published in the NICE guideline (10) to address this question is taken from a Cochrane SR (13) that had already been included in the 2004 NICE Caesarean Section Guideline (65) and was updated in the NICE Intrapartum Care CPG (10).

In 2006 this review, which included 15 trials and 12,791 women, had not identified any studies that specifically researched the efficacy of continuous support by the woman's partner or someone chosen by her.

Update (2006 to June 2008)

In our update, the same Cochrane SR, which had been updated in 2007 (14), was selected again. It included 16 studies with a total of 13,391 women, from both countries with high admissions rates and those with low admissions rates. In ten of the studies the hospital's policy allowed women to be accompanied by their husbands, partners or other family members during labour, while in the other six studies accompaniment was not permitted.

The main aim of the review was to assess the effects of support during labour, comparing continuous accompaniment with standard care. In the intervention group, the person who provided continuous support could be a healthcare professional (nurse, midwife); someone trained as a labour assistant; or a family member, friend or stranger with no specific training in labour support. The control group received standard care that, in accordance with the researchers' definition, did not include continuous accompaniment but could include other measures such as epidural anaesthesia or other standard aids for labour

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The results of the review show that women who received continuous, personal support during labour had a higher probability of spontaneous vaginal delivery (15 trials with n=13,357) RR 1.07 [CI 95%, 1.04 to 1.12], and a lower probability of:

SR/MA of RCTs
1+

- Receiving local analgesia/anaesthesia (7 trials; n=10,648); RR 0.92 [CI 95%, 0.85 to 0.99] and any type of analgesia/anaesthesia (12 trials; n=11,651); RR 0.89 [CI 95%, 0.82 to 0.96]
- Having an instrumental vaginal delivery (15 trials; n=13,357); RR 0.89 [CI 95%, 0.82 to 0.96]
- Having a caesarean section (16 trials; n=13,391); RR 0.91 [CI 95%, 0.83 to 0.99]
- Reporting dissatisfaction with the birth experience (6 trials; n=9,824); RR 0.73 [CI 95%, 0.65 to 0.83]
- Slightly shorter labour (10 trials; n=10,922); WMD -0.43 hours [CI 95%, -0.83 to -0.04]

One of the secondary aims of the study was to determine whether the effects of continuous support are influenced by standard practices and policies for childbirth that may affect a woman's autonomy, freedom of movement and ability to handle childbirth. To do this, subgroup analysis was carried out of establishments in which women were allowed to be accompanied by the person of their choice during labour, versus establishments in which they were not allowed to be supported by the person of their choice.

In subgroup analysis of establishments that did or did not allow women to be accompanied, comparison of women who received continuous support and those who received standard care yielded the following results:

In establishments in which accompaniment was permitted, the probability of receiving anaesthesia during labour was as follows: RR 0.97 [CI 95%, 0.96 to 0.99]. In those in which accompaniment was not permitted, the results were as follows: RR 0.72 [CI 95%, 0.49 to 1.05]. The difference between subgroups was not statistically significant (χ^2=3.33; p=0.07).

The probability of *spontaneous vaginal delivery* in establishments that allowed women to be accompanied by the person of their choice was as follows: RR 1.03 [CI 95%, 1.00 to 1.06] was lower than the probability observed in those that did not allow women to be accompanied in this way: RR 1.11 [CI 95%, 1.04 to 1.19]. The effect of continuous support seems to be greater in contexts in which the woman was not allowed to be accompanied by other people (x^2 =9.89; p<0.01).

SR/MA of RCTs
1+

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Comparison of the probability of having an instrumental vaginal delivery in establishments that allowed women to be accompanied yielded the following results: RR 0.90 [CI 95%, 0.84 to 0.97], versus the following probability in establishments that did not allow this: RR 0.68 [CI 95%, 0.42 to 1.10]. The difference was not statistically different (x^2=1.25; p=0.26).	SR/MA of RCTs 1+
Comparison of the probability of having a caesarean delivery in establishments that allowed accompaniment: RR 0.97 [CI 95%, 0.88 to 1.07], versus the probability in those that did not allow it: RR 0.71 [CI 95%, 0.54 to 0.93], did not show statistically significant differences. The effect of continuous support seems to be greater in contexts in which other people were not permitted to be present to provide support (x^2=4.83; p=0.03), as it showed a trend towards lower caesarean rates.	SR/MA of RCTs 1+
Comparison of the probability of reporting dissatisfaction in establishments that allowed accompaniment: RR 0.83 [CI 95%, 0.67 to 1.02] versus those that did not allow it: RR 0,67 [CI 95%, 0.58 to 0.78] showed a greater tendency towards dissatisfaction in contexts in which other people were permitted to be present to provide support (x^2=3.09; p=0.08), although the differences were not statistically significant.	SR/MA of RCTs 1+
To summarise, the overall results of the review show a beneficial effect for continuous accompaniment. However, subgroup analysis performed to evaluate the effects of the practices and policies of different establishments, shows that the effect of continuous support, though always beneficial, is more so in establishments with no accompaniment policies. This fact suggests that continuous support should be provided, especially in establishments with no accompaniment policies.	SR/MA of RCTs 1+

Summary of Evidence

Women who receive professional continuous support during labour had a higher probability of spontaneous vaginal delivery and a lower probability of receiving local anaesthesia, having an instrumental vaginal delivery, having a caesarean delivery and reporting dissatisfaction with the childbirth experience (14).	1+
The effect of professional continuous support, though always beneficial, is more so in establishments that do not have accompaniment policies (14).	1+

Recommendations

A	Women should have the option of being accompanied by the person of their choice during labour.

More than 5 years have passed since the publication of this clinical practice guideline and its validity has not been reviewed

4.2. Restriction of Fluids and Solids

4.2.1. Restriction of Food

- How effective is the restriction of fluids and solids during labour?

The restriction of fluids and solids during labour is a care routine aimed at preventing the risk of gastric aspiration in the event of a surgical intervention under general anaesthesia, although it is known that it does not guarantee reduction of stomach contents by evacuation and that a woman's well-being can be affected by being unable to eat or drink.

General anaesthesia in obstetrics has now given way to neuraxial techniques, which are normally used in labour and caesarean sections. Moreover, guidelines such as that of the WHO (4) encourage offering fluids orally during labour. This has led to the need to reconsider this restriction.

The NICE guideline (10) uses a randomised controlled trial (15) published in 1999 with a population of 88 women at 37 or more weeks' gestation and the fetus in cephalic presentation, the aim of which was to evaluate ketosis prevention interventions during labour. The intervention consisted of a low-residue diet (n=45), versus fasting (water only, n=43). The results of the trial showed that restricting food intake during labour could lead to ketosis, as it causes a significant increase in plasma hydroxybutyrate levels ($p<0.001$) and non-esterified fatty acids ($p<0.001$), when compared to a low-residue diet. A significant increase in plasma glucose ($p=0.003$) and plasma insulin ($p=0.017$) was also observed in the group with no restriction on food when compared to the fasting group. The transverse surface area of the gastric antrum in the first hour of labour was significantly higher in the group with no restriction on food ($p=0.001$), and these women had twice the risk of vomiting when giving birth ($p=0.046$) and significantly higher volumes vomited ($p=0.001$). Lactic acid levels were similar in both groups. The study found no significant differences in maternal outcomes (duration of first and second stage of labour, oxytocin needs, type of delivery) or neonatal outcomes (Apgar score, gases in arterial and venous umbilical blood) between the two groups.

RCT
1+

More than 5 years have passed since the publication of the clinical practice Guideline and its validity has not been reviewed

Update (2006 to March 2008)

The ASA Task Force CPG for obstetric anaesthetic (16) was selected for this update. This is a CPG based on expert opinion. It assesses the restriction of fluids and solids to prevent aspiration in women who may eventually receive anaesthesia. The group that compiled the Task Force guideline agreed that *the ingestion of clear liquids* during labour improves maternal comfort and satisfaction and does not increase maternal complications. However, sufficient evidence was not found to draw conclusions on the relationship between the clear liquid fasting time and the risk of reflux or pulmonary aspiration during labour. The group compiling this American guideline also determined that due to a lack of evidence it is not possible to establish a specific safe period of fasting prior to unplanned surgical interventions. The group is of the opinion that *oral ingestion of solids* increases maternal complications and feels that solids should not be ingested during labour.

CPG, expert opinion 4

The RCT (17) by O'Sullivan (2009) was also selected for the update, as a result of the alerts established in the search strategies used for the update. This RCT aimed to assess the effect of food intake during labour on obstetric and neonatal outcomes. It included 2,443 women giving birth for the first time, with no clinical complications, at 36 or more weeks' gestation and with cervical dilatation up to 6 cm. The women were allocated at random to a group in which they were permitted and encouraged to eat a low-residue diet in small, regular quantities (n=1,227), or to another in which they were only allowed to drink water (normal practice in the hospital where the trial was conducted). All women had the choice of various forms of pain relief, such as immersion in water, inhaling Entonox® (a 50:50 mixture of nitrous oxide and oxygen) and modern, low-dose epidural anaesthesia. However, use of parenteral opioids was an exclusion criterion for the trial since they cause a delay in gastric evacuation, increasing the risk of vomiting.

This RCT (17) suggested that a low-residue diet did not affect neonatal outcomes (Apgar, admission to NICU) or obstetric outcomes such as the rate of spontaneous deliveries: RR 0.99 [CI 95%, 0.90 to 1.06], duration of labour: GMR (geometric mean ratio) 0.97 [CI 95%, 0.92 to 1.02], rate of instrumental deliveries: RR 1.04 [CI 95%, 0.91 to 1.19], rate of caesarean sections: RR 0.98 [CI 95%, 0.87 to 1.12] and vomiting: RR 1.05 [CI 95%, 0.94 to 1.17]. However, due to the extremely low prevalence of pulmonary acid aspiration in obstetrics, the trial did not have the statistical power necessary to assess the safety of this practice with regard to aspiration.

RCT 1+

Another of the studies selected as a result of the update alerts used in the search strategies is a new Cochrane SR (18) that aims to answer this question by determining the benefits and harm of ingesting fluids or restricting food intake during labour, with or without intravenous hydration.

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The SR (18) included five studies with a total of 3,130 women at low risk who might require general anaesthesia during birth (e.g. for a caesarean section). One of the studies compared a complete nil-by-mouth regime with the freedom to eat and drink at will; another two studies (among them the O'Sullivan study (17) chosen in the update and the study selected for the NICE guideline (15)) compared intake of water only with intake of fluids and a low-residue diet in small, regular quantities; the remaining two studies compared intake of water only with intake of carbohydrate drinks.

The meta-analysis, which was dominated by one study (17) conducted in a highly medicalised environment, compared any restriction on fluids and solids with intake of any type of nutrition during labour and did not show any statistically significant differences regarding caesarean sections (5 studies, 3,103 women): RR 0.89 [CI 95%, 0.63 to 1.25], vaginal deliveries (5 studies, 3,103 women): RR 0.98 [CI 95%, 0.88 to 1.10], Apgar scores below seven at five minutes (3 studies, 2,574 neonates): RR 1.43 [CI 95%, 0.77 to 2.68] or any of the other outcomes evaluated. The women's opinions were not evaluated. Grouped data was insufficient to assess the incidence of Mendelson's syndrome, a serious and extremely rare outcome. The group that compiled the guideline therefore makes no recommendation on intake of solids.

SR/MA of RCTs
1+

In the SR, and in the group compiling the guideline, it was concluded that as the evidence shows neither benefits or harm there is no justification for restricting fluids during labour for women with a low risk of complications.

Summary of Evidence

There is no evidence with which to evaluate the safe fasting time after intake of solids in women in labour (16).	4
Intake of solids during labour has not been found to affect obstetric outcomes (type of birth, duration of labour) or neonatal outcomes. The studies do not have sufficient power to evaluate maternal safety from serious, extremely rare events and complications such as Mendelson's syndrome (17;18).	1+
Ingesting clear liquids during labour does not affect the progression of labour, type of delivery, duration and use of oxytocin or neonatal outcomes. In addition, it is considered to improve maternal comfort and satisfaction and not to increase maternal complications (17;18).	1+

Recommendations

A	Intake of clear liquids should be permitted during labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

4.2.2 Prevention of Ketosis

- What can be recommended to prevent ketosis during labour?

The onset of ketosis during labour is a cause for concern, as it is believed that it can cause nausea, vomiting and headaches and lead to maternal exhaustion. It has been suggested that a light diet or intake of carbohydrate drinks during labour may reduce the production of ketone bodies, although the increased volume of gastric content can lead to discomfort.

Scientific Evidence

The evidence published in the NICE guideline (10) includes studies that compare the effect of *ingesting carbohydrate solutions versus placebo*, and *ingesting isotonic drinks versus water*. The outcome measures were the acid-base balance of the foetus and neonate, and delivery outcomes.

Carbohydrate Solutions vs Placebo

To address this question, this section included three randomised controlled trials (19-21), all conducted by the same researchers in the same hospital in the Netherlands (Leyenburg Hospital). The first (19) (also included in the Cochrane meta-analysis selected for the previous question (18)) included 201 women giving birth for the first time, with cervical dilatation 2-4 cm, who were randomised to two study groups (carbohydrate solution, n=102; placebo, n=99). The women were allowed to consume small, standardised amounts of food and drink on request, and the total number of kilojoules consumed was calculated for each woman at the end of the study. In the second (20), 202 women giving birth for the first time, with cervical dilatation 8 10 cm, were recruited (carbohydrate solution, n=100; placebo, n=102), and were not allowed to ingest any other solution. In the last study (21), 100 women giving birth for the first time, with cervical dilatation 8 10 cm, were recruited and randomised to receive carbohydrate solution (n=50) or placebo (n=50). Unlike the other two studies, in this study the women were allowed to drink water as well as the solutions involved in the study. Water with flavouring and artificial sweeteners was used as a placebo. None of the studies found significant differences between the intervention groups in terms of outcomes concerning the acid-base balance of the foetus or neonate. However, there were differences regarding the type of delivery: in the first study (19), it was observed that ingesting carbohydrate solutions on request could increase the risk of a caesarean section: RR 2.9 [CI 95%, 1.29 to 6.54], but these results should be interpreted with caution, as the sample size was small. The study concluded that ingesting carbohydrate solutions during the first stage of labour could have an adverse effect on labour progression and outcomes, although these results are attributed to possible confounding factors. The researchers therefore feel that the effects of these drinks must be assessed and that further studies are necessary before conclusive statements can be made.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Because 80% of the women in the study sample were at high risk, we cannot apply these results to a population of healthy women.

Isotonic Drinks vs Water

For this section, a randomised controlled trial conducted in the UK and published in 2002 (22) was examined. The trial included 60 women at 37 or more weeks' gestation, with a single foetus in cephalic position. They were randomised to two groups: one group drank isotonic drinks (n=30), and the other drank water (n=30). This study was also included in the Cochrane meta-analysis (18).

In the isotonic drink group, a significant reduction was observed in hydroxybutyrate and non-esterified fatty acids levels when compared to the group that drank water. The average plasma glucose level remained unchanged in the isotonic drink group, and fell significantly in the group that ingested water. The total amount of fluid ingested was higher in the isotonic drink group (p=0.001), as was the average number of calories ingested (47 kcal/hour), when compared to the group that drank only water (0 kcal/hour). However, there were no differences between the groups in the surface area of the gastric antrum, volume vomited after one hour of labour or volume vomited throughout labour. There were also no differences between the two groups with respect to the duration of labour, use of oxytocin, delivery method or use of epidural anaesthesia. Although the study only presents the data with averages or proportions and warns that the results were not significant, it is concluded that ketosis may be prevented by ingesting a relatively small number of calories in the form of isotonic drinks.

RCT
1+

Update (2006 to June 2008)

Seven studies were found but not selected, as they did not meet the inclusion criteria established. The volume and quality of evidence is therefore provided by the NICE guideline (10).

To summarise, there is evidence supporting the claim that ketosis can be prevented by ingesting a relatively small number of calories in the form of isotonic drinks. However, it is not clear whether carbohydrate solutions ingested during the first stage of labour can have an adverse effect on labour progression or outcomes, so the group that compiled the guideline feels that the effects of these drinks must be assessed before conclusive statements can be made.

More than 5 years have passed since the publication of the Clinical practice Guideline, and its validity has not been reviewed

Summary of Evidence

Ketosis may be prevented by ingesting a relatively small number of calories in the form of isotonic drinks (22).	1+

Recommendations

A	Women should be informed that isotonic drinks are effective against ketosis, and are therefore preferable to water.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5. First Stage of Labour

5.1. Definition of the First Stage of Labour

- What is the definition of the latent phase of the first stage?
- What is the definition of the active phase of the first stage?

The definitions of the stages of labour must be clear in order to ensure that both women and professionals share the same ideas, making communication easier.

Scientific Evidence

After a systematic search, the NICE guideline (10), the first CPG to address the definitions of the stages of labour, did not identify any studies comparing the results of defining the stages of labour in different ways. Various definitions, which have been used in practice and in a range of research studies, have been considered.

The various definitions of the start of labour are based on the commencement of uterine contractions (23-26), evidence of changes in the cervix (27), or both (23). Using only the presence of uterine contractions to define the start of labour means that it is established by the woman herself, while the inclusion of changes in the cervix means that confirmation by a professional is required.

By general agreement, labour has been divided into three stages: the first stage, the second stage, and the third stage, The first stage starts with the beginning of labour and ends at full dilatation. This first stage has in turn been subdivided into two phases, in both clinical practice and the literature: the latent phase and the active phase.

The latent phase starts with the beginning of labour. It is characterised by contractions that vary in intensity and duration, accompanied by cervical effacement and slow or slight progression of dilatation to 2 cm (25) or 4 cm (28-30).

Case series 3

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The active phase is characterised by an increase in the regularity, intensity and frequency of contractions and fast progression of dilatation. It can be defined using criteria on cervical dilatation only, ranging from 2 to 10 cm dilatation (25) or from 4 to 10 cm dilatation (28-30). Alternatively, it may include the mother's perception, for example from the start of regular contractions to the beginning of pushing (26). As the most characteristic feature of the active phase is faster dilatation, when dilatation is slight (2 cm) it cannot be determined whether the woman is in the latent or the active phase on the basis of dilatation alone. It is therefore only possible to verify the start of the active phase retrospectively, or by choosing a point on the dilatation curve which is clearly situated at the start of the active phase (4 cm).

Update (2006 to July 2008)

No study has been identified that assesses the various definitions of the first stage of labour. The group compiling the guideline has therefore based its recommendations on several of the definitions used in normal practice and on research (the observational studies mentioned above and the definitions used in six different studies researching the duration of labour [see point 4.2 Duration and Progress]).

Summary of Evidence

The *latent phase* starts with the beginning of labour. It is characterised by contractions that vary in intensity and duration, accompanied by cervical effacement and slow progression of dilatation to 2 or 4 cm. The *active phase* is characterised by an increase in the regularity, intensity and frequency of contractions and fast progression of dilatation.	3

Recommendations

√	The definition of the latent phase that should be adopted is the period of labour between the start of labour and 4 cm dilatation. The definition of the active phase that should be adopted is the period of labour between 4 and 10 cm dilatation and accompanied by regular contractions.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

5.2. Duration and Progress of the First Stage of Labour

- What is the duration of the latent phase of the first stage of labour?
- Do the duration and progress of the first stage of labour influence outcomes?

When considering a normal labour, it is important to define the cut-off points for what is accepted as a normal duration, versus what may be considered an abnormal duration. These cut-off points can be used to inform women about the possible duration of labour, to detect dystocia and to indicate when midwives should request the assistance of an obstetrician.

The duration of the first stage has traditionally been considered a very important determining factor for the health of mothers and perinatal outcomes. Although current knowledge seems to indicate that within certain limits duration need not be a key factor for concern, if it lasts beyond these limits this may indicate a problem.

Scientific Evidence

The NICE guideline (10) identified six studies, among others, describing the duration of the first stage of labour or assessing the effect of the progression of the first stage on obstetric and clinical outcomes, and its impact on various factors associated with the duration of labour.

The largest of the studies describing the duration of labour (23) included data for 6,991 women in the UK who had complication-free labours between 1978 and 1987. This study analysed the duration of the first stage of labour with respect to both parity and whether or not epidural anaesthesia was used. Longer labour times were observed in women for whom it was the first birth than in those who had previously given birth, and in women who used neuraxial analgesia than in those who did not (mean duration of first stage and upper limit (95th percentile): first birth without analgesia: mean duration 8.1 hours (95th percentile 16.6 hours); first birth with analgesia: 10.2 hours (19.0 hours); second and subsequent births without analgesia: 5.7 hours (12.5 hours); second and subsequent births with analgesia: 7.4 hours (14.9 hours).

Case series 3

A smaller, older study (25) conducted in the USA described the duration of the latent phase and the first stage for 100 women giving birth for the first time. The sample was very heterogeneous, as it included women with breech presentation, women carrying twins and induced labours, with only 29 spontaneous labours.

Another study from the USA (30) described full-term spontaneous labour lasting over 3 hours in 1,162 women giving birth for the first time. It found that the mean duration of the first stage of labour was 7.3 hours (10th and 90th percentiles: 3.3 and 13.7 hours respectively).

Case series 3

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

A study conducted in Germany analysed the factors associated with normal duration of labour (26). It involved 932 women cared for in a midwife-led unit and at home, between 1994 and 1995. The average duration of the first stage of labour, excluding women whose labour was prolonged, was 7.3 hours (range: 1-17 hours) for first births and 3.9 hours (range: 0.5-12 hours) for subsequent births. Regression analysis showed that labour was shorter in second and subsequent births than in first births, but did not find other demographic variables associated with the duration of the first stage of labour. A short interval between the start of labour and midwife care beginning was associated with a shorter duration of the first stage of labour; the effect was more pronounced in second and subsequent births and for women whose waters had broken before midwife care was started.

Case series
3

Another study from the USA (28) investigated the duration of labour in 1,473 women at low risk, by ethnic group (non-Hispanic white, Hispanic, native American). The mean duration and upper limit (two standard deviations) for the active phase of labour were 7.7 hours (19.4 hours) for first births and 5.7 hours (13.7 hours) for second and subsequent births, and there were no statistically significant differences between ethnic groups.

Case series
3

An observational study conducted in the UK (31), which included 403 women in established labour, described the progress of labour in women who had given birth previously, who had no complications, and who had given birth in a midwife-led unit. On the basis of the findings of vaginal examinations carried out every 2 hours, the simple regression model demonstrated that the mean cervical dilatation was 2.9 cm/hour, and the median 1.9 cm/hour (10th percentile 0.7 cm/hour, 5th percentile 0.5 cm/hour). The women included in the study with dilatation below 4 cm tended to exceed these figures. Also detected were profiles of women with periods with no progression, followed by periods of progression. Thus, if 4 cm is taken as the start of the active phase of labour and the median is used as a parameter for dilatation, the duration of the active phase was estimated at 3 hours, 9 minutes. If the 10th percentile is used as the upper limit, the duration is 13 hours.

Observational study
3

To summarise, the NICE guideline (10) determines that the duration of labour varies between women and is influenced by the number of times the woman has become pregnant, and that dilatation may not necessarily progress in a linear fashion.

In established labour, most women giving birth for the first time reach the second stage of labour without intervention within the first 18 hours. In women who have previously given birth, however, this figure is 12 hours.

Update (2006 to January 2009)

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In the search carried out for the update of both the definition and the duration of the first stage of labour, four studies were pre-selected but ultimately not used as they did not meet the selection criteria. As a result, the recommendations are based on the findings described by the NICE guideline (10).

The group that compiled the guideline considered it important to emphasise that the duration of the first stage of labour is not *per se* a determining factor for maternal and fetal well-being, and it is not a key factor for concern. However, if it lasts beyond the limits indicated, this should be considered a sign that there is a problem.

Summary of Evidence

The duration of labour varies between women and is influenced by the number of times the woman has become pregnant (23;26;28), and it may not necessarily progress in a linear fashion (31).	3
In established labour, most women giving birth for the first time reach the second stage of labour within the first 18 hours, and those who have previously given birth in 12 hours, without intervention (23; 26; 28; 31).	3

Recommendations

√	The duration of the latent phase of the first stage of labour cannot be established, due to the difficulty in determining the start of labour.
C	The duration of the active phase of labour varies between women and depends on parity. It does not necessarily progress in a linear fashion. For first child: o The average duration is 8 hours. o It is unlikely to last for more than 18 hours. For second and subsequent children: o The average duration is 5 hours. o It is unlikely to last for more than 12 hours.
√	The decision to intervene if the first stage of labour seems to be prolonged must be taken on the basis of the progress of dilatation and other obstetric factors, rather than on the basis of duration alone.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

5.3. Maternity Admission

- What is the ideal moment for a woman in labour to be admitted to a maternity ward?

Women generally arrive for admission to the maternity ward when uterine contractions start, when they may still be only in an early phase of labour. Early admission means waiting for several hours until the active phase of labour starts. This situation may cause anxiety in women and those accompanying them if they wrongly think that dilatation should progress faster simply because they have been admitted, and this can lead to procedures that are not strictly indicated for normal labour. There is also concern about the effect of the start of labour on fetal well-being, and there is a widespread belief that early admission will improve the perinatal outcome.

Scientific Evidence

The NICE guideline (10) includes a Canadian randomised controlled study with LE 1-, identified on the basis of an SR, which investigates the ideal time for admission to a maternity ward in a population of 209 women with low-risk labours. Three other observational studies concerning cervical dilatation and admission time were included, two of which were low-quality cohort studies conducted in Canada (33; 34) with LE 2-, and the other a large cross-sectional study (n=8,818) conducted in the USA (35) with LE 3. The last of the studies included in the NICE guideline (10) was a low-quality RCT (36), also conducted in Canada, which assessed the impact of the first contact made at home.

The most recent study, conducted in the USA (35), included the most women (n=8,818) and compared the labour outcomes of women going to maternity wards in the active phase with those of women who did so in the latent phase. Women who went to a maternity ward in the latent phase yielded the following results: a slower active phase: OR 2.2 [CI 95%, 1.6 to 2.6]; greater use of oxytocin: OR 2.3 [CI 95%, 2.1 to 2.6]; greater use of epidural anaesthesia: OR 2.2 [CI 95%, 2.0 to 2.4]; more neonates intubated after birth: OR 1.2 [CI 95%, 1.0 to 1.4]; more women with amnionitis: OR 2.7 [CI 95%, 1.5 to 4.7]; and more women with postpartum infection: OR 1.7 [CI 95%, 1.0 to 2.9].

Observational study
3

The evidence found concerning the ideal time for admission shows that admission to a maternity ward early or during the latent phase is associated with longer duration and higher rates of intervention during labour (use of oxytocin and epidural anaesthesia). There is still insufficient evidence concerning morbidity and mortality of mothers and neonates.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Update (2005 to May 2008)

Two studies were pre-selected in the search carried out for the update of this question but ultimately not included, as they did not meet the selection criteria. As a result, the recommendations are based on the findings described by the NICE guideline (10).

It has been observed that admission during the active phase of labour leads to lower levels of intervention than admission during the latent phase. The group that compiled the guideline therefore considers that it is important to avoid early admission of women in labour.

The active phase of labour has been defined as the period of labour between 4 and 10 cm dilatation and accompanied by regular contractions. The group that compiled the guideline has therefore adopted the admission criteria established in the Standards and Recommendations Document for Hospital Maternity Wards of the Ministry for Health (37) (2009), which can be used to identify women who are in the active phase of labour: regular uterine contractions, cervical effacement >50%, dilatation 3-4 cm.

◊ Consensus document 4

Summary of Evidence

Admission to a maternity ward early or during the latent phase is associated with a higher rate of interventions during labour (use of oxytocin, epidural anaesthesia and intubation of neonates) (35).	3
There is still insufficient evidence available concerning its effects on morbidity and mortality of mothers and neonates (35).	3
The following criteria have been defined for admission to hospital maternity wards: regular uterine contractions, cervical effacement > 50%, dilatation 3 4 cm (37).	4

Recommendations

√	Admission is recommended when the following criteria are met: regular uterine contractions, cervical effacement > 50% and dilatation of 3-4 cm.
√	Individualised support should be offered to women who arrive with painful contractions and are not in the active phase of labour. They should be encouraged to return home until the active phase of labour starts.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5.4. Care on Admission

Questions to Answer

- What is the benefit of carrying out amnioscopy on all women with suspected labour arriving for admission?
- What is the benefit of carrying out cardiotocography (CTG) on all women with suspected labour arriving for admission?

5.4.1 Amnioscopy

Amnioscopy is a procedure performed to assess the quantity and/or colour of amniotic fluid (AF) in order to detect alterations that could indicate fetal compromise. However, it is an invasive procedure which is not free from complications and yields a substantial proportion of incorrect results. Its benefit-risk balance is therefore dubious.

Scientific Evidence (to May 2008)

Although it reviews the examinations and texts that should be performed on mother and child on admission, the NICE guideline (10) does not cover the subject of amnioscopy. In fact, other documents evaluated also fail to mention amnioscopy, such as the *Strategy for Care* in *Normal Childbirth of the Spanish National Healthcare System* (5), recommendations developed by the Ministry for Health in 2007, the SEGO's 2008 recommendations on care during childbirth (38) and the WHO guideline *Care During Normal Childbirth: A Practical Guide* (4). Additionally, a French non-systematic review (39) concludes that it has not been demonstrated that systematic inspection of the appearance of amniotic fluid via amnioscopy at the start of labour is useful.

The systematic search conducted to answer this question found six reviews and ten studies, of which only two studies were ultimately selected.

A study (40) carried out in 1988, which included 289 consecutive women, aimed to assess the effectiveness of amnioscopy to detect meconium in pregnancies with gestation age > 41 weeks, and its correlation with fetal distress and fetal morbidity and mortality. It also assessed whether the rupture of membranes when meconial fluid was detected reduced fetal morbidity and mortality.

The results showed that amniotic fluid containing meconium tends to be associated with pregnancy complications such as ABO incompatibility ($p<0.05$), a need for surgical delivery ($p<0.02$) and fetal distress at birth ($p<0.05$). Amnioscopy did not detect meconium before birth in most cases (57%) and positive results for meconium were not related to the incidence of fetal distress. Furthermore, when meconium was present inducing labour was not effective in reducing the incidence of fetal distress. Consequently, this study did not recommend amnioscopy for monitoring post-term pregnancies.

Cross-sectional study III

More than 5 years have passed since the publication of the Clinical Practice Guidelines and its validity has not been reviewed

The aim of the second of the 2005 studies (41), LE 3, was to determine the prevalence and clinical significance of any change in the colour or density of amniotic fluid (AF) during labour and its value in predicting perinatal outcomes. To this end the authors examined AF on admission via amnioscopy or inspection of the fluid itself if the waters had broken.

A total of 19,090 women were selected between 1992 and 1999. To analyse the results, the women were divided into four groups according to the features of the AF: group 1 (n=16,975): AF clean on admission and delivery; group 2 (n=973): AF with light or thick meconium on admission or delivery; group 3 (n=986): AF clean on admission and with light or thick meconium on delivery; group 4 (n=156): AF with light meconium on admission and thick meconium on delivery. However, data analysis did not take into consideration other confounding variables between the study groups, such as early breaking of waters, alarming fetal heart rate, gestational age, first-time labour or induced labour.

Analysis demonstrated that a higher percentage of women giving birth for the first time presented a change in AF colour during labour. Gestational age over 42 weeks was associated not with a higher rate of meconial AF on admission but with a higher risk of change in AF colour during labour. In addition, a higher percentage of women with meconial AF on admission presented induced labour. Cohort study III

Women in whom a change of AF colour occurred during labour, from clean to meconial, presented low Apgar scores at 5 minutes and pH<7.10. This was also associated with a higher rate of admission to NICUs. The highest percentage of children with aspiration of meconium occurred in group 4, in which the woman had light meconial AF on admission and thick meconial AF on delivery. Cohort study III

To summarise, it was found that qualitative changes in AF during labour have a higher predictive value for adverse neonatal outcomes than the colour of AF on admission. The presence of meconium in AF at the start of labour had little or no predictive value for umbilical pH <7.10, Apgar score <7 at 5 minutes, meconium aspiration syndrome (MAS) or admission to neonatal intensive care units. Furthermore, the risk of MAS is associated only with thickening of meconium during labour, not with the presence of meconium at the start of labour.

The evidence found is consistent with amnioscopies yielding a high level of false negatives. Although there may be some advantages to assessing the colour of amniotic fluid on admission, amnioscopy is not considered an effective procedure for doing this, and new techniques are required to assess the colour of amniotic fluid on admission.

More than 5 years have passed since the publication of the Clinical Practice Guideline and its validity has not been reviewed

5.4.2 Cardiotocography

External cardiotocographic monitoring is an increasingly widespread practice used in pregnant women who arrive at hospital with suspected labour. There are doubts as to whether it is conducted in a context of defensive medicine and increases the level of obstetric intervention due to false positives, or whether it is a truly useful procedure for improving perinatal outcomes.

Scientific Evidence

The NICE guideline (10) assesses *Cardiotocography* (CTG) as one of the examinations and tests to be conducted on admission. The evidence found in the NICE guideline (10) includes a high-quality SR (42) published in December 2005. The SR evaluates three RCTs (11,259 women) and 11 observational studies (5,831 women). It assesses the effectiveness of CTG on admission in preventing possible adverse effects, comparing it with auscultation. The document includes a meta-analysis of the results of the three RCTs.

MA of RCTs Ia

Women undergoing CTG on admission were more likely to require epidural anaesthesia: RR 1.2 [CI 95%, 1.1 to 1.4]; electronic fetal monitoring: RR 1.3 [CI 95%, 1.2 to 1.5]; and fetal blood samples: RR 1.3 [CI 95%, 1.1 to 1.5]. There is also weak evidence that women who undergo electronic fetal monitoring may be more likely to have instrumental births: RR 1.1 [CI 95%, 1.0 to 1.3] and caesarean sections: RR 1.2 [CI 95%, 1.0 to 1.4] than the group in whom auscultation was performed. No evidence was found of differences in induction, infant mortality or neonatal morbidity.

The review concludes that there is no evidence suggesting that CTG on admission is beneficial for women with low-risk pregnancies.

Update (2005 to March 2008)

The update of the search for the NICE guideline (10) found 16 references. Howver, as none of them met the inclusion criteria established for selecting studies the group that compiled the guideline has based its recommendations on the evidence provided by the NICE guideline (10).

Summary of Evidence

Amnioscopy presents a large number of false negatives. It is therefore not an effective procedure for assessing the colour of amniotic fluid on admission for women at low risk (40).	III
Women who undergo *CTGs* have a higher probability of needing epidural anaesthesia, electronic fetal monitoring and fetal blood samples (42).	Ia

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CTG on admission has not been shown to be beneficial for women at low risk (42).	Ia

Recommendations

C	*Amnioscopy* is not recommended for initial assessment of women with low-risk labour.
A	*Cardiotocography* is not recommended when low-risk pregnant women are admitted.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5.5. Possible Routine Interventions during the First Stage of Labour

- How effective is *routine enema* during labour?
- How effective is routine *perineal shaving* during labour?
- How effective is *one-to-one care* during labour?
- What is the effect of mobility and *adopting different positions* on labour and its outcomes?
- How effective is *routine artificial amniorrhexis* and routine perfusion of oxytocin?
- Should antiseptics be used in *vulvovaginal lavage* prior to vaginal examination?
- Does the use of a partogram improve outcomes?
- What is the *optimum frequency of vaginal examinations* during the first stage of labour?
- What methods are effective in treating *delays in the first stage* of labour?

5.5.1 Enema

- How effective is routine enema during labour?

For many years enemas have been administered at the start of labour to reduce encopresis during the second stage of labour and the distress this may cause to women. Other reasons used to justify this practice were the belief that evacuation of the intestines would provide more space for delivery of the foetus and that the stimulus provided by the enema would improve uterine contractions and reduce the duration of labour. It was also thought that evacuation of the intestines reduced faecal contamination of the perineum and so reduced the probability of infection for the mother and the neonate.

These supposed benefits have been questioned, and disadvantages and risks associated with the use of cleansing enemas have even been put forward. Disadvantages cited include the unpleasantness of the procedure, increased pain during labour, staff workloads and costs. It has also been noted that enemas tends to cause watery faecal losses that can increase the risk of infection, and that in reality their use simply reflects a preference by healthcare professionals.

Due to the conflicting criteria and uncertainties about this practice, the effects of enemas on women and their babies should be reviewed.

Scientific Evidence (to May 2008)

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Although it reviews various types of intervention performed during the first stage of labour, the NICE guideline (10) does not cover the subject of enema use.

The systematic search performed to answer this question found seven articles (two in Cochrane and five in PubMed), of which only one Cochrane SR, from 2007, (43) was included. The other articles were excluded as they did not meet the inclusion criteria.

The SR included a total of three RCTs: one with LE 1+ and two with LE 1-. The aim of the SR was to study the effects of enemas administered during the first stage on the rate of postpartum infection, neonatal infection, non-infectious maternal and neonatal morbidity, episiotomy dehiscence rate, faecal encopresis during dilatation and labour, and finally the duration of labour.

Only the results of the RCT with LE 1+ for some of the variables studied were taken into account (44).

The results demonstrated that there were no significant differences between the two groups (with and without enema) for neonatal umbilical infection variables: RR 7.47 [CI 95%, 0.39 to 143.55]; puerperal infection: RR 0.66 [CI 95%, 0.42 to 19.04]; perineal tear without compromised anal sphincter: RR 1.11 [CI 95%, 0.65 to 1.90]; perineal tear with comprised anal sphincter: RR 0.59 [CI 95%, 0.14 to 2.42]. RCT 1+

Regarding other variables, the SR did not find significant differences between the two groups in neonate outcomes (infection or Apgar score), puerperal outcomes (episiotomy dehiscence) or duration of labour, because although the duration of labour was lower in the group undergoing enemas (1,077 women, 409.4 minutes vs 459.8; $p<0.001$), no adjustments were made for parity. Furthermore, no significant differences were found in maternal satisfaction, using the 5-point Likert scale, $p=0.922$. SR of RCTs 1+

The SR concluded that enemas do not improve maternal or neonatal infection rates, episiotomy dehiscence rates or maternal satisfaction. The use of enemas is unlikely to provide benefits for mothers or neonates. Systematic enema use should therefore be discouraged.

Additionally, in view of the evidence available it is believed that no new research is required to assess the general effects on either mothers or neonates, and that if new studies are carried out they should be focused on women's perception, pain, discomfort, costs or other non-clinical variables.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Summary of Evidence

The use of enemas does not reduce rates of maternal or neonatal infection or episiotomy dehiscence or improve maternal satisfaction. Their use is unlikely to provide benefits for mothers or neonates (43).	1+

Recommendations

A	Enemas should not be used routinely during labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5.5.2. Perineal Shaving

- How effective is routine perineal shaving during labour?

Perineal and even pubic shaving has been carried out in the belief that it reduces the risk of infection and is necessary to enable episiotomies, which have been performed systematically for many years, to be sutured. However, shaving causes cutaneous erosion, which may give rise to colonisation by microorganisms. It is also unpleasant and causes intense discomfort and pruritus during the regrowth period. It is therefore important to determine whether pre-operative hair removal really reduces surgical site infections.

Scientific Evidence (to May 2008)

As with the use of enemas, although it reviews various types of intervention performed during the first stage of labour, the NICE guideline (10) does not cover the subject of perineal shaving. In fact, this practice has been eliminated from routine obstetric care in the UK.

A Cochrane SR (45) with LE 1- was selected in the search carried out for the update. The review includes two RCTs involving a total of 539 women and aims to assess the effects of routine perineal shaving on admission to the delivery room on maternal and neonatal outcomes (febrile morbidity, postpartum maternal morbidity, perineal trauma, wound infection, wound dehiscence and need for repeat suturing, neonatal infection, levels of maternal discomfort, levels of pain, degree of discomfort and satisfaction level).

Both trials date from over thirty years ago, the first from 1922 and the second from 1965. The objective data provided are insufficient and the potential risk of bias is very high, as the trials provide limited details concerning the research methods used, making it difficult to assess quality. Furthermore, the trials provide only a limited analysis of the effects of perineal shaving, as they did not assess any neonatal outcomes or those associated with material criteria such as pain or discomfort, outcomes which the review aimed to examine.

When the results of the two trials were combined, no differences were found between women who were shaved and those who were not with respect to febrile morbidity: OR 1.26 [CI 95%, 0.75 to 2.12]. SR of RCTs 1+

In the smaller trial (150 women), those who were not shaved presented less Gram-negative bacterial colonisation than women who had been shaved: OR 0.43 [CI 95%, 0.20 to 0.92]. However, the clinical significance of this difference is unclear. RCT 1-

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Standard regimens provide most patients with access to treatment, while tailor-made treatment requires considerable infrastructure for laboratory diagnosis even for second-line drugs, although it can prevent exposure to potentially toxic, expensive drugs to which a patient is resistant.

This same trial also describes the side effects experienced by women who had been shaved: irritation, reddening, multiple superficial scratches, and vulvar stinging pruritus. However, there is no information on the number of side effects for the unshaved group, so it has not been possible to include this information in the analysis.

The study concludes that the evidence available at this time does not support systematic perineal shaving before childbirth.

Summary of Evidence

There is insufficient evidence on the effectiveness of systematic perineal shaving on admission to the delivery room for neonatal outcomes, although less Gram-negative bacterial colonisation was observed in women who had not been shaved (45).	1-

Recommendations

√	Systematic perineal shaving is not recommended for women in labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5.5.3. One-to-One Care

- How effective is one-to-one care during labour?

The routine use of EFM, often with central supervision, neuraxial analgesia, and recognition of women's right to be accompanied by the person of their choice during labour has led to midwives focusing essentially on technical procedures and spending little time with women. Many women in labour are frightened in the usual semi-surgical environment of delivery rooms, where they are alone, despite being surrounded by technical equipment that attracts all the attention, and isolated but with no privacy. Certainly, women have never before been monitored so closely and strictly, but from so far away. The persons accompanying them also require support and guidance so that they can provide suitable company.

The importance of continuous support, including emotional, informational, physical and psychological support, provided by midwives has been highlighted in the light of studies that demonstrate that it can improve the obstetric outcome and maternal satisfaction.

Scientific Evidence

The NICE guideline (10) assesses one-to-one care during labour. This includes the presence of and continuous care by the partner, relatives and professionals (midwives); and care by other types of companions. However, in this case we are interested only in care by professionals.

The NICE guideline (10) included an SR (13) of 15 studies conducted in countries with low and high admissions rates (Australia, Belgium, Botswana, Canada, Finland, France, Greece, Guatemala, Mexico, South Africa and the USA), with a total of 12,791 women. The SR assessed the presence of and continuous support by the partner or relatives, professionals (midwives) and other types of companions.

Within the study, a secondary analysis was performed to analyse whether the effects of continuous support were influenced by the type of caregiver. Subgroup analysis was conducted according to carer status: in eight of the studies care was provided by a member of hospital staff (midwives, trainee midwives or nurses), and in the other seven studies the carers were women with or without special training, childbirth educators, retired nurses or a close female relative, generally the woman's mother (people who did not belong to the hospital's workforce).

To answer our question, we are interested only in care by professionals, so it is sufficient to consider the results of analysis stratified by professional carers (with 8 trials). However, it is also of great interest to include the results of a comparison between trials in which the carers were employees at the institution and trials in which the carers were not employees.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The results of analysing the studies that compared *one-to-one professional support with standard care* showed that the women in the group receiving one-to-one care had a lower probability of use of anaesthesia: RR 0.97 [CI 95%, 0.95 to 0.99]; a higher probability of spontaneous vaginal delivery: RR 1.03 [CI 95%, 1.01 to 1.06]; and a lower probability of instrumental vaginal delivery: RR 0.92 [CI 95%, 0.85 to 0.99]. SR of RCTs 1+

No significant differences were found between the two groups in the following adverse effects: caesarean section: RR 0.95 [CI 95%, 0.86 to 1.06]; mother's dissatisfaction or negative experience of the birth: RR 0.83 [CI 95%, 0.67 to 1.02]; Apgar score at 5 minutes: RR 0.83 [CI 95%, 0.67 to 1.02]; postpartum depression (after support by specially trained nurses or otherwise): RR 0.89 [CI 95%, 0.75 to 1.05]; worsened relationship with partner after birth: RR 1.00 [CI 95%, 0.80 to 1.23]; postpartum urinary incontinence: RR 0.93 [CI 95%, 0.81 to 1.06]; or postpartum faecal incontinence RR 0.89 [CI 95%, 0.64 to 1.24]. SR of RCTs 1+

Analysis of the studies that analysed *support by persons not connected to the hospital*, revealed that the significant differences were maintained in terms of the positive effect on spontaneous vaginal delivery: RR 1.12 [CI 95%, 1.07 to 1.18]; and instrumental delivery: RR 0.59 [CI 95%, 0.42 to 0.81]. Additionally, in this case it was also observed that women who received support from persons not connected to the hospital had a lower rate of caesarean sections: RR 0.74 [CI 95%, 0.61 to 0.90] and dissatisfaction: RR 0.64 [CI 95%, 0.58 to 0.78] than those who received standard care. SR of RCTs 1+

Generally, it is suggested that women receiving one-to-one care during labour have a lower probability of anaesthesia use and instrumental vaginal deliveries or caesarean sections, and a higher probability of spontaneous vaginal deliveries, achieving higher levels of satisfaction and having a positive experience of the birth. This impact is more obvious when the care is provided by persons not connected with the hospital.

Update (2005 to May 2008)

The article selected in the evidence update is a Cochrane review (46). It is an update of the review included in the NICE guideline (10) and contains a new clinical trial in which support was provided by persons not connected with the hospital.

On the basis of the results of the analysis stratified by *care provided by hospital professionals* only, the results were the same as those of the 2004 SR, since the new trial included in the update did not evaluate professional support: women who received one-to-one care have a lower probability of anaesthesia use (6 trials; n=9,152): RR 0.97 [CI 95%, 0.95 to 0.99]; a higher probability of spontaneous vaginal deliveries (8 trials; n=10,713): RR 1.03 [CI 95%, 1.01 to 1.06]; and a lower probability of instrumental vaginal deliveries (8 trials; n=10,713): RR 0.92 [CI 95%, 0.85 to 0.99]. SR of RCTs 1+

More than 5 years have passed since the publication of the Clinical Practice Guideline, and its validity has not been reviewed

No significant differences were found between the two groups in the following adverse outcomes: caesarean section rate (8 trials; n=10,713): RR 0.95 [CI 95%, 0.86 to 1.06]; maternal dissatisfaction or negative experience of the birth (3 trials; n=8,499): RR 0.83 [CI 95%, 0.67 to 1.02]; Apgar score at 5 minutes: RR 0.83 [CI 95%, 0.56 to 1.02]; postpartum depression (after support by specially trained nurses or otherwise): RR 0.89 [CI 95%, 0.75 to 1.05]. SR of RCTs 1+

Regarding the results of the studies that analysed support by *persons not connected with the hospital*, it was observed that the significant differences were maintained in the positive effect on lesser use of analgesia (6 trials; n=2,499): RR 0.80 [CI 95%, 0.66 to 0.97]; higher rates of spontaneous vaginal delivery (7 trials; n=3,244): RR 1.10 [CI 95%, 1.05 to 1.14]; and lower risk of instrumental delivery (7 trials; n=2,644): RR 0.59 [CI 95%, 0.44 to 0.79]. Better outcomes were also observed for women who received support with regard to the rate of caesarean sections (8 trials; n=2,678): RR 0.80 [CI 95%, 0.68 to 0,95]; Apgar score <5 at 5 minutes (3 trials; n=1,201): RR 0.36 [CI 95%, 0.14 to 0,90]; and lower levels of dissatisfaction or a negative experience: RR 0.67 [CI 95%, 0.58 to 0.78]. SR of RCTs 1+

With regard to *comparison between the two subgroups* (to evaluate the influence of the caregiver's profile on the effect), when the caregiver is not a professional, the use of analgesia is reduced even further (care by professionals RR 0.97 [CI 95%, 0.95 to 0.99] versus non-professionals: RR 0.80 [CI 95%, 0.66 to 0.97]): chi squared = 3.82; p=0.05; the rate of spontaneous vaginal delivery is further increased: chi squared = 9.14; p=0.01; and instrumental vaginal delivery is further decreased: chi squared = 7.21; p=0.01. SR of RCTs 1+

However, it appears that the status of the caregiver does not influence the effects of one-to-one care on the rate of caesarean sections or maternal dissatisfaction, as the difference between the two subgroups was not significant (chi squared = 1.92; p=0.17 and chi squared = 3.09, p=0.08 respectively). SR of RCTs 1+

There is insufficient evidence on perinatal mortality and maternal and neonatal well-being in the long term. The update of the review also fails to consider results for mothers' long-term mental and psychological health, although these aspects were assessed in the previous review, included in the NICE guideline (10).

To summarise and analyse the results of the subgroups as a whole, i.e. without considering the profile of the caregiver, women receiving continuous intrapartum support were likely to have a slightly shorter labour, were more likely to have a spontaneous vaginal birth and less likely to have intrapartum analgesia or to report dissatisfaction with their childbirth experience. When the results are analysed by subgroup, continuous intrapartum support was associated with greater benefits when the caregiver was not a member of hospital staff. The main conclusion of the study is therefore that all women should be supported throughout labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Moreover, considering that better results are obtained when the person providing care is not an employee of the maternity ward, the review informs hospital managers in countries with high levels of admissions who wish to make clinically significant reductions in caesarean section rates that continuous support by midwives cannot achieve this goal unless other changes are made to policies and routines. As delivery room care is based on risks and dominated by technology, it is likely that staff cannot offer women in labour the same benefits as persons who are not members of staff, unless fundamental changes are made to the care provided.

Summary of Evidence

Receiving one-to-one support throughout labour is associated with less likelihood of use of analgesia and of instrumental vaginal delivery, and a greater probability of a spontaneous vaginal delivery (13;46).	1+

Recommendations

A	Women in labour should have one-to-one midwife care from admission onwards, at all times.
A	Women in the active phase of labour should not be left without professional care except for short periods of time or when they so request.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5.5.4. Mobility and Adopting Different Positions

- What is the effect of mobility and adopting different positions on labour and its outcomes?

Currently, in Spain most women remain recumbent from hospital admission onwards. Systematic electronic fetal monitoring, intravenous infusions, the widespread use of neuraxial analgesia and care routines have limited women's opportunity to walk around during the first stage or adopt different positions. It has been suggested, however, that upright positions and walking around may shorten the duration of the first phase of labour, and that freedom of movement enables women to adopt positions that relieve pain and improve their comfort and their feeling of prominence and control.

Scientific Evidence

The NICE guideline (10) assesses mobility and different positions during the first stage of labour (standing, squatting, kneeling, semi-supine, etc.), on the basis of an SR (47) with LE 1-, four RCTs with LE 1+ (48-51) and another RCT with LE 1- (52).

The SR (47) included fourteen RCTs. In seven of these, women provided their own control and the number of women included was very small (n≤23); in the other seven, the number of women ranged from 40 to 1,067. The studies compared walking or standing during the first stage of labour with one or more horizontal positions in bed. However, due to the differences in study design, the lack of details to assess the presence of any bias in many of the studies and the different scales of measurement, it was not possible to perform meta-analysis.

One of the consistent findings was that none of the women included in the studies indicated that she experienced greater comfort in a supine position. Furthermore, alternating between different pairs of positions showed differing effects on uterine activity.

Alternating between a supine and seated position appears to reduce uterine activity in comparison to alternation between a supine position and standing or lying on one side. In addition, most women had difficulties remaining standing and/or walking during labour, especially towards the end of the first stage of labour and during the second stage. RCT 1-

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The first of the RCTs with a high quality level (48) was conducted in the USA with a total of 1,067 women and compared walking (536 women) during the first stage of labour with not walking (531). 79% of women wished to walk and did so for a mean of 56 minutes (SD=46 minutes). No significant differences were observed between the two groups in terms of birth outcomes (duration, use of oxytocin, use of analgesics), type of delivery, or maternal or neonatal outcomes. When women (n=278) were asked if, in a future birth, they would want to be in the group allowed to walk, 99% responded affirmatively. RCT 1+

The second of the trials (49) was conducted in Australia. It included a total of 196 women in two groups, and compared walking and not walking. During recruitment, 389 women declined to participate, 46% of them due to the fear of losing the option of walking during labour. Of the group of 96 women allocated to walk, 39% walked for more than 30 minutes and the average time for remaining upright was 1.5 hours (SD=0.8 hours). No differences were found between the two groups, as in the previous case for birth outcomes, type of birth and maternal or neonatal outcomes. RCT 1+

Another small study in the USA (51) compared two groups of 20 women each, one group adopting upright positions (kneeling, squatting, walking or seated) and the other recumbent positions (supine, side-lying or semi-supine). The women allocated to the upright group had a significantly shorter active phase of labour: MD 90.25 minutes, p=0.003, and had longer and more frequent contractions than the women in the recumbent group. There were no significant differences with respect to the physical comfort of the mother. RCT 1+

An Argentinian trial (50) compared pain in two groups of 50 women, one group alternating between upright positions every 15 minutes (seated, standing or walking) and the other alternating between horizontal positions (lying on side or back), with checks carried out for each dilatation interval (2-3 cm, 4-5 cm, 6-7 cm, 8-9 cm). No differences in pain were found during the first half of the first stage of labour (2 5 cm) between the two groups. However, as labour progressed pain from both abdominal contractions and the lumbar region was significantly more severe in the recumbent positions. RCT 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The last of the RCTs included in the NICE guideline (10) is a small study conducted in the UK (52) with LE 1-. This also compared the effect of walking and not walking, in 68 women. The women included were selected from a group of women who before labour had expressed a wish to walk. Differences between the groups were found, such as less need for analgesia in the walking group, with less frequent and stronger contractions, shorter labour, more normal deliveries and babies with higher Apgar scores. They walked for an average of 2.2 hours, with a range of (0.8 8.3) hours.

RCT
1-

Mobility of Women Receiving Anaesthesia

In the chapter covering the second stage of labour (Chapter 5), the NICE guideline (10) also addresses position during labour when analgesia is used, in both the first and the second stages of labour.

The NICE guideline (10) identified a SR from 2004 (53) which included five RCTs, and performed a meta-analysis with a total of 1,161 women. The aim was to analyse the effect of walking around versus not doing so in the first stage of labour, in women who had received epidural anaesthesia.

There were no statistically significant differences between the two groups for the type of delivery: RR 0.91 [CI 95%, 0.93 to 1.44] or caesarean sections: RR 0.91 [CI 95%, 0.70 to 1.19]. There were also no differences in the use of oxytocin, duration of labour, satisfaction with anaesthesia, hypotension, fetal heart rate or Apgar score of the neonate.

SR of RCTs
1+

To summarise, the results presented differ between studies: some find no differences between the groups (walking versus not walking), others find differences, and some find differences in pain while others do not. It is difficult to compare groups as they are not homogenous and the research questions are different.

No studies were found comparing the effect of freedom of movement during labour with restricted movement on outcomes such as comfort, labour progression or fetal well-being. There is a lack of good-quality evidence to suggest that mobility or any specific position affects outcomes.

Update (2005 to March 2008)

The update of the evidence included the only study found in the search: an SR (54) which includes nine RCTs of variable quality (two of them included in the NICE guideline (10)), with a total of 2,220 women (the number of women included in the studies ranged from 14 to 1,067). The SR aimed to assess the effect of the mother's position during the first stage of labour. The main question was whether an upright position (seated, standing, kneeling or squatting) or walking around reduced the duration of the first stage when compared to any other position.

More than 6 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The SR includes a meta-analysis of different outcome measurements, with a statistically significant difference only observed in the duration of the first stage, which was shorter in the group walking around (7 studies with 2,166 women): WMD -0.83 hours [CI 95%, -1.60 to -0.06 hours], but there was a high level of heterogeneity (I2=88.4%), which makes interpretation difficult. Examination of the other outcomes that were assessed did not reveal differences in the type of delivery (8 studies involving 2,180 women): OR 0.98 [CI 95%, 0.67 to 1.43]; use of analgesia (6 studies involving 1,966 women): OR 0.69 [CI 95%, 0.37 to 1.30]; induced delivery (4 studies involving 1,802 women): OR 0.81 [CI 95%, 0.65 to 1.01]; or Apgar score <7 at 5 minutes (6 studies involving 913 women): WMD 0.11 [CI 95%, -0.07 to 0.28]. Although the results were not significant, all the studies showed the same tendency towards the protective effect of walking around.

SR of RCTs
1+

Outcomes concerning maternal comfort were measured differently in the three studies which assessed them, so it was not possible to group them together. Two of the studies showed no differences between the two groups, and in the other a more positive evaluation of the birth experience was observed in the group allowed to walk around.

SR of RCTs
1+

The SR concludes that although an upright position or walking around in the first stage of labour appears to be safe, it is not recommended as an effective intervention to reduce the duration of the first stage of labour. It is also recommended that new, well-designed studies should be conducted to investigate the effectiveness of maternal position on the duration of labour and other outcomes.

To summarise, there is high-quality evidence concerning the impact of adopting different positions (upright vs recumbent), which does not reveal significant differences on birth outcomes, such as the use of oxytocin and analgesics, type of delivery and maternal or neonatal outcomes. Moreover, with respect to the duration of labour and maternal comfort the evidence found is inconsistent between studies and is inconclusive.

Although Souza (54) assessed different positions as interventions to reduce the duration of the first stage of labour, it should be noted that duration is not as clinically significant as originally believed, and moreover the evidence found concerning the relationship between different positions and duration is inconsistent between studies and is inconclusive.

The evidence suggests that adopting different positions during the first stage of labour is safe and does not affect birth outcomes.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Summary of Evidence

No significant differences were found between women (with and without epidural anaesthesia) who adopt different positions during the first stage of labour with respect to the use of oxytocin and analgesics, type of delivery or maternal or neonatal outcomes (48-51;53;54).	1+
The evidence on the effect of adopting different positions on the duration of the first stage of labour and on maternal comfort is inconsistent and inconclusive (48;51;54).	1+

Recommendations

A	Women should be encouraged and helped, even when epidural anaesthesia is used, to adopt any position they find comfortable during the first stage and to be mobile if they wish, following a check of motor and proprioceptive block.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

5.5.5. Amniorrhexis and Use of Oxytocin

- How effective is routine artificial amniorrhexis and routine perfusion of oxytocin?

Whether or not accompanied by perfusion of oxytocin, routine artificial amniorrhexis is one of the most common obstetric procedures. Its main purpose is to increase contractions and so reduce the duration of labour. However, doubts have been raised concerning unwanted effects on mother and baby.

Scientific Evidence

The NICE guideline (10) assesses the effectiveness of routine artificial amniorrhexis and the use of amniorrhexis together with oxytocin on birth outcomes, as an intervention used during the first stage of labour.

Early Amniorrhexis + Selective Oxytocin vs Conservative Management

The studies included compared routine amniorrhexis performed early on (and oxytocin administered if labour was slow) and no intervention (conservative management). The existing evidence is based on two RCTs, (55) and (56). The first of these involved 306 women giving birth for the first time, and the second involved 705. Due to homogeneity, a meta-analysis was performed using the data from both trials with LE 1+.

The results of the meta-analysis did not demonstrate any significant differences with respect to the type of delivery: RR 0.80 [CI 95%, 0.55 to 1.17]; duration of first stage of labour: RR 1.06 [CI 95%, 0.97 to 1.16]; use of epidural anaesthesia: WMD 65.06 minutes [CI 95%, -134.83 to 4.71 minutes]; duration of the second stage of labour: 1.80 minutes [CI 95%, -1.83 to 5.44 minutes]; Apgar score <7 at 5 minutes: RR 1.22 [CI 95%, 0.38 to 3.93]; or admission to a neonatal unit: RR 0.90 [CI 95%, 0.47 to 1.72]. SR/MA of RCTs 1+

There is no evidence of differences in type of delivery, use of epidural, duration of labour or neonatal outcomes between routine early amniorrhexis performed plus selective use of oxytocin, and more conservative management.

Early Amniorrhexis + Oxytocin vs Conservative Management

The NICE guideline (10) includes an RCT conducted in the USA (57), with a total of 150 women giving birth for the first time (75 in each group). The study compared the routine use of oxytocin and early amniorrhexis with more conservative management in women who were healthy at the start of labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The results did not show that management affected the type of delivery: rate of spontaneous deliveries: RR 0.97 [CI 95%, 0.82 to 1.14]; caesarean sections: RR 0.91 [CI 95%, 0.41 to 2.01]. Although slight differences were observed between the routine use of oxytocin and amniorrhexis, and conservative management, they were not clinically significant: duration of latent phase: MD 0.73 hours [CI 95%, -0.84 to -0.62 hours]; duration of active phase: MD 0.24 hours [CI 95%, 0.12 to 0.36 hours]; Apgar score at one minute: MD 0.35 [CI 95%, 0.30 to 0.40]; Apgar score at 5 minutes: MD 0.02 [CI 95%, 0.00 to 0.04].

RCTs
1+

Update (2005 to July 2008)

In the systematic search for the update of this subject, a high-quality (LE 1+) SR (58) was selected. This included a total of fourteen RCTs with 4,893 women (range per study: n=32 to n=1,463).

The purpose of the review was to determine the efficacy and safety of amniorrhexis alone for systematically shortening all spontaneous-onset labours, and shortening labours that began spontaneously but were prolonged. The SR included a meta-analysis for each of the variables studied, comparing the effect of performing amniorrhexis and not performing it.

The main results of the meta-analysis show that no differences exist between the two treatment groups in the duration of the first stage of labour (5 trials involving 1,127 women): WMD -20.43 minutes [CI 95%, -95.93 to 55.06]; women giving birth for the first time -57.93 minutes [CI 95%, -152.66 to 36.80] and second and subsequent births 23.10 minutes [CI 95%, -50.89 to 97.09]; in the caesarean section rate (9 trials involving 4,370 women): RR 1.26 [CI 95%, 0.98 to 1.62]; maternal satisfaction with the birth experience (2 trials involving 123 women): MD 0.27 [CI 95%, -0.49 to 1.04] and Apgar score <7 at 5 minutes (6 trials involving 2,947 women): RR 0.55 [CI 95%, 0.29 to 1.05]. However, there is a significant difference in the subgroup of women giving birth for the first time: RR 0.42 [CI 95%, 0.20 to 0.88].

SR/MA of RCTs
1+

There were also no significant differences observed in secondary outcomes such as use of analgesia (8 trials involving 2,824 women): RR 1.01 [CI 95%, 0.94 to 1,09]; rate of instrumental vaginal delivery (10 trials involving 4,470 women): RR 1.01 [CI 95%, 0.88 to 1.15]; morbidity due to maternal infection (2 trials involving 1,460 women): RR 0.81 [CI 95%, 0.38 to 1.72]; admission to a neonatal intensive care unit (5 trials involving 2,035 women): RR 1.12 [CI 95%, 0.79 to 1.57]; or fetal heart rate during the first stage of labour (4 trials involving 1,284 women): RR 1.09 [CI 95%, 0.97 to 1.23].

SR/MA of RCTs
1+

The SR concludes by stating that amniorrhexis should not be introduced as part of standard treatment and care during labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

There is a high level of evidence in favour of not performing routine amniorrhexis in vaginal births that are progressing normally, as tests show it does not improve outcomes.

Summary of Evidence

There is no evidence of differences in type of delivery, use of epidural, duration of labour or neonatal outcomes between routine amniorrhexis performed early plus use of oxytocin, and more conservative management of the first stage of labour (10; 55; 56; 58).	1+

Recommendations

A	Artificial amniorrhexis and perfusion of oxytocin should not be used routinely in vaginal births that are progressing normally, as tests show that they do not improve outcomes.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

5.5.6. Perineal Lavage

- Should antiseptics be used in vulvovaginal lavage prior to vaginal examination?

There is a longstanding concern that vaginal examinations facilitate the spread of pathogenic germs to the upper genital tract. Different approaches have been used to reduce the risk of causing maternal or neonatal infection, such as rectal contact, thorough vaginal lavage before examination, minimising vaginal contact, especially if membranes have ruptured, and using the purple line or other indirect signs of progress of dilatation. Being aware of the hygiene conditions in which vaginal examination should be performed will help to prevent these infections.

Scientific Evidence

The NICE guideline (10) assesses the effectiveness of different hygiene strategies on infection rates in mothers, neonates and healthcare professionals during vaginal births. It assesses hygiene measures during vaginal examinations and antisepsis; it analyses two studies: an SR (59) and a controlled study (60) which evaluates two different strategies for vaginal lavage.

Chlorhexidine Vaginal Irrigation vs Irrigation with Sterilised Water

The SR (59) with LE 1++ included three RCTs conducted in the USA, which compared chlorhexidine vaginal irrigation with irrigation using sterilised water as a control, for a total of 3,012 women in labour.

The results of the three trials showed insignificant differences in the incidence of chorioamnionitis (1,514/,1498 women in the chlorhexidine/control groups respectively): RR 1.10 [CI 95%, 0.86 to 1.42] and incidence of postpartum endometritis: RR 0.83 [CI 95%, 0.61 to 1.13]. The studies did not obtain data concerning other maternal outcomes or side effects of the chlorhexidine.

SR of RCTs 1++

With regard to outcomes for neonates, the three studies included data on 1,495 and 1,492 neonates in the chlorhexidine and control groups respectively. No statistically significant differences were found between the two groups in terms of the risk of neonatal pneumonia (1 trial with 910 neonates): RR 0.33 [CI 95%, 0.01 to 8.09]; neonatal meningitis (1 trial with n=1021): RR 0.34 [CI 95%, 0.01 to 8.29]; blood cultures confirming sepsis (2 trials with n=2,077): RR 0.75 [CI 95% 0.17 to 3.35]; perinatal mortality (2 trials with n=2,077): RR 1.00 [CI 95%, 0.17 to 5.79]; or risk of neonatal sepsis (3 trials, n=2,987): RR 0.75 [CI 95%, 0.17 to 3.35]. A trend was also observed that suggested an association between the use of vaginal chlorhexidine during labour and greater use of antibiotics in neonates, although this association was not significant (RR 1.65 [CI 95%, 0.73 to 3.74]). No other neonatal outcomes or side effects of chlorhexidine were studied.

SR of RCTs 1++

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Perineal Lavage with Cetrimide/Chlorhexidine vs Water

A cohort study (60) conducted in the UK and involving 3,905 women compared cetrimide/chlorhexidine for perineal lavage during labour with tap water. Patients were allocated to the control or intervention group in alternate months and the study population included women with history of caesarean sections (17.2% for the cetrimide/chlorhexidine group and 16.3% for the control or tap water group).

With respect to maternal outcomes, no significant differences between the two groups were found in terms of the number of women developing a fever (temperature >38°C): OR 1.0 [CI 95%, 0.9 to 1.9]; use of antibiotics: OR 1.02 [CI 95%, 0.8 to 1.9]; perineal infection: OR 1.4 [CI 95%, 0.8 to 2.7]; perineal tearing: OR 5.8 [CI 95%, 0.3 to 999]; or the rate of surgical site infection for caesarean sections: OR 1.3 [CI 95%, 0.9 to 1.9]. One maternal death occurred in each group, although both were due to anticardiolipin syndrome. Cohort study 2+

Neonatal outcomes also showed no differences in eye infections: OR 1.1 [CI 95%, 0.8 to 1.7]; umbilical cord infections: OR 1.3 [CI 95%, 0.7 to 2.1]; other unspecified infections: OR 0.9 [CI 95%, 0.6 to 1.2]; admission to a neonatal unit: OR 1.1 [CI 95%, 0.9 to 1.4]; use of antibiotics: OR 1.0 [CI 95%, 0.8 to 1.2]); or fever (temperature >38°C): OR 1.4 [CI 95%, 0.7 to 3.0]. Although 27 neonatal deaths occurred in the cetrimide/chlorhexidine group and 21 in the control group, most were due to congenital abnormalities or weight below 1,000 g; in the chlorhexidine group there was one case due to uterine rupture and three cases due to intrapartum hypoaxia; in the control group there was one case due to necrotising enterocolitis and another due to neonatal septicaemia). Cohort Study 2+

Update (2005 to April 2008)

The new SR search did not reveal any new documents. As a result, the recommendations are based on the findings described by the NICE guideline (10).

There is substantial evidence that the use of cetrimide/chlorhexidine for perineal lavage is no more effective than running water.

Summary of Evidence

The use of cetrimide/chlorhexidine for perineal lavage is no more effective than running water (59;60).	1++

Recommendations

A	Running water should be used if lavage is required before a vaginal examination; the use of antiseptics is not necessary.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

5.5.7. Use of Partogram

- Does the use of a partogram improve outcomes?

Most maternity units use graphs, usually called partograms, to record examinations during the active phase of dilatation. Midwives record a woman's vital signs, frequency and intensity of contractions, descent of fetal head and cervical dilatation.

Various types of partogram have been used, some of which have lines to guide interventions, generally called alert and action lines. The action line is drawn to the right of the line showing the progression of cervical dilatation, at a rate of 1 cm per hour. A two-hour action line is located two hours to the right of the progression line, and if dilatation slows enough for the progression line to cross the action line, delayed dilatation is diagnosed. A four-hour action line is located 4 hours to the right of the progression line, giving more time before action is taken due to delayed dilatation.

Scientific Evidence

The NICE guideline (10) assesses the effectiveness of using a partogram and compares it to partogram use. It also compares the effectiveness of partograms with different types of action line.

Use/Non-Use of Partogram

The NICE guideline (10) included a study (61) conducted by the WHO in South-East Asia (n=8 hospitals; 35,484 women) which compared use of the WHO partogram (partogram with an action line) with no partogram use. The study was presented by the NICE guideline (10) as an RCT, but was not, as allocation was partially non-randomised. Moreover, the study included gestations from 34 weeks, inductions, malpositions and multiple gestations, so the results may not be directly applicable to normal births.

The results of the study are presented separately for women giving birth for the first time and those doing so for the second or subsequent time. In women giving birth for the first time, partogram use appears to reduce the proportion of prolonged labours (duration >18 hours): RR 0.56 [CI 95%, 0.47 to 0.67]; use of oxytocin: RR 0.43 [CI 95%, 0.39 to 0.47]; rate of postpartum sepsis: RR 0.09 [CI 95%, 0.03 to 0.31]; and rate of caesarean sections: RR 0.70 [CI 95%, 0.61 to 0.81], whilst the spontaneous cephalic delivery index increases: RR 1.05 [CI 95%, 1.03 to 1.08] when compared to no partogram use. CCT II

The conclusions were similar for women giving birth for the second or subsequent time.

No studies were identified that assessed outcomes using partograms without action or alert lines.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

On the basis of these results, the WHO recommends using partograms with four-hour action lines.

Comparison of Partograms with Different Action Lines

The NICE guideline (10) includes three RCTs that compare two possible locations of partogram action lines.

The first trial (62), conducted in Liverpool, UK, involved 928 women in labour. It compared the use of partograms with two-hour, three-hour and four-hour action lines.

The findings of this RCT (62) suggest that the use of *two-hour action lines, versus three-hour action lines*, increases maternal satisfaction levels: DM 3.5 [CI 95%, 1.7 to 5.3]. It provides no evidence of differences in the use of interventions, such as amniorrhexis, epidural, caesarean section due to a delay in normal progression or instrumental delivery. There were also no differences observed between two- and three-hour action lines in neonatal outcomes. RCT lb

Comparison of *three-hour action lines and four-hour action lines* reveals an increase in the rate of caesarean sections for three-hour lines: OR 1.8 [CI 95%, 1.1 to 3.2], but not in the rate of caesarean sections due to fetal stress or anomalies in normal progress. No differences were observed in other interventions, maternal satisfaction or neonatal outcomes. RCT lb

Finally, the use of *two-hour action lines compared with four-hour lines* increased maternal satisfaction: MD 5.2 [CI 95%, 3.4 to 7.0]. There was no evidence of differences in indices on interventions or neonatal outcomes. RCT lb

A second study conducted in South Africa (63) involving 694 women compared a *partogram with a single two-hour action line with the WHO partogram (with two parallel lines, one for alert and the other for action, at four hours)*.

The results showed that the use of a single *two-hour alert line compared to the WHO partogram* (with two parallel lines, one for alert and the other for action, at 4 hours) reduced the caesarean section rate: RR 0.68 [CI 95%, 0.50 to 0.93] and the instrumental birth rate: RR 0.73 [CI 95%, 0.56 to 0.96], and increased the use of oxytocin: RR 1.51 [CI 95%, 1.10 to 2.07]. No differences were found in the use of analgesia or in neonatal outcomes (Apgar scores and perinatal mortality). RCT lb

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The third and last RCT (64) compared a *partogram with a two-hour action line with a partogram with a four-hour action line*. The study included 2,975 women giving birth for the first time and compared the results of monitoring using a partogram with action lines at two and four hours to the right of the alert line. If the labour progression line crossed the action line, prolonged labour was diagnosed in accordance with standard protocol. The primary outcomes measured were the caesarean section rate and the degree of maternal satisfaction. For the latter outcome, 1,925 women (65%) filled in postal questionnaires between two and ten days after the birth.

No differences were observed between the two- and four-hour action lines in any primary outcome (caesarean sections or maternal dissatisfaction with the birth experience). However, a higher number of women in the group with the two-hour action line crossed the action line on the partogram (854/1,490 vs 673/1,485): RR 1.27 [CI 95%, 1.18 to 1.37], so they received more interventions to stimulate labour (772/1,490 vs 624/1,485): RR 1.23 [CI 95%, 1.14 to 1.33]. No significant differences were found between the two groups in terms of the number of instrumental deliveries, umbilical cord pH <7.1, Apgar score <7 at 5 minutes or admission to neonatal units.

RCT
Ib

The 2004 NICE guideline on caesarean sections (65) recommended using a four-hour action line partogram in normal births due to the reduced caesarean section rate, and the NICE guideline on intrapartum care (10) reiterates this recommendation.

CPG

Update (2005 to June 2008)

No documents were found in the systematic search carried out for the update of this question. However, it was possible to select an SR published in October 2008 (66) as a result of the alerts included in the search strategies.

The SR selected for the update included five randomised trials. Three of which were quasi-randomised studies also included in the NICE guideline (10), with a total of 6,187 women, comparing the use of a partogram with no partogarm use (in two studies with 1,590 women) and the use of different types of partogram. A meta-analysis of the results was performed in the SR.

SR/MA of RCTs
Ia

There was no evidence of differences between the *partogram use versus non-use* in the rates of caesarean sections: RR 0.64 [CI 95%, 0.24 to 1.70]; instrumental delivery: RR 1.00 [CI 95%, 0.85 to 1.17]; or Apgar score <7 at 5 minutes: RR 0.77 [CI 95%, 0.29 to 2.06].

SR/MA of RCTs
Ia

When a partogram with a *two-hour action line* was compared to one with a four-hour action line, the first group showed a higher liklihood of requiring stimulation with oxytocin: RR 1.14 [CI 95%, 1.05 to 1.22].

SR/MA of RCTs
Ia

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

When a partogram with a *three-hour action line* was compared to one with a four-hour action line, the caesarean section rate was higher for the group with partograms with a three-hour action line (n=613): RR 1.70 [CI 95%, 1.07 to 2.70].

SR/MA of RCTs
Ia

On the basis of these findings, the SR concludes by stating that routine use of a partogram during labour cannot be recommended and that further trials are necessary to determine whether the use of a partogram is effective.

As a result of the substantial inconsistencies found with regard to the effectiveness of using partograms for various clinical outcomes, the group compiling the guideline can neither recommend their systematic use nor recommend non-use. However, there is evidence to recommend that if partograms are used they should have four-hour action lines, as two- and three-hour action lines increase interventions with no benefits for the mother or baby.

See Appendix 4.1.

Summary of Evidence

Use of the partogram, compared to non-use, appears to reduce the proportion of labours lasting over 18 hours, the use of oxytocin, the rate of postpartum sepsis and the rate of caesarean sections, while it increases the ratio of spontaneous births (61).	II
There is no evidence of any differences *between the use and non-use of partograms* in rates of caesarean sections, instrumental vaginal delivery or Apgar score <7 at 5 minutes (66).	Ia
Partograms with two-hour action lines, *versus partograms with three- and four-hour action lines*, appear to improve maternal satisfaction, but they increase the use of oxytocin (62;66).	Ia
Partograms with *three-hour action lines versus four-hour action lines* increase the number of caesarean sections (but not caesarean sections due to fetal distress) (62;66).	Ia
No differences were observed between two- and four-hour action lines in any primary outcome (caesarean sections or maternal dissatisfaction with the birth experience). However, more women in the group with a two-hour action line received more interventions to stimulate labour (64).	Ib

Recommendations

A	If a partogram is used, a 4-hour action line is recommended.

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5.5.8. Frequency of Vaginal Examinations

- What is the optimum frequency of vaginal examinations during the first stage of labour?

The purpose of vaginal examinations is to check the progress of labour. However, there are publications that associate the risk of infection with the number of vaginal examinations (67;68). Moreover, vaginal examinations during labour can be uncomfortable and often cause anxiety and distract women's attention from their labour.

Scientific Evidence

The NICE guideline (10) assesses the evidence concerning the impact of vaginal examinations during the first stage on birth outcomes. It also addresses the risk factors associated with maternal infection after premature membrane rupture, with vaginal examinations included as one of these factors.

For the first stage of labour, the evidence given in the NICE guideline (10) consists of two studies. The first is a clinical trial (69) conducted in the UK involving 109 women giving birth for the first time and with a high risk of showing biases. It compared vaginal examinations performed *every two and every four hours*.

No differences were found between the two groups in terms of the duration of labour. There were no differences in the number of vaginal examinations performed in each group.

RCT
1-

The other is a low-quality (LE 2, with inappropriate statistical analysis) Swedish case and control study (70) which included a total of 68 women and aimed to analyse which factors were predictive of neonatal sepsis, considering seven possible variables as being predictive of neonatal sepsis, including vaginal examination.

Case and control study
2-

The results did not contain any factors predictive of neonatal sepsis.

Another international multicentre study (71) included in the NICE guideline (10) also associated the risk factors related to maternal infection after premature membrane rupture and studied factors that are predictive of chorioamnionitis and postpartum fever.

Cohort study
2+

A study (72) that conducted a secondary analysis of the results of the international study referred to above (71) compared the immediate management after premature membrane ruptures with expectant management up to the fourth day. It found that the number of vaginal examinations was the most important independent factor in predicting an infection, and that the risk of infection increased with the number of vaginal examinations.

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When *fewer than three examinations were compared to 3-4 vaginal examinations*, a higher incidence of choriamnionitis was observed in the former group: OR 2.06 [CI 95%, 1.07 to 3.97], and when fewer than 3 were compared to 7 8, a higher incidence was also observed: OR 3.80 [CI 95%, 1.92 to 7.53], with the incidence of chorioamnionitis increasing from 2% to 13%.

Case and control study 2++

Another retrospective case and control study (73) conducted in Israel, which included 411 women, also observed that the number of vaginal examinations was an independent predictor of infection (both maternal and neonatal). Women who underwent seven or more vaginal examinations versus those who underwent fewer than seven examinations presented a higher risk of both maternal and neonatal infection): OR 2.70 [CI 95%, 1.66 to 4.34].

Case and control study 2+

Another of the studies (74), which was also a secondary analysis of the results of the international multicentre trial (71), attempted to identify factors predictive of neonatal infection. In this study it was observed that the most reliable predictor of neonatal infection was clinical chorioamnionitis in labours with premature breaking of the waters: OR 5.89 [CI 95%, 2.02 to 4.68]. Another independent predictive factor was undergoing 7-8 vaginal examinations (compared to 0-2 examinations): OR 2.37 [CI 95%, 1.03 to 5.43].

Cohort study 2+

Update (2005 to March 2008)

No studies were selected in the update of the search of the NICE guideline (10), so the group compiling the guideline has based its recommendations on the evidence provided in the NICE guideline (10).

Summary of Evidence

The risk of infection increases with the number of vaginal examinations. In addition, the number of vaginal examinations in management the first stage of labour after premature membrane rupture is the most important factor in predicting maternal and/or neonatal infection (71-74).	2++

Recommendations

√	In normal conditions, vaginal examinations should be carried out every 4 hours.
√	More frequent vaginal examinations should be carried out in women with slow labour progress, if there are complications or if the woman experiences a pushing sensation.

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√	Before carrying out a vaginal examination, the following action should be taken: • Confirm that it is really necessary and that the information it provides will be relevant to decision-making. • Be aware that vaginal examination is uncomfortable and invasive, and associated with an increased risk of infection. • Guarantee the woman's privacy, dignity and comfort. • Sensitively explain the reason it is being carried out and the findings, especially if they are not as expected by the woman.

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5.5.9. Treatment for Delayed Dilatation

- What methods are effective in treating delays in the first stage of labour?

The NICE guideline (10) recommends that diagnosis of delay in the first stage of labour should be based on consideration of all aspects of the progression of labour, including the following: cervical dilatation below 2 cm at 4 hours for women giving birth for the first time, cervical dilatation below 2 cm at 4 hours or slowing of the progression of labour in the second and subsequent births, descent and deflection of fetal head and changes in the strength, duration and frequency of uterine contractions.

As stated in the NICE guideline (10), although the duration of labour should not constitute a key factor for concern in itself, if it surpasses the normal limits, this may be the first indication of a problem. The progression of dilatation is of greater relevance than the total duration of the first stage of labour, as it can be used to identify and treat the problem early on. Although the aetiological factors that may lead to a delay in the first stage of labour may vary, insufficient uterine activity is the most common and correctable cause of abnormal progression of labour.

A diagnosis of dystocia is currently the main indication for a caesarean section. As the caesarean section rate is continuing to rise, identifying problems with dilatation and correction of abnormal patterns in uterine contractions may make it possible not to perform many of these caesarean sections without compromising maternal or fetal outcomes.

Scientific Evidence

The NICE guideline (10) assesses the interventions to manage detected delays in the first stage of labour, and uses four sections to address the issue:

Amniorrhexis vs Expectant Management

In this section, an SR (75) published in 1999 and updated in 2005 was used. It included nine studies. The high-quality review, with LE 1++, included a meta-analysis with the results stratified by the number of previous births of the women (parity). The intervention was amniorrhexis in women who required stimulation for labour, versus expectant management.

The meta-analysis showed strong evidence that amniorrhexis performed on women giving birth for the first time significantly reduces the duration of labour (2 studies, n=117): MD=-53.67 minutes [CI 95%, -66.50 to 40.83 minutes]; total dilatation time (3 studies, n=298): MD 39.45 minutes [CI 95%, -50.10 to -28.80 minutes]; rate of dystocia (one study, n=925): OR 0.63 [CI 95%, 0.48 to 0.82]; and the proportion of women suffering unbearable pain (3 studies, n=1,283): OR 0.76 [CI 95%, 0.60 to 0.97].

SR/MA of RCTs
1++

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There was no evidence of differences in other maternal outcomes such as the use of oxytocin, use of analgesia, caesarean section rate, incidence of abnormalities in fetal heart rate, febrile maternal morbidity, maternal blood transfusions or maternal satisfaction.

SR/MA of RCTs
1++

With respect to neonatal outcomes, there was also no evidence of differences in the umbilical cord prolapse rate, poor deflection of fetal head, Apgar score <7 at 5 minutes, neonatal jaundice, the NICU admission rate or infectious neonatal morbidity.

SR/MA of RCTs
1++

Moreover, in women who had given birth previously and on whom amniorrhexis was performed, a reduction in complete dilatation time was observed (one study, n=269: MD 54.00 minutes [CI 95%, -101.37 to -6.63 minutes]. No differences were found in the other variables assessed.

SR/MA of RCTs
1++

There is high-quality evidence that amniorrhexis shortens the duration when a delay occurs in the first stage of labour.

Amniorrhexis and Oxytocin vs Oxytocin

An RCT (76) conducted in the United States was identified (n=118 women: amniorrhexis = 58, control = 60). The study population included women giving birth for the first time or for the second or subsequent time with a delayed active phase of labour. Routine amniorrhexis followed by oxytocin was compared with a control group receiving oxytocin followed by selective amniorrhexis. Although no statistically significant differences were found, there were more women with postpartum infection in the first group than in the control group (amniorrhexis 7/60; control 0/58; p=0.01).

RCT
1+

No differences were observed in the duration of labour: MD 0.70 hours [CI 95%, -1.55 to 0.15 hours]; caesarean section rate: RR 1.21 [CI 95%, 0.34 to 4.28]; or neonatal infection: RR 4.83 [CI 95%, 0.58 to 40.13].

RCT
1+

Amniorrhexis vs Amniorrhexis and Oxytocin

Three studies conducted in the UK were identified. The first (77) included 926 women giving birth either for the first time or for the second or subsequent time who required stimulation of labour (oxytocin = 465, control = 461). The second study (78) included 61 women giving birth for the first time and progressing slowly, in three groups (amniorrhexis + high doses of oxytocin = 19, amniorrhexis + low doses of oxytocin = 21, control = 20). The third study (79) included women giving birth for the first time and for the second or subsequent time who required stimulation of labour (oxytocin + amniorrhexis = 21, amniorrhexis only = 20).

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Meta-analysis of the three studies, performed in the NICE guideline (10), showed no evidence of differences in the caesarean section rate (3 studies, n=443): RR 0.82 [CI 95%, 0.47 to 1.40]; use of epidural (2 studies, n=967): RR 1.01 [CI 95%, 0.79 to 1.30]; Apgar score <7 at 5 minutes (2 studies, n=82): RR 0.95 [CI 95%, 0.13 to 7.09]; admissions to neonatal units (1 study, n=41): RR 3.00 [CI 95%, 0.12 to 78.04]; or maternal satisfaction (1 study, n=41): MD 9.00 [CI 95%, -6.73 to 24.73]. SR/MA of RCTs 1++

Amniorrhexis and Oxytocin vs Delayed Amniorrhexis and Oxytocin

One study included in the previous question (79) also made this comparison. The study population consisted of women giving birth for the first time and for the second or subsequent time who required stimulation of labour, divided into two intervention groups: oxytocin + amniorrhexis = 21 women, expectant management = 19.

The study demonstrated significant positive differences for amniorrhexis and oxytocin, with a shorter duration of labour: intervention = 266 minutes (SD=166 minutes), control = 463 minutes (SD=164 minutes), p<0.001; and higher level of maternal satisfaction: intervention = 149 (SD=23), control = 118 (SD=33), p=0.002. RCT 1+

No differences were observed for the use of epidural anaesthesia, caesarean section rate or neonatal outcomes (Apgar score <7 at 5 minutes, NICU admission). RCT 1 RCT 1+

Moreover, the NICE guideline (10) also assesses the *effects of stimulation* (by amniorrhexis or oxytocin) *on the fetal heart rate.*

To examine the effect of *amniorrhexis*, NICE (10) uses three of the nine studies included in the SR mentioned in the first point above (75) and assesses the RCTs which analyse the effect of amniorrhexis on fetal heart rate.

No differences were found in fetal heart rate between the two groups of women giving birth for the first time: RR 1.06 [CI 95%, 0.80 to 1.42], or in women giving birth for the second or subsequent time: RR 0.93 [CI 95%, 0.67 to 1.31]. SR/MA of RCTs 1+

To analyse the effect of *oxytocin* on fetal heart rate, NICE (10) assessed two trials (77;79), also mentioned above, which analyse the effect of oxytocin on the rate of caesarean sections due to fetal distress.

In these cases, there were also no differences observed either in the first trial (77): RR 2.86 [CI 95%, 0.32 to 25.24] or in any of the subgroups of the second trial (79): women giving birth for the first time: RR 0.40 [CI 95%, 0.45 to 1.03], and women giving birth for the second or subsequent time: RR 0.66 [CI 95%, 0.20 to 2.13]. RCT 1 RCT 1+

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In the opinion of the group compiling this guideline, there is no evidence of an effect of oxytocin on the fetal heart rate trace or the rate of caesarean sections due to fetal distress. However, it does consider it necessary to monitor the fetal heart rate when oxytocin is used to induce labour.

Finally, the NICE guideline (10) analyses the effect of *different oxytocin dosing regimes* when treating a delay in the first stage of labour.

The NICE guideline (10) included four RCTs (78-82) with good levels of evidence, comparing high doses (initial dose and increment equal to or higher than 4.5 mU/min) and low doses of oxytocin (initial dose and increment up to 2 mU/min) with different dosing intervals (between 15 and 40 minutes: fast administration and slow administration respectively) to stimulate labour.

The guideline performed meta-analysis with the four RCTs. The results obtained show that there is high-quality evidence that women who receive high doses of oxytocin during stimulation of labour present a lower total number of caesarean sections (4 studies involving 1,041 women): RR 0.69 [CI 95%, 0.49 to 0.95] and a higher number of spontaneous vaginal deliveries (1 study involving 310 women): RR 1.38 [CI 95%, 1.15 to 1.65]. SR/MA of RCTs 1+

No statistically significant differences were observed between high and low doses of oxytocin for other outcomes (birth, maternal or neonatal). SR/MA of RCTs 1+

The evidence on the use of high doses of oxytocin versus low doses is clinically inconsistent, as high doses have been associated with a lower number of caesarean sections in four studies, and with more spontaneous vaginal deliveries in one study. This may be due to the high level of heterogeneity between the studies.

Women with induced labour receiving high doses of oxytocin may have shorter labours, fewer caesarean sections and more spontaneous vaginal deliveries than those who receive low doses of oxytocin. SR/MA of RCTs 1+

Nevertheless, the NICE guideline (10) advises caution when using high doses, as there is insufficient evidence on the effects of this intervention on neonatal outcomes, and none on the pain experienced by women who receive high doses of oxytocin to stimulate labour.

The NICE guideline (10) also assesses *different ways of administering different dosing regimes to stimulate labour*. However, the evidence is limited, as the studies included (82-86) do not have sufficient power, and use many different regimes.

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To summarise, women with fast increments in of *high doses of oxytocin, as compared to slow increases* (at high doses), appear to present lower rates of caesarean sections due to dystocia: OR 0.6 [CI 95%, 0.4 to 0.9], and greater uterine hyperstimulation is suggested: OR 1.3 [CI 95%, 0.9 to 1.7] (83). RCT 1+

In comparison between l*ow doses of oxytocin with fast increments and slow increases*, there is no difference in the caesarean section rate. However, women with fast increments of low doses of oxytocin appear to experience greater fetal distress: RR 1.68, p<0.005; and uterine hyperstimulation: RR 1.69 p<0.001, compared with those who received slow increments (84). RCT 1+

When *pulsatile administration* of oxytocin was compared to *continuous administration*, the limited evidence showed a smaller quantity of oxytocin when pulsatile administration was used (pulsatile: 1300 mU (SD 332 mU), versus continuous: 1803 mU (SD 302 mU); p<0.001), with no differences in other outcomes (85). RCT 1+

The evidence on other birth outcomes, including neonatal outcomes and maternal satisfaction, was also insufficient.

Update (2005 to March 2008)

The update of the SR summarised above was found when updating this clinical question (87).

The RS (87) aims to determine the efficacy and safety of *amniorrhexis alone* in systematically shortening all spontaneous-onset labours, and shortening labours that began spontaneously but were prolonged. Fourteen RCTs involving 4,893 women were included

There were no statistical differences in the duration of the first stage of labour (8 trials involving 1,127 women): WMD 20.43 minutes [CI 95%, -95.93 to 55.06]; maternal satisfaction with the birth experience (two RCTs involving 123 women): WMD 0.27 [CI 95%, -0.49 to 1.04]; or Apgar score <7 at 5 minutes (six RCTs involving 2,947 women): RR 0.55 [CI 95%, 0.29 to 1.05]. SR/MA of RCTs +

Amniorrhexis was associated with a higher risk of caesarean delivery than that of the women in the control group, although the difference was also statistically insignificant (ten RCTs involving 4,370 women): RR 1.26 [CI 95%, 0.98 to 1.62]. There was no agreement between the articles concerning when to administer amniorrhexis during labour, in terms of cervical dilatation. SR/MA of RCTs +

The review concludes that introducing systematic amniorrhexis as part of treatment and care during normal labour or prolonged labour cannot be recommended.

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Summary of Evidence

Performing *amniorrhexis* does not demonstrate better outcomes than expectant management (87).	1+
When there is a delay in labour, *amniorrhexis* followed by infusion of low-dose *oxytocin* shortens the duration of the first stage of labour and improves the level of maternal satisfaction, but does not improve the rates of vaginal deliveries or other outcomes (79).	1+
There is no evidence concerning the effect of *oxytocin* on the fetal heart rate trace.	
There is clinical uncertainty concerning the use of high-dose oxytocin, as women who receive it during stimulation of labour present a lower total number of caesarean sections, and a higher number of spontaneous vaginal deliveries (78;80;81;88).	1+
The evidence on *oxytocin dosing* regimes to stimulate labour is limited, as the studies lack power and use different comparisons (78;80;81;88). Increasing the frequency of administration to less than 20 minutes may be associated with higher levels of uterine hyperstimulation (83).	1+

Recommendations

√	When a delay in the active phase of the first stage of labour is suspected, the following action should be taken: • Offer the woman support, hydration and an appropriate and effective method of pain relief. • If the membranes are intact, amniorrhexis should be carried out. • Vaginal examination 2 hours later; if dilatation is less than 1 cm, delayed dilatation is diagnosed. • Once delayed dilatation has been diagnosed, oxytocin stimulation should be offered. • Ongoing monitoring should be carried out and epidural anaesthesia should be offered before oxytocin is used. • Another vaginal examination should be carried out 4 hours after oxytocin perfusion is begun. If dilatation is less than 2 cm, the case should be reassessed, considering the option of a caesarean section. If dilatation is greater than 2 cm, another examination should be carried out 4 hours later.

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6. Second Stage of Labour

6.1. Definition

- What is the definition of the latent phase of the second stage of labour?
- What is the definition of the active phase of the second stage of labour?

The definitions of the stages of labour should be clear, in order to ensure that both women and professionals share the same ideas, making communication easier.

Scientific Evidence

The NICE guideline (10) addresses these questions for the first time, as no previous guideline has addressed the definitions of the stages of labour.

Although no relevant studies that investigated the outcomes of different definitions of labour were identified, the NICE guideline (10) examined various definitions used in practice and research, based on the definitions of the stages of labour used in six descriptive studies that researched the duration of labour.

According to some definitions of the second stage of labour, it starts with full cervical dilatation and ends with the birth of the foetus (23). Others take into consideration maternal pushing, from the onset of this with full dilatation (26). A distinction is made between an active phase and an early or passive second stage. This distinction is useful when a woman reaches the second stage with the fetal head relatively high in the pelvis, with no need to push or with epidural anaesthesia.

Case series 3

Update (2005 to January 2009)

The search carried out for the update did not find any new studies. Consequently, the group compiling the guideline used the evidence from the NICE guideline (10) for the discussion and for preparing recommendations.

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Summary of Evidence

According to some definitions of the second stage of labour, it starts with full cervical dilatation and ends with the birth of the foetus. Others consider to it commence from the start of maternal pushing with full dilatation to birth (26). Also, a distinction is made between an active phase of the second stage of labour and an early or passive second stage (23).	3

Recommendations

√	The second stage of labour is the stage between full dilatation and fetal expulsion. It is subdivided in turn into two phases: • Passive period: full dilatation of cervix, before or without involuntary expulsion contractions. • Active period when: The foetus is visible, or There are expulsion contractions during full dilatation, or Maternal pushing during full dilatation without expulsion contractions.

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6.2. Duration and Progress

- Do the duration and progress of the second stage of labour influence outcomes?

Safe and effective management of the second stage of labour is a clinical challenge for women in labour and for obstetric care professionals. However, the optimum duration of the second stage of labour has still not been firmly established.

The current belief is that intensive intrapartum monitoring can be used for the early detection of foetuses that are not tolerating labour, and actions can be taken to prevent fetal asphyxia. Hence, as the ACOG (American Congress of Obstetricians and Gynecologists) stated that the duration of the second stage is not in itself an indication for bringing labour to an end (89). Management of the second stage of labour should maximise the chances of vaginal delivery and at the same time minimise the risk of maternal and neonatal morbidity and mortality (90).

Scientific Evidence

The NICE guideline (10) used 16 studies to answer this question: ten observational studies of variable quality, which analysed the duration of the second stage of labour and its consequences, three descriptive studies and another three which did not specify the stages of labour.

The *observational studies* included a cross-sectional study conducted in the USA (90) which included 15,759 women and investigated prolonged duration of the second stage (over 4 hours) and its consequences.

The logistic regression performed with the confounding variables controlled showed moderate evidence of an association between a prolonged second stage of labour and chorioamnionitis: OR 1.79 [CI 95%, 1.44 to 2.22]; third- or fourth-degree tears: OR 1.33 [CI 95%, 1.07 to 1.67]; caesarean sections: OR 5.65 [CI 95%, 4.46 to 7.16]; instrumental vaginal delivery: OR 2.83 [CI 95%, 2.38 to 3.36]; and Apgar score <7 at 5 minutes: OR 0.45 [CI 95%, 0.25 to 0.84]. In contrast, no association was found between a prolonged second stage and endometritis, postpartum haemorrhage, meconial fluid or admission to neonatal units.

Cross-sectional study 3

Another US cross-sectional study (91) assessed the maternal and neonatal outcomes of the labours of 7,818 women, to determine the risk factors of a prolonged second stage. It compared the outcomes of the group of women with a second stage of over 121 minutes versus the outcomes of the group with a second stage of between 1 and 120 minutes. Additionally, the subgroups with the second stage of labour between 121 and 140 minutes and >241 minutes were also compared.

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The analysis, which did not take confounding factors into consideration, showed some evidence that a second stage lasting over 120 minutes versus 1-120 minutes, and over 240 minutes versus 121 240 minutes, is associated with various medical interventions such as episiotomy, instrumental vaginal delivery and a higher frequency of perineal trauma.

Cross-sectional study 3

The German cross-sectional study (92), in which 1,200 women were included, investigated the effect of a prolonged second stage (>2 hours) on birth outcomes. The results showed an association between a prolonged second stage and low Apgar scores in the first minute, postpartum haemorrhage, perineal tears and postpartum fever, although confounding factors were not taken into consideration.

Cross-sectional study 3

Another cross-sectional study conducted in Taiwan that involved 1,915 women (93) assessed the effect of a prolonged second stage (without controlling for confounding factors) on birth outcomes. It did not find any association between a prolonged second stage and intrapartum maternal or neonatal outcomes.

Cross-sectional study 3

Another retrospective case and control study (94) analysed the association between the duration of the second stage of labour in 173 women giving birth for the first time and stress urinary incontinence, and found no evidence of an association over a period of 7-8 years after childbirth: OR 1.07 [CI 95%, 0.9 to 1.3].

Case and control study 2

Another large cross-sectional study in Canada (95) including 6,041 women analysed the duration of the second stage of labour and perinatal outcomes, and found no association between duration and low Apgar scores at 5 minutes, neonatal convulsions or NICU admission rate.

Cross-sectional study 2+

Another cross-sectional study conducted in the UK (96;97) investigated the effect of a prolonged second stage of labour on perinatal outcomes in 25,069 women.

The logistic regression analysis performed showed evidence of an association between a long second stage of labour and higher rates of postpartum haemorrhage: duration 120-179 minutes: OR 1.6 [CI 95%, 1.3 to 1.9]; duration 180-239 minutes: OR 1.7 [CI 95%, 1.3 to 2.3]; duration >240 minutes: OR 1.9 [CI 95%, 1.2 to 2.8]. However, there was no evidence of an association with postpartum infection or an Apgar score <7 at 5 minutes.

Cross-sectional study 2+

A population study from the USA (98) investigated the relationship between a prolonged second stage and birth outcomes in 1,432 women. The results showed an association between a prolonged second stage of labour and higher indices of caesarean sections and instrumental deliveries, although these results should be interpreted with care as the analysis was not controlled for confounding factors. There was no evidence of an association with adverse neonatal outcomes.

Population study 2+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

A small (n=30) descriptive longitudinal study conducted in the USA (99) investigated the association between the duration of the second stage (from 10 cm cervical dilatation to delivery) and anxiety scores. No evidence was found of any such association.

Observational study
2-

Another cross-sectional study conducted in the USA (100) investigated different durations of the second stage of labour and their association with birth outcomes in 4,403 women. The analysis, which was not controlled for confounding factors, did not show any evidence of an association between duration and neonatal outcomes, except for low Apgar scores at one minute ($p<0.003$). On the other hand, an association between puerperal haemorrhage and febrile morbidity and the duration of labour was demonstrated ($p<0.001$ for both).

Cross-sectional study
2-

The NICE guideline (10) also selected three small studies in which the stage of labour was not specified:

A matched case and control study (101) with a high risk of bias (n=34) showed some evidence that a longer duration of labour is associated with puerperal psychosis: MD 4.6 hours; $p<0.05$.

Case and control study
2-

A cross-sectional study (102) that investigated the impact of a short duration (<3 hours of first and second stage) on perinatal outcomes used matched controls (by maternal age, parity and birth weight). It did not observe any association between short duration and perineal laceration, postpartum haemorrhage or Apgar score <7 at 5 minutes.

Cross-sectional study
3

The last nested case and control study, with a high risk of bias (103), assessed the effect of prolonged labour on maternal complications during labour. The study showed evidence of an association between prolonged labours and maternal complications, both for women with vaginal deliveries: RR 12.5 [CI 95%, 4.94 to 23.38]; and for caesarean sections: RR 28.89 [CI 95%, 20.00 to 39.43].

Case and control study
2-

The three *descriptive studies* studied only the duration of the second stage of labour, although in some cases the factors associated with the duration of labour were also evaluated.

In a US study (29) which aimed to describe the duration of labour and the clinical factors associated with prolonged labour, data were collected on 2,511 women from nine birthing centres.

The average duration of the second stage was 54 minutes (upper limit: 164 minutes) in nulliparous women and 18 minutes (upper limit: 64 minutes) in multiparous women. Moreover, multivariate logistic regression analysis showed that prolonged labours were associated with EFM, mobility and the use of analgesic drugs (second and subsequent births). Also, maternal age over 30 years was associated with a longer second stage, especially in nulliparous women.

Case series
3

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

In this and other studies, it should be remembered that using means and standard deviations is inappropriate when describing the duration of labour, as duration of labour does not follow a normal distribution (instead, it presents a long tail to the right).

An earlier study conducted in the USA (28) examined the duration of labour in 1,473 women at low risk. The aim of this study was to identify differences between ethnic groups: non-Hispanic white, Hispanic and native American women. The average duration of the second stage of labour was 53 minutes (upper limit: 147 minutes) in nulliparous women and 17 minutes (upper limit: 57 minutes) in multiparous women. Native American nulliparous women showed a significantly shorter duration than non-Hispanic nulliparous white women ($p<0.05$).

Case series
3

A secondary analysis conducted in the USA (23) used data from births occurring between 1976 and 1987 to describe the duration of labour of 6,991 women. Four subgroups of women were analysed: nulliparous or multiparous women, with or without anaesthesia (epidural in 95% of cases). The average duration and upper limits (95th percentile) of the second stage of labour were as follows: nulliparous women without anaesthesia: 54 minutes (132 minutes); nulliparous women with anaesthesia: 79 minutes (185 minutes); multiparous women without anaesthesia: 19 minutes (61 minutes); multiparous women with anaesthesia: 45 minutes (131 minutes).

Case series
3

The following table summarises the mean and upper limits of the duration of the second stage of labour in women without epidural anaesthesia. These were calculated using the data from the three descriptive studies included (101-103).

	Mean (SD) (minutes)	Upper limit (mean + 2 SDs) (minutes)
Nulliparous (n=3,664)	54 (44)	142
Multiparous (n=6389)	18 (21)	60

Observational studies
3

Update (2006 to July 2008)

Of the ten references found in the search, a review (104) was selected. All the studies included in this review had already been covered in the NICE guideline (10). A Canadian clinical practice guideline on the second stage of labour (105) was also selected (it was found during the search performed for another question).

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This guideline (105) was compiled according to the seven steps of the ADAPTE framework: literature review (CPGs and new studies), assessment of the quality of the evidence using validated tools, compilation of recommendations, development of a draft, obtaining feedback on the draft from clinical professionals, reassessment, final compilation of the guideline and implementation.

The protocol of this Canadian guideline (105) provides more chances for a vaginal birth than the other guidelines included in it: Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) (106) (duration in women giving birth for the first time with anaesthesia 3 hours, without anaesthesia 2 hours; second and subsequent births with anaesthesia 2 hours, without anaesthesia 1 hour) and the Society of Obstetricians and Gynaecologists of Canada (SOGC) (107) (2 hours in nulliparous women, 1 hour in multiparous women). The Canadian guideline selected (105), however, considers a normal duration for the second stage to be up to 4 hours for nulliparous women with epidural anaesthesia, up to 3 hours for nulliparous women without anaesthesia and for multiparous women with anaesthesia, and up to 2 hours for multiparous women without epidural anaesthesia.

CPGs
2+

Repeat examination and the use of measurements that facilitate progress and reduction are also recommended. Obstetrics professionals should be informed that they should re-examine women at the start of the fourth hour of the second stage of labour, to determine whether spontaneous birth is likely. If it is not likely, an estimate must be made of how much longer than four hours the second stage of labour will last, so that possible options can be considered. The probability of spontaneous vaginal delivery in nulliparous women who have not given birth after four hours is 24% for women without epidural anaesthesia and 28% for women with epidural anaesthesia.

A prolonged second stage of labour may sometimes be the result of cephalopelvic disproportion or malpositioning, so these causes should be assessed in order to decide whether to perform assisted delivery.

Summary of Evidence

There is moderate evidence of an association between a prolonged second stage of labour and chorioamnionitis, third- and fourth-degree tears, caesarean sections, instrumental vaginal delivery and low Apgar scores (<7 at 5 minutes) (90).	3

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There is some evidence that a second stage lasting more than 120 minutes versus 1-120 minutes, and more than 240 minutes versus 121-240 minutes, is associated with various medical interventions such as episiotomy, instrumental vaginal delivery and a higher frequency of perineal trauma (91).	3
There is an association between a prolonged second stage and low Apgar scores in the first minute, postpartum haemorrhaging, perineal tears and postpartum fever, although confounding factors were not taken into account (92).	3
There is no association between a prolonged second stage of labour and intrapartum maternal or neonatal outcomes (93).	3
The evidence shows that a prolonged second stage of labour is not associated with stress urinary incontinence in the long term (measured over a period of up to 7-8 years after childbirth) (94).	2+
There is no association between the duration of the second stage of labour and a low Apgar score at 5 minutes, neonatal convulsions or NICU admission rates (95).	2+
There is evidence of an association between a long second stage and postpartum **haemorrhage** (PPH), the risk increasing with the length of the second stage. However, there was no evidence of an association with postpartum infection or an Apgar score <7 at 5 minutes (96; 97).	2+
There is evidence of an association between a prolonged second stage and high indices of caesarean sections and instrumental births. There was no evidence of an association with adverse neonatal outcomes (98).	2+
No association was observed between a short second stage of labour and perineal laceration, postpartum haemorrhage or Apgar score <7 at 5 minutes (102).	3
Prolonged labours were associated with EFM, mobility and the use of analgesic drugs (in multiparous women). Also, maternal age over 30 years was associated with a longer second stage, especially in nulliparous women (29).	3
The average duration of the second stage in women without epidural anaesthesia is 54 minutes (upper limit: 142 minutes) in nulliparous women and 18 minutes (upper limit: 60 minutes) in multiparous women (23; 28; 29).	3
A normal duration of the second stage of labour is considered to be up to 4 hours for nulliparous women with epidural anaesthesia, up to 3 hours for nulliparous women without anaesthesia and multiparous women with anaesthesia, and up to 2 hours in multiparous women without epidural anaesthesia (105).	2+

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Recommendations

√	The normal duration of the passive phase of the second stage of labour in a nulliparous women is up to 2 hours with or without epidural anaesthesia.
√	The normal duration of the passive phase of the second stage of labour in a multiparous women is up to 1 hour without epidural anaesthesia and 2 hours with an epidural.
√	The normal duration of the active phase of the second stage of labour in a nulliparous women is up to 1 hour without epidural anaesthesia and 2 hours with an epidural.
√	The normal duration of the active phase of the second stage of labour in a multiparous women is up to 1 hour with or without epidural anaesthesia.

See Appendix 6.

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6.3. Asepsis Measures

- Do asepsis measures during labour influence outcomes?

Care during labour and delivery exposes professionals to contact with maternal and neonatal bodily fluids. Additionally, the asepsis measures necessary to prevent infections must be taken when invasive procedures, including vaginal examination, are performed.

Scientific Evidence

General questions on infection control were reviewed by NICE (10) in its guideline *Infection Control* published in June 2003 (108). On the basis of the evidence from 169 studies included, the NICE guideline (10) makes 26 recommendations on hand hygiene, clothing and safe use and disposal of sharp materials.

The evidence on which the specific recommendations for infection control for women in labour are based is summarised below.

Hand Hygiene

Two non-randomised controlled trials (109; 110) and two descriptive studies that confirmed the association between hand disinfection and infection reduction were identified (111; 112).

In the first non-randomised controlled trial (109) a hand-washing programme was assessed, and it was observed that, after intervention, respiratory disease fell by 45%. — CCTs 2+

The second trial (110) assessed the introduction of an alcohol-based hand-cleansing gel during long-term care of hospitalised elderly persons. A 30% reduction of healthcare-associated infections was demonstrated over a period of 34 months, when compared to the control group. — CCTs 2+

A descriptive study (111) demonstrated a risk of cross-infection as a result of the failure to disinfect the hands in patients' homes. — Cross-sectional study 2+

The opinion of expert professionals, taken from various documents (113-115), is consistent with effective disinfection leading to a significant reduction in possible pathogens transported on the hands, and logically reducing the incidence of preventable infections associated with healthcare, thus decreasing morbidity and mortality.

Hand-Washing Options

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An earlier SR (116) conducted by the same professionals did not identify any evidence in favour of routine use of anti-microbial agents instead of soap for hand-washing, or of the superiority of any one anti-microbial agent over any other. The update carried out to compile the infection control guideline did not identify any new evidence.

SR of RCTs, CCTs and descriptive studies

The SR included seventeen studies that compared hand hygiene involving various products, including alcohol-based lotions and gels, products containing antibiotics and liquid soap. Five of the studies were RCTs in clinical settings, and compared the use of alcohol-based preparations with other agents. Four quasi-experimental clinical trials, seven controlled laboratory trials and a descriptive study were also included.

Generally, it was observed that effective hand washing with non-medicated liquid soap eliminated transient microorganisms and hands were effectively cleaned. This level of disinfection is sufficient for the majority of clinical care activities and for social contact in general.

SR of RCTs 1+

The use of anti-microbial liquid soap reduced transient microorganisms and resident flora, thus achieving effective antiseptic cleaning of the hands. Although alcohol does not remove dirt or organic material, effective use of alcohol-based products on contaminated hands will lead to a significant reduction in transient microorganisms. Alcohol-based products are therefore a practical method and aperfectly acceptable alternative when hands are not very dirty. They are recommended for routine use in hand-cleaning.

SR of RCTs 1+

Use of Personal Protection Equipment

Clothing

The expert opinion documents included in the infection control guideline suggest that the main use of protective equipment, namely to protect healthcare staff and women, reduces the opportunities for transmission of microorganisms in hospitals. In general there is a tendency to abolish the unnecessary use of aprons, gowns and masks, due to the lack of evidence that they are effective in preventing healthcare-related infections (117).

Expert opinion 4

The decision on whether or not to use personal protection equipment should be based on an assessment of the level of risk associated with the specific activity, and must take account of current health and safety legislation.

Sterile Gloves

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The use of gloves for personal protection has become an everyday part of clinical practice since the mid-1980s. Experts agree that there are two main indications for the use of gloves to prevent healthcare-related infections (118): Expert Advisory Group on AIDS and the Advisory Group on Hepatitis, 1998; Centers for Disease Control Update 1987 (117):

- To protect hands from contamination with organic matter and microorganisms. — Expert opinion 4
- To reduce the risks of microorganism transmission between patients and staff.

Gloves should not be used unnecessarily, as prolonged indiscriminate use can cause adverse reactions and cutaneous sensitivity. Gloves should therefore be disposed of after each care activity, in order to prevent the transmission of microorganisms to another part of the same woman's anatomy or to other women. Washing gloves instead of changing them is unsafe (117-123). — Expert opinion 4

NICE's labour care guideline (10) also assesses the use of double gloving during episiotomy and other procedures. Two clinical trials (124; 125) were found, conducted in Thailand, which compared double gloving during episiotomies to single gloving; the only outcome variable studied was the number of perforations. The first trial (124) included 2,058 sets of gloves (double gloving: n=1,316; single gloving: n=742), and the second (125) included 300 sets of gloves (double gloving: n=150; single gloving: n=150). These are open-label studies, so the results must be interpreted cautiously. — RCT 1-

The first trial showed puncture rates of 2.7% for the inner glove ($p<0.05$) and 5.9% for the outer glove, while in single gloving 6.7% of gloves were punctured. The second study showed puncturing in 4.6% of inner gloves ($p<0.05$) and 22.6% of outer gloves, versus 18.0% for single gloving.

Masks, Eye Protection and Other Facial Protection

An SR based on expert opinion (116) did not reveal any robust experimental studies that suggested a clinical benefit for any use of surgical masks to protect women during routine procedures or invasive medical procedures. The SR also indicated that the various types of goggles available provide physical protection for the eyes against splashes of infected substances (although not in 100% of cases), but they were not always used rigorously in many of the studies included in the review. — SR/expert opinion 4

Update (2006 to July 2008)

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The search carried out for the update did not find any new studies. Consequently, the group compiling the guideline used the evidence from the NICE guideline (10) for the discussion and for preparing recommendations.

Summary of Evidence

Hand hygiene	
Ordinary hand-washing or washing with alcohol-based gel is effective in reducing healthcare-associated infections (109; 110)	2+
Effective hand-washing with non-medicated liquid soap eliminates transient microorganisms and effectively cleans the hands (116).	1+
Clothing	
In general there is a tendency to abolish the unnecessary use of aprons, gowns and masks, due to the lack of evidence that they are effective in preventing healthcare-related infections (117).	4
Use of gloves	
The use of gloves to prevent healthcare-related infections is indicated to protect hands from contamination with organic matter and microorganisms and to reduce the risks of microorganism transmission between patients and staff (118).	4
Use of masks and gloves	
There is no study that suggests a clinical benefit for any use of surgical masks to protect women during routine procedures or invasive medical procedures (116).	4

Recommendations

Hand hygiene	
B	Hands should be washed immediately before any direct contact with the patient and after any activity or contact that might lead to potential contamination of the hands.
A	Visibly dirty hands or hands that are potentially highly contaminated with dirt or organic material must be washed with liquid soap and water.
A	Unless they are visibly dirty, hands should preferably be cleaned by rubbing in alcohol-based solution between caring for different patients or between different care activities for one person.

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Clothing	
D	Choice of protective equipment should be based on assessment of the risk of transmission of microorganisms to the patient and the risk of contamination of healthcare professionals' clothing and skin with blood, bodily fluids and excretions or secretions.
√	Full-body waterproof overalls should be used when there is a risk of frequent splashing of blood, bodily fluids, secretions or excretions other than sweat, on healthcare professionals' skin or clothing. This is the case when attending childbirth.
Use of gloves	
D	Gloves must be used for invasive procedures; contact with sterile locations, mucous membranes and non-intact skin; and all activities with a risk of exposure to blood, bodily fluids, secretions or excretions, or cutting or contaminated instruments.
D	Gloves must always be disposable. They must be put on immediately before an episode involving contact with a patient and removed as soon as the activity has ended. Gloves must always be changed between patients and between different activities for a single patient.
Use of masks	
D	Face masks and eye protection should be used when there is a risk of splashing of blood and bodily fluids in the face or eyes.

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6.4. Position During the Second Stage

- What is the most appropriate position during the the second stage?

For centuries there has been controversy over whether remaining in an upright position has advantages over a supine position for women in labour. As early as 1882, Engelmann described the position woman naturally adopt during labour (126). He observed that "primitive" women, uninfluenced by western conventions, tried to avoid the dorsal position and changed position as and when they wished.

The factors that influence the position adopted by women during labour are numerous and complex. It is difficult to identify "instinctive" behaviour, as it is strongly influenced by cultural norms. In societies in which the majority of births occur in a hospital setting, cultural norms have been moulded over the years by the expectations and demands of professionals, and by the restrictions imposed by procedures such as fetal monitoring, intravenous treatment, analgesia, including local analgesia, clinical examinations, etc.

Position during the the second stage is an area to which particular care should be paid, due to the indirect evidence that a positive, supportive environment during labour promotes a feeling of competence and personal achievement in women, has a positive influence on their later confidence as mothers and reduces the risk of postnatal depression.

It is therefore necessary to assess the evidence available concerning the effectiveness, benefits and potential disadvantages of the use of different positions during the the second stage of labour.

Scientific Evidence

The NICE guideline (10) addresses the subject of "*Women's position and pushing in the second stage*" via an SR published in 2005 (127), an observational cohort study (28) and two RCTs (128;129).

The SR (127) is an update of another, earlier SR included in the NICE guideline on caesarean sections (65), which recommends informing all women that a non-supine position during the second stage of labour does not affect the probability of undergoing a caesarean section.

The updated SR (127) selected in the NICE guideline (10) on labour and childbirth included nineteen RCTs with a total of 5,764 women, in whom the benefits and risks of various positions during the second stage of labour were assessed. To do this, a comparison was made between the combination *of upright positions* (seated in birthing chairs, semi-recumbent, squatting) *with lateral positions, and a supine or lithotomy position*.

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When compared to supine or lithotomy positions, upright or lateral positions were associated with a shorter second stage of labour (ten studies): WMD 4.29 minutes [CI 95%, 2.95 to 5.64 minutes]; fewer assisted deliveries (18 studies): RR 0.84 [CI 95%, 0.73 to 0.98]; lower episiotomy rates (12 studies): RR 0.84 [CI 95%, 0.79 to 0.91]; more second-degree tears (11 studies): RR 1.23 [CI 95%, 1.09 to 1.39]; more blood losses over 500 ml (11 studies): RR 1.68 [CI 95%, 1.32 to 2.15]; less acute pain during the second stage (1 study): RR 0.73 [CI 95%, 0.60 to 0.90]; and fewer abnormal patterns in fetal heart rate (1 study): RR 0.31 [CI 95%, 0.08 to 0.98].

SR/MA of RCTs
1+

No significant differences were found for analgesia or anaesthetic used during the second stage of labour (7 studies), third- or fourth-degree perineal tears (4 studies), need for blood transfusion (2 studies), manual placenta removal (3 studies), unpleasant experience of birth (1 study), dissatisfaction with the second stage of labour (1 study), feeling out of control (1 study), admission to NICUs (2 studies), injuries (1 study) or neonatal death (3 studies).

SR/MA of RCTs
1+

The second study, an observational cohort study (28) conducted in the USA over 12 months, included a total of 3,049 women giving birth for the first time and for the second and subsequent time. The analysis, performed using logistic regression, aimed to identify factors that could predict episiotomy and spontaneous tears.

The results obtained suggested that the *lateral position* was associated with a lower incidence of spontaneous tears in women giving birth for the first time (n=919): OR 0.6 [CI 95%, 0.2 to 1.0]. This trend was not found in women giving birth for the second or subsequent time.

Cohort study
2+

A 2005 multi-centre RCT (128) that investigated the effect of being on hands and knees (on all fours) in 147 women giving birth for the first time, with babies in occipito-posterior position during labour, in comparison to a second group of women, who were permitted to adopt the position they wished.

There were no significant differences between the two groups in a primary outcome on the rate of foetuses in occipito-anterior position: RR 2.4 [CI 95%, 0.88 to 6.62]. With respect to secondary outcomes, it was observed that the women allocated to the group on all fours had less persistent lumbar pain according to all measuring methods (using three pain scoring scales): the VAS scale: MD -0.85 [CI 95%, -1.47 to -0.22], p=0.0083; the PPI scale: MD -0.50 [CI 95%, -0.89 to -0.10], p=0.014; and the SF-MPQ scale: MD -2.60 [CI 95%, -4.91 to -0.28]. There was no significant difference on any other point.

RCT
1+

Finally, NICE (10) included a 2006 study (129) conducted in Sweden that compared the effect of *being on hands and knees (on all fours)* and *being seated* on the duration of the second stage of labour in 271 women.

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No significant differences were observed between the two groups in the duration of the second stage of labour. However, several positive results were observed for being on hands and knees, including that women found the position more comfortable for delivering: OR 0.5 [CI 95%, 0.1 to 0.9], p=0.030; had a perception of a shorter labour (although there were no real differences): OR 1.4 [CI 95%, 0.8 to 0.9], p=0.002; less pain: OR 1.3 [CI 95%, 1.1 to 1.9], p=0.01; less postpartum perineal pain in the first three days after birth: OR 1.9 [CI 95%, 1.3 to 2.9], p=0.001. There were no significant differences in clinical outcomes between the women in the two groups or their babies.

RCT
1+

In relation to mobility of *women with epidural analgesia* during the second stage of labour, the NICE guideline (10) identified a 2005 SR (130) that assessed the effectiveness of *upright positions* (including standing, walking, kneeling, squatting and seated at more than 60 degrees from the horizontal) *versus the supine position* during the the second stage. The aim was to reduce the number of instrumental deliveries in women who choose epidural anaesthesia. The SR included only two high-quality studies, involving a total of 281 women.

No differences were found between the two groups with respect to instrumental delivery: RR 0.77 [CI 95%, 0.46 to 1.28]; or caesarean sections: RR 0.57 [CI 95%, 0.28 to 1.16]. Both studies found a significant reduction in the duration of labour for upright positions. There were insufficient data on perineal trauma, postpartum haemorrhage, maternal satisfaction and well-being of the neonate to be able to draw conclusions.

SR/MA of RCTs
1+

The guideline also includes another RCT conducted in the UK in 2004 (131). This compared the *lateral position* (n=49) with a *seated position* (n=58) in women giving birth for the first time with epidural anaesthesia, during the passive phase of the second stage of labour. However, the trial has methodological weaknesses, such as an excessively small sample size due to difficulties during recruitment and differences between the groups compared. As a result, the results have a high risk of bias.

The results indicated that women in a lateral position had lower rates of instrumental deliveries, with an associated reduction in the number of episiotomies, although there were no statistically significant differences. In addition, no differences were observed in overall perineal trauma rates.

RCT
1-

Another chapter of the NICE guideline (10) (on prevention of genital trauma) identified a high-quality RCT (132) which included 1,211 women. This assessed various (manual) interventions to prevent genital trauma, and included logistic regression to assess the prognosis of clinical factors potentially related to genital trauma.

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The analysis showed two measures to protect against perineal trauma, including the seated position: RR 0.68 [CI 95%, 0.50 to 0.91), which in addition to reducing the incidence of genital trauma, also provides greater comfort and autonomy for the mother during birth. RCT 1+

Update (2006 to March 2008)

In the systematic search performed for the update of the evidence, a review carried out by the Andalusian Health Technology Assessment Agency (133) in 2006 was selected.

Ten high- or medium-quality RCTs were included in the review, which aims to determine whether there are differences in maternal and/or fetal outcomes for births in which women adopted any upright position versus horizontal position (including the lithotomy position and angles no more than 45 degrees from the horizontal) during the the second stage, in addition to ascertaining whether the differences (if any) are influenced by epidural anaesthesia.

There is weak evidence that upright positions lead to a lower number of episiotomies, less pain (significant difference observed in only one of the three trials that assessed pain) and a trend towards greater maternal satisfaction (significant differences observed in only one of the four RCTs). Upright positions also showed a trend towards a higher percentage of tears and some tendency towards higher levels of bleeding. SR of RCTs 1-

No differences were found between the two positions with respect to the duration of the the second stage, Apgar score at 1 minute and after the first minute, or pH of the umbilical artery.

Neither the NICE guideline (10) nor the Andalusian review found any significant differences between the two positions for the second stage of labour. However, the recommendation made both by NICE (10) and by the review is to allow women to adopt the position in which they are most comfortable, although the NICE guideline (10) advises women not to adopt the supine or lithotomy positions.

In all studies there is a tendency towards better outcomes in an upright position during the second stage of labour, although the differences are not statistically significant.

Summary of Evidence

When compared with supine or lithotomy positions, upright or lateral positions are associated with a shorter second stage of labour, fewer assisted deliveries, lower episiotomy rates, less acute pain during the second stage and fewer abnormal patterns in fetal heart rate. They are also associated with more of second-degree tears and more postpartum haemorrhages over 500 ml (127).	1+

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Women who are on their hands and knees (on all fours) present less persistent lumbar pain (128) and find this position the most comfortable for delivering, with less postpartum perineal pain and a perception of shorter labour (although there were no real differences in duration) (129).	1+
In women who received epidural anaesthesia, shorter labour is observed for upright positions (including standing, walking, kneeling, squatting and seated at more than 60 degrees from the horizontal) versus the supine position during the second stage of labour (130).	1+
The seated position provides protection against perineal trauma, as well as greater comfort and autonomy for women during childbirth (132).	1+

Recommendations

A	Women should adopt the position that is most comfortable for them during labour.

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6.5. Maternal Pushing and Directed Pushing

6.5.1. Directed or Spontaneous Pushing

- How effective are the different pushing techniques during the second stage on maternal and neonatal outcomes?

Directing maternal pushing during the second stage of labour is a controversial obstetric practice. In fact, the benefits of directed pushing are increasingly debated, although the widespread use of neuraxial analgesia often makes it necessary to direct pushing.

Scientific Evidence

The NICE guideline (10) answers this question in two sections; the first considers only articles concerning women in labour without neuraxial analgesia, while the second section considers articles that assess the effects in women who receive some kind of neuraxial analgesia.

Maternal Pushing in Women Without Neuraxial Analgesia.

The NICE guideline (10) included two high-quality RCTs (134;135) conducted in the USA, which compared the effect of directed and non-directed pushing during the second stage of labour. Three other RCTs from earlier than 1994 were also included, but had a high risk of bias [LE 1-].

TThe aim of the most recent trial (134) was to compare directed and non-directed pushing in the second stage of labour. The women giving birth for the first time allocated to the directed group (n=163) were instructed on how to push with the glottis closed during contractions, and they were encouraged to breathe normally between contractions. The non-directed group (n=157) was cared for by the same group of midwives, but they were not given any instructions on pushing and were encouraged to act "naturally".

The average duration of the second stage was significantly shorter for the women in the directed group than for the women without directed pushing: 46 minutes compared to 59 minutes; p=0.014, although this was not clinically relevant. There were no differences in any other maternal or neonatal variable. RCT 1+

The second trial (135) included 128 women who were randomised, when they reached full dilatation, to directed or non-directed pushing. The study aimed to determine whether not directing pushing affected postpartum urogynaecological parameters and the pelvic floor function. The pelvic floor was assessed three months after birth by nurses unaware of which group the women had belonged to during the second stage of labour.

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There were no significant differences between the two groups with respect to demographic factors, incidence or duration of the second stage (>2 hours), episiotomy rate, anal sphincter tears, epidural anaesthesia during the second stage, forceps, use of oxytocin in the second stage or weight of the neonate (over 4 kg). Urodynamic testing showed reductions in bladder capacity (p=0.51) and urinary urgency (p=0.5) in the directed group. RCT 1+

The third RCT (136), conducted in Denmark, compared spontaneous pushing with a "forced" sustained breathing technique in the second stage, in women giving birth for the first time by vaginal delivery. The pushing method allocated was not established until the head of the neonate was visible; until then the women were permitted to make expulsion efforts as they wished, without advice or help from the midwife. However, recruitment was difficult and only 350 of the 1,413 women chosen took part. The others refused to participate due to reluctance to be allocated to the spontaneous pushing group for fear of a lack of guidance and encouragement from midwives. Additionally, 44 women were lost during follow-up after randomisation, mostly because they gave birth by caesarean section. These difficulties made the findings of the study less reliable; ultimately it included 151 women with spontaneous pushing and 155 with a "forced" sustained respiration technique. The two groups were well matched in terms of maternal and neonatal characteristics.

The study did not show any significant differences in the duration of labour, duration of the second stage (from the head becoming visible to delivery), type of delivery, perineal trauma, Apgar scores or pH of umbilical blood. The study explains these similarities in terms of failure to perform the pushing technique allocated and frequent use of oxytocin (40.1% in the spontaneous pushing group, 45.8% in the forced pushing group) and episiotomy (36% in the spontaneous pushing group, 30% in the other group). RCT 1-

A small RCT (137) conducted in England and published the same year aimed to analyse the effect of spontaneous pushing (n=15) versus directed pushing with sustained breathing (n=17) on the duration of labour and other outcomes, and on maternal satisfaction.

The first stage of labour was significantly longer in the spontaneous pushing group (mean (SD)): 12.32 hours (5.3 hours) vs 7.88 hours (2.62 hours), p=0.005; and the duration of the second stage: 121.4 minutes (58.4 minutes) vs 58 minutes (42 minutes), p=0.002. However, these findings are probably due to differences in the duration of the first stage, rather than the type of pushing technique used. There were no differences between the two groups in connection with the type of delivery, perineal trauma, estimated maternal blood loss, resuscitation of neonates, level of venous umbilical cord blood or pH. RCT 1-

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The last of the RCTs included in the NICE guideline (138) compared the sustained breathing pushing technique (n=10) with an exhalation pushing technique (n=17) in women who gave birth sitting in a birthing chair. This study also had recruitment problems, and the final sample of women was only a small proportion of the 94 women who agreed to participate. In addition, some were eliminated from the analysis after randomisation because they did not comply with the protocol (not using a chair during the second stage of labour: n=20, not using the allocated pushing technique: n=20).

RCT
1-

No significant differences were found between the two groups in the duration of the second stage of labour: the average duration was 45.6 minutes in both groups. Many differences in fetal heart rate were described (more decelerations in the group with sustained breathing: 30% vs 17.6%), but the article does not discuss the clinical significance of this finding.

Update (2006 to July 2008)

A high-quality SR published in 2007 (139) was selected. A total of 7 studies were included, involving a total of 2,827 women. The aim of the review was to determine the most beneficial pushing method (directed pushing versus spontaneous pushing) in *women who received epidural anaesthesia* during the second stage of labour.

The meta-analysis performed showed that women without directed pushing presented a higher number of spontaneous vaginal deliveries: RR 1.08 [CI 95%, 1.01 to 1.15], p=0.025; lower risk of instrumental delivery: RR 0.07; [CI 95%, 0.71 to 0.85], p≤0.0001; and shorter pushing time: MD -0.19 hours [CI 95%, -0.27 to -0.12], p≤0.0001). No differences were found in the rates of caesarean sections, lacerations or episiotomies.

SR/MA of RCTs
1+

The results obtained indicate that non-directed pushing during labour increases the number of vaginal deliveries safely and effectively and reduces the number of instrumental deliveries and pushing time.

The meta-analysis (139) published in 2007 was carried out on studies including women with epidural anaesthesia during labour, while in the studies included in the NICE guideline (10) the women were not treated with any type of anaesthesia. Despite the differences, it is observed both in the NICE guideline (10) and in the later review that in the second stage of labour women should be guided by their own desire to push. Additionally, the meta-analysis showed significantly higher rates of vaginal deliveries and fewer instrumental deliveries in women without directed pushing.

Summary of Evidence

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Comparison between a group of women whose pushing was directed and another group with spontaneous pushing did not show any differences after three months in the incidence of labours with a second stage lasting over two hours, episiotomy rate, anal sphincter tears, epidural anaesthesia during the second stage, forceps or the use of oxytocin in the second stage. However, a reduction in bladder capacity and urinary urgency was observed in the group of women with directed pushing (135).	1+
It has been observed that labour with non-directed pushing increases vaginal deliveries and reduces instrumental deliveries and pushing time for *women who receive epidural anaesthesia* (139).	1+

Recommendations

A	Spontaneous pushing is recommended. If there is no pushing sensation, pushing should not be directed until the passive phase of the second stage of labour has ended.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

6.5.2 When to Push

- What is the optimum moment to recommend directed pushing?

Over the last 35 years, epidural anaesthesia has become the most common method for managing pain during labour in hospitals. One of the adverse effects of epidural anaesthesia is that it frequently inhibits the natural urge to push once the the second stage has begun. Obstetricians have often tried to compensate for this by encouraging women to push as soon as full dilatation is reached. This method may not be evidence-based (140).

Delaying pushing has been proposed as an option to enable the descent and spontaneous rotation of the fetal head, thus reducing the rate of instrumental births. However, delaying pushing prolongs the second stage of labour, and this fact has been associated with traumas to the pelvic floor and subsequent maternal morbidity (141;142). Also, the second stage of labour has been considered to be of particular risk for the foetus (143).

Scientific Evidence

The NICE guideline (10) assessed only late and immediate pushing in women who received analgesia. The ideal time to push for women without analgesia was not assessed.

One of the two SRs included in the NICE guideline (144) was selected to answer this question. This compared the potential benefits and harm of a policy of delayed pushing in women with complication-free labours and with epidural anaesthesia from the first stage of labour onwards [LE 1+]. The duration of the delay until pushing began in the experimental group varied between studies from 1 to 3 hours. The primary outcomes assessed were instrumental deliveries, and secondary outcomes included other types of delivery, the scope of maternal complications, long-term maternal outcomes and fetal outcomes.

Nine studies were included in the review, involving a total of 2,959 women. Several studies excluded women with medical or obstetric complications. Management of the active phase of the second stage varied between studies and included various pushing techniques and the use of oxytocin. The methodological quality of the studies included varied.

The meta-analysis showed a slight, statistically insignificant reduction in the incidence of instrumental deliveries: RR 0.94 [CI 95%, 0.84 to 1.01] in the delayed pushing group; and a significant reduction in rotational or forceps instrumental deliveries: RR 0.69 [CI 95%, 0.55 to 0.87].

SR/MA of RCTs
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The total duration of the second stage was significantly longer in the delayed pushing group in seven of the eight studies in which it was reported, with an overall increase of 58 minutes. However, the duration of the active phase of the second stage varied between studies. Only two studies discussed fever during labour: in one no significant differences were observed, while in the other a significantly higher incidence was found in the delayed pushing group. One of the studies published pelvic floor morbidity at three months postpartum and did not find any significant differences between the two groups. No study reported data on urinary incontinence. Few studies provided information on neonatal outcomes and there were no significant differences between the two groups in the outcomes examined.

SR/MA of RCTs
1+

One RCT (145) compared immediate pushing (n=22) with delayed pushing (n=23) in two groups of women giving birth for the first time, in full-term induced deliveries and with epidural anaesthesia [LE 1+] and oxytocin perfusion. The group with immediate pushing started pushing when full dilatation was reached and were trained to hold their breath and push three or four times on a count of ten during each contraction. The group with delayed pushing were advised to wait until they felt the urge to push or when their second stage had already lasted two hours. During pushing they were encouraged to push without holding their breath for no more than 6 8 seconds on each push. The two groups had similar demographic profiles, although the women in the group with immediate pushing were significantly younger.

The second stage was longer in the group with delayed pushing: average duration 38 minutes, p<0.01. However, the duration of active pushing time was longer in the group with immediate pushing: average duration 42 minutes, p=0.002.

RCT
1+

Fetal oxygen desaturation was significantly higher in the group with immediate pushing, and decelerations in fetal heart rate were more variable and prolonged. There were no significant differences in other variables such as number of caesarean sections and instrumental vaginal deliveries, prolonged second stage (>3 hours), episiotomy, umbilical cord gases, Apgar scores or other fetal heart rate patterns. There were more perineal tears in the group with immediate pushing: 13 vs 5, $x2$=6.54, p=0.01.

RCT
1+

Finally, a cohort study conducted in Ireland (140) was identified. This compared delayed pushing with early pushing during the second stage of labour. In both groups, the women were giving birth for the first time, full-term and similar in terms of age and weight. No details were given concerning the position of neonates or situation of the second stage of labour. Women in the group with delayed pushing (n=194) were advised to push when the head was visible or three hours after full dilatation; those in the group with early pushing (n=219) were encouraged to push as soon as the second stage started.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The duration of the second stage was longer in the group with delayed pushing (p<0.001) even though the women in the early pushing group waited an average of 0.7 hours before starting to push, while those in the group with delayed pushing waited an average of 0.9 hours. The use of non-rotational forceps was lower in the group with delayed pushing: 44.84% vs 54.79%, p<0.04. Abnormal fetal heart rate patterns and/or the appearance of meconium were more common in the group with delayed pushing: 27.8% vs 3.91%, p<0.01. The number of admissions to neonatal intensive care units was also higher in the group with delayed pushing: 14 vs 5, p=0.017.

Cohort study 2+

No differences were found in the following factors: spontaneous delivery index, episiotomy index, complications in the third stage, Apgar scores, need for fetal intubation, postnatal morbidity.

Cohort study 2+

Update (2006 to August 2008)

The search carried out for the update did not find any new studies. Consequently, the group compiling the guideline used the evidence from the NICE guideline (10) for the discussion and for preparing recommendations.

All the evidence from the studies included in the NICE guideline (10) indicates that the total duration of the second stage is significantly longer in the group with delayed pushing and that the risk of mid forceps and rotational instrumental delivery is reduced.

Summary of Evidence

The total duration of the second stage is significantly longer when pushing is delayed, although the duration of active pushing is shorter. Additionally, when pushing is delayed there is a lower risk of delivery with mid forceps and rotational instrumental delivery. There were no significant differences in other outcomes examined (140; 144; 145).	1+

Recommendations

A	For women with neuraxial analgesia, pushing should be directed once the passive phase of the second stage of labour has ended.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

6.6. Preventing Perineal Trauma

- How effective are the following interventions in preventing genital trauma: perineal massage, application of heat to the perineum, use of local anaesthetics on the perineum, application of cold to the perineum, protection of the perineum, active deflection of the head and active extraction of shoulders versus doing nothing?

Interest in finding strategies that can reduce the risk of perineal trauma during labour has intensified in the face of evidence that episiotomy should be performed in only restricted cases, and the controversy surrounding the best way to protect the perineum during the second stage of labour.

Scientific Evidence

The NICE guideline (10) proposes a series of interventions (perineal massage, change of position, heat, cold, maternal position, analgesia, episiotomy and surgical vaginal delivery) to reduce perineal trauma.

Perineal Massage During Labour

The NICE guideline (10) found only one RCT, which was conducted in Australia (146). Its aim was to study the effects of perineal massage during the second stage of labour. The study included a total of 1,340 women (massage group n=708).

The results did not find any significant differences between the two groups for the variables studied: intact perineum, first-degree tear, second-degree tear, episiotomy, vaginal pain after three days, vaginal pain after ten days, vaginal pain after three months, dyspareunia, failure to resume sexual relations, urinary and faecal control. However, there was a lower incidence of third-degree tears in the massage group, 12/708 vs 23/632; RR 0.47 [CI 95%, 0.23 to 0.93].

RCT
1+

Application of Heat/Cold

The only study used by NICE (10) to examine the use of heat/cold in perineal care is an observational cohort study conducted in the USA (147) to analyse factors associated with perineal trauma during childbirth. 2,595 women were studied over 12 months, and the results obtained indicated that the use of hot compresses during the second stage of labour had a slight effect in preventing spontaneous tears in women giving birth for the second or subsequent time without episiotomy: OR 0.6 [CI 95%, 0.3 to 0.9]; and episiotomies in women giving birth for the first time: OR 0.3 [CI 95%, 0.0 to 0.8].

Cohort study
2+

Hand Position During Birth

More than 5 years have passed since the publication of the Clinical Practice Guideline and its validity has not been reviewed

NICE (10) includes three studies on this subject. An initial RCT conducted in the UK (148) included a total of 5,471 women. It compared two techniques for protecting the perineum during spontaneous vaginal delivery: one in which one hand controlled the deflection of the head and protected the perineum and another in which the hands were ready but did not touch the fetal head or the perineum.

The results showed statistically significant differences, with less pain, in the group in which hands controlled deflection of the head and protected the perineum, in the last 24 hours, asked 10 days after birth (910/2,669 hands ready but not touching versus 823/2,647 with hands controlling and protecting the perineum): RR 1.10 [CI 95%, 1.01 to 1.18]; with more episiotomies performed (10.2% [n=280] with hands ready but not touching versus 12.9% (n=351) with hands controlling and protecting the perineum): RR 0.79 [CI 95%, 1.02 to 2.78]; and fewer manual placenta removals (2.6% [n=71] with hands ready but not touching versus 1.5% [n=42] with hands controlling and protecting the perineum): RR 1.79 [CI 95%, 1.02 to 2.78].

RCT
1+

The NICE guideline also includes a quasi-experimental clinical trial conducted in Austria (149), involving a total of 1,076 women. The aim of the study was to compare a technique in which one hand controlled the deflection of the head and the other protected the perineum with a technique in which the hands were ready but did not touch the fetal head or the perineum.

The rates of first- and second-degree tears were similar in both intervention groups: hands on perineum: 29.8% versus hands not touching the perineum: 33.7%, with no significant differences. However, the third-degree tear rate was higher in the group positioning the hands to protect the perineum: n=16 (2.7%) vs n=5 (0.9%), although the study did not have sufficient statistical power to detect differences for this very infrequent event. The episiotomy rate was also higher in this group of women: 17.9% vs 10.1%, p<0.01. In contrast, there were no significant differences in labial and vaginal trauma, duration of the second stage of labour, manual placenta removal or neonatal outcomes.

Quasi-experimental study
1+

The third study included was an RCT conducted in the USA (132) in 2005, which compared the *application of hot compresses and massage combined with the use of lubricant with hands ready but not touching the perineum*. The percentage of episiotomies performed in the study was low (0.8%); 23% (n=278) of the women presented no genital trauma, 20% (n=242) presented severe perineal trauma (second-, third- or fourth-degree tear), while 57% (n=691) presented minor trauma (first-degree tear).

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

When the use of *hot compresses* was compared with *the technique in which hands were kept ready* but not touching the head or perineum, the differences were insignificant: RR 1.04 [CI 95%, 0.81 to 1.35]. The average length of compress use was 17.8 minutes in women with perineal trauma versus 13.4 minutes in women without trauma, p=0.06. RCT 1+

The same occurred when massage was compared with the *technique in which hands were kept ready*: RR 1.05 [CI 95%, 0.81 to 1.35]. The average length of massage was 11.6 minutes in women with perineal trauma versus 5.8 minutes in women without trauma, p<0.01. RCT 1+

Stratified analysis adjusted for parity, use of epidural and neonate weight did not show any significant differences between the three groups. Final analysis of a regression model showed two factors that protected against perineal trauma: the squatting position and expulsion of the head between contractions rather than during contractions. RCT 1+

Local Anaesthetic Spray

A high-quality RCT published in 2006(150) assessed the effectiveness and acceptability of a lidocaine spray to reduce perineal pain during spontaneous vaginal delivery. The trial included a total of 185 women (n=93 with lidocaine and n=92 with placebo).

The results showed no significant differences in the pain experienced by the women in the two groups: mean [standard deviation]: lidocaine 76.9 [21.6] vs placebo 72.1 [22.2]; MD: 4.8 [CI 95%, 1.7 to 11.2]; p=0.14. However, there were differences in favour of the lidocaine group in the incidence of second-degree tears: RR 0.63 [CI 95%, 0.42 to 0.93], p=0.019; and dyspareunia: RR 0.52 [CI 95%, 0.35 to 0.76], p=0.0004. These adverse effects may be due to the differences between the two treatment groups in the trial with respect to the parity of the women (more women who had previously given birth in the intervention group) and fetal weight (lower in the intervention group).

Update (2006 to July 2008)

An RCT (151) published in 2007 that addresses the question of applying heat/cold was selected. An article (152) on the head deflection technique, located manually, was also included; although on the basis of its type (it is an observational study) it should not have been included, it is included because it was published recently (May 2008) and because there were no previous references on the subject in NICE (10).

Application of Heat/Cold

More than 5 years have passed since the publication of this clinical practice guideline, and its validity has not been reviewed

The aim of the RCT published in 2007 (151) was to determine the effects of applying hot compresses to the perineum (compresses soaked in boiled water at a temperature of 45º C) on perineal trauma and maternal comfort during the late second stage of labour. The study included 717 women giving birth for the first time, with full-term single pregnancies and cephalic presentation, for whom normal delivery was planned and who had not performed perineal massage. The women were randomly allocated to two groups; in the intervention group hot compresses were applied from the end of the second stage of labour until the baby crowned, versus normal management of the control group, which does not include warm cloths. Although it was not possible to hide the procedure from the women in labour or those attending the birth, the external assessors were blinded. The trial was conducted in an ethnically diverse population in Australia, and 75% of the women were immigrants from other countries.

With a sample size large enough to detect a difference of 10%, no differences were found between the groups for the main outcome, the need for perineal suturing: OR 1.0 [CI 95%, 0.69 to 1.47]. However, the rate of third- and fourth-degree lacerations was higher in the control group: OR 2.16 [CI 95%, 1.15 to 4.10]. The women who received hot compresses had a significantly lower probability of intense pain during childbirth than those who did not receive them: 59% and 82% respectively. A modest but significant reduction was also found in average perineal pain scores on days 1 and 2 postpartum using a 10-point visual analogue scale, with an average difference less than one point. At 3 months postpartum, women who had received hot compresses were less likely to present urinary incontinence: 26/277 vs 59/262; p<0.0001.

RCT
1+

Deflection of the Head

The last study included in the update (152) is a cohort study, conducted as part of a Norwegian national programme, with the aim of establishing whether an intervention programme can reduce the frequency of anal sphincter rupture. The intervention performed was to slow the phase of expulsion of the head using manoeuvres, controlling the deflection of the head and telling the mother not to push, in order to protect the perineum. Data on 12,369 vaginal deliveries that took place between 2002 and 2007 were analysed in the study, and the impact of the intervention programme (performed from October 2005 until March 2007, after a training period from January to September 2005) on the anal sphincter rupture rate was compared in two subgroups consisting of different types of delivery (instrumental and non-instrumental deliveries).

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

An overall reduction in anal sphincter tearing during the intervention period was observed: from 4.03% of tears during 2002-2004 to 1.17% during 2005-2007 (p<0.001). This trend was observed in both non-instrumental delivery (from 16.26% to 4.90%, p<0.001) and instrumental delivery (from 2.70% to 0.72%, p<0.001). Cohort study 2+

An increase in instrumental deliveries during the intervention period was also observed: from 9.8% during 2002-2004 to 11.7% during the first 9 months of 2005 (p=0.011) and 12.2% during the last 9 months of the intervention period (p<0.001). There was also an increase in the number of episiotomies performed: 13.9% during 2002-2004, 23.1% in the first 9 months of 2005 (p<0.001) and 21.1% in the last 9 months of the intervention period (p<0.001). Cohort study 2+

Thus the results show that manual protection of the perineum, via slowing deflection of the fetal head, reduces the number of anal sphincter ruptures.

Summary of Evidence

Perineal massage	
Performing perineal massage, when compared with not doing so, did not show any significant differences in the rates of intact perineum; first- and second-degree tears; episiotomies; vaginal pain at three days, ten months and three months; dyspareunia; or failure to resume sexual relations (146).	1+
Application of heat/cold	
The application of hot compresses during the second stage of labour does not prevent perineal trauma (147).	2+
The application of hot compresses beginning during the second stage of labour reduces the risk of third- and fourth-degree perineal lacerations but not the rate of perineal suturing. Additionally, it reduces pain during childbirth and the first three days postpartum, and may also reduce the risk of urinary incontinence during the first three months postpartum (151).	1+
Active protection of the perineum and active deflection of the head	
When the hands are positioned to protect the perineum and deflection of the head is controlled, in comparison with the technique in which the hands are kept ready but not touching the fetal head or the perineum, less pain is observed at ten days and there is a higher number of episiotomies, although the overall perineal trauma rate is similar in both groups (148).	1+
Manual protection of the perineum, via controlled deflection of the fetal head, reduces the number of anal sphincter ruptures (152).	2+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Application of local anaesthetic	
The use of lidocaine spray during the second stage of labour does not reduce perineal pain (150).	1+
Active extraction of the shoulders	
No studies have been identified that provide results on this intervention.	

Recommendations

Perineal massage	
A	Perineal massage is not recommended during the second stage of labour.
Application of heat/cold	
A	The application of hot compresses should be made available during the second stage of labour.
Active protection of the perineum and active deflection of the head	
B	The perineum should be actively protected using controlled deflection of the fetal head, asking the woman not to push.
Application of local anaesthetic	
A	Local anaesthetic spray should not be used to reduce perineal pain during the second stage of labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

6.7. Episiotomy

- How effective is episiotomy?

Episiotomy, which was introduced into clinical practice in the eighteenth century, is widely used during childbirth despite a lack of scientific evidence on its benefits. It is still a very controversial procedure. Its use was justified on the basis of reducing the risk of perineal tears, pelvic floor dysfunction and urinary and faecal incontinence. It was thought that the potential benefits to the foetus were due to a shorter the second stage, making a higher number of spontaneous deliveries possible. Despite the limited data, episiotomy became virtually routine and its potential adverse effects, including expansion to third- and fourth-degree tears, anal sphincter dysfunction and dyspareunia, were underestimated.

Scientific Evidence

NICE includes an SR (141) that analyses the outcomes of women who underwent routine episiotomy, versus restrictive episiotomy. The review includes seven RCTs, involving a total of 5,001 women, and eight cohort studies, involving 6,463 women. Within the review, meta-analysis was carried out to assess pain and incontinence, amongst other outcomes.

In the trial considered to be of the highest quality (n=1,000), the incidence of intact perineum was 33.9% in the restrictive episiotomy group and 24% in the routine episiotomy group. In the trial with most participants (n=2,606), the need for surgical repair was 63% in the restrictive episiotomy group and 88% in the routine group. In the other five trials, the need for perineal repair was also lower in the restrictive episiotomy group: RR 0.46 [CI 95%, 0.30 to 0.70], and the need for any kind of suturing was 26% higher in the routine episiotomy group: RR 1.26 [CI 95%, 1.08 to 1.48]. The seven RCTs had little statistical power to detect differences in third- and fourth-degree tears between the two groups, with an incidence of 105/5,001.

SR/MA of RCTs
1+

Pain was another of the parameters analysed by the SR, and was assessed in five RCTs. The severity of pain in the routine episiotomy group (n=885) was as follows: mild 14.6%, moderate 7.8%, severe 0.2%; in the restrictive episiotomy group (n=1,000) it was 14.1%, 7.5% and 0.9% respectively. Analgesic use and pain assessment at 3 months were similar between the two groups. The study with most participants (n=2,422) reported pain on the day of discharge in 42.5% of women in the routine episiotomy group versus 30.7% in the restrictive episiotomy group. Another study assessed pain using an analogue visual scale for four different activities, between one and five days postpartum. In all activities, less perineal pain was observed in the restrictive episiotomy group than the routine episiotomy group (p=0.048).

SR/MA of RCTs
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Urinary incontinence (defined as urine losses for three months and the use of incontinence pads) was assessed in two RCTs (n=895 and n=1,000), but no statistically significant differences were observed between selective and routine episiotomy: RR 1.02 [CI 95%, 0.83 to 1.26]. Five prospective cohort studies, also included in the review, analysed urinary incontinence in women with episiotomies and with spontaneous tearing, and also found no differences between the two groups: RR 0.88 [CI 95%, 0.72 to 1.70]. Additionally, four studies also analysed rectal incontinence and did not find that episiotomy was connected with a higher risk of faecal incontinence or flatulence. However, when the data from two cohort studies was combined with measurements of comparable results, an increase in the risk of rectal incontinence associated with episiotomy appeared: RR 1.91 [CI 95%, 1.03 to 3.56].

SR/MA of RCTs
1+

Two clinical trials assessed sexual function, with an intention-to-treat analysis (n=895 and n=1,000). They observed that more women in the restrictive episiotomy group resumed their sex lives after one month than in the routine episiotomy group (27% vs 37%; $p<0.01$). No statistically significant differences were found between the two groups when renewed sexual relations and dyspareunia at 3 months or pain during intercourse at 3 years were assessed. There were also no differences found in sexual function in five cohort studies that assessed women who had undergone an episiotomy and others who had suffered a spontaneous tear.

SR/MA of RCTs
1+

NICE (10) also included an RCT conducted in Germany (142), in which restrictive episiotomy was compared with routine episiotomy in a total of 109 women. The episiotomy rate was 41% in the restrictive group and 77% in the routine group: RR 0.4 [CI 95%, 0.3 to 0.7]. The incidence of intact perineum and minor perineal trauma (first-degree tear) was higher in the restrictive episiotomy group (14/49 vs 6/60): RR 2.9 [CI 95%, 1.2 to 6.9]; intact perineum or first-degree tear (19/49 vs 8/60): RR 2.9 [CI 95%, 1.6 to 10.5]. No significant differences were found when anterior perineal trauma was analysed (27/49 vs 25/60): RR 1.1 [CI 95%, 0.8 to 1.8]. Pain during activities such as sitting or walking was significantly lower in the restrictive episiotomy group (sitting: p=0.0009, walking: p=0.005). When the study analysed Apgar scores or umbilical artery pH, there were no significant differences between the two groups. No differences were found between the groups when the Apgar score of neonates and umbilical artery pH were analysed.

RCT
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The NICE guideline (10) found a similarity between the results measured in the German study (142) and an earlier SR (153) updated by NICE (10). A meta-analysis was carried out using the data from these two studies, and significant differences in outcomes were observed only for any posterior perineal trauma (five studies n=2,198): RR 0.87 [CI 95%, 0.83 to 0.91], with a lower rate in women who underwent episiotomy, and for any type of anterior perineal trauma (five studies, n=4,451): RR 1.75 [CI 95%, 1.52 to 2.01]; with higher rates in the restrictive episiotomy group. In other outcomes the differences were insignificant: severe perineal trauma (third- or fourth-degree tear) (six studies, n=3,959): RR 0.77 [CI 95%, 0.54 to 1.12]; Apgar score below 7 in the first minute (five studies, n=3,908): RR 1.05 [CI 95%, 0.76 to 1.45].

SR/MA of RCTs
1+

NICE (10) also analysed the cutting angle of the episiotomy, including an observational prospective study (154), the aim of which was to identify the risk factors associated with a third- or fourth-degree tear. 241 women were included, of whom 25% sustained an injury to the anal sphincter. Logistic regression indicated that excess weight of the child (p=0.021) and mediolateral episiotomy: OR 4.04 [CI 95%, 1.71 to 9.56] were independent risk factors for sphincter injury. The results indicated that orientation of the episiotomy towards the midline was associated with a higher number of anal sphincter injuries (p=0.01) and that no midwives and only 22% of obstetricians performed true mediolateral episiotomies (defined as at least 40 degrees from the midline).

Observational study
3

Vaginal Delivery After Previous Third- or Fourth-Degree Perineal Tear

The NICE guideline (10) includes two descriptive studies (155;156) in this section, which assessed the recurrence of third- or fourth-degree tears in women who had experienced them in previous births. A third retrospective cohort study (157) examined the incidence of anal incontinence with previous third- or fourth-degree tears.

The retrospective population study conducted in the UK (155) studied the incidence of recurrence of third- or fourth-degree tears in a population of 16,152 women. Of these women, 14,990 had vaginal deliveries and the incidence of recurrence of severe lacerations was 5.7%. Additionally, recurrence was higher in the group of women who had suffered fourth-degree tears than in women with third-degree tears (7.7% and 4.7% respectively). Multiple logistic regression analysis was carried out to evaluate the association between the use of forceps, vacuum extraction, episiotomy, age of mother and year of birth as independent risk factors for recurrent laceration. All appeared to be significant independent risk factors. However, it should be observed that some other important confounding factors were not included in the statistical model, such as parity, birth weight and indication for instrumental vaginal delivery.

Descriptive study
3

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

A second prospective descriptive study (156) investigated the risk of alterations to the anal sphincter subsequent to serious perineal damage in women with damage in previous births. 342 women (1.7%) were identified as having third-degree tears, of a total of 20,111 consecutive vaginal births. Follow-up was performed over the 3 months following the labour of each of these 342 women, to determine perineal function (using continence measuring scales and manometry) and identify anal defects (using ultrasound). 56 of these women had further births over the following three years; they formed the study sample. All of these 56 women were assessed during the last trimester of pregnancy using scoring scales, anal manometry and ultrasound. Of the women with vaginal deliveries (n=45), 62% (n=28) underwent episiotomies, 7% (n=4) instrumental deliveries and 27% (n=12) perineal tears, three of which were third-degree, and similar faecal function was observed after the second birth as after the previous birth. The study concluded that after repair of third-degree tears faecal continence outcomes were excellent for all women.

Descriptive study
3

A Swiss retrospective cohort study (157) also investigated the incidence of anal incontinence in women who had had a vaginal delivery, after third- or fourth-degree perineal trauma. The women included in the study were identified by means of a hospital's electronic records and contacted by telephone to ask them to participate in the study. 208 (46%) of the 448 women identified were contacted. 177 of them agreed to participate and 114 subsequent had vaginal deliveries.

Cohort study
3

The results suggest that subsequent births are not associated with a higher incidence of rectal incontinence in women with third-degree anterior perineal tears. However, a trend towards higher incidence was observed in women with previous fourth-degree tears. The authors observed that the majority of third- and fourth-degree tears in this study were in extensions of midline episiotomies and it was suggested that the various degrees of tears might entail different risks of sphincter tearing, complicating spontaneous tearing or mediolateral episiotomy.

In summary, it is observed that women with severe perineal trauma in previous births have a similar incidence of recurrent severe perineal trauma to the incidence in the previous delivery. There is no evidence on the effectiveness of episiotomy after births with third- or fourth-degree traumas.

Update (2006 to March 2008)

No new studies were selected for the update of this question. The recommendations were therefore based on the evidence provided by NICE (10), which can be summarised as stating that there is a high level of evidence that routine episiotomy versus restrictive episiotomy does not improve maternal outcomes in the short or long term.

More than 5 years have passed since the publication of this Clinical Practice Guideline, so its validity has not been reviewed

Summary of Evidence

Restrictive episiotomy versus routine episiotomy increases the number of women with intact perineum and the number who resume sexual relations after one month. It also reduces the need for perineal repair and suturing and the number of women with pain on discharge (141).	1+
There is a high level of evidence that routine episiotomy versus restrictive episiotomy does not improve maternal outcomes in the short or long term (142; 153).	1+
Excess weight of the baby and mediolateral episiotomy are independent risk factors for sphincter damage, although it should be noted that actually only 22% of mediolateral episiotomies were performed correctly during the study. Episiotomy towards the midline is associated with a higher number of anal sphincter injuries (154).	3
In women with severe perineal trauma in previous deliveries, the incidence of recurrence of severe perineal trauma is similar to that of any other woman. There is no evidence on the effectiveness of episiotomy after births with third- or fourth-degree injuries (155-157).	3

Recommendations

A	Routine episiotomy should not be performed in spontaneous labour.
√	Episiotomy should be performed if there is a clinical need, such as an instrumental labour or suspected fetal compromise.
√	Before episiotomy an effective analgesia should be used, except in an emergency due to acute fetal compromise.
D	When episiotomy is performed, the recommended technique is mediolateral episiotomy, starting at the posterior commissure of the labia minora and usually moving towards the right side. The episiotomy should be at an angle of 45-60 degrees from the vertical
√	Episiotomy should not be performed routinely during a vaginal birth in women with third- or fourth-degree tears from previous births.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

6.8. Suturing Method and Materials for Perineal Repair

6.8.1. Suturing Method for Perineal Repair

- How effective is the suturing of first- and second-degree perineal tears?
- What is the most effective suturing technique for episiotomy and/or first- and second-degree perineal tears?

Millions of women throughout the world undergo perineal suturing after childbirth. Most of these women suffer perineal pain during puerperium, and up to 20% continue to have problems such as superficial dyspareunia in the long term. The maternal morbidity associated with perineal repair may have a significant impact on the mother's general health and cause her major discomfort and distress. This in turn may affect the mother's ability to care for her baby and other members of her family.

Conventionally, the vagina is sutured with continuous closed stitches and the perineal muscles and skin are repaired using approximately three to four individual stitches, which must be tied off separately to prevent them from coming loose. For over 70 years researchers have suggested that the "continuous suture without closure method" is superior to "traditional interrupted methods".

Scientific Evidence

The NICE guideline (10) assesses "perineal repair" and considers approach, analgesia, suturing method and suturing material used in perineal repair.

Concerning the **approach to repair**, the NICE guideline (10) found two studies. The first is an RCT (158) with LE 1+ in which suturing of first- or second-degree tears is compared with no suturing. The second article included is a qualitative study (159), based on unstructured interviews and with LE 3, which analyses the experience of women who underwent perineal repair, both during and immediately after repair.

In the first RCT (158), 33 women giving birth for the first time were included in the continuous subcutaneous suturing group, and 41 in the group with no suturing.

The results assessed did not show any differences between the groups in terms of the degree of postpartum pain measured using the McGill pain questionnaire and the VAS. However, closer wound edges were observed in the group of women receiving suturing for first- or second-degree perineal trauma, with better healing of the wound in the sixth week (differences of average scores on REEDA scale): 0 [CI 95%, 1.0001 to 0.0003], p=0.003. RCT 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The second study (159) was a small study (n=6) consisting of unstructured in-depth interviews with women, aiming to explore their experiences with perineal trauma during repair and during the immediate postnatal period. Analysis of the results, using snowball sampling, showed the significance of severity and the scale of the negative experiences of the care received. It highlighted the importance of interpersonal relationships between women and those caring for them, reflected in four emerging topics: communication between the woman and staff, adequate pain relief during suturing, a feeling of being "stapled" and a feeling of going through an unavoidable process.

Qualitative study
3

Postnatally, the women's feelings revolved around the idea of trauma and negative emotions, their severity (anger, discomfort, frustration), concern about the staff's skills and lack of care when there were problems with perineal healing.

With respect to the **repair method** used, the NICE guideline (10) found an SR (160) (including four RCTs with LE 1+) and another RCT with LE 1+ (161) which compare the effects of *continuous intradermal suturing versus transcutaneous suturing with individual stitches* to repair the perineum. It also includes two other RCTs (162;163) and a follow-up study for one of them (164), which compare *two-layer repair* (leaving the skin unsutured) with *three-layer repair*:

The results show a high level of evidence (three RCTs) favouring continuous intradermal suturing when compared with transcutaneous suturing with interrupted stitches, as it is associated with less pain in the short term (10 days) (160): OR 0.68 [CI 95%, 0.53 to 0.86] and discomfort in the short term (10 days) (161): OR 0.58 [CI 95%, 0.46 to 0.74] and a higher level of maternal satisfaction at three and twelve months: OR 1.64 [CI 95%, 1.28 to 2.11] and OR 1.68 [CI 95%, 1.27 to 2.21] respectively. A higher level of "returning to normal" after three months was also observed: OR 1.55 [CI 95%, 1.26 to 1.92] (161) in women with continuous intradermal suturing.

SS-MA of RCTs and RCT
1+

Two-layer versus three-layer suturing does not show greater wound dehiscence: RR 1.27 [CI 95%, 0.56 to 2.85]. However, it does present greater opening of the wound (edges more than 0.5 cm apart) on the tenth day: 26% vs 5%, p<0.00001 (162), RR 4.96 [CI 95%, 3.17 to 7.76] (163). However, this difference in frequency of wound opening was not statistically significant after 14 days: 21% vs 17%, RR 1.25 [CI 95%, 0.94 to 1.67] (163).

RCT
1+

Women receiving two-layer suturing reported a lower incidence of the following: overly taut sutures: RR 0.77 [CI 95%, 0.62 to 0.96] (162); removal of sutures: 3% vs 8% p<0.0001; and dyspareunia at 3 months: RR 0.80 [CI 95%, 0.65 to 0.99] (162), RR 0.61 [CI 95%, 0.43 to 0.87] (163). Additionally, the sensation of "feeling normal in the perineal area" is higher in this group of women: RR 0.75 [CI 95%, 0.61 to 0.91] (164).

RCT
1+

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One of the studies (163) also found differences in connection with perineal pain and analgesia. Women with two-layer repair had less pain than those with three-layer repair: 57% vs 65%, RR 0.87 [CI 95%, 0.78 to 0.97] and a lower level of inflammation or haematoma: 7% vs 14%, RR 0.50 [CI 95%, 0.33 to 0.77]. There was also less use of analgesics: 34% vs 49%, RR 0.71 [CI 95%, 0.60 to 0.83]. However, it is stated that the differences found in short-term pain outcomes may have been due to the use of catgut for the perineal repairs in most women, instead of an absorbable synthetic suture material.

RCT
1+

Update (2006 to June 2008)

The search found a total of 11 references, of which three were ultimately selected which met the inclusion criteria: a review carried out by Cochrane (165), a French review (166) and a recently-published RCT (167).

The first of the reviews (165) aims to assess the effects of continuous sutures versus absorbable interrupted sutures for repair of episiotomy and second-degree perineal tears after childbirth. This is a translation and update of the review (160) included in the NICE guideline (10) and includes seven studies conducted in four countries, involving 3,822 women. The trials were heterogeneous in terms of the skill and training of the surgeons.

Meta-analysis demonstrated that continuous suturing techniques to close the perineum, versus any of the *interrupted suturing techniques* (all layers or perineal skin only), continues to be associated with less pain up to 10 days after birth (six RCTs involving 3,527 women): RR 0.70 [CI 95%, 0.64 to 0.76].

SR/MA of RCTs
1+

Subgroup analysis showed that there is a greater reduction in pain when *continuous suturing of all layers is used, versus interrupted stitches* to repair the skin (four RCTs involving 2,459 women): RR 0.65 [CI 95%, 0.60 to 0.71] and a reduction in the use of analgesia (four RCTs with 2,821 women): RR 0.70 [CI 95%, 0.58 to 0.84]. Less dyspareunia was observed in the participants in groups receiving continuous suturing of all layers (five RCTs with 2,149 women): RR 0.83 [CI 95%, 0.70 to 0.98]. There was also less need for stitches in the continuous suturing groups than interrupted suturing groups (all layers) (three RCTs involving 2,650 women): RR 0.54 [CI 95%, 0.45 to 0.65], but no significant difference was observed in the need to re-suture the wounds or in pain in the long term.

SR/MA of RCTs
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The second of the reviews (166) included articles comparing different suturing techniques for episiotomy repair, all already included in the previous SR (165). Thus it was concluded that continuous suturing is preferable to interrupted suturing, as it significantly reduces pain and the risk of dehiscence as well as leading to higher levels of satisfaction amongst women, and that interrupted suturing can increase the rate of dyspareunia at 3 months. SR of RCTs 1+

Finally, the RCT (167) selected aims to compare continuous suturing with interrupted suturing, both without perineal shaving, in 395 women giving birth for the first time, with full-term vaginal delivery, allocated at random to two groups.

The results of the trial showed that there are no significant differences between interrupted and continuous suturing techniques, and yields the same results for pain: RR 0.90 [CI 95%, 0.68 to 1.18]; need for oral analgesia: RR 1.04 [CI 95%, 0.59 to 1.87]; satisfaction: RR 0.99 [CI 95%, 0.91 to 1.08]; number of re-sutures: RR 0.99 [CI 95%, 0.25 to 3.92]; and frequency of dyspareunia during the first episode of intercourse and after 6 months: RR 1.13 [CI 95%, 0.96 to 1.33] and RR 0.81 [CI 95%, 0.58 to 1.12] respectively. However, continuous suturing is more cost-effective, as it is faster: time needed for repair: 15 minutes for continuous suturing vs 17 minutes for interrupted suturing, p=0.03, and fewer materials are required: one packet vs two packets, p<0.01. RCT 1+

The differences found in the NICE guideline (10), the Cochrane review and the new RCT included after the update are all in favour of continuous versus interrupted suturing.

Summary of Evidence

Suturing first- and second-degree tears is associated with better healing in the sixth week (158).	1+
Continuous suturing to repair the perineal muscles is associated with less pain and discomfort in the short term (160;162) and a higher level of maternal satisfaction after 3 months (161).	1+
Women receiving two-layer repair, versus those receiving three-layer repair, do not present greater wound dehiscence. However, an open wound on the tenth day is more common in two-layer repairs, although this difference disappears at 14 days. These women present less dyspareunia, less excessive tautness and removal of sutures, a higher frequency of "feeling normal in the perineal area", less pain and a lower level of inflammation or haematoma. They also show less use of analgesics (162-164).	1+

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Continuous suturing versus interrupted suturing is associated with less pain in the short term. If suturing is continuous for all layers (vagina, perineal muscles and skin), pain reduction is greater than with continuous suturing in the perineal skin only (165). However, a recent trial did not find any significant differences between interrupted and continuous suturing in terms of pain, need for oral analgesia, satisfaction, number of re-sutures or frequency of dyspareunia (167).	1+

Recommendations

A	First-degree tears should be sutured in order to improve healing, unless the edges of the skin are close together.
A	Second-degree perineal tears should be repaired using continuous suturing.
A	If the edges of the skin are close together after muscle suturing of a second-degree tear, there is no need to suture the skin. If the skin needs to be closed, continuous intradermal suturing should be used.

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6.8.2. Suturing Materials for Perineal Repair

- What is the most effective suturing technique for episiotomy and/or first- and second-degree perineal tears?
- Which synthetic material is most suitable for perineal repair?

The type of suturing material used for perineal repair after childbirth can have an effect on the level of pain and superficial dyspareunia experienced by women, in both the short and the long term.

Scientific Evidence

NICE (10) addresses the question of perineal repair. It includes a total of four studies with LE 1+: one RS (168), two RCTs (169;170), comparing the effects of absorbable synthetic suturing material now withdrawn from the market with those of catgut, an absorbable non-synthetic material made from collagen, and a final RCT (161) conducted in the UK that compares rapidly-absorbed synthetic suturing material with standard synthetic suturing material.

The most recent SR (168) compared absorbable *synthetic sutures (polyglycolic acid, Dexon®, and polyglactin, Vicryl®) with simple or chromic catgut, absorbable non-synthetic sutures* in perineal repair, analysing the duration of pain in the short and long term. The review included 8 studies, involving a total of 3,642 women. In each of the eight studies the suturing technique was identical for both groups in the study, but each study used different suturing techniques.

The women in the absorbable synthetic material group had lower levels of pain in the short term than those in the other group: first three days (8 studies): OR 0.62 [CI 95%, 0.54 to 0.71]; 4 10 days (3 studies): OR 0.71 [CI 95%, 0.58 to 0.87]. They also had less need for analgesia (5 studies): OR 0.63 [CI 95%, 0.52 to 0.77]; less suture dehiscence at 10 days (5 studies): OR 0.45 [CI 95% 0.29 to 0.70]; and less need for resuturing at 3 months (4 studies): OR 0.26 [CI 95%, 0.10 to 0.66]. Meanwhile, removal of suturing material at 3 months was more frequent in the absorbable synthetic material group (2 trials): OR 2.81 [CI 95%, 1.56 to 2.58]. With respect to pain in the long term there were no differences between the groups (2 trials): OR 0.81 [CI 95%, 0.61 to 1.08].

SR/MA of RCTs
1+

The 2002 Australian study (169) drew a comparison between *suturing using polyglactin* (Vicryl®) (n=194) and *suturing with chromic catgut* (n=197).

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No significant differences were found between the two groups in terms of short-term pain, although there was a tendency toward less pain in women with polyglactin suturing: first day: OR 0.64 [CI 95%, 0.39 to 1.06]; at 3 days: OR 0.70 [CI 95%, 0.46 to 1.08]. Equally, no significant difference was found in terms of pain in the long term (6 weeks, 3 months or 6 months): OR 2.61 [CI 95%, 0.59 to 12.41]. RCT 1+

The 2004 study from the USA (170) also compared *chromic catgut with polyglactin* (Vicryl®) in 910 women, and observed the level of pain at perineal level (vaginal pain) and uterine level.

No differences were found between the groups with respect to vaginal pain at 24 48 hours, or at 10 14 days or 6 8 weeks. The women in the polyglactin suture group had less moderate/severe perineal pain at 24 48 hours and at 6 8 weeks (p=0.006); there were no differences for mild or no pain at 24 48 hours, 10 14 days or 6 8 months. No explanation was found for these differences in pain. RCT 1+

The last of the RCTs (160) included in the NICE guideline (10) is the only one that compares *rapidly-absorbed synthetic suturing material (Vicryl®) (n=772) with standard synthetic suturing material (n=770)* in women with second-degree tears or episiotomies.

No significant differences were observed between the two groups in the prevalence of women suffering pain at 10 days: OR 0.84 [CI 95%, 0.68 to 1.04]. However, the number of women with persistent perineal pain between the first 24 hours and 10 days: OR 0.55 [CI 95%, 0.36 to 0.83] and with pain on walking: OR 0.74 [CI 95%, 0.56 to 0.97] was significantly lower in the group of women with rapidly-absorbed sutures. Additionally, the need to remove suturing material at 10 days: 0.38 [CI 95%, 0.23 to 0.64] and at 3 months: OR 0.26 [CI 95%, 0.18 to 0.37] was also lower in this group. However, the number of women with dehiscence on the tenth day after repair was higher: OR: 1.83 [CI 95%, 1.14 to 2.92]. RCT 1+

Update (2006 to June 2008)

Only one SR (166) which met the inclusion criteria was selected in the update. This is a review carried out in France, including some of the studies already included in the NICE guideline (10).

The SR (166) addresses various aspects of episiotomy: general recommendations, studies that compare suturing materials and studies that compare suturing techniques. The results referred to in the section on suturing materials are reflected in this section.

Two comparisons are made in the SR (166): firstly, studies that analyse absorbable suturing material versus non-absorbable material, and secondly studies that compare different absorbable suturing materials.

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Absorbable suturing material vs non-absorbable material (absorbable synthetic Dexon® vs silk or nylon).

One SR that included a total of six studies (171) showed that women with Dexon® suturing had less pain in the short term than those in the silk suturing group: OR 0.72 [CI 95%, 0.57 to 0.92] and those in the nylon suturing group: OR 0.39 [CI 95%, 0.28 to 0.55]. Long-term pain and dyspareunia were not reported on.

SR/MA of RCTs
1+

Different absorbable suturing materials

**Catgut (animal) vs Dexon® or Vicryl® (synthetic)*:

Comparison analysed in the SR (160) included in the NICE guideline (10) and mentioned above.

**Standard Vicryl® vs rapid Vicryl®*:

Comparison analysed in another SR (161), also included in the NICE guideline (10) and mentioned above.

**Biological adhesive (Enbucrilate Histoacryl®) vs Dexon® or Vicryl®:*

The evidence was gathered in a quasi-randomised comparative study, which included only 62 women. It was observed that perineal pain resolved quickly: 18 days vs 25 days; p<0.01, and that sexual relations were resumed earlier: 34 days vs 52 days, p<0.001, among women in whom biological adhesive was used, versus those with intradermal suturing using more than one absorbable synthetic material.

RCT
1+

There is a high level of evidence in favour of absorbable sutures (Dexon®) versus non-absorbable sutures (silk, nylon), as these generate less immediate pain. Additionally, better pain-related outcomes are observed with synthetic asborbable materials (Dexon®) than with natural materials (catgut). Rapidly-absorbed synthetic sutures give better pain-related outcomes in the short term than standard synthetic materials, but have higher levels of dehiscence.

Summary of Evidence

The women in the synthetic absorbable suturing group had less pain in the short term (first 3 days and 4 10 days) than those in the group in which catgut was used, and there was less need for analgesia, less suturing dehiscence at 10 days and less need for re-suturing at 3 months. However, removal of suturing material at 3 months was more frequent in the group with absorbable synthetic material, and with respect to pain in the long term there were no statistically significant differences (168-170).	1+

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When rapidly-absorbed suturing material is used, versus non-rapidly-absorbed synthetic material, persistent perineal pain and pain on walking were significantly lower between the first 24 hours and 10 days. This group also had less need for removal of suturing material at 10 days and 3 months. However, the number of women with dehiscence on the tenth day after repair was higher in the group with rapidly-absorbed material (161).	1+
Better pain-related outcomes in the short term are demonstrated with absorbable synthetic suturing material (Dexon®) than with silk suturing (non-absorbable) or nylon suturing (166).	1+

Recommendations

A	A synthetic material with normal absorption should be used to suture perineal wounds.
√	A rectal examination must be performed after the repair has been completed, to ensure that no suturing material has accidentally been inserted through the rectal mucosa.

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6.9. Kristeller Manoeuvre

- How effective is the Kristeller manoeuvre?

Of the manoeuvres used in the second stage of labour, the Kristeller manoeuvre is one of the most controversial. It is not known how prevalent its use is. It must be ascertained whether there is any current justification for its use.

Scientific Evidence

The NICE guideline (10) does not address this issue. In a document entitled Care in Normal Birth: a practical guide (4) published in 1996, the WHO makes a type C recommendation on fundal pressure during childbirth (the Kristeller manoeuvre). It specifies that there is no clear evidence to encourage its use, and that it should be used with care until new studies shed more light on the subject.

Update (to June 2008)

The new search found a total of 17 references, although for methodological reasons only one was selected.

While this guideline was being compiled, a Cochrane SR published in 2009 (173) was also identified and selected. This assesses whether uterine fundal pressure, or the Kristeller manoeuvre, is effective in achieving spontaneous delivery and preventing a prolonged second stage of labour or an instrumental delivery. There are also potential maternal and fetal adverse effects connected with the Kristeller manoeuvre.

The recent review (173) includes only the trial selected in our first bibliographic search as the basis of evidence. This is an RCT (174) conducted in London which includes 500 women giving birth for the first time and receiving epidural anaesthesia, to determine whether an inflatable obstetric belt, used to apply pressure to the uterine fundus during contractions, reduces instrumental delivery rates when used in the second stage of labour.

42.7% of the 260 women in the group with belts had a spontaneous delivery, versus 39.2% of the 240 in the control group, although this difference was not significant; p=0.423. The instrumental delivery rate was similar in the two groups: RR 0.94 [CI 95%, 0.80 to 1.11], without significant differences. The caesarean section rate was also similar. The perineum remained intact in more women in the intervention group: RR 1.73 [CI 95%, 1.07 to 2.77], and the anal sphincter tear rate was also more favourable: RR 15.69 [CI 95%, 2.10 to 117.02].

SR of RCT
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The review concludes that the Kristeller manoeuvre, performed using an inflatable belt, does not increase the rate of spontaneous vaginal deliveries or reduce the rate of instrumental deliveries, that the evidence of its effect on the perineum is not conclusive and that the evidence on the safety of the neonate is insufficient.

In addition, a recent RCT from 2009 (175) was also selected. This RCT was not included in the SR of the same year, and was identified via the search strategy's update alerts. The study aimed to determine the effect of performing the Kristeller manoeuvre on shortening the second stage of labour and on fetal outcomes. 197 women at 37 42 weeks' gestation who had not received any type of neuraxial analgesia were included.

The results did not show any significant differences in the average duration of the second stage of labour between the two groups, or in secondary outcome measurements (pH of the umbilical artery, HCO_3-, base excess, pO_2, pCO_2 values and instrumental delivery rate, serious maternal morbidity and mortality, neonatal trauma, admission to a neonatal intensive care unit and neonatal death), except for pO2 values, which were lower in the intervention group, and pCO2, which was higher. However, values still remained within normal ranges and there were no neonates with an Apgar score <7 in either group. The conclusion drawn is that the Kristeller manoeuvre is ineffective in shortening the second stage of labour. RCT 1+

There is no evidence that performing the Kristeller manoeuvre during the second stage of labour is beneficial. Also, there is some evidence, though limited, that the manoeuvre is a risk factor for maternal and fetal morbidity, so it is thought that during the second stage of labour its use should be limited to research protocols designed to assess its effectiveness and safety for the mother and foetus.

Summary of Evidence

The Kristeller manoeuvre, performed using an inflatable belt, does not increase the rate of spontaneous vaginal deliveries or reduce the rate of instrumental deliveries (173).	1+
The Kristeller manoeuvre is ineffective in reducing the duration of the second stage of labour (175).	1+

Recommendations

A	The Kristeller manoeuvre is not recommended.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

7. Third stage of labour

7.1. Duration of the third stage of labour

- What is the duration of the third stage of labour?

The third stage of labour is that which occurs between birth and placental expulsion. The chief complication during this stage is PPH, which continues to be a cause of primary concern (176) given that it is responsible for a fourth of maternal deaths in the world (177). The degree of blood loss is associated with the speed with which the placenta separates from the uterus and with the effectiveness of uterine contraction.

The duration of the third stage of labour is important given that prevalence of PPH increases in prolonged deliveries (178; 179), although there are no generally accepted criteria as to the optimum duration of the third stage.

Scientific Evidence

The NICE guideline (10) answers this question for both spontaneous and actively managed deliveries. The information comes from two observational studies, one cohort study (180) with LE=2+ and another cross-sectional study (181) with LE=3. Data were also extracted for the duration of the third stage of labour (delivery) in women with physiological management, from three studies with LE=3, included in an SR (182).

The cohort study analysed the possible association between the duration of the third stage of labour with *active management* and the risk of PPH. The results revealed that from 10 minutes duration of the third stage onwards, the risk of PPH was significant, increasing progressively the longer this stage lasted. — Cohort study 2+

According to the cross-sectional study (181) the incidence of PPH and other complications remained constant in deliveries under 30 minutes and progressively increased to reach the maximum in 75 minutes. This increased incidence of PPH and complications was observed both in cases of spontaneous delivery, and those with manual removal of the placenta. — Cross-sectional study 3

The SR (182), which compares physiological management with active management, shows the following results for average duration (and standard deviation) of the third stage of labour in women in the physiological management group in three studies (LE=1+) conducted in: Saudi Arabia WMD =14 minutes (DE=2.5 minutes), Dublin WMD =11.6 minutes (DE=8.4 min) and United Kingdom WMD =20.8 minutes (DE=20.5 minutes). The women in the group in which active management of the delivery was performed showed the following results, in the same studies: Saudi Arabia WMD =4 minutes (DE=2.5 minutes), Dublin WMD =11.26 minutes (DE=19.62 min) and United Kingdom WMD =11.84 minutes (DE=21.4 minutes). — SR 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In summary, it can be stated that the duration of spontaneous delivery is below 60 minutes in 95% of women. When active management of delivery is performed, a duration of over 30 minutes is associated with increased incidence of PPH.

Update (2006 to July 2008)

The new update search carried out found 25 references, none of which have been incorporated. Fifteen of the references were from the Cochrane Library database, three from DARE and HTA and seven from Medline. None complied with the established inclusion criteria.

Therefore the recommendation has been established by adopting that of the NICE guideline and by consensus of the GCG.

Summary of Evidence

From 10 minutes of actively-managed third stage of labour onwards, the risk of postpartum haemorrhage progressively increases the longer its duration is (180).	2+
A third-stage duration of more than 30 minutes following active management of delivery is associated with an increase in the incidence of postpartum haemorrhage (181).	3
The spontaneous third stage of labour lasts for less than 60 minutes in 95% of women (182).	1+

Recommendations

D	The duration of the third stage of labour is considered to be dealyed if it is not complete within 30 minutes after birth of the neonate with active management, or within 60 minutes with a spontaneous third stage.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

7.2. Managing the Third Stage of Labour

- Does the management method of the third stage influence outcomes?

There are two contradictory approaches for management of the third stage of labour: active management and physiological or expectant management.

Expectant management is a non-interventionist approach, still widely used (183;184). The factors which contribute to choosing this method are the desire for a more natural birth experience, the belief that active management is unnecessary in low-risk women and the desire to avoid the effects associated with the use of normal uterotonics (185). Active management generally involves the doctor or midwife and the main described advantage associated with this type of management is a reduction of PPH. However, there is controversy over the advantages and disadvantages of early clamping and cutting of the umbilical cord.

Scientific Evidence

To respond to this question, the NICE guideline (10) uses an SR (182) published in 2000, which includes five studies of reasonably good quality. Only studies which defined active management as the use of uterotonics (e.g. oxytocin, prostaglandins, alkaloid derivatives of ergot of rye), use of early clamping of the umbilical cord and controlled cord traction were included. The SR contains a meta-analysis for the group of all women (n= 6477) and another for the subgroup of only those women with a low risk of postpartum bleeding. The results did not show statistically significant differences between the two groups.

The outcome variables used were 500 ml or more blood loss, severe PPH, with 1000 ml or more blood loss, average blood loss, maternal haemoglobin less than 9 g/dl at 24-48 hours postpartum, the need for blood transfusions and administration of iron during puerperium.

Active management of delivery reduced the risk of PPH: RR 0.38 [95% CI 0.32 to 0.46] and severe PPH: RR 0.33 [95% CI 0.21 to 0.51] in four trials with 6284 women. — SR/MA of RCTs 1+

It also reduced the need to administer oxytocic agents: RR 0.20 [95% CI 0.17 to 0.25] in five trials with 6477 women and shortened the duration of the third stage of labour, reducing the risk of it lasting over 20 minutes: RR 0.15 [95% CI 0.12 to 0.19] in three trials with 4637 women and of it lasting over 40 minutes: RR 0.18 [95% CI 0.14 to 0.24] in three trials with 4636 women.

No differences were found in the manual removal of placenta rate. However, an increase was observed in maternal complications such as diastolic pressure greater than 100 mm Hg, nausea, vomiting and cephalalgia. — SR/MA of RCTs 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

No evidence was observed for other complications such as increased pain during the third stage, secondary PPH, readmissions due to bleeding, need for antibiotics or maternal fatigue at six weeks. No differences were found in neonatal outcomes.

Update (2006 to January 2009)

The new literature search found 15 references, but none were included as they were not pertinent to the question or the inclusion criteria (see Avaliat report (8)).

The GCG draws up the recommendation in a similar manner to NICE (10) but taking into consideration that compliance with the recommendations of the International Confederation of Midwives (ICM) and the International Federation of Gynaecology and Obstetrics (FIGO), which decided not to include early clamping and cutting in the active delivery management protocol (186).

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Summary of Evidence

There is a good level of evidence that active management of the third phase of labour reduces the risk of PPH, reduces the need to administer oxytocic agents and shortens the duration of the third stage of labour (182).	1+
Although there is good evidence that active management of labour increases some maternal complications, such as diastolic pressure above 100 mm Hg, nausea, vomiting and cephalalgia, no other complications were observed, such as increased pain during the third stage, secondary PPH, readmissions due to bleeding, need for antibiotics or maternal fatigue at six weeks. No differences were found in neonatal outcomes (182).	1+

Recommendations

A	Active management of delivery is recommended.
√	Women must be informed (preferably during pregnancy) that active management of the third stage of labour decreases its duration and reduces the risk of postpartum haemorrhage and the need for therapeutic oxytocin.
√	Spontaneous or physiological delivery is an option if the patient requests it.

7.3. Use of Uterotonics

- Which uterotonic is most suitable for the active management of the third stage? (oxytocin, ergotinic, prostaglandins and carbetocin)

Uterotonics were originally introduced to treat PPH. Routine prophylactic administration of an oxytocic agent forms part of active delivery management. Uterotonic agents can be divided into three groups: rye ergot alkaloids, oxytocin and prostaglandins and finally carbetocin was also introduced, an equivalent to oxytocin. Their mechanisms for preventing PPH are different, as is their effectiveness and collateral effects. It is necessary to be aware of the effectiveness and safety of the prophylactic use of the different uterotonics.

Scientific Evidence

To respond to this question, the NICE guideline (10) uses various high-quality SRs which cover different comparisons between uterotonics: On the one hand the SRs by Elbourne and McDonal (187;188) and six studies, (189-194) of sufficiently high quality and similar design which assessed umbilical injection of oxytocin. Two of these studies were RCTs (191;192).

Elbourne's 2005 SR (187) included seven studies and assessed the routine use of oxytocin in the third stage compared to not using uterotonics and ergotinic alkaloids. Another SR (188) published in 2004 included six studies and 9332 women [LE=1+]. In the latter analysis subgroups were created according to oxytocin dose. A meta-analysis was carried out in accordance with two comparisons: umbilical oxytocin compared with intravenous oxytocin and umbilical oxytocin compared with a placebo.

NICE (10) also identified two systematic reviews from 2005 and 2006 (195;196) and four studies (197-200) in which the routine administration of prostaglandins was compared with other uterotonics (ergometrine and/or oxytocin) in the third stage of labour. The systematic reviews were of high quality and all the studies had a good level of quality and homogeneity, which made it possible to carry out a new meta-analysis including all of the studies [LE=1+].

When the *use of oxytocin versus non-use* is compared and all of the studies are analysed, the results show that with oxytocin there is less PPH >500 ml: RR 0.50 [CI 95% 0.43 to 0.59]) in six studies with 3193 women; less PPH > 1000 ml: RR 0.61 [CI 95% 0.44 to 0.87] in four studies with 2243 women and less therapeutic use of uterotonics: RR 0.50 [CI 95% 0.39 to 0.64] in five studies with 2327 women.

SR/MA of RCTs 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

When the randomised studies with oxytocin are included there is less PPH (loss > 500ml: RR 0.61 [CI 95% 0.51 to 0.72]) in four studies with 2213 women but there were no differences in the reduction of losses due to severe PPH (>1000 ml).

The studies that compared the exclusive use of oxytocin (without any other component of active delivery management) showed that there was less HPP >500 ml : RR 0.50 [CI 95% 0.42 to 0.58] in five studies with 2253 women and less severe PPH (>1000 ml): RR 0.61 [CI 95% 0.44 to 0.87] in four studies with 2243 women and less therapeutic need for uterotonics: RR 0.64 [CI 95% 0.47 to 0.87] in three studies with 1273 women. SR/MA of RCTs 1+

When the *use of oxytocin versus ergotinics* is compared, NICE (10) analyses all the studies and does not observe different outcomes in terms of reduction of PPH >500ml: RR 0.90 [CI 95% 0.70 to 1.16] in five studies with 2719 women nor in the reduction of PPH >1000 ml: RR 0.99 [CI 95% 0.56 to 1.74] in three studies with 1746 women. SR/MA of RCTs 1+

A significant reduction in manual placenta removal was observed in the oxytocin group: RR 0.57 [CI 95% 0.41 to 0.79] in 3 studies with 1746 women.

When all the studies are included and the *use of oxytocin + ergotinics versus ergotinics* is compared, no differences are found in the reduction of PPH, duration of the third stage of labour (>20 min) or the rate of manual placenta removal. SR/MA of RCTs 1+

When only the randomised studies are analysed, differences are found in the reduction of PPH > 500ml in favour of the use of oxytocin +ergotinics: RR 0.44 [CI 95% 0.20 to 0.94] in 2 studies with 1161 women, but there is no evidence of differences in the duration of the third stage (>20 min).

The next analysis compared *oxytocin +ergotinics/oxytocic agents*. When all the studies are included, differences are observed in favour of the combination oxytocin + ergotinics for reducing PPH > 500ml: RR 0.82 [CI 95% 0.71 to 0.95] in 6 studies with 9332 women and for the need for therapeutic use of uterotonics: RR 0.83 [CI 95% 0.72 to 0.96]) in 3 studies with 5465 women. No other differences are observed. SR/MA of RCTs 1+

When the analysis of subgroups by oxytocin dose (5 or 10 UI) is carried out, for PPH defined as loss > 500 ml, both doses showed a significant reduction when using ergometrine-oxytocin compared to the use of oxytocin, although the effect was greater when compared with a dose of 5 IU or, in other words: the use of 10 IU of oxytocin alone shows an effect that is more similar to that of ergotinic alkaloids +oxytocin in reducing PPH than the use of 5 IU of oxytocin alone. With regard to severe PPH (losses >1000 ml) none of the doses showed any significant differences. SR/MA of RCTs 1+

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However, in the combined ergometrinics + oxytocin group evidence can be found of greater maternal complications, such as raised diastolic pressure: RR 2.40 [CI 95% 1.58 to 3.64] in 4 studies with 7486 women, vomiting: RR 4.92 [CI 95% 4.03 to 6,00]) in 3 studies with 5458 women, nausea; RR 4.07 [CI 95% 3.43 to 4.84] in 3 studies with 5458 women and vomiting and/or nausea): RR 5.71 [CI 95% 4.97 to 6.57]) in 4 studies with 7486 women. SR/MA of RCTs 1+

Comparing use of *prostaglandins versus other uterotonics* shows that the use of prostaglandins was less effective in reducing postpartum haemorrhage: PPH (loss > 500 ml) (21 studies): OR 1.49 [CI 95% 1.39 to 1.59], and severe PPH (loss > 1000 ml, 16 studies) OR 1.31 [CI 95% 1.14 to 1.50]. Additionally, the group with prostaglandins had more adverse effects: vomiting (19 studies): OR 1.27 [CI 95% 1.04 to 1.55], diarrhoea (15 studies): OR 1.97 [CI 95% 1.44 to 2.70], fever (12 studies); OR 6.67 [CI 95% 5.57 to 7.99], shivering (19 studies); OR 3.51 [CI 95% 3.25 to 3.80]. SR/MA of RCTs 1+

Update (2005 to May 2008)

In the search carried out to update this question 35 references were selected. After reading the abstracts five were chosen to read the full text. Four Cochrane reviews (201-204) were included, having LE=1+ and complying with inclusion criteria, and data was extracted from three SRs as one of them (202) presented ergotinic results obtained versus a placebo instead of versus oxytocin, which is the comparison intervention for this question.

The 2008 Cochrane review (201); (46 studies with 42621 women) evaluated the effect of the use of prostaglandins in delivery.

When *misoprostol versus uterotonics* is compared 25 studies are analysed (16 oral, 5 rectal and 4 sublingual). SR-MA of RCTs 1+

- The use of oral misoprostol increases the risk of severe PPH (16 studies; n=29,042; RR 1.31; CI 95% 1.16 to 1.59).
- Rectal misoprostol was similar to uterotonics with respect to serious PPH.
- *Misoprostol combined with oxytocin* was more effective than the placebo and oxytocin in reducing PPH and serious PPH.
- Oral misoprostol (600 µg) was associated with high levels of nausea, vomiting, diarrhoea, shivering and pyrexia compared to the placebo and conventional uterotonics. The secondary effects were lesser with a dose of 400 µg and with rectal misoprostol.

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- When the use of *prostaglandins versus uterotonics* is compared (10 studies) it is shown that with prostaglandins there were lower levels of blood loss and a shorter delivery duration than with uterotonics, but they also had more side effects such as vomiting, abdominal pain and diarrhoea.

Mousa's SR, 2008 (203) with 3 studies and 462 women, assessed the effectiveness and safety of radiological, surgical and pharmacological interventions used for PPH. Amongst the latter is an analysis of the comparison between *misoprostol and oxytocin/ergometrinics* (1 study):

Compared to the combination of syntometrine (IM) + infusion of oxytocin rectal misoprostol had slightly better results in stopping haemorrhaging at 20 minutes: RR 0.18 [CI 95% 0.04 to 0.76], n=64 and reduction of use of additional uterotonics: RR 0.1 [CI 95% 0.04 to 0.76] n= 64. With respect to the side effects, a significant increase in maternal pyrexia and shivering was observed.

RCT
1+

The SR by Su, 2008 (204) included four studies and 1037 women. It assessed whether carbetocine is as effective as conventional uterotonic agents in reducing PPH. Three studies dealt with caesarean section births and one study was on women with vaginal births (n=152).

The results show that carbetocine reduced the need for uterine massage: RR 0.70 [CI 95% 0.51 to 0.94] and no significant differences were observed in PPH, blood loss, haemoglobin and the use of therapeutic uterotonics. With respect to adverse effects, women who received carbetocine had a lower risk of cephalalgia, nausea and vomiting, although the difference was not statistically significant.

SR/MA of RCTs
1+

In summary, the evidence level is high and consistent, since the studies and systematic reviews included both in the NICE guideline (10) and in the update present an LE=1+ and outcomes along the same lines, since all the interventions analysed achieve lower blood losses than the placebo. With respect to oxytocin, the other uterotonic agents achieved the same or better results for blood loss, but they all displayed a greater incidence of adverse effects, except for carbetocine according to (204), a medication only approved for use in caesarean sections.

The variability in the studies included, in relation to third stage of labour management, means that when drawing up the recommendations the possible benefits and adverse effects of prostaglandins versus the use of oxytocics has been carefully assessed when establishing the recommendations.

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Summary of Evidence

There is high quality evidence that demonstrates that routine use of oxytocin as a uterotonic in active management of delivery reduces the risk of PPH>500 ml and the therapeutic need to use uterotonics. These effects are also observed with the exclusive use of oxytocin (without any other component of active delivery management) (187).	1+
No differences were observed between the use of oxytocin and the use of ergotinics with respect to reducing PPH >500 ml. A reduction in the risk of manual placenta removal was observed in the oxytocin group in comparison with ergotinics (10).	1+
Differences were observed, with greater reduction of PPH >500 ml when oxytocin +ergotinics were used, compared to ergotinics. No differences were found in the duration of the third stage of labour or in the rate of manual placenta removal (10).	1+
It was observed that the combination of oxytocin and ergotinics reduces PPH>500 ml and the need for therapeutic use of uterotonics, when compared with oxytocin (10).	1+
The combination of oxytocin and ergotinics produces an increase in maternal complications such as: raised diastolic pressure, vomiting and nausea. There is no evidence of other complications such as blood loss of over 1000 ml, blood transfusion rate, manual placenta removal, duration of third stage of labour or neonatal outcomes (10).	1+
The use of prostaglandins shows less blood loss and shorter delivery duration when compared with the use of uterotonics, although the prostaglandins had more side effects such as vomiting, abdominal pain and diarrhoea (201).	1+

Recommendations

A	Oxytocin should be used routinely in the third stage of labour.

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7.4. IV Dose of Oxytocin for Actively Managed Delivery

- What is the most appropriate dose of intravenous (IV) oxytocin for the active management of the third stage of labour?

Oxytocin is used as a uterotonic in the active management of the third stage of labour. However, there is a controversy concerning the optimal dose to be used, as clinical practice varies greatly.

Scientific Evidence

The NICE guideline (10) does not answer the question concerning the most suitable dose of intravenous oxytocin in active management of delivery. It is also important to point out that the guideline states that at the time of publication (September 2007), oxytocin was not authorised for this indication, so informed consent had to be requested and documented.

Update (to May 2008)

None of the 23 literature references found in the search were included, and none were selected from a grey literature search either.

Four RCTs were selected since they assessed IV oxytocin versus other treatments or a placebo, although none of these studied the effect of 2-3 IU doses compared to 5-10 UI.

The four studies were high-quality RCTs [LE=1+] conducted in Japan (205), Nigeria (206), USA (207) and Mexico (208). In all of the studies a comparison was made between intravenous oxytocin (at different concentrations) and other oxytocics (ergometrine, methylergometrine) or placebo, to see their effect on reducing postpartum haemorrhaging and other variables such as the duration of the third stage of labour, blood pressure or haemoglobin concentrations.

When the use of 5 IU of IV *oxytocin* (n=229) versus 0.2 mg of IV or drip methylergometrine (n=209), is compared after the third stage or at the end of the second (205), the results indicate that IV oxytocin immediately after the delivery of the neonate's anterior shoulder produced more pronounced reductions in postpartum blood loss than methylergometrine. There were no significant differences in haemoglobin concentrations or blood pressure. RCT 1+

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When the use of 10 IU of IV *oxytocin* (n=256) is compared with 0.5 mg of IM ergometrine (n=254) (206) the results showed a rise in blood pressure of 52.6% in the ergometrine group and 11.3% in the oxytocin group, p=0.001. There was less blood loss in the ergometrine group. The study concluded that in routine obstetric practice the use of oxytocin is preferred, with ergometrine being reserved for women with a risk of PPH due its better results for blood loss. RCT 1+

The use of 20 IU of IV oxytocin (n=39) compared to placebo (saline solution) (n=40) (207) produced a duration of the third stage that was two minutes shorter (ns) in the oxytocin group and lower falls in haemoglobin levels in the oxytocin group (p=0.02). Three cases of PPH occurred in the group with saline solution and one in the oxytocin group. Placenta retention >15 minutes was significantly lower in the oxytocin group. RCT 1+

The study which compared 10 *IU of IV oxytocin* (n=32) with saline solution (n=32) (208) found insignificant results with respect to the outcome variables studied: blood loss was lower in the oxytocin group: 263.7±220.9 ml and placebo: 286.7±230.4 ml (p=0.64). Delivery duration was longer using oxytocin 265.3±383.9 seconds than using placebo 197.1±314.3 seconds (p=0.44) and placenta retention occurred in one case in the oxytocin group and two cases in the placebo group (RR 0.5 CI 95% 0.04 to 5.24). RCT 1+

In summary, the volume of evidence is provided by four RCTs published between 2006 and 2008 and with an LE=1+, with low risk of bias. Although doses are heterogeneous, the evidence is consistent in relation to a reduction of postpartum haemorrhage with IV oxytocin. None of the studies used doses below 5 IU, so it was not possible to assess the results of IV oxytocin 2-3 IU compared to IV oxytocin 5-10 IU.

Summary of Evidence

The evidence is consistent that the use of IV oxytocin reduces the risk of postpartum haemorrhage, but there are no studies assessing the result of IV oxytocin 2-3 IU compared to IV oxytocin 5-10 IU (205-208).	1+

Recommendations

√	10 IU slow IV should be administered as prophylaxis for postpartum haemorrhage.

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8. Care for neonates

8.1. Clamping the umbilical cord

- What is the most suitable time to clamp the umbilical cord?

It is believed that early clamping of the umbilical cord reduces the risk of PPH and neonatal icterus (209). However, some data suggests that there may be benefits if clamping is delayed. The benefits described include a reduction in the probability of fetal-maternal transfusion (210), increase in haemoglobin levels (209) and iron deposits with a reduction in anaemia during infancy (4; 211), better cardiopulmonary adaptation and increase in the duration of breastfeeding (212).

Scientific Evidence (to May 2008)

The NICE guideline (10) that answers this question used an SR (213) and three studies conducted in countries with medium and low income levels (214-216).

The SR, published in 2004, has LE=1+ and includes eight studies, of which four (217-220) were conducted in high-income countries and the other four (221-224) in countries with low or medium income levels. From amongst the first four, there was only one RCT (220). Amongst the seven studies conducted in countries with a medium or low-income level there were five randomised controlled trials and one quasi-randomised.

All the studies compared early clamping of the cord with late clamping and were reasonably homogeneous. However, the description and time of clamping varied enormously. They were all included in a meta-analysis, although analysis and interpretations were carried out according to the income levels of the countries.

In two trials in high-income countries (217;219) it was observed that the haematocrit level 24 hours after birth was significantly higher in neonates with late clamping: WMD 14.19% [CI 95% 11.27% a 17.12%] as it was at 2 to 4 hours: WMD 13.12% [CI 95% 11.21% a 15.03%] in four studies (217-220) and at 120 hours after birth: WMD 10.46% [CI 95% 8.31% a 12.61%] in three studies (217-219). An increase in the proportion of neonates with bilirubin above 15 mg/dl: OR 8.68 [CI 95% 1.49 to 50.48]. RCT 1+

When the studies conducted in countries with low and medium income levels were analysed, the results were favourable to late clamping: the level of haematocrit at 24 hours was higher in this group: WMD 4.56% [CI 95% 3.01% to 6,10%] (214-216). The proportion of neonates with anaemia was reduced significantly: OR 0.14 [CI 95% 0.05 to 0.40] (222;224) and mean infant haemoglobin was higher: WMD 0.96 g/l [CI 95% 0.29 to 1.64 g/l] measured in six studies (215;216;221-224). RCT 1+

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In a study in a country with medium-low income level (214) it was seen that there was a lower frequency of neonatal anaemia at 6 and 24 hours in the late clamping group (haematocrit <45%) and an increase in neonatal polycythaemia (haematocrit >65%) at 6 and 24 hours of birth. RCT 1+

In its conclusions NICE (10) states there is a limited and average level of evidence that shows that in high-income countries late clamping of the cord reduces the incidence of anaemia in neonates, and the main adverse effect is an increased incidence of icterus.

For low-income countries where anaemia in neonates is more prevalent, the high-quality evidence shows that late clamping reduces the incidence of anaemia in neonates. There were no significant outcomes in other variables such as mean cord haemoglobin, mean fetal ferritin, cord haematocrit and blood bilirubin.

For this reason, due to the limitations of the studies in high-income countries and the variability in describing the cord clamping time, they consider that there may be some confusion and that the impact of delaying clamping in countries where anaemia is less prevalent is unknown.

Update (2005 to May 2008)

The literature search found 15 new references, of which four were selected to be read in full, including two systematic reviews (225; 226).

Hutton's meta-analysis (225) analysed 15 studies: eight RCTs and seven non-randomised studies which included 1912 women. Early clamping (n=911) of the umbilical cord versus late clamping (n=1.001) of at least two minutes was compared in births of neonates with gestation periods of 37 weeks or more.

With late clamping the advantages at 2 and 6 months included improved haematological state, measured by haematocrit, iron (ferritin concentration) and iron reserves, with significant reductions in the risk of anaemia. There was a lower risk of anaemia at 24 and 48 hours in neonates with late clamping. SR/MA of RCTs 1+

No significant differences were found between the two groups in terms of the risk of icterus. The risk of polycythaemia was significantly higher in the late clamping group. When the analysis was conducted using high-quality studies only the differences still remained, but the statistical significance was lost.

McDonald's Cochrane SR of 2008 (226) included eleven RCTs with n=2989 women [LE=1+]. All the studies were RCTs so that the review also has LE=1+. It aims to determine the effects of clamping the cord at different times on maternal and neonatal outcomes.

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Maternal ferritin levels were significantly higher in the group with immediate clamping: WMD 9.10 μg/L [CI 95% 7.86 to 10.34; n=107].

No significant differences were observed in other variables such as average PPH blood loss, need for transfusion, use of uterotonics or duration of third stage of labour. SR-MA of RCTs 1+

Neonatal icterus was observed in a lower number of neonates in the group with early clamping and was measured by the need for phototherapy for icterus: RR 0.59 [CI 95% 0.38 to 0.92], 5 studies, n=1762. SR-MA of RCTs 1+

There is a significantly higher neonatal haemoglobin level in the late clamping group: WMD 2.17 g/dL [CI 95% 0.28 to 4.06], 3 studies, n=671. Differences have also been observed in haemoglobin concentration at 24-48 hours, although there was a significant heterogeneity between the different studies. However, from two months onwards the differences were neither statistically or clinically different. SR-MA of RCTs 1+

Fewer neonates were found to have haematocrit values below 45% in the late clamping group both at 6 and at 24-48 hours. No significant differences were observed in other variables such as polycythaemia, Apgar test values, breastfeeding, respiratory problems and admission to NICU. SR-MA of RCTs 1+

In summary, late clamping of the umbilical cord (2 or 3 minutes from birth) was demonstrated not to increase the risk of postpartum haemorrhage. Furthermore, late clamping may be beneficial for neonates as it improves their iron levels, which may have a clinical value in children whose access to good feeding is deficient, although it increases the risk of icterus requiring phototherapy.

The GDG considered the evidence to be of high quality given that both the studies included in NICE (10) and the JAMA meta-analysis, conducted by Hutton et al. (225), have LE=1+ and the Cochrane review includes medium and high quality studies.

When assessing the NICE guideline (10) results, the focus is on the location of the studies, emphasising that it is difficult to extrapolate the data to the general population as some were conducted in low-income countries.

Summary of Evidence

There is high quality evidence indicating that late clamping of the umbilical cord in full-term neonates, at least two minutes after birth, does not increase the risk of postpartum haemorrhaging and improves neonatal iron levels (225; 226).	1+

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Despite the fact that there is an increase in children with polycythaemia amongst those in the late clamping groups, this fact appears to be benign (225).	1+
It was observed that in the group with early clamping there were less neonates with icterus, which was measured by the need for phototherapy (226).	1+

Recommendations

A	Delayed clamping of the umbilical cord is recommended.
B	One suggestion is to clamp the umbilical cord after the second minute or after it stops pulsing.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.2. Skin-to-Skin Contact

- What is the benefit of skin-to-skin contact?

In many cultures babies are placed directly on their mother's bare chest at birth. Historically this was necessary for the baby's survival. In recent times, most children are born in a hospital and are separated from the mother or dressed before being given to her. It has been suggested that this hospital routine may disrupt early interaction between mother and child and have harmful effects on both of them.

Scientific Evidence

For this point, the NICE guideline (10) uses the evidence from the guideline (227) which analyses only the effects of skin-to-skin contact and breastfeeding. The studies included were one SR with 17 low-quality studies (228), two RCTs with LE=1+ (229;230) and one observational study LE=3, (231).

The SR found that early skin-to-skin contact between mother and neonate appears to have some clinical benefit in relation to breastfeeding and crying and has no apparent negative effects in the short or long term. SR -1

The RCT published in 1985 (229) found that early skin-to-skin between mother and child with suction is associated with a longer duration of breastfeeding, ($p<0.001$) and the second RCT of 2005 (230) carries out an analysis adding the data from the Anderson SR (228) and obtains a lower OR value but with a more specific estimate and with statistical meaning: OR 1.89 [CI 95% 1.06 to 3.34] on the benefits for breastfeeding. RCT 1+ MA of RCTs 1+

There is low-quality evidence that finds significant differences in the increase in the duration of breastfeeding to between 1.55 and 3.10 months more ($p<0.001$). Observational study 3

Update (2005 to May 2008)

In the update search four studies were found, two SR (232;233), a review of intervention studies (234), and PCG proposal (235) which does not present evidence but does present the criteria used for grading their recommendations for skin-to-skin contact.

The objective of the Mercer review (232) is to examine evidence on the effects of existing practices in the transition of the neonate, measured in one case as temperature control. It includes the SR and one of the RCTs analysed by the NICE guideline (10).

It concludes that early skin-to-skin contact has benefits in both the short and long term: in the short term it increases and maintains the neonate's temperature, and he or she sleeps longer and cries less. In the long term, when skin-to-skin contact and breastfeeding occur in the first hour, the duration of breastfeeding and maternal affection are increased, and higher scores are obtained in levels of maternal feeling. SR 1-

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The Moore SR (233) includes 30 studies (29 RCTs and 1 quasi-randomised trial), with a total of 1,925 participants and analyses whether early skin-to-skin contact has beneficial or adverse results on breastfeeding, behaviour and mother-child adaptation. Other results such as axillary temperature and heart and breathing rate do not show significant differences.

These are the most significant results:

- Breastfeeding one month to four months after birth, 10 studies and 552 participants: OR 1.82 [CI 95% 1.08 to 3.07]. SR of RCTs 1+
- Affectionate contact during breastfeeding 36-49 hours after birth, 4 studies and 314 participants: DME 0.52 [CI 95% 0.07 to 0.98]. SR of RCTs 1+
- Maternal attachment behaviour during feeding in the first or second day postpartum, six studies and 396 participants: DME 0.52 [CI 95% 0.31 to 0.72]. SR of RCTs 1+

In summary, both in the NICE guideline (10) and in the later high-quality reviews, it was observed that skin-to-skin contact between mother and child has benefits for the neonate and the mother in relation to certain parameters such as breastfeeding duration, temperature control of the neonate and the mother-child relationship. No adverse effects of skin-to-skin contact were found.

Summary of Evidence

There is evidence from high-quality RCTs which found that skin-to-skin contact is beneficial in the short term for maintaining the temperature and reducing the child's crying, and in the long term for increasing breastfeeding duration (232;233).	1+

Recommendations

A	Women should have skin-to-skin contact with their babies immediately after birth.
√	To keep the baby warm, he or she should be covered and dried with a blanket or towel that has previously been warmed, whilst maintaining skin-to-skin contact with the mother.
√	The mother and baby should not be separated for the first hour or until the first feed has been given. During this period the midwife should remain vigilant and periodically observe, interfering as little as possible in the relationship between the mother and neonate, checking the neonate's vital signs (colour, respiratory movements, tone and if necessary heart rate). The midwife should inform the specialist of any cardiorespiratory change.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

8.3. Breastfeeding

- Should the neonate take the breast spontaneously?

The concern to facilitate early onset of breastfeeding has led to many centres adopting the practice of stimulating latch in the delivery room, in the traditional manner. However, it is now being proposed to wait until the neonate is prepared to initiate sucking and that he or she should find the nipple and latch onto the breast spontaneously. In this way, the adaptation process of neonates would be respected and correct latch would be facilitated.

Summary of the Evidence

In its section on "Mother-child relationship and promoting breastfeeding", the NICE guideline (10) uses the recommendations of the guideline created in 2006 under the title "Postnatal Care: Routine postnatal care of women and their babies" (227).

In this guideline it is said that, although it has not been analysed if the first breastfeeding moment is important, there are studies, such as the (236) study published in 2005 that concludes by saying that early onset of breastfeeding encourages a greater relationship between mother and child. — SR 1++

With respect to the start of breastfeeding, it includes the following studies: a Cochrane SR by Anderson et al. 2003 (228) which concluded that healthy full-term neonates latch on to the nipple spontaneously and start to feed approximately 55 minutes after birth and during the first 30 minutes they only lick the nipple. — SR of RCTs and CCT 1++

The cohort study by Jansson *et al*. 1995 (237) studied the feeding behaviour of 46 neonates, by means of reflexes such as finger in the mouth or head turning when the cheek is touched. The results indicate that neonates who are bathed at 17 minutes after birth display fewer pre-breastfeeding signs that those bathed 28.5 minutes after birth. — Cohort Study 3

The RCT by Taylor *et al* 1985 (229) found that early skin-to-skin contact between mother and child with sucking was associated with a longer breastfeeding duration ($p<0.001$), compared with skin-to-skin contact alone. — RCT 1++

The NICE guideline (10) states that breastfeeding may be facilitated if the mother is at ease, in a comfortable position and the neonate is brought to the breast.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In category A of the recommendations published by the WHO in 1996 on "Care in Normal Birth: A Practical Guideline" (4), it was stated as follows: *Clearly useful practices which should be promoted*, early skin-to-skin contact between mother and child and support for the initiation of breastfeeding within 1 hour postpartum. In 2006, on the UNICEF website, we found a document covering the main factors which encourage the initiation of breastfeeding and which are summarised in 10 steps: "*Ten Steps to Successful Breastfeeding*". This document is a Baby-Friendly Hospital Initiative (BFHI) by UNICEF/WHO, now an initiative to humanise childbirth and breastfeeding care by UNICEF/WHO. In this document, one of the ten steps is to help mothers to initiate breastfeeding within half an hour postpartum: After the birth, the neonate should be dried and placed on the mother to encourage early attachment and skin-to-skin contact between them. *In 30 minutes the neonate initiates the sucking reflexes. Allowing the neonate to feed, with skin-to-skin contact, within the first hour of life in the delivery or recovery room, leads to the mother's oxytocin reflex being triggered, encouraging uterine retraction and preventing haemorrhaging. Skin-to-skin contact and colostrums prevent stress in the neonate, provide immunity and maintain body temperature and glycaemia levels (238).*

Expert opinion 4

Update (2005 to May 2008)

Of 48 studies identified only one was selected as the others either did not comply with the inclusion criteria or were already included in Moore's Cochrane SR, conducted in 2007, which was finally selected (233).

This SR is also included in the question concerning "Early Skin-To-Skin Contact between Mother and Child". To analyse whether early skin-to-skin contact has beneficial or adverse results on breastfeeding it extracts results from 16 studies.

Fifteen of the sixteen studies allowed neonates to breastfeed during skin-to-skin contact, but only three studies documented the success of the first feeding attempt. Early skin-to-skin contact produced a significant improvement in breastfeeding measurements using BAT scoring (Breastfeeding Assessment Tool) in these three studies with 223 participants: OR 2.65, [CI 95% 1.19 to 5.91] when compared with neonates held by their mothers wrapped in blankets. At 28 days the results were not significant.

SR of RCTs 1+

The results of the different studies are influenced by the different assistance conditions provided for to the mother, which are not well documented. Assistance with initial breastfeeding may be a necessary component of skin-to-skin contact, as mothers sometimes feel insecure about their ability to initiate breastfeeding satisfactorily.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

To summarise, it has been observed that early onset of breastfeeding encourages a better mother-child relationship and longer breastfeeding duration.

Summary of Evidence

Most full-term healthy neonates show spontaneous feeding behaviour in the first hour of life (228).	1++
Early skin-to-skin contact with suckling is associated with longer breastfeeding duration (233).	1+

Recommendations

A	Breastfeeding should be encouraged as soon as possible after birth, preferably within the first hour.
√	Women should be informed that if the neonate is not trying to feed, he or she can be placed in front of the breast to facilitate the reflexes necessary to obtain sufficient latch-on, but that this first feed should not be forced.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.4. Bathing the Neonate

- What is the effect of bathing the neonates?

There does not appear to be any evidence that bathing neonates produces benefits; on the contrary, it causes a drop in body temperature and interferes with the recommendation to maintain skin-to-skin contact for at least the first hour. Additionally, there is no contraindication to the fact of not bathing the neonate.

The real function of the vernix is unknown, but we do know that if the baby is not bathed the fatty substance is reabsorbed by the skin. This effect suggests that it may have protective effects on the skin, improving acidification, hydrating and protecting from a drop in temperature and infections.

Scientific Evidence

The NICE guideline (10) does not cover bathing neonates and no study has been found which complies with the selection criteria for the update (to March 2008).

Summary of the Evidence

There is no evidence in order to recommend whether or not to bathe neonates immediately. However, different publications emphasise the need to wait to bathe the infant when his or her temperature has stabilised, and at the time of birth only excess vernix should be cleaned away. Furthermore, the importance of not interfering in skin-to-skin contact is also highlighted.

Recommendations

√	The neonate should not be bathed routinely in the first few hours after birth.
√	If the mother requests it, bathing is acceptable as long as the neonate has achieved thermal stability and it does not interfere with the recommended time for skin-to-skin contact.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.5. Nasopharyngeal Aspiration and use of Gastric-Rectal tubes in Neonatal Period

- Does the use of gastric-rectal examinations and/or systematic nasopharyngeal aspiration in the immediate neonatal period improve neonatal prognosis?

The systematic use of tubes to aspirate secretions, blood or meconium in neonates with good vitality, and for verification that the oesophagus, anorectum and choanas are permeable continues to be common practice in many centres (239; 240).

Oronasopharyngeal aspiration is carried out in order to minimise the risks of respiratory complications, mainly meconium aspiration syndrome (241); however some publications have questioned its usefulness (242; 243).

As the practice of aspirating the neonate has potential risks, there is a need to assess this widely practised procedure (242-244).

Scientific Evidence

The NICE guideline (10) does not address this point.

Update (to December 2008)

No studies were found in the first SR search and meta-analysis for the update, so in a second search RCTs were included in the strategy. Two studies that comply with the inclusion criteria were found, which assessed nasopharyngeal aspiration in healthy neonates compared to not aspirating.

The Estol trial of 1992 (245) used a small sample (n=40) with risk of bias due to the lack of correct randomisation and allocation concealment. No significant differences were found in the variables studied. The study concluded that since respiratory mechanics and heart rate do not benefit from oronasopharyngeal aspiration, its routine use should be limited in healthy neonates born vaginally. RCT 1-

The study published in 2005 by Gungor S. *et al* (246) and conducted in Turkey included 140 vaginally delivered neonates with clear amniotic fluid. Two randomised groups were formed, with 70 neonates in each (one with oropharyngeal aspiration and one without aspiration). The results obtained showed a significantly lower heart rate at 3-6 minutes in the group without aspiration ($p<0.001$). The maximum time for obtaining SaO_2 levels above 92% was 6 and 11 minutes (non-aspirated and aspirated) respectively ($p<0.001$). The Apgar test at one minute reached a score of 8-9 in either of the groups, whilst the Apgar test at 5 minutes in aspirated neonates did not reach a score of 10. The authors concluded by recommending the review of the policy of routine oronasopharyngeal aspiration in healthy neonates. RCT 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Both studies reached the same conclusion: nasopharyngeal aspiration is not necessary in healthy vaginally delivered neonates. In the face of this evidence the GCG considers it appropriate not to recommend oronasopharyngeal aspiration.

There is no evidence concerning catheterisation to diagnose oesophageal atresia. The GCG considers that there are other warning signs of suspected oesophageal atresia and agrees with the most recent recommendations by the Spanish Paediatrics Association concerning care of healthy neonates during childbirth and in the first hours postpartum (247) that tubes should not be passed through nostrils, oesophagus or anus, since a simple examination of the neonate is sufficient to eliminate most serious neonatal problems.

Summary of Evidence

Neonates on whom aspiration has not been carried out have a lower heart rate at 3-6 minutes, and shorter maximum time to obtain SaO2 levels above 92% and better Apgar test outcomes at 5 minutes (246).	1+

Recommendations

A	Systematic oropharyngeal and nasopharyngeal aspiration are not recommended for neonates.
√	The systematic use of nasogastric and rectal examination should not be used to rule out atresia in healthy neonates.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.6. Ophthalmic Prophylaxis

Neonatal ophthalmia, also known as neonatal conjunctivitis, is an inflammation of the eye surface caused mainly by bacteria and less frequently by viruses or chemical agents. It may lead to permanent eye damage and blindness. Contagion mainly occurs in the birth channel, although it may also occur intrauterine or after birth by contaminated secretions from healthcare personnel or family members (249; 250).

It has been stated that prophylaxis by antibiotic ointments significantly reduces the risk of developing neonatal ophthalmia (251). However, the matter of which prophylactic medication is most effective, and the most suitable regimen and time of administration are still to be determined.

Furthermore, there is concern about the consequences that alteration of the neonate's sight and sense of smell caused by the prophylaxis may have on recognising the mother's breast and the onset of breastfeeding.

8.6.1. Effectiveness of systematic ophthalmic prophylaxis

- How effective is systematic ophthalmic prophylaxis in neonates?

Scientific Evidence

The NICE guideline (10) does not address this point.

Update (to July 2008)

One study (252) was included in the update search. It is a review document drawn up by Goldbloom RB en 1994 (252) for the Canadian Task Force, on ophthalmic prophylaxis for gonococcis and chlamydia in neonates. The review included studies which assessed the effectiveness of neonatal ocular prophylaxis with 1% silver nitrate solution, 1% tetracycline ointment or 0.5% erythromycin in a single dose, applied in the neonate's conjunctival sac.

The evidence from before-after studies which compare the application of prophylaxis with not doing so showed a sharp reduction in the incidence of gonococcal ophthalmia and blindness. With respect to chlamydia infection, the evidence from quasi-experimental trials showed that the different agents were of a comparable although not conclusive efficacy.

SR of RCTs, Quasi-experimental study and Cohort Studies 2+

In short, there is high-quality evidence to justify the routine use of ophthalmic prophylaxis for gonococcal infection, at least in the absence of universal prenatal tests for gonorrhoea.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Summary of Evidence

Ophthalmic prophylaxis significantly reduces the incidence of gonococcal ophthalmia and blindness (252).	2+
The evidence on the efficacy of neonatal ophthalmic prophylaxis for chlamydia infection is not conclusive (252).	2+

Recommendations

B	Ophthalmic prophylaxis should be performed as part of routine care for neonates.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.6.2. Ideal time for ophthalmic prophylaxis

- What is the ideal time to carry out ophthalmic prophylaxis in neonates?

Update (to July 2008)

To answer this question a report drawn up in 2002 on routine nursing practices in Canada (253) was used. On the basis of the evidence available at the time and by consensual methods, it establishes the time for administration of erythromycin in neonatal ophthalmic prophylaxis. Until then it was administered within one hour postpartum and from this year onwards the period for administering ophthalmic prophylaxis was extended to two hours in order to encourage mother-child bonding. These changes were supported by the knowledge that the incubation period is nine days for gonorrhoea and 3-4 days for chlamydia. The authors recommend that the ideal time for ophthalmic prophylaxis is four hours postpartum. — Expert opinion 4

On the other hand, the 1994 SR by the Canadian Task Force, mentioned in the question above (252), proposed that prophylaxis be carried out within one hour from birth, as this was what was done in the studies included in the review. — CPG 2+

Summary of Evidence

There is evidence regarding incubation periods of ophthalmic infections (nine days for gonorrhoea and three-four for chlamydia) which have been used to support delaying the time when ophthalmic prophylaxis is carried out (253).	4

Recommendations

√	The time for administration of ophthalmic prophylaxis may be extended to four hours after birth.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.6.3. Most Effective Product for Ophthalmic Prophylaxis

- What is the most effective product for ophthalmic prophylaxis in neonates?

Ophthalmic prophylaxis of neonates has been performed since 1884, both for gonococcal infections and for chlamydia, with different substances, obtaining different results for each of them. The different products used have also been replaced over time. Currently various different types of antibiotics and antiseptics are used (tetracycline, aureomycin, erythromycin, silver nitrate and even iodised solutions), in different formulations (drops, cream or ointment).

Scientific Evidence

The NICE guideline (10) does not address this point.

Update (to July 2008)

Goldbloom RB's 1994 review (252) recommends prophylaxis with 0.5% erythromycin ophthalmic ointment, 1% tetracycline or 1% silver nitrate, in a single application and dose. However, it should be noted that the use of silver nitrate may produce side effects such as transient chemical conjunctivitis.	SR of RCTs, Quasi-experimental studies and Cohort study 2+
In our context a range of scientific organisations, including the Spanish Paediatrics Association (AEP) in its protocols on diagnosis and therapeutics of neonatology in paediatrics (revised in 2003) (254), recommend that as part of the general care given in the delivery room, neonatal ophthalmia is prevented by administering 1% tetracycline (aureomycin) ophthalmic ointment or 0.5% erythromycin n both eyes. Said organisations recognise that this is a very useful practice in infections caused by Neisseria gonorrhoeae and partially effective to treat infections due to chlamydia.	Expert opinion 4
Furthermore, in the document published in 2009 by the Spanish Paediatrics Association on care of healthly neonates during childbirth and in the first hours postpartum (247), it is recommended that the best means of preventing vertical neonatal infection is diagnosis and treatment of gonococci and C. trachomatis infections in the pregnant woman, as well as administration of a single dose of antibiotic ointment or eye drops to the neonate, as soon as possible. However, as these medications may affect the neonate's vision and interfere with establishing the mother-child bond administration should be delayed until the skin-to-skin contact period has ended (50–120 min).	Expert opinion 4
The GDG is in full agreement with the evidence for administering pharmacological treatment and for delaying said treatment until the end of the skin-to-skin period.	

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Summary of Evidence

Single doses of 0.5% erythromycin ophthalmic ointment, 1% tetracycline or 1% silver nitrate are effective and comparable in neonate ophthalmic prophylaxis. Silver nitrate may cause transient chemical conjunctivitis in the neonate (252).	2+

Recommendations

√	Erythromycin 0.5% ointment should be used as ophthalmic prophylaxis, or alternatively tetracycline 1%. Silver nitrate 1% should only be used if neither erythromycin nor tetracycline is available.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.7. Haemorrhagic Disease Prophylaxis Using Vitamin K

Vitamin K deficiency bleeding (VKDB) can be present in three ways:

- Early onset, within 24 hours from birth.
- Normal onset, during the first week after birth, traditionally occurring as oral, umbilical or rectal bleeding or due to circumcision when it has been performed.
- Late onset, after the first week, almost exclusively in breastfed babies and often occurring in neonates with liver disease or malabsorption. Intracranial haemorrhaging occurs in over 50% of children diagnosed with VKDB.

8.7.1. Risk-Benefit Ratio of Neonatal Prophylaxis with Vitamin K?

- What is the risk/benefit ratio of carrying out neonatal prophylaxis using vitamin K?

The risk of neonates developing bleeding problems due to vitamin K deficiency (VKBD) is well known. VKBD may endanger the child's life from the first hours of life until several months later and administering vitamin K may prevent this disease.

In different parts of the world various vitamin K prophylaxis methods have been used. The benefits of oral prophylaxis are related to the fact that it is an easy and non-invasive method. The main disadvantage is the uncertainty of the dose absorbed, which can also be affected by vomiting or regurgitation. Additionally, if several doses are necessary, complying with the required doses may be a problem (255). Intramuscular prophylaxis is an invasive method which could cause pain and/or generate a haematoma at the injection site. Furthermore an increase in the risk of developing child cancer after intramuscular injection of vitamin K has been reported (256;257).

Scientific Evidence

The NICE guideline (10) does not address this point. However, it is covered in the NICE "Postnatal Care" guideline (227), published in July 2006, which in addition to describing the effectiveness of vitamin K aims to clarify the possible association between administering vitamin K and the development of cancer in children.

When this guideline was published the evidence available was of medium quality and it states that prophylaxis with vitamin K is effective and it significantly prevents both morbidity and mortality due to VKBD (258).

An observational study in 1992 (257) found an association between cancer and IM vitamin K administration (p = 0.002), OR 1.97 [95% CI 1.3 to 3.0] vs. oral vitamin K or no vitamin K administration.

Observational studies
2+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

However, later studies conducted in 1998 by other researchers did not support this relationship between cancer and IM administration of vitamin K (259). Observational studies 2+

A more recent study conducted in 2002 (260) analysed 2431 children who developed cancer before the age of 15 with 6338 controls matched by sex and age, but not by place of birth. The study confirmed that solid tumours were no more common in children who received IM vitamin K at birth, however the situation in relation to leukaemia was less clear. Observational studies 2+

The United Kingdom Childhood Cancer Study (261) retrospectively analysed data relating to 7017 children (1174 with leukaemia). It did not find any association between IM vitamin K and any diagnosis group, and the odds ratio for leukaemia diagnosed between 12 and 71 months of age was 0.98 [CI 95% 0.79 to 1.22).

The authors concluded that it was highly probable that the findings associating IM vitamin K and infant cancer were casual. Observational studies 2+

Update (2005 to July 2008)

A Cochrane SR published in 2006 adequately answers the question and it was selected (262).

To assess the effectiveness of intramuscular vitamin K in preventing bleeding (clinical outcome) two RCTs were selected, which compared the use of a single dose of intramuscular vitamin K with a placebo or with nothing (263;264).

The RCT by Sutherland, 1967, researched all cases of bleeding between the first and seventh day and found a significant difference in favour of the prophylactic use of vitamin K, RR 0.73 [CI 95% 0.56 to 0.96), DR -0.02 [CI 95%-0.04 to 0.00). The RCT by Vietti, 1960, investigated the presence of bleeding after circumcision and found a significant difference in favour of the prophylactic use of vitamin K, RR 0.18 [CI 95% 0.08 to 0.42), DR -0.11 [CI 95% -0.16 to -0.07]. Both trials support the existence of an effect derived from intramuscular vitamin K to prevent traditional VKBD. RCT 1+

Summary of Evidence

A single injection of vitamin K prevents the occurrence of traditional VKBD (262-264).	1+
At the light of the current evidence there is not a direct relationship between childhood cancer and IM vitamin K prophylaxis (259-261)	2++

More than 5 years have passed since publication of this Clinical Practice Guideline, and its validity has not been reviewed

Recommendations

A	A Prophylaxis of neonates using vitamin K should be offered to prevent the rare but serious and sometimes fatal haemorrhagic syndrome due to vitamin K deficiency

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

8.7.2. Route of administration of prophylaxis with vitamin K

- What is the most advisable route for prophylaxis using vitamin K?

Until the Golding report (256;257), the intramuscular route was the most common route of administration of vitamin K to neonates. Later, oral supplementation of vitamin K in several doses was recommended for breastfed children. Due to uncertainty concerning the optimal dose, dose regimens vary.

Moreover, there are certain problems with oral administration which could compromise its effectiveness. One of these problems is low fulfilment due to the fact that several doses of oral vitamin K are required over several weeks (227;255).

In December 1992, the Australian Paediatric Society and the Australian Royal College of Obstetrics and Gynaecology recommended replacing IM vitamin K with three oral doses of 1 mg each. However, the decision was annulled in 1994 due to an increase in the incidence of VKBD, and the effectiveness of IM administration of prophylaxis was highlighted. In view of the Golding report (256) in various European countries vitamin K started to be administered orally.

Scientific Evidence

The NICE Postnatal Care guideline (227) published in July 2006 answers the question as to which is the best route for administering vitamin K.

For this purpose it used the results of a Cochrane review (265), which assessed eleven RCTs in which oral administration of vitamin K was compared with IM administration, using as outcome measurements, biochemical parameters of coagulation status. The results obtained showed that in comparison to a single IM dose, a single oral dose displayed lower levels of vitamin K at two weeks and at one month, whilst administration of three oral doses gave higher doses of vitamin K at two weeks and at two months than with a single IM dose.

SR
1+

An intervention study conducted in England over six years (266) described how 182,000 neonates were administered 1 mg of vitamin K orally and if there was a high risk of bleeding (13,472) 0.1 mg/kg of vitamin K IM. Regardless of the treatment received at birth, the parents of breastfed children were recommended to give them three capsules of 1mg of vitamin K orally, once every two weeks. None of the children treated with vitamin K orally showed signs of vitamin K deficiency in the next seven days. Four cases of delayed VKBD were documented, two in children with alpha-1-antitripsine deficiency and two others because the mothers did not receive the information.

Cross-sectional study
2+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

In the light of the Golding report (256), vitamin K started to be administered orally. In several European countries studies were conducted to monitor the appearance of VKBD between days 8 and 84, which showed that when 1 mg of intramuscular vitamin K was administered at birth (325,000 neonates) there were no cases of VKBD, whilst other studies in which oral vitamin K was administered at birth and then two additional doses, showed that VKBD occurred in a range of 0.9 to 4.8 cases per 100,000. Observational studies 3

Only in the case of the study conducted in Denmark with 396,000 neonates who received 1 mg vitamin K orally at birth and 1 mg weekly were there no cases of delayed VKBD (267).

Update (2005 to July 2008)

The Cochrane SR update by Puckett was identified (262).

In relation to the comparison between *intramuscular and oral administration*, neither of the trials included specifically evaluated the occurrence of VKBD.

The trials that presented intermediate results such as the presence of proteins caused by the lack of vitamin K (PIVKA II) were analysed. The four trials with this result did not show significant differences between the first and the seventh day (268-270) at two weeks (271) and one month (270; 271). SR of RCTs 1+

Two trials measured the effect of vitamin K administered intramuscularly and orally by analysing the concentration of vitamin K in plasma (ng/ml) (271; 272).

Significant differences were only found in the Cornelissen study (271), which was the only one that assessed this outcome at two weeks. This trial showed a significant difference, and found higher levels in plasma in the group treated with intramuscular administration: mean difference –0.79 ng/ml [CI 95% -1.02, to 0.56]. Maurage (272) conducted the only study that assessed this outcome between the first and the seventh day. No significant differences between the groups were found. SR of RCTs 1+

Both trials analysed this outcome after one month: the combined results of these trials showed a significant difference, finding higher levels of vitamin K in plasma in the group with intramuscular administration; the mean difference was -0.23 ng/ml (-0.30 to 0.16). MA of RCTs 1+

The review (262) did not find significant differences in its assessment of other intermediate outcomes such as prothombin time, coagulation factors, etc.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

There was also an analysis of the comparison of *three oral doses with one dose of intramuscular vitamin K*. The only trial which investigated this comparison was Greer 1998 (273), which did not specifically assess the occurrence of VKBD but analysed vitamin K in plasma (ng/ml). At two weeks, Greer found a significantly higher level in the group with oral administration, mean difference: 0.80 ng/ml (0.34 to 1.27). After one month, no significant differences were found. At three months, Greer found a significantly higher level in the group with oral administration, mean difference: 0.30 ng/ml (0.10 to 0.50).

The review concluded that, taking into consideration the fact that the correlation between the child's vitamin K levels and coagulation status is unknown, and given that the coagulation status does not necessarily correlate with the clinical outcomes, it cannot be concluded that a single oral dose is as good as a single intramuscular dose.

An implication for clinical practice that can be highlighted is that a single dose (1 mg) of intramuscular vitamin K after birth is effective to prevent traditional VKBD.

Prophylaxis with intramuscular vitamin K or oral vitamin K (1 mg) improves biochemical indices of coagulation status between the first and the seventh day.

Intramuscular vitamin K and/or oral vitamin K was not evaluated in randomised trials with respect to the effect they have on the key clinical outcome, delayed VKBD.

No randomised trials assessed the effect of orally administered vitamin K in a single dose compared to multiple doses on coagulation status and vitamin K levels; the clinical significance of such outcomes is unknown.

When *three doses of "orally administered vitamin K"* are compared with a single dose of intramuscularly administered vitamin K, the vitamin K levels in plasma are higher in the group with oral administration, after two weeks and after two months, but again, there is no evidence showing differences in coagulation status.

Summary of Evidence

A single dose (1 mg) of vitamin K administered intramuscularly after birth is effective in preventing traditional VKBD (262).	1+
If vitamin K is administered orally multiple doses are required for adequate protection of breastfed children against delayed bleeding due to vitamin K deficiency (262).	1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Recommendations

A	Vitamin K should be administered in a single intramuscular dose (1 mg), as this is the route of administration that gives the best clinical results.
√	If parents refuse IM vitamin K, it may be offered orally as a second treatment option, and parents must be informed that a 1 mg dose will be required at birth, at one week and at one month. If the baby is exclusively breastfed, additional doses should be given.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9. Pain Relief during Labour

In recent years great attention has been paid to the importance of pain relief during labour, with widespread use of neuraxial analgesia, a technique that is very effective but invasive and not exempt from risks. Neuraxial analgesia requires greater monitoring and makes mobility and the perception of the pushing sensation more difficult, consigning women to a more passive role. However, implementation of other methods of pain relief recognised to be effective and safe and which interfere less in the physiology of labour and the role of the woman, has been minimal.

As the NICE guideline (10) states: "The desire for analgesia and the choice of method are influenced by many factors, including the woman's expectation, the complexity of labour and the intensity of pain. For many women the pain experienced during labour is severe, and most require some kind of pain relief. Extreme pain may lead to psychological trauma in some women, whilst for others the undesirable side effects of analgesia may be detrimental to the birth experience. Effective forms of pain relief are not necessarily associated with greater satisfaction with the birth experience; conversely, failure of the chosen method may lead to dissatisfaction".

Therefore, adequate prenatal preparation for what will happen during labour may have a favourable influence on maternal satisfaction, by dispelling unrealistic expectations about how it will proceed, and providing accurate information on the different methods of pain relief and access to the widest possible range of such methods.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

9.1. Pain, Analgesia and Maternal Satisfaction

- How do pain and pain relief during labour influence women's satisfaction?

For many women pain during labour is a concern, and most require some kind of pain relief. It is therefore important to understand the relationship there may be between pain and effective pain relief methods and to study whether failure of the method chosen for pain relief may lead to maternal dissatisfaction with the birth experience.

Scientific Evidence

The NICE guideline (10) analyses women's viewpoints and experiences of pain and pain relief during childbirth on the basis of four studies: one SR (11) which includes 137 articles, one RCT (274) and two other studies (275; 276) which were conducted through interviews and/or surveys with the women.

The SR (11) included 137 reports of different types of studies (descriptive studies, RCTs and SRs) which assessed pain and maternal satisfaction. In the review it was found that there are four factors that most influence women's experiences with childbirth: their personal expectations, the support received by the people who are caring for them, the quality of the relationship between these people and women and their involvement in making decisions. It was also observed that these factors are so important that they cancel out other factors such as age, ethnicity, preparation for the birth, pain, immobility, medical interventions and follow-up care. It was therefore concluded that the mother's satisfaction, pain, pain relief and interventions during childbirth are less important factors than the attitude and behaviour of those who care for them. It was also observed that the impact of pain and pain relief on satisfaction is much greater when women's expectations are not met.

SR of descriptive studies, RCTs and SR
2++

The Australian RCT (274) assessed, through surveys, satisfaction with childbirth and pain relief in nulliparous women randomly assigned to a group with patient-controlled intradural-epidural analgesia treatment (PCEA), compared to women in the group with continued care by the midwife and other forms of analgesia (intramuscular (IM) pethidine, Entonox® and pharmacological methods).

The trial found that despite the fact that the women randomly assigned to the epidural group were significantly more satisfied with pain relief during birth, overall satisfaction with the labour experience and birth was high and similar in both groups. This fact reflected the existence of factors other than pain relief which are involved in maternal satisfaction outcomes.

RCT
1+

More than 5 years have passed since the publication of the Clinical Practice Guideline, and its validity has not been reviewed

The last two observational studies were based on interviews or surveys. One was conducted in Finland (275), the other was a European multi-site study (276), and 1091 and 611 women, respectively, were included. They aimed to assess women's expectations of pain during the birth and their experience in managing it.

These studies found that overall satisfaction was not related to number of previous births, pain level or pain relief experienced. The most satisfied women were those who expected a more painful birth and those who had a less painful experience. Additionally, dissatisfaction with the overall birth experience was related to instrumental delivery, but this was not the case for the use of or need for analgesia.

Update (2006 to August 2008)

In the literature search seventeen studies were found, of which four were selected that complied with the established inclusion criteria: two systematic reviews (277;278), one RCT (279) and one observational cohort study (280).

Observational study 3

The objective of the first of the SRs (277) was to examine the effects of complementary therapies for treating pain on maternal and perinatal morbidity. Several clinical trials included in this review assessed maternal satisfaction or the emotional experience of women with pain relief treatment during labour. However, most of the treatments used in the trials were therapies not used in our context (acupuncture, audioanalgesia, hypnosis and some massage techniques), so the results cannot be applied to our hospital environment.

The other SR (278) was carried out in the United Kingdom and included 32 quantitative and qualitative studies, conducted by means of surveys and interviews. The review evaluated the expectations and experiences of women with pain and pain relief during childbirth, and their involvement in making decisions.

SR of Observational studies 2++

The review revealed four key aspects: the level and type of pain, pain relief, participation in making decisions and control. It was observed that the experience of women on many occasions was very different from their expectations concerning pain relief, control and decision-making. Women expected births without pain relief, but many required it, as the level of pain experienced was greater than expected.

Finally, the study concluded that prenatal preparation should provide an adequate approximation of what will happen during childbirth to limit the mismatch between expectations and experiences and to increase greater overall satisfaction.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The Canadian RCT (279), which included 5,002 women giving birth for the first time, without complications, assessed the influence of two different types of care during labour on obstetric, fetal and maternal outcomes, including maternal satisfaction (analysed in 4,131 women). The women were randomly assigned either to a group with normal care or another group in which they were provided with structured "one-to-one" care, for at least one hour, focused on assessing factors such as the emotional state of the women, pain and fetal position.

RCT
1+

With respect to satisfaction outcomes, it was observed that the number of women who considered the help received as "*not very useful*" was lower in the group with structured care compare to the group with normal care, OR 0.67 [CI 98.75% 0.50 to 0.85]. The same occurred with the number of women "disappointed" with the care received, OR 0.51 [CI 98.75% 0.32 to 0.70]. The study concluded that structured care for women during childbirth increases their satisfaction and suggests a modest increase in spontaneous vaginal births: OR 1.12 [CI 95% 0.96 to 1.27].

The last of the studies selected for the update was an observational cohort study (280) including 605 Belgian and Dutch women giving birth in hospitals and in maternity homes. The study aimed to assess, in two different fields of practice, the association between various factors (experiences with birth pain, personal control and own abilities and fulfilment of expectations) and maternal satisfaction during childbirth.

Cohort study
2+

The study found that fulfilment of expectations is the factor that is most related to satisfaction.

The new evidence found in the update is consistent with the evidence summarised in the NICE guideline (10), concluding that women's expectations, together with personal control, are the most important factors related to women's satisfaction during childbirth.

Taking this into account, GDG considers that adequate information on the birth process should be offered during prenatal care, allowing women to clarify concepts and define preferences so that their expectations are more realistic and consequently higher maternal satisfaction during childbirth is achieved.

Summary of Evidence

The birth experience is influenced by various factors such as expectations, level of preparedness, birth complications and the level of pain experienced (11).	2++

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The attitude and behaviour of carers is the factor that most influences maternal satisfaction. Women are more satisfied when their expectations of pain and choice of pain management are met (11)	2++
Women with combined intradural-epidural neuraxial analgesia administered via PCEA (controlled by them) achieve greater satisfaction with pain relief during birth than those who receive continuous support from the midwife with other forms of analgesia (IM pethidine, Entonox® and non-pharmacological methods). Overall satisfaction with the labour experience and birth is high and similar in women in both groups (274).	1+
Satisfaction with the birth experience is related to four key aspects: the level and type of pain, pain relief, participation, structured care and control in making decisions (278).	2++
Fulfilment of expectations is the factor most related to satisfaction (280).	2+

Recommendations

B	The mother's expectations for pain relief during labour should be met as far as is possible.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.2. Non-pharmacological Pain Relief Methods

9.2.1. Immersion in water during the First Stage of Labour

- How effective is immersion in water as pain relief during the first stage of labour?

Throughout the history of humankind water has been used for therapeutic purposes. Immersion in or application of hot water has been used with success in many painful processes. In the late 1970s the birthing tub or pool was introduced in Pithiviers Maternity Hospital, en France (281). From the hospital's experience, immersion in body-temperature water during labour provided immediate pain relief from contractions and helped the mother to relax and remain mobile. They also found that it helped dilatation to progress, which has been attributed to an enhanced release of oxytocin by reducing anxiety and stress as a result of immersion in hot water.

From the time that birthing tubs were first used in childbirth facilities they have received varying attention. The current interest in intervening as little as possible during childbirth suggests that this physical method of pain relief must be taken into consideration.

Scientific Evidence

To answer this question the NICE guideline (10) refers to its previous guideline on caesarean sections (65) in which it is recommended that women should be informed that immersion in water does not influence the probability of having a caesarean birth, although it may affect other outcomes.

The SR (11) included 137 reports of different types of studies (descripIn this section the NICE guideline (10) includes a Cochrane SR (282) and an RCT (283) by the same author (classed as 1-), which examined the efficacy of using immersion in water during the first stage of labour. Due to the risk of bias it will not be considered for our guideline.

The SR includes eight studies. Six examined labour in water or waterbirths during the first stage of labour, another examined them during the second stage and the final one examined the time that water was used in the first stage of labour.

No relevant study that studied hygienic measures for waterbirths was identified.

The SR found that the use of immersion in water in the first stage of labour reduced the use of local analgesia, OR 0.84 [CI 95% 0.71 to 0.99]. SR of RCTs 1+

Another trial included in the SR found that immersion in water reduced pain, OR 0.23, [CI 95% 0.08 to 0.63].

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

There is evidence that there are no significant differences in adverse outcomes (rates of instrumental vaginal delivery, caesarean section rate, perineal trauma: episiotomy, second- or third-/fourth-degree tear, number of neonates with Apgar below 7 at five minutes and admissions to neonatal unit) when immersion in water was or was not used, nor in the duration of labour. SR of RCTs 1+

With respect to the time of immersion in water, a randomised pilot study (284) conducted on 200 women included in the SR compared early immersion (<5 cm dilatation) with delayed immersion (>5cm) during the first stage of labour. In the early water immersion group a significantly higher rate of use of epidural analgesia was observed OR 3.09 [CI 95% 1.63 to 5.84] and a greater use of oxytocin OR 3.09 [CI 95% 1.73 to 5.54]. RCT 1+

Update (2006 to October 2008)

No new studies have been found that comply with the inclusion criteria and provide quality evidence on immersion in water as a method of pain relief during childbirth.

Summary of Evidence

The use of immersion in water during the first stage of labour reduces pain and the use of local analgesia (282).	1+
Early immersion in water increases the use of epidural analgesia and oxytocin (284).	1+

Recommendations

A	Immersion in hot water is recommended as an effective pain relief method during the later phases of the first stage of labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.2.2. Massage

- How effective is massage as pain relief during labour?

Massage and a soothing touch during labour aim to help women to relax and relieve the pain of contractions; these actions transmit interest and understanding and offer comfort. It appears that women appreciate such interventions, which make them feel cared for and lead to a feeling of well-being. However, further examination of the effects of massage in pain relief during labour is required.

Scientific Evidence

To answer this question the NICE guideline (10) uses the evidence provided by two systematic reviews (47; 285) which include three studies: two RCTs with small samples (n=24 and n=60) and a prospective cohort study. The RCTs were conducted in the USA and Taiwan, respectively.

Due to the heterogeneity of the RCTs data could not be pooled. Both trials showed a significant reduction in pain during labour, reported by nurses and women, in the massage group. The use of another type of analgesia during labour was not mentioned for either of the groups. In the smallest study, both the women involved and blind observers reported a significant reduction in stress and anxiety during labour. There was also a significant improvement in the mother's mood (using a depression scale) during labour and after the birth.

2 SR of RCTs
1+

The prospective cohort study (n=90) (286), conducted in USA, examined the effect of physical contact for therapeutic purposes during labour. The women in the experimental group received contact from the midwife (e.g. handholding) for a period of 5–10 seconds after each verbal expression of anxiety. The study was conducted during a 30-minute period of intervention at the end of the first stage of labour (dilatation 8–10 cm). The control group received "normal care". Despite the apparently short intervention period, maternal anxiety (measured via blood pressure, verbal expression of anxiety and scores of anxiety as reported by the women during the early postnatal period) was reduced significantly in the experimental group, compared to the control group ($p<0.05$).

Cohort study
2+

The evidence suggests that massage and a soothing touch reduce the pain and anxiety expressed during labour.

There is not sufficient evidence on the influence of massage on birth outcomes.

Update (2006 to October 2008)

Two studies were selected: one Cochrane SR (277) and one RCT (287).

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The medium-quality SR (277) studied complementary and alternative treatments for managing pain during labour, including massage, amongst other actions. The evidence on massage comes from a trial conducted in Taiwan (288), which included 60 women.

The intervention consisted of gentle massage, pressure on the sacrum and firm massage of shoulders and back for thirty minutes during the three stages of labour through contractions, performed by a previously trained accompanying person. The control group received standard nursing care and 30 minutes of informal conversation with those conducting the research.

The study found no differences in the duration of labour: WMD 1.35 minutes [CI of 95% -0.98 to 3.68] or in general satisfaction with the birth experience: WMD -0.47 [CI of 95% -1.07 to 0.13]. RCT 1-

The small sample size and low quality of the trial prevented conclusions being drawn on the effectiveness of massage. The context of conducting the studies, in a country with a long tradition of massage, means that external validity of it is low, and it is difficult to apply in our context.

The second study selected in the update (287) forms part of the RCT (288) included in the Cochrane SR (277). It analyses the findings on the dimensions of pain as measured with the Short Form McGill Pain Questionnaire (SF-MPQ). The results indicate that the experience of pain varies and that intensity and characteristics are highly individual and subjective.

This study also included a qualitative analysis on the words most frequently chosen by women to describe their pain: "*Painful, acute, strong, stabbing and cramp*" were five of the twelve "sensorial words" with highest scores in both groups and "*terrifying and exhausting*" were two of the four "emotional words" chosen in both groups. RCT 1-

The study concluded that although massage does not change the characteristics of labour pain, it can be effective in reducing the intensity of pain in the first and second phases of the first stage of labour.

The evidence in favour of massage comes from a study where the accompanying persons are trained, which should be taken into consideration to assess the possible effect in our context. It should also be emphasised that in addition to massage simple physical contact has been demonstrated to be beneficial during labour.

Summary of Evidence

Massage by the accompanying person reduces pain and anxiety during labour and improves the mother's mood (47;285).	1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

A soothing touch reduces the anxiety expressed during labour (286).	2+

Recommendations

B	Massage and calming physical contact are recommended as a pain relief method during the first and second stages of labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.2.3. Birthing Balls

- How effective is the use of birthing balls as pain relief during labour?

The use of large rubber balls has become popular in gyms and rehabilitation centres to improve pelvic mobility and to relax muscles, amongst other uses. In recent years, they have started to be used in childbirth facilities, in an attempt to achieve the wellbeing of women by providing them with a comfortable seat which allows pelvic mobility with the resulting relief.

Scientific Evidence

The NICE guideline (10) covers the use of birthing balls together with a wide range of strategies used by women to help them endure labour, that do not require professional supervision.

However, no study was identified which examines the use of birthing balls, so no recommendation is made in this respect.

Update (2006 to October 2008)

In the search performed only a descriptive study of the intervention was found, which did not comply with the inclusion criteria. Thus there is no evidence that supports a recommendation for the use of rubber birthing balls for pain relief, the birth experience or other clinical outcomes.

However this may be, the GDG considers that they may be useful in helping women to find a comfortable position if they are instructed in how to use them.

Summary of Evidence

No studies have been identified concerning the use of birthing balls as a method of pain relief.

Recommendations

√	Women who choose to use birthing balls should be encouraged to do so, to seek more comfortable postures.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.2.4. Relaxation Techniques

- How effective are relaxation techniques as pain relief during labour?

Normally when pregnant women are preparing for childbirth they are taught, amongst many other matters, how to use artificial breathing techniques, in the belief that they will contribute to pain relief. However, it is considered that there can be an involuntary regulation of breathing that allows adaptation to different situations and needs, including labour. Moreover, this type of technique could interfere with the need to be calm and relaxed, and cause hyperventilated states and lead to exhaustion.

Scientific Evidence

To address relaxation techniques, the NICE guideline (10) identified a low-quality controlled trial (285) which randomly assigned women to a group which received autogenic breathing training whilst the control group received the normal psycho-prophylactic course.

Despite the significant reduction in pain during labour for women in the experimental group, this difference was only found after adjusting for women who were very anxious during pregnancy. Postnatal reports of pain during labour and the birth experience did not differ significantly between the two groups. RCT 1-

NICE (10) concludes that there is a lack of scientific evidence on the effectiveness of breathing and relaxation techniques for pain relief during labour or on other clinical outcomes but it recommends supporting women who choose to use relaxation and breathing techniques.

Update (2006 to January 2009)

Nine references were found in the update, of which only one was selected to be read in full, although finally it was excluded due to failing to comply with quality criteria.

Summary of Evidence

There is a lack of scientific evidence on the effectiveness of breathing and relaxation techniques for reducing the pain measured during labour or on other clinical outcomes.

Recommendations

√	Women who choose to use breathing or relaxation techniques should be supported in their choice.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

9.2.5. Injection of Sterile Water

- How effective is the injection of sterile water as pain relief during labour?

The method of injecting sterile water was used as a local anaesthetic in minor surgery in the late nineteenth century, and from the late 1920s it was begun to be used in obstetrics (289).

Approximately 30% of women suffer continuous pain in the lumbar region during labour. This pain is probably due to the pressure of the foetus on pelvic structures sensitive to pain (290).

Injecting sterile water has been described as a very simple and cheap method for alleviating this type of lumbar pain. The use of this analgesic method is not widespread in our context and one its greatest disadvantages is the intense stinging feeling reported by women during administration of the intradermal injection.

Scientific Evidence

The NICE guideline (10) identified two SRs (47;285) with LE=1+, which included the same four RCTs, examining the effectiveness of cutaneous injection of distilled water on lumbar pain.

The four trials were of high quality. They included women in labour who reported lumbar pain or severe lumbar pain. The heterogeneity of the trials made it impossible to synthesise the data.

In the four trials, lumbar pain, measured using the Visual Analogue Scale (VAS), was reduced significantly for 45 to 90 minutes after intradermal injection of sterile water. However, in three of the trials there were no significant differences in the subsequent use of analgesia, in which the women who received cutaneous water injections said they would choose the same option again for a future birth. SR of RCTs 1+

In the fourth study, the subsequent use of analgesia was higher in the experimental group than in the control group (in which the women received massages, a bath and were encouraged to be mobile). In this trial it was more probable for the women in the control group, compared to those in the experimental group, to say they would use the same option for pain relief in a subsequent birth.

One of the greatest disadvantages of this method of pain relief is the intense stinging reported by women when the intradermal injection is administered.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

To study the disadvantages of the method, the RCT conducted in Sweden (291) in 2000 compared the pain perceived during intradermal administration of sterile water with subcutaneous administration. The study included 100 non-pregnant healthy women in a controlled blind clinical trial with a crossover design. Perceived pain was measured by means of the VAS. The findings showed that the intradermal injection was more painful than the subcutaneous injection (average 60.8 mm versus 41.3 mm, p<0.001). However, it is not known whether this finding can be applied to women in labour.

RCT
1+

Update (2006 to 2008)

Eight studies were identified, of which two by the same author were selected: One SR which covers six low-quality RCTs (292) and compared the injection of sterile water with a placebo and one RCT (293), which compared the injection of sterile water with acupuncture. Both studies are from 2008.

The SR (292) found that injecting sterile water reduces lumbar pain during labour, by approximately 60%, the effect being maintained for up to two hours. The review concluded that an injection of sterile water appears to be a good alternative for treating lumbar pain during labour.

SR of RCTs
1-

The RCT (293), which compares sterile water injections with acupuncture, when it analyses the main result which is the difference between the pain level before treatment and the maximum pain reached in the two groups, found that women treated with sterile water injections achieved better pain relief during labour than those treated with acupuncture: water -4.7±24.9 versus acupuncture: 12±14.1 p<0.001. The same occurs when the difference in average pain is measured: water: 57.0±22.7 versus acupuncture: 75.6±18.7 p<0.001, although no differences were observed in neuraxial analgesia requirements.

RCT
1+

A secondary result measured relaxation and showed that women in the sterile water group reached a higher level of relaxation: Maximum relaxation: water: -4.4±23.9 versus acupuncture: 11.4±21.2; p<0.001 and average relaxation: water: 56.6±22.2 versus acupuncture: 68.6±22.7 p<0.003.

RCT
1+

It concludes that women treated with sterile water experience greater lumbar pain relief than those treated with acupuncture.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In the new evidence found, a significant reduction in pain was observed with the use of sterile water compared to acupuncture, in addition to achieving greater relaxation. Although the studies selected in the update may have some risk of bias, it seems that the effect of the treatment is always in the same direction. However, it must be taken into account that the evidence is indirect due to the fact that the comparison is with acupuncture, which is a technique that is not regularly used in our context.

The GDG considers that although limited, the evidence supports the use of sterile water injection for lumbar pain relief during labour.

Summary of Evidence

Women's preferences on the choice of injection of sterile water for lumbar pain relief, or on the need for subsequent analgesia, are not consistent (285) (47).	1+
In a healthy population, intradermal injection of sterile water is more painful, and produces more stinging sensation, than subcutaneous injection (291).	1+
The use of sterile water injections reduces lumbar pain to a greater degree and provides greater relaxation than acupuncture (293).	1+

Recommendations

B	Injecting sterile water is recommended during labour as an effective method of relieving low-back pain; women should be informed that intradermal injection causes short-term stinging and intense pain.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

9.2.6. Transcutaneous Electrical Nerve Stimulation (TENS)

- How effective is transcutaneous electrical nerve stimulation (TENS) as pain relief during labour?

The TENS method is an analgesic technique used in various pathologies and is based on sending, from the skin, a repeated nerve stimulation to inhibit the transmission of nociceptive impulses at the spinal cord level, that is, to inhibit information on pain. Stimulation with TENS is perceived by the patient in the underlying area of the electrode site as a tingling sensation or fibril contractions.

Although it is believed that the analgesic effect of the TENS method is very limited, women can control it themselves, it allows mobility and does not affect the state of consciousness and provides an option for those who do not want medication.

Scientific Evidence

The evidence provided by the NICE guideline (10) is based on a SR (294) carried out in 1997 which included ten RCTs in which the different types of TENS were compared. Only one of the RCTs reached an adequate level of masking with LE=1+.

The pain outcome was measured in the ten RCTs, the medication method was not consistent, and no study recorded differences in the intensity of pain or scales of pain relief between TENS and the control. The need for additional analgesia intervention was described in eight RCTs, and no differences were found between the groups: combined RR 0.88 [CI 95% 0.72 to 1.07] and no adverse effects were reported in any of the ten RCTs. SR of RCTs 1+

From these results the NICE guideline (10) concluded that there is a high level of evidence that the TENS method is not an effective analgesia in established labour and there is not a high level of evidence on the analgesic effect of the TENS method in the latent phase of labour.

Update (2006 to January 2009)

In the new search two RCTs were identified, of which one was selected (295).

This trial included 52 healthy women in the active phase of the first stage of labour who wished to give birth without an epidural. The TENS method was applied to four acupuncture points and it was compared with a group of 53 women who were given a TENS placebo.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The decrease of three or more points in the VAS scale was significantly more frequent in the treatment group: 31/50 vs.7/50 p<0.001; and the desire to use the same analgesic method again: 48/51 vs.33/50; p<0.001. A tendency towards a higher rate of non-spontaneous deliveries was also observed in the same group: TENS 12/50 (24%) vs.4/50 (8%) p=0.05. The study concluded that the application of the TENS method to specific acupuncture points could be a non-invasive adjuvant treatment for pain relief during the first phase of labour as it significantly reduces pain compared to the placebo. RCT 1+

The trial was conducted in Taiwan, where there is a long tradition of practising acupuncture, to which society in general and women in labour in particular attribute great therapeutic value.

The GDG considers that there is inconsistency in the results obtained by the NICE guideline (10) and this new clinical trial published in 2007 as the evidence it provides is very indirect and therefore not applicable in our context.

Summary of Evidence

There is inconsistency between the results of the different studies and the evidence provided by the study which considers it effective pain relief is very indirect and so it would not applicable in our context (294; 295).	1+

Recommendations

A	A The TENS method should not be offered to women in established labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

9.3. Pharmacological Pain Relief Methods

- How effective are the following methods for pain relief during labour: nitrous oxide and pethidine, pentazocine and remifentanil opioids?

9.3.1. Nitrous Oxide

The utilization of nitrous oxide (N2O) in a 50% mix with oxygen is an alternative form of analgesia for labour. In countries such as Canada, England, Finland, Sweden and Australia, this analgesic technique is used in 40 to 60% of births. The N2O is inhaled by the woman through a mask or mouthpiece. It has the advantage of being fast-acting (fast start and stop), not cumulative and not depressing uterine contractility. In concentrations up to 50%, self-administration by the mother is considered safe under supervision, and is not normally associated with unconsciousness, as is the case with higher concentrations. The associated use of parenteral opioids to increase analgesic effectiveness increases this risk.

The administration of nitrous oxide for pain during labour may be by means of continued inhalation or intermittently only during contractions. Continued administration provides better analgesia but more dysphoria and unconsciousness. Intermittent administration however reduces the risk of overdosing but at the cost of a delay in onset of its action, so to increase its effectiveness inhalation should occur before the pain of the contraction occurs.

For appropriate use women should be informed about the analgesic capacity, technique and the possibility of side effects such as dizziness and/or nausea.

Scientific Evidence

The NICE guideline (10) covers this point within the inhaled analgesia section. The evidence comes from an American SR (296) published in 2002, which included eleven RCTs to assess effectiveness, whilst 19 studies were used to evaluate the adverse effects, of which eight were RCTs, already included in the evaluation of effectiveness, and eleven were observational studies. Most of the studies included used concentrations of 50% nitrous oxide, and nine studies made comparisons between concentrations ranging from 30% to 80%. Due to the inconsistencies in the methodology of the studies included, the results were summarised as follows:

Analgesic effectiveness was duly reported in eleven studies. These did not provide clear, quantitative and objective evidence of said effectiveness, but in seven of the studies significant analgesia was observed with nitrous oxide, although in five of them it had been administered at the same time as opioids and in another this point was not clarified. Two other studies reported that women chose to keep using nitrous oxide, even after the study period ended.

SR of RCTs
2+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In connection with other obstetric outcomes, no differences were found in contractions, alterations to them or progress of labour.

With respect to adverse effects, seven trials with inadequate controls reported nausea and vomiting in a range of 5% to 36%. Other effects described were somnolence, dizziness, dry mouth, buzzing sound, memory alterations and paresthesia. Two RCTs reported loss of consciousness, but without statistically significant differences between doses. There were no differences in the Apgar test and neurobehavioural assessment (neonate).

SR of RCTs
2+

Update (2006 to November 2008)

Nine references were found in the search, of which only one SR was selected to be read in full, but it was finally excluded due to not complying with the inclusion criteria.

See appendix 2.3.1.

Summary of Evidence

Nitrous oxide shows moderate pain relief during labour, and may cause nausea, vomiting, slight light-headedness and alteration of the recollection of childbirth. There is no evidence on fetal damage (296).	2+

Recommendations

B	Inhaling nitrous oxide is recommended during labour as a pain relief method; women should be informed that its analgesic effect is moderate and that it can cause nausea and vomiting, somnolence and altered memories.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

9.3.2. Opioids: Pethidine, Pentazocine and Remifentanil

Meperidine or **pethidine** is a synthetic derivative of phenylpiperidine. Despite its widespread use, its efficacy has been questioned and it has been suggested that its effect is mainly sedative rather than analgesic.

Meperidine, like other opioids, delays gastric emptying, and so increases gastric volume during labour. It also causes sedation, dose-dependent respiratory depression and its metabolite, normeperidine, has convulsive effects.

Meperidine crosses the placenta barrier and its effects on the foetus depend on the dose and time of administration. Higher concentrations in fetal plasma occur 2-3 hours after intramuscular administration to the mother. Neonatal effects are aggravated by normeperidine which causes more sedation and respiratory depression.

Despite such disadvantages, meperidine continues to be popular in many obstetrics units as it is easy to administer and therefore constitutes a useful means of analgesia when other methods are contraindicated or unavailable.

When local analgesia is contraindicated or unavailable, controlled administration of opioids by the patient (PCA) is a useful method of controlling pain, when the equipment and staff are available. PCA provides the woman with a certain level of control, and this in itself is associated with greater satisfaction; however, it is important that women are instructed on how to use the system effectively.

Many opioids have been used in PCA systems, most recently remifentanil.

Pentazocine is an analgesic agent with sedative properties. It is a drug which slightly affects the analgesic effect of morphine and meperidine and partially reverses the cardiovascular, respiratory and behavioural depression caused by morphine and meperidine. It also has a very slight effect as antagonist of nalorphine.

Remifentanil, a very short-acting opiate, is quickly hydrolysed by blood esterases and tissues and is not accumulated, even after prolonged infusions. There is an increasing number of reports on its use via PCA although, as with fentanyl, the ideal dosing regime is not very clear. The dose most successfully used is 0.2 – 0.8 μg/Kg with a closing time of two minutes. However, close supervision and monitoring of SaO_2 are required and additional oxygen may also be required.

Scientific Evidence

The NICE guideline (10) classifies the evidence found on the use of opioids in analgesia, according to the means of administration: intravenous (IV), intramuscular (IM) and patient-controlled administration (PCA).

IM Administration of Opioids

The NICE guideline (10) recommendations are based on IM administration in evidence from two SRs with meta-analysis (297;298) and one RCT (299).

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

One of the SRs (297) compared the administration of *pethidine with a placebo*, including the results of the RCT (299) also included in the NICE (10) guideline, which evaluates said interventions in 244 women. They found that in the pethidine group there were fewer women dissatisfied with the pain relief one hour after treatment than in the placebo group: RR 0.86 [CI 95% 0.74 to 0.99], and two hours after treatment: RR 0.47 [CI 95% 0.32 to 0.67].

SR-MA o RCTs 1+

Less pain was also observed after half an hour: MD -17 [CI 95% -30 to -4], p<0.05 and there was a higher level of sedation at 15 and 30 minutes: MD 24 [CI 95% 8 to 43], p<0.05 and MD 26 [CI 95% 8 to 41], p<0.05 respectively.

SR/MA of RCTs 1+

The effect of IM administration of opioids on neonatal outcomes was not assessed in this comparison.

With respect to the studies which compared *IM administration of pethidine with other opioids* included in our question, it should be mentioned that in the outcomes assessed only small differences were observed in the incidence of nausea due to pethidine compared to pentazocine (10% vs. 4%, p= 0.01). Both meta-analyses included (297;298) in the NICE guideline (10) were consistent in that administering pentazocine demonstrated a lower incidence of vomiting and somnolence, although the differences were not significant. However, it also appeared to be less effective, as the need for additional analgesia was significantly higher in the pentazocine group compared to the pethidine group: OR 1.95 [CI 95% 1.31 to 2.8]. The studies which compared different IM opioids also failed to report neonatal outcomes.

SR/MA of RCTs 1+

Two other trials conducted in 1970 and included in the aforementioned reviews compared the administration of *high doses of IM pethidine* (80-100 mg) *compared to low doses* (40-50 mg) in a total of 173 women in the two studies. It was found that the need for additional analgesia was significantly higher in the group with low doses: OR 3.74 [CI 95% 1.75 to 8.00]. The high dose group presented a greater tendency towards vomiting and a higher degree of somnolence, despite the fact that the differences were not statistically significant. There were also no differences found concerning: dissatisfaction with pain relief, scores on the pain scale and nausea. There was no data on neonatal outcomes.

SR/MA of RCTs 1+

IV Administration of Opioids

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

A Thai RCT (300) assessed the efficacy and adverse effects of *IV administration of pethidine compared to a placebo* in 84 women. Greater maternal satisfaction with pain relief was observed in the pethidine group compared to the placebo group: 23.8% compared to 7.10%, p=0.0347, and higher levels of adverse effects, nausea y vomiting: 36% compared to 4.8%, p=0.001 and dizziness 26.4% compared to 0%, p<0.001. No information on neonatal outcomes was given. RCT 1+

A Canadian RCT (301) compared the use of *IM pethidine* (50-100 mg/2h up to a maximum of 200 mg) *with IV pethidine* (bolus of 25 mg plus infusion of 60 mg/h and additional bolus of 25 mg/h, if necessary, up to a maximum of 200 mg). In this trial, lower pain intensity was observed from one and a half hours after administering the treatment until the fourth hour, in the group that received IV pethidine, although the group randomly assigned to IM pethidine received a lower dose: average 121 mg vs.82 mg, p=0.0007. When pain scores were compared in a smaller group of participants (n=18) who received similar doses of meperidine (100- 150 mg), the women in the IV group also had lower pain scores: p=0.0092. RCT 1+

No significant differences were found in other outcomes such as duration of labour, vital signs of the mother, fetal heart rate, Apgar scores, level of maternal sedation or side effects reported by the patient.

Two small RCTs (302; 303) conducted in the United Kingdom analysed the analgesic efficacy of *IV PCA of remifentanil* compared to *PCA of pethidine*. The first of the studies (302), with only nine women included, was suspended early due to concern about the preliminary neonatal results for the pethidine group. 2 RCTs 1-

The most recent of the trials (303) included 40 women with IV PCA of remifentanil (40 µg with 2 min closing) compared to IV PCA of pethidine (15 mg with 10 min closing), and both groups had access to Entonox®. It was reported that the women who received remifentanil obtained a higher degree of satisfaction compared to those who received pethidine and a lower neurological adaptative capacity score (NACS) of the neonate at 30 minutes in those who received pethidine. However, the intensity of the pain perceived, nausea, sedation, fetal heart rate (FHR), Apgar test and other maternal and neonatal outcomes did not demonstrate differences between the two groups. RCT 1+

A small open RCT (n=36) with high risk of bias (304) compared, in nulliparous women giving birth, *IV PCA of remifentanil* (20 µg with 3 min closing) in labour with *IM administration of pethidine* (100 mg) together with an antiemetic. A lower intensity of pain was observed in the first two hours in the group which received remifentanil and a lower rate of spontaneous deliveries was suggested amongst the women in this group. RCT 1-

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Update (to January 2008)

The NICE guideline (10) does not assess the same opioids as those used in our context. Although its literature search strategies included pethidine and pentazocine, they did not include remifentanil. This means that the interval of dates used in the update for remifentanil was longer (1985 – January 2009).

After excluding studies which did not comply with the inclusion criteria, and five pilot trials conducted to generate hypotheses to be investigated concerning the effectiveness of remifentanil, four small RCTs (305-308) on the effectiveness of remifentanil during labour were selected.

Evron *et al*., in their study from 2005 (305), *compared* the analgesic effect of administering increasing doses of *remifentanil* (bolus of 0.27-0.93 mcg/kg) in patient-controlled analgesia (PCA) during labour, with the effect of an *infusion* of 150 mg (range 75-200 mg) of *IV meperidine*. The study included 88 women, of whom 43 were randomly assigned to the remifentanil group and 45 to the meperidine group. The administration of IV remifentanil by PCA was more effective and safer for analgesia than IV infusion of meperidine, as the visual analogue score for pain was lower: 35.8±10.2 compared to 58.8±12.8; p<0.001 and the level of maternal satisfaction was higher: 3.9±0.6 compared to 1.9±0.4; p<0.001, with lower sedative effect: 1.2±0.1 compared to 2.9±0.1; p<0.001 and less haemoglobin desaturation: 97.5%±1.0 compared to 94.2%±1.5; p<0.007. The percentage of analgesia failure (or rate of change to treatment with epidural) was also lower for remifentanil compared to meperidine: 10.8% compared to 38.8%; p<0.007. There were no significant differences between the groups in the type of birth or neonatal outcomes. In the remifentanil group there were fewer alarming abnormal fetal heart rate patterns, that is, greater variability and reactivity with less deceleration, p<0.001.

RCT 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Two years later, another RCT (306) was published, which compared the analgesic effectiveness and safety of *IV PCA remifentanil* (25-50 mg every 4 minutes, IV) during labour *with IM meperidine* (1 mg/kg) in women in labour without complications, with single pregnancies and cephalic presentation. This study included 40 women and had considerable risk of bias due to doubtful random assignment and lack of masking. The pain scores measured using the VAS scale at 60 minutes after administration of analgesia were lower in the remifentanil group than in the meperidine group (p<0.0001), during the first (p<0.0001) and second (p=0.013) stages of labour. Ninety-five percent of women classed analgesia as good to excellent in the remifentanil group compared to 35% in the meperidine group (p<0.0001). Side effects such as sedation, nausea and vomiting, respiratory depression and Hb oxygen desaturation were infrequent. There were also no significant differences between the groups in the type of birth or neonatal outcomes.

RCT
1-

The third study selected is from 2008, a Finnish RCT (307), which included a total of 52 healthy women with full-term single pregnancies without complications and compared the use of IV PCA *remifentanil with epidural analgesia* (20 ml levobupivacaine 0.625 mg/ml + fentanyl 2 mg/ml in saline solution).

The RCT that includes a total of 52 healthy women with full-term single pregnancies without complications analyses the outcomes of 45 of them given that 3 in each comparison group pass into the second stage of labour before the study is concluded and one more in the epidural analgesia group who was excluded due to (non-intentional) dural puncture. The remifentanil group showed statistically significant results of greater pain during contractions (measured on a pain scale of 0 to 10, from less to most pain): 7.3 (5.6 to 8.2) vs.5.2 (2.2 to 6.7) p=0.004, greater sedation: 2.3 (1.3 to 2.6) vs. 0 (0 to 0.8) p=0.001 and more women with nausea: 9 vs.24, 2=21, p=0.04.

RCT
1+

However, no statistically significant differences were found in outcomes which measured the level of pain relief (scale from 0 to 4, from least to most pain relief): 2.5 (2.2 to 2.9) vs.2.8 (2.3 to 3.5); p=0.11, or in secondary outcomes such as: future use of the same analgesic option, TA (mmHg), FC (pul/min), SaO2 before and during oxygen supplementation, fetal heart rate during the period studied and 30 minutes later, caesarean section rate, umbilical cord pH and Apgar scores.

RCT
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Amongst the women in the remifentanil group the need to administer additional oxygen in response to a respiratory depression was significantly more frequent. This occurred even in some cases where only an average low dose of 0.15 µg/kg/min remifentanil was used, similar to the effective average dose observed in said study (0.03 to 0.32 µg/min). This suggests that it is not possible to determine a safe dose in terms of preventing hypoxemia whilst administering remifentanil, meaning that additional oxygen must always be used and SaO2, must be monitored, due to the risk of hypoxia. RCT 1+

In the same year Evron *et al*. published another RCT (308) for the purpose of investigating whether the hypothesis which states that the fever associated with labour (due to the use of epidural, or due to other causes) can be suppressed by administering opioids, is true. The study included 201 women during spontaneous delivery, without fever (tº<38° C) to be randomly assigned to the four treatment groups: (1) *epidural ropivacaine only, (2) IV remifentanil only, (3) epidural ropivacaine plus IV remifentanil and (4) epidural ropivacaine plus IV paracetamol*. In the epidural ropivacaine only group, the maximum increase in oral temperature was higher: 0.7±0.6° C compared to the lowest in the remifentanil only group: 0.3±0.4°C; p= 0.013. The percentage of women with fever (≥38 ° C) was also higher during the first six hours of labour: 14% versus 2%, although the difference was not statistically significant. Vasoconstriction was lower in the remifentanil group in comparison with epidural analgesia: 1.4±1.8 versus 3.0±1.7, respectively; p<0.001. These facts go to confirm the theory that low doses of opioids used in analgesia of women in labour without epidural analgesia inhibit fever. RCT 1+

From this new evidence it can be concluded that neuraxial analgesia is more effective in terms of reducing pain and that the safety of IV PCA of remifentanil is still to be clarified. Additionally, the risk of respiratory depression justifies close supervision of the anaesthetist when using remifentanil. There is no evidence concerning the optimal dose, type or means of administration of opioids to women.

Summary of Evidence

Parenteral *opioids* have a moderate effect on pain relief during labour, regardless of the drug or route of administration and can cause nausea and vomiting (297-299).	1+

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IV PCA remifentanil compared to analgesia by infusion of *IV meperidine*, appears to be more effective and have less analgesic failure, less sedative effect, lower rate of appearance of anomalous fetal heart rate patterns and less haemoglobin desaturation, along with greater maternal satisfaction. No significant differences were observed between the two treatments in the type of delivery and neonatal outcomes (305).	1+
Analgesia with *IV PCA remifentanil* is less effective in reducing pain than *neuraxial analgesia* (307).	1+
Analgesia by means of *IV remifentanil* produces lower rates of intrapartum maternal fever rates, compared to epidural analgesia *with ropivacaine* (308).	1+
Analgesia with IV PCA remifentanil leads to the need to administer additional oxygen due to the respiratory depression effect, and to monitor SaO_2 due to the existing risk of hypoxemia (307).	1+
There is a lack of evidence as to the optimal dose, and as to the effect of opioids on the neonate, particularly in breastfeeding.	

Recommendations

A	If parenteral **opioids** are chosen as analgesia, patients should be informed that they have a limited analgesic effect and can cause nausea and vomiting.
A	Anti-emetics should be administered when intravenous or intramuscular opioids are used.
A	In women who receive **remifentanil**, maternal SaO_2 should be monitored and extra oxygen should be administered.

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9.4. Pharmacological Pain Relief Methods

- How effective is neuraxial analgesia?
- How effective are the following obstetric neuraxial analgesia techniques: traditional epidural vs low-dose epidural vs combined (intradural/epidural)?
- Is it beneficial to carry out a systematic coagulation study before administering neuraxial analgesia?
- How effective is the perfusion of intravenous solutions (crystalloids, colloids) before performing an obstetric neuraxial analgesia technique?
- Should the use of obstetric neuraxial analgesia be postponed until an advanced stage of labour?
- How does the form of analgesia administration influence labour and its outcomes?
- How effective is maternal monitoring during the establishment and maintenance of neuraxial analgesia?
- How does the use of local anaesthetic influence obstetric neuraxial analgesia?
- How does the use of opioids and neuraxial coadjuvants influence labour and its outcomes?
- Should epidural analgesia be maintained during the second stage of labour?

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9.4.1. Neuraxial Analgesia Versus no Analgesia

- How effective is neuraxial analgesia?

Many women describe childbirth as one of the most painful experiences of their lives. This has led to a decades-long search for pain-relief strategies. In Spain, neuraxial techniques came onto the obstetrics scene in the 1970s, achieving major pain relief by interrupting the transmission of pain reception impulses in the spinal cord using drugs (local anaesthetics with or without opioids) which were administered close to the spinal cord, minimising fetal drug exposure. The high efficacy of this technique led to its rapid expansion over the following decades, and it became the standard technique for pain relief during childbirth.

This point therefore aims to assess the efficacy of the obstetric pain relief method most commonly used in Spain; also, to determine the extent to which it may interfere with the progression of labour, and what effects on mother and child can really be attributed to it, in order to provide women with sufficient information and so aid them in taking decisions.

Scientific Evidence

This section investigates the efficacy of all forms of neuraxial analgesia: neuraxial analgesia versus no analgesia versus non-epidural pharmacological analgesia (parenteral opioids or others).

The NICE guideline (10) provides a significant amount of evidence, with two SRs and nine RCTs. The SRs and seven of the nine RCTs included were of LE=1+.

One RCT, LE=1+ (309), included in a Cochrane SR (310) investigates the efficacy of *neuraxial analgesia vs no analgesia*. It found that the first stage of labour was significantly shorter in women who received analgesia than those who did not (WMD -19.00 minutes [CI 95%, 1.54 to 83.50 minutes]), with no significant differences in the duration of the second stage of labour (WMD 6.03 minutes [CI 95%, 12.61 to 0.55 minutes] or type of birth. Labour was described as very painful by 9% of women receiving epidural analgesia versus 100% of women receiving no analgesia.

RCT
1+

The 2005 Cochrane SR (310), which included 21 RCTs (n=6,664 women), involved a meta-analysis of 17 of the trials. This included 5,576 healthy women who met the inclusion criteria of the NICE guideline (10). All the trials compared *neuraxial analgesia (all forms) to opioid analgesia.*

Two of the trials (n=164) investigated the perception of pain relief and found significant results that showed better pain relief in the neuraxial analgesia group in both the first stage of labour (WMD -15.67 [CI 95%, 16,98 to -14.35]) and the second (WMD -20.75 [CI 95%, -22.50 to -19.01]).

SR/MA of RCTs
1+

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Meta-analysis of thirteen RCTs found that there was less need for additional analgesia in the group receiving neuraxial analgesia: RR 0.05 [CI 95%, 0.02 to 0.17]. The onset time of rescue medication's analgesic effect was also shorter in this group: WMD -6.70 minutes [CI 95%, -8.022 to -5.38 minutes].	SR/MA of RCTs 1+
The duration of the second stage of labour, which was investigated in ten RCTs, is longer in the neuraxial analgesia group: WMD 18.96 minutes [CI 95%, 10.87 to 27.06 minutes]. This is also true of the risk of instrumental delivery (fifteen RCTs): RR 1.34 [CI 95%, 1.20 to 1.50] and the use of oxytocin (ten RCTs): RR 1.19 [CI 95%, 1.02 to 1.38].	SR/MA of RCTs 1+
Turning to maternal outcomes, the risk of hypotension is greater in the neuraxial analgesia group (six RCTs): RR 58.49 [CI 95%, 21.29 to 160.66], as is the risk of maternal fever above 38 °C (two RCTs): RR 4.37 [CI 95%, 2.99 to 6.38] and urinary retention (three RCTs): RR 17.05 [CI 95%, 4.82 to 60.39].	SR/MA of RCTs 1+
No significant differences in caesarean section rates were found.	
There was less administration of naloxone to babies in the neuraxial analgesia group (four RCTs): RR 0.15 (CI 95%, 0.06 to 0.40].	SR/MA of RCTs 1+
Using trials included in the SR by Anim *et al* (310), the NICE guideline (10) involved another meta-analysis that included only trials that used *low-dose neuraxial analgesia* (<0.25% bupivacaine or equivalent) *versus opioid analgesia*. Low-dose neuraxial analgesia is also associated with an increase in the risk of instrumental delivery (seven RCTs): RR 1.31 [CI 95%, 1.14 to 1.49], a longer second stage of labour (four RCTs): WMD 20.89 minutes [CI 95%, 10.82 to 29.57 minutes] and an increase in the risk of oxytocin use (four RCTs): RR 1.31 [CI 95%, 1.03 to 1.67].	SR/MA of RCTs 1+
Another, earlier SR (311) comparing *neuraxial analgesia to opioids* supported the findings of the Cochrane review. This review included fourteen RCTs involving 4,324 women, and two prospective studies involving 395 women. This made it possible to evaluate data on breastfeeding and long-term urinary incontinence, which had not been studied in previous RCTs.	
No significant differences were found regarding the success of breastfeeding at 6 weeks. However, results on short-term urinary retention were significant: it was greater with neuraxial analgesia.	SR/MA of RCTs 1+
Regarding the degree of pain, women in the neuraxial analgesia group reported less pain during the first stage of labour (WMD 40 mm [CI 95%, 42 to 38] p<0.0001) and in the second stage (WMD 29 [CI 95%, 38 to 21), p<0.0001). Maternal satisfaction with pain relief was higher in the neuraxial analgesia group: OR 0.27 [CI 95%, 0.19 to 0.38], p<0.001.	SR/MA of RCTs 1+

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The following were also greater in the neuraxial analgesia group (duration of second stage of labour (15 minutes [CI 95%, 9 to 22], p<0.05), use of oxytocin (OR 2.80 [CI 95%, 1.89 to 4.16], p<0.05), instrumental delivery (OR 2.08 [CI 95%, 1.48 to 2.93], p<005), maternal fever above 38 °C (OR 5.6 [CI 95%, 4.0 to 7.8], p<0.001) and hypotension (74.2 [4.0 to 137.5], p<0.001). SR/MA of RCTs 1+

Another SR from 2002 (312) was performed to evaluate the effect of *neuraxial analgesia versus opioids* during labour on the neonate's acid-base status. The results of six RCTs, which were also included in the Cochrane review mentioned above (310), showed that umbilical pH was better in the neuraxial analgesia group: WMD 0.009 [CI 95%, 0.002 to 0.015], p<0.007. Base excess was also better: WMD 0.779 mEq/l [CI 95%, 0.056 to 1.502 mEq/l], p<0.035. The study concluded that neuraxial analgesia was associated with better neonatal acid-base status than opioids, suggesting that placental exchange is sufficiently maintained during neuraxial analgesia. SR of RCTs 1+

A hospital-based RCT (313) which was conducted in the USA and recruited 715 women compared *epidural analgesia to pethidine PCA* and studied their effects on maternal fever above 38 °C via secondary analysis of data obtained in the trial.

32% of women in the epidural group and 28% of women in the control group received no treatment because their labours and births progressed rapidly. Five women who were allocated to receive pethidine PCA actually received epidural analgesia. This trial is assigned LE 2+, due to its methodological weaknesses. RCT 1+

15% of women in the epidural group and 5% of those in the PCA group had a fever above 38 °C, p<0.001 (although this effect was not apparent in the subgroup of multiparous women). In the subgroup of nulliparous women, meanwhile, 24% of those in the epidural group and 5% of those in the PCA group had a fever, p<0.001. RCT 2+

Step-by-step logistic regression analysis found that there was a significant, independent association between fever above 38 °C and the following factors: prolonged labour lasting more than 12 hours, internal Fetal monitoring and use of oxytocin. The authors conclude that nulliparity and dysfunctional labour are significant contributing factors in fever attributed to epidural analgesia. RCT 1+

A population cohort study conducted in Sweden, in which 94,217 women were enrolled (314), examined the association *between epidural analgesia and type of delivery*. 52 sites were included between 1998 and 2000. The caesarean section and instrumental delivery rates within each category of site were compared, according to the rate of epidural analgesia use.

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No association was found between the rate of epidural analgesia use and the rates of non-scheduled caesarean sections or instrumental delivery. Cohort study 3

In summary, the NICE guideline (10) concludes that there is a high level of evidence to suggest that neuraxial analgesia has the following effects when compared to drug-based analgesia:

- It provides more effective pain relief.
- It is associated with a longer second stage of labour and an increase in instrumental deliveries, although this effect may be due to the type of care provided in the UK at the time.
- It does not prolong the first stage of labour or increase the caesarean section rate.
- It is associated with better neonatal acid-base status than opioids.

Update (2006 to November 2008)

A 2008 RCT (307) with **LE=1+** was selected. 52 healthy women at full term with single, non-complicated pregnancies took part in the trial. It compared the use of remifentanil PCA IV with neuraxial analgesia (20 ml levobupivacaine 0.625 mg/ml and fentanyl 2 µg/ml in saline).

This RCT yields significant results, indicating greater pain (0-10) in the remifentanil group: 7.3 (5.6 to 8.2) versus 5.2 (2.2 to 6.7), p=0.004; greater sedation: 2.3 (1.3 to 2.6) versus 0 (0 to 0.8), p=0.001; and more nausea: 9/24 versus 2/21, p=0.04. However, when pain relief achieved was evaluated using a scale from 0 to 4, no significant differences were found: 2.5 (2.2 to 2.9) versus 2.8 (2.3 to 3.5), p=0.11. RCT 1+

This new evidence leads us to conclude that neuraxial analgesia is more effective in terms of lessening pain.

See Appendix 2.4.1.

Summary of Evidence

Neuraxial analgesia provides effective pain relief during labour (309).	1+
The first stage of labour is significantly shorter in women who receive neuraxial analgesia than those who do not receive any type of analgesia (309).	1+
Neuraxial analgesia versus parenteral opioid analgesia	
Neuraxial analgesia provides greater satisfaction, greater pain relief during the first and second stages of labour and less need for additional analgesia than opioids (310).	1+

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The duration of the second stage of labour, the risk of instrumental delivery and the use of oxytocin are greater when neuraxial analgesia is administered, whether at conventional or at low doses (310).	1+
Women have a higher risk of hypotension, fever above 38 °C and urinary retention when neuraxial analgesia is administered (310).	1+
Neuraxial analgesia is associated with better neonatal acid-base status than opioids. Neonates also have a lower risk of requiring naloxone (310, 312).	1+
No differences have been demonstrated between neuraxial analgesia and parental opioids regarding breastfeeding at 6 weeks (311).	1+
Women manifest more pain, suffer greater sedation and experience more nausea with intravenous remifentanil than with epidural analgesia (307).	1+

Recommendations

A	Women should be informed that neuraxial analgesia is the most effective method of pain relief, but that it can cause hypotension, fetal heart rate alterations, urinary retention, pruritus and fever, and lengthens the second stage of labour, increasing the risk of instrumental birth.
√	Women should be informed of the risks, benefits and implications for the birth of neuraxial analgesia.

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9.4.2. Traditional Epidural Analgesia Versus Low-Dose Versus Combined Epidural Analgesia

- How effective are the following obstetric neuraxial analgesia techniques: traditional epidural vs low-dose epidural vs combined (intradural/epidural)?

Neuraxial (regional) analgesia may be epidural, intradural or a combination of the two. Due to its short duration, intradural analgesia is not normally used in obstetrics.

In obstetrics, neuraxial analgesia was first used as an epidural technique in which a catheter was usually placed in the epidural space, and drugs then injected through it. *Traditional, or high-dose regimens* used only local anaesthetics at concentrations of 0.25% or more; this achieved good pain control but a significant motor block, probably one reason for its association with prolonged labour and instrumental delivery. Attempts were therefore made to preserve women's motor function and so enable them to achieve spontaneous delivery and walking by reducing doses to concentrations below 0.25%, usually combined with opioids to maintain a high analgesic effect. At the beginning of this century, combined intradural and epidural analgesia became increasingly popular. This is an injection of an opioid and/or local anaesthetic into the intradural space and the insertion of an epidural catheter immediately beforehand or afterwards for subsequent maintenance of the analgesia, usually in the form of low-dose epidural administration. The aim was to combine the advantages of intradural and epidural techniques, with a very swift onset of effect, a powerful sensory block and lower quantities of drugs. However, the actual advantages are unclear and other side effects, such as pruritus, appear more frequently. This calls into doubt the use of a more invasive technique.

This section attempts to clarify any potential advantages of one technique over another.

Scientific Evidence

The NICE guideline (10) used one SR (315), two RCTs (316, 317) and one cohort study (318) to address this question.

The SR (315) found that combined (introduced/epidural) analgesia provided swifter onset of analgesic effect than epidural alone (four RCTs): WMD 5.50 minutes (CI 95%, 6.47 to 4.52 minutes). However, once the analgesia has taken effect both techniques are equally effective. The review also found that women were more satisfied with the administration of combined analgesia (three RCTs): OR 4.69 (CI 95%, 1.27 to 17.29), but with a greater incidence of pruritus: OR 2.79 (CI 95%, 1.87 to 4.18). No differences were observed in terms of neonatal outcomes or type of delivery.

SR/MA of RCTs
1+

The RCT conducted in Saudi Arabia in 2004 (316) yielded similar results regarding the onset of analgesic effect and the appearance of pruritus, but not regarding maternal satisfaction.

RCTs
1+

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The second RCT (317) was the COMET trial, conducted in the UK and published in 2001. It compared three different epidural regimens, one traditional and two modern, in 1,054 women giving birth for the first time.

- *Conventional-regimen epidural administration*: 10 ml bolus of 0.25% bupivacaine.
- *Modern regimen with low-dose epidural infusion*: mixture of 0.1% bupivacaine plus 2 µg/ml fentanyl at 10 ml/hour, following an initial epidural bolus of 15 ml.
- *Modern regimen with combined analgesia administration*: initial intradural administration of 1 ml 0.25% bupivacaine and 25 µg fentanyl, subsequently maintained using low-dose epidural 0.1% bupivacaine plus 2 µg/ml fentanyl (initial bolus 15 ml, subsequent boluses 10 ml).

There was no evidence of differences in severity of pain following epidural administration. The proportion of women able to push during labour was similar in the combined analgesia group (29%) and the traditional regimen group (20%). However, the proportion of women able to push in the low-dose epidural infusion group (38%) was significantly higher than in the traditional administration group, p=0.01. RCT 1++

Turning to obstetric outcomes, women allocated the modern dosing regimens had more spontaneous deliveries (RR 1.39 [CI 95%, 1.02 to 1.88]) and second stages of labour lasting ≤60 minutes (RR 1.36 [CI 95%, 1.01 to 1.84]) than women in the group receiving the traditional regimen. There was no evidence of differences in the caesarean section rates between groups. RCT 1++

There was evidence that neonates in the low-dose epidural infusion group were more likely to receive low Apgar scores ≤7 at 1 minute than those receiving the traditional regimen: 18% versus 11%, p=0.01. However, there were no differences in the Apgar test at 5 minutes or in admission to a neonatal unit. Comparison of these two groups required a high level of resuscitation (ambulatory and/or intubation and/or naloxone): in 16 of 350 women receiving low-dose epidural and 5 of 353 women receiving traditional regimen, p=0.02. There were no significant differences between the neonatal outcomes of the combined and traditional groups. The quantity of fentanyl used was lower in the combined group than the low-dose epidural group. RCT 1++

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The women who took part in the COMET trial were enrolled into a prospective paired cohort study (318) to analyse long-term outcomes. No differences were found between the intervention groups in terms of long-term maternal satisfaction with the birth experience, long-term back pain, head and neck pain or paraesthesia, although women allocated to modern regimens had lower rates of stress urinary incontinence and fewer problems with intestinal control than women in the traditional group.

Cohort study 2+

Update (2006 to November 2008)

The SR by Simmons *et al* (319) has been selected. This is an update of the SR (315) mentioned in the NICE guideline (10), and includes the other two RCTs (316, 317) selected for the guideline. This new review includes a total of 19 studies and 2,658 women.

When combined analgesia is compared with *traditional epidural analgesia*, the combined technique required less rescue analgesia (RR 0.31 [CI 95%, 0.14 to 0.70]), rates of urinary retention were lower (RR 0.87 [CI 95%, 0.80 to 0.95]) and a lower incidence of instrumental delivery was suggested (RR 0.82 [CI 95%, 0.67 to 1]). In contrast, a higher incidence of pruritus was observed (RR 1.73 [CI 95%, 1.39 to 2.14]).

SR/MA of RCTs 1+

When *combined analgesia* is compared with *low-dose epidural analgesia*, combined analgesia shows a somewhat faster onset of analgesic effect: MD 5.59 (CI 95%, 6.59 to 4.58). More women experienced effective analgesia 10 minutes after the first dose: RR 1.94 (CI 95%, 1.49 to 2.54). It also yields higher pruritus rates: RR 1.62 (CI 95%, 1.34 to 1.97), with no differences in ability to walk, maternal satisfaction, obstetric outcome or neonatal outcomes.

SR/MA of RCTs 1+

In conclusion, combined analgesia and traditional and low-dose epidural analgesia have demonstrated effective pain relief during childbirth.

Summary of Evidence

Combined (intradural and epidural) analgesia provides a faster onset of analgesic effect than epidural alone. However, once analgesia has taken effect both techniques are equally effective. Women were more satisfied with combined analgesia, but a higher incidence of pruritus was observed. No differences were observed regarding neonatal outcomes or type of delivery (315, 316).	1+
Comparison of traditional and modern, low-dose and combined (intradural and epidural) regimens showed no differences regarding severity of pain following administration of epidural or the number of women able to push (317).	1++

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The differences observed between traditional and modern, low-dose regimens included more women with spontaneous deliveries, with second stages of labour lasting ≤60 minutes and more women able to push in the low-dose epidural infusion group. Caesarean section rates were similar. The neonates in this group were more likely to have a low Apgar score ≤7 at 1 minute, although not at 5 minutes or regarding admission to a neonatal unit (317).	1++
Long-term outcomes show no differences between the regimens in terms of maternal satisfaction with the birth experience, back pain, head and neck pain or paraesthesia. However, women allocated to modern regimens had lower rates of stress urinary incontinence and fewer problems with intestinal control than those in the traditional group (317).	1++
The advantage of combined analgesia is rapid onset of analgesic effect. Its disadvantages are a higher incidence of pruritus and its more invasive nature. It also provides a better analgesic effect (less rescue medication needed) than traditional epidural analgesia, and less urinary retention. There are no differences in maternal satisfaction between combined and low-dose epidural analgesia (319).	1+

Recommendations

A	Any low-dose neuraxial technique is recommended: epidural or combined.
A	If analgesia needs to be established quickly, combined epidural (epidural/intradural) should be used.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

9.4.3. Coagulation Testing

- Is it beneficial to carry out a systematic coagulation study before administering neuraxial analgesia?

Coagulation testing prior to neuraxial analgesia has become an essential requirement in many hospital maternity units. In fact, it has become one of the tests routinely performed during the last weeks of pregnancy. However, its clinical usefulness in healthy women is currently being questioned, as is whether it should be a routine procedure or reserved for women with pregnancy hypertensive disorders, pre-eclampsia, HELLP syndrome or coagulation disorders, or when considered necessary on an individual basis after taking clinical history and performing examination.

It therefore seems sensible to evaluate the effectiveness, safety and usefulness of routine use of this procedure in labour care for healthy women.

Scientific Evidence

The NICE guideline (10) does not address the issue of usefulness of routine coagulation testing before administering neuraxial analgesia.

Update (to July 2008)

Three documents (16, 320 322) have been selected for the update. The first is a CPG on obstetric anaesthesia, developed by the American Society of Anaesthesiologists Task Force in 2007 with *LE=4* (16). It includes 473 studies.

The group that developed the American guideline on obstetric anaesthesia states that it is impossible to determine whether a **platelet count** is a predictor of neuraxial anaesthesia-related complications, due to a lack of evidence. It therefore recommends that a routine intrapartum platelet count is not necessary for healthy women as it does not reduce anaesthesia-related maternal complications. In contrast, the observational studies and case series evaluated suggest that a platelet count is clinically useful in women with suspected pregnancy-related hypertension, pre-eclampsia or HELLP syndrome and other coagulation-related disorders, and concludes that a routine platelet count is unnecessary in healthy women giving birth.

Consensus
CPG
IV

The second study selected for the update (320) is an SR published in 2005. It aimed to determine whether abnormal coagulation tests might be a predictor for bleeding during invasive procedures (e.g. liver or kidney biopsy, insertion of nephrostomy tube, insertion of transhepatic biliary tube, epidural injection, lumbar puncture, central venous channelling or insertion of venous access device, angiography, venography, cardiac catheter insertion, thoracocentesis, paracentesis or endoscopy).

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Of the studies included, 24 were observational (prospective or retrospective case series), and one was an RCT. The studies involved coagulation tests for prothrombin time (PT) or international normalisation ratio (INR) performed before an invasive procedure. Taking an abnormal result to be increased INR above 1.2 or 1.5, and increased PT between >11.5 seconds and >16 seconds. The studies that provided information on bleeding were included. The studies were grouped together according to the various procedures performed, and narrative synthesis was performed, as there was evident qualitative variation between the studies and they exhibited methodological shortcomings. The results showed similar bleeding rates for patients with abnormal and normal coagulation test results. The study concludes that there is insufficient evidence to conclude that an abnormal coagulation test result is a predictor for bleeding.

SR of observational studies III

The last document selected is another SR by the British Society for Haematology, published in 2008 (321). This includes results of the SR mentioned above (320).

The SR aims to determine whether a history of bleeding in patients and routine coagulation tests before surgery are predictors of abnormal perioperative haemorrhaging. Following a Medline search, the review included nine observational studies (three of them prospective) with sufficient data to calculate the predictive value (PV) and probability quotients (PQs) of the test. The studies included varied in terms of inclusion criteria, confounding factors, definition of abnormal coagulation test result, methods of taking haemorrhaging history, definition of post-operative haemorrhaging and patients enrolled. Because of this, no meta-analysis was performed. However, all the studies show unfavourable results for the clinical usefulness of the coagulation tests evaluated: activated thromboplastin time (APTT) and prothrombin time (PT).

Coagulation testing showed a positive PV ranging from 0.03 (CI 95%, 0.00 to 0.15) to 0.22 (CI 95%, 0.09 to 0.43) in the studies, and a positive PQ between 0.94 (CI 95% 0.56 to 1.57) and 5.1 (CI 95%, 1.18 to 21.96). Only three of the studies showed statistically significant values. The absolute difference in the risk of bleeding between patients with abnormal and normal coagulation test results was also statistically insignificant in eight of the nine studies. The absolute range was 0.008 (CI 95%, 0.07 to 0.069) to 0.166 (CI 95%, 0.037 to 0.372).

SR of observational studies III

These data indicate that coagulation tests are poor predictors of perioperative haemorrhaging. We therefore conclude that the bleeding history of patients undergoing surgery must be taken, including details of previous operations and traumas, family history and details of antithrombotic use. Patients with no history of bleeding do not require routine coagulation testing before surgery.

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In contrast, taking a bleeding history showed a positive PV between 0.02 and 0.23 in the four studies that investigated it. It also showed a positive PQ between 1.27 (CI 95%, 0.99 to 1.64) and 5.04 (CI 95%, 3.48 to 7.31), which was statistically significant in only one of the four studies.

SR of observational studies
III

The evidence provided by the studies included shows that predicting the risk of bleeding on the basis of medical history depends on how specific the history is and on positive family history of bleeding and bleeding after traumatic events (other than childbirth) for the identification of patients with a coagulation disorder.

The group that developed the guideline recommends that a history of bleeding should include information on symptoms of bleeding, previous haemostatic alterations, family history and drug history. If this yields a positive result for symptoms of bleeding, quantitative examination of symptoms should be performed.

Summary of Evidence

Coagulation tests are poor predictors of perioperative haemorrhaging, because patients with normal and abnormal coagulation test results have similar risks of bleeding (321).	III
There is insufficient evidence to determine whether a platelet count is a predictor of neuraxial anaesthesia-related complications (16).	IV
Medical histories' predictive capacity for bleeding depends on how specific histories are and on positive family history of bleeding and bleeding after traumatic events (other than childbirth) (321).	III

Recommendations

C	A routine coagulation study should not be carried out before neuraxial analgesia in healthy women in labour.
√	A routine intrapartum platelet count should not be carried out before neuraxial analgesia in healthy women in labour.
√	The decision to carry out a platelet count and a coagulation test should be tailored to each case and based on the patient's history, physical examination and clinical signs.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.4.4. Intravenous fluid preload

- How effective is the perfusion of intravenous solutions (crystalloids, colloids) before performing an obstetric neuraxial analgesia technique?

When neuraxial analgesia during labour was introduced in the 1970s, it involved high doses that could cause maternal hypotension and consequent changes in fetal heart rate. In order to avoid this common side effect, which could have serious consequences, prior perfusion of intravenous liquids was performed.

Due to the current use of modern, low-dose neuraxial analgesia regimens, it was thought appropriate to review the need to continue this practice.

Scientific Evidence

The evidence provided by the NICE guideline (10) is based on six RCTs included in a high-quality SR (323), which included 473 women.

Two of trials used high doses of local anaesthetic, two used low-dose fentanyl and the remaining two used combined intradural and epidural analgesia. The controls used were simulated infusion as a placebo and no administration of any prior treatment.

In the trials that used *high doses of anaesthetics*, prior administration of intravenous fluids reduced the incidence of maternal hypotension (two RCTs involving 102 women): RR 0.070 (CI 95%, 0.01 to 0.53) and FHR abnormalities: RR 0.36 (CI 95%, 0.16 to 0.83). There was no evidence of any differences in other maternal or perinatal outcomes.

SR/MA of RCTs
1+

In the trials that used *low-dose anaesthetics,* there was no evidence of significant differences in hypotension (two RCTs involving 260 women): RR 0.73 (CI 95%, 0.36 to 1.48) or abnormalities in FHR: RR 0.46 (CI 95%, 0.39 to 1.05), although the prior administration group showed a slight trend towards lesser abnormalities in FHR. No other outcomes were observed.

In contrast, in the studies that used *combined intradural and epidural analgesia* no differences were observed in either the incidence of maternal hypotension or abnormalities in FHR.

No differences in type of delivery were observed between the groups with and without prior administration.

Update (2006 to July 2008)

No new studies have been found on the perfusion of intravenous solutions prior to neuraxial analgesia.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Summary of Evidence

There is evidence that intravenous administration prior to neuraxial analgesia reduces the rates of maternal hypotension and FHR abnormalities when high-dose epidural analgesia is administered. However, the existing evidence is insufficient to confirm whether it is useful at low doses (323).	1+

Recommendations

√	Intravenous access should be ensured before starting neuraxial analgesia.
A	Intravenous preloading need not be carried out routinely before low-dose epidural anaesthesia or with combined intradural/epidural anaesthesia.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.4.5. Beginning Analgesia Administration

- Should the use of obstetric neuraxial analgesia be postponed until an advanced stage of labour?

The best time to begin administering neuraxial analgesia has been the subject of controversy. For a long time it was thought that early administration was harmful to the progression of labour, and administration before the beginning of the active phase of labour was therefore not recommended. However, recent studies call this into question.

Scientific Evidence

The NICE guideline (10) includes a total of six studies on which to base recommendations. Of these, two RCTs conducted in Israel (324, 325) compare early and late administration of neuraxial analgesia.

The first RCT, which enrolled 449 nulliparous women with cervical dilatation under 3 cm, compared beginning analgesia immediately the first time a woman required it with delaying administration until at least 4 cm dilatation. It found no evidence of differences in the caesarean section rate (RR 1.18, p=0.779), use of oxytocin during the first stage (RR 1.07, p=0.57) or spontaneous vaginal delivery: RR 0.91, p=0.85. In addition, 78% of women who received epidural analgesia in the second stage of labour reported that they would prefer to be in the other group in a subsequent labour. The differences are significant; p<0.001. RCT 1+

The second Israeli RCT found no differences between the two groups regarding duration of the second stage, type of delivery or Apgar score at 1 or 5 minutes. RCT 1+

NICE (10) concludes that early administration of neuraxial analgesia during the first stage of labour does not affect the progression of labour, type of delivery or condition of the neonate.

Update (2006 to September 2008)

The search identified seven studies, six of which were excluded because they did not meet the inclusion criteria. An SR performed in 2007 was selected (326). A RCT conducted in China (327) was also selected. This was detected thanks to alerts included in the search strategies.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

SR of RCTs & observational studies

This SR (326) was of medium quality. It included nine studies: five RCTs already included in the NICE guideline (10), one cohort study and three retrospective studies, involving a total of 3,320 women. Its aim was to determine the effect of early administration of neuraxial analgesia in nulliparous women on caesarean sections, instrumental deliveries and neonatal well-being. The effect on the duration of labour was also measured. The meta-analysis studies involved different interventions in the control group, including opioid administration before late administration of epidural analgesia.

The results obtained did not show any differences in caesarean section rates (OR 1.00 [CI 95%, 0.82 to 1.23]) or the rates of instrumental vaginal delivery (OR 1.00 [CI 95%, 0.83 to 1.21]). However, women who received opioids during the first stage and late epidural analgesia had a higher incidence of instrumental deliveries, indicated as result of Fetal compromise, than the group that received early epidural analgesia.

No differences were found between early administration and the control group in the duration of the first or second stage of labour or the use of oxytocin.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The very high-quality RCT conducted in China (327) aimed to evaluate whether epidural analgesia controlled by the woman and administered at 1 cm cervical dilatation or more increased the risk of prolonged labour or caesarean section. The 12,793 women enrolled in the trial were randomised to a group receiving early administration of epidural analgesia (cervical dilatation at least 1.0 cm) or another group receiving late administration (cervical dilatation at least 4.0 cm), bolus of 0.125% ropivacaine plus sulfentanil 0.3 µg/ml, initiated (following a test dose) with a 15 ml bolus and maintained using a PCEA (patient-controlled epidural analgesia) pump via 10 ml continuous infusion boluses. The primary outcome was the caesarean section rate. Intention-to-treat analysis did not show any statistically significant differences between the two groups: 23.2% [CI 95%, 18.7 to 24.5] in the early analgesia group versus 22.8% [CI 95%, 18.7 to 24.9] in the late analgesia group. The duration of vaginal delivery as of the request for analgesia is the same in both groups: 11.3±4.5 hours for early epidural versus 11.8±4.9 hours for women in the late epidural group; p=0.90. There were no statistically significant differences in the duration of vaginal delivery, the latent and active phases of the first stage of labour or duration of the second stage of labour. The incidence of vomiting during labour was significantly lower in the early epidural administration group: 535 (8.4%) women with nausea versus 659 (10.3%) women with nausea in the late epidural group, p=0.002, although the latter result may be related to the fact that late administration was performed together with meperidine administration. No significant differences were observed in any other epidural-related adverse effects (maternal fever, urinary retention and incontinence, shivering, hypotension). Neonatal outcomes were also similar in both groups. However, there was a higher rate of successful breastfeeding at 6 weeks in the late epidural analgesia group, p<0.0001.

RCT
1+

The results support administration of neuraxial analgesia in early phases of the first stage of labour. The SR concludes that delaying administration of neuraxial analgesia when it is requested is not considered good medical practice.

Summary of Evidence

Early administration (<3 4 cm cervical dilatation) of epidural analgesia does not affect the use of oxytocin, type of delivery or duration of labour (324, 325, 327).	1+

Recommendations

A	Local analgesia can be provided when the woman requests it, even in early phases of the first stage of labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.4.6. Method of Epidural Analgesia Administration

- How does the form of analgesia administration influence labour and its outcomes?

There are various ways to maintain epidural analgesia in women: continuous perfusion, boluses administered by hospital staff (PCA) and patient-controlled administration (PCEA) of either boluses only or boluses combined with basic continuous perfusion (CP), or PCEA+CP.

The analgesia administration methods available can affect efficacy of analgesia, maternal satisfaction, total quantity of anaesthetic used, side effects, costs and, in the case of PCEA, management of hospital staff's time. It is therefore advisable to be aware of the effects of these differences in order to select the most suitable administration method in each individual case.

Scientific Evidence

The volume and quality of evidence provided by the NICE guideline (10) includes a total of seventeen RCTs and one SR in order to address the issue of type of analgesia administration. All the studies included have LE 1+.

The NICE guideline (10) selected eight trials that compared *intermittent boluses administered by hospital staff with bupivacaine* in four trials (328-331), *bupivacaine plus fentanyl* in three trials (332-334) and *ropivacaine plus fentanyl* in one trial (335), *versus PCEA*. The trials were homogenous, so their results were combined in a meta-analysis with LE 1+. The meta-analysis showed that CP required higher doses of anaesthetic than intermittent administration: WMD -5.78 [CI 95%, -7.61 to -3.96]. SR/MA of RCTs 1+

Turning to side effects, no differences were found between treatment groups in terms of hypotension, pruritus, motor block, FHR abnormalities or other neonatal outcomes. However, the trials are inconsistent where maternal satisfaction is concerned: one of the RCTs found no differences between the groups, while in another the women in the CP group showed greater satisfaction. SR/MA of RCTs 1+

An SR that included a meta-analysis (336) with LE=1+ and an RCT (337) with LE=1+ were used to compare *PCEA to CP* (ropivacaine or bupivacaine).

The results showed that PCEA reduced the need to call the anaesthetist a second time and the total dose of anaesthetic, and that it caused less motor block. There were no differences in outcomes related to maternal or neonatal side effects, or those related to type of delivery or duration of labour. SR/MA of RCTs 1+

When *PCEA was compared to intermittent boluses administered by hospital staff*, using various dosing regimens, a moderate level of evidence and heterogeneity between trials were found.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

A trial conducted in 1990, LE=1+ (338), found no difference between the two methods of administering epidural analgesia. RCT 1+

A second trial, LE=1+ (339), found a limited trend towards less pain 2 3 hours after the beginning of analgesia in the intermittent bolus group. There were no differences in mean pain, hypotension, shivering, pruritus or vomiting. RCT 1+

The most recent trial, LE=1+ (340), was conducted in 2004. It found significantly less pain during the first and second stages of labour for PCEA, but using higher doses of bupivacaine. RCT 1+

Although there were no apparent differences in analgesic, obstetric or neonatal outcomes, it is worth highlighting that PCEA may increase in maternal satisfaction.

Regarding *different doses and PCEA closure times,* it was found that there were no differences in terms of severity of pain or motor or sensory block, and that women in the group with higher doses needed less rescue anaesthesia. In addition, a higher dose of PCEA may reduce pain and increase women's satisfaction.

In summary, all methods of epidural administration were shown to achieve effective pain relief.

PCEA entails a lower total dose of local anaesthetic than CP. This implies less motor block and less need for further interventions by the professional anaesthetist.

When compared to intermittent boluses administered by hospital staff, PCEA increased women's satisfaction regarding pain relief.

Update (2006 to June 2008)

No new studies were selected.

Summary of Evidence

Intermittent boluses administered by hospital staff entails a lower total dose of local anaesthetic than CP. This implies less motor block (10).	1+
When compared to intermittent boluses administered by hospital staff, PCEA increases women's satisfaction regarding pain relief (10).	1+

Recommendations

A	PCEA administration is recommended. Depending on the different resources CP and boluses administered by hospital staff are valid options.

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9.4.7. Maternal surveillance

- How effective is maternal monitoring during the establishment and maintenance of neuraxial analgesia?

One of the adverse effects that may arise during the establishment of neuraxial analgesia is hypotension, which fundamentally occurs in high dose regimens. Other possible adverse effects such as pruritus, urinary retention or fever may appear later on.

Intraoperative anaesthetic techniques, including neuraxial techniques, require a minimum of monitoring, including electrocardiograms (ECG), blood pressure, oxygen saturation (SaO2) and body temperature. However, it seems necessary to know the type of monitoring that is appropriate and its effectiveness when analgesic techniques are used on healthy women giving birth.

Scientific Evidence

The evidence responding to this question in the NICE Guide (10) are two SR aimed at evaluating the adverse effects and co-interventions due to neuroxaial analgesia.(310; 341)

The first SR (341) brings together nineteen RCTs published between 1990 and 2000 that include 2,708 women and resumes, in a narrative format, the chief adverse effects related to neuraxial analgesia. Hypotension was found to have an average incidence of 10.5% in the 44 treatment groups in 16 studies. Urinary retention had an average incidence of 26.5% in the three studies, pruritus was also observed in 17 studies, having an average incidence of 62%. The incidence of pruritus was greater when opioids were given in higher doses. Incidence of motor block was 13.3% and sedation 21%.

SR of RCTs 1+

The second SR (310) with a LE=1+ compares epidural analgesia with non-epidural analgesia. A meta-analysis is performed with 18 studies (n=5,705 mujeres). All of them included women in labour at more than 36 weeks gestation and the use of different types of neuraxial analgesia.

The findings show that epidural versus non-epidural analgesia is associated with a significant increase in the following adverse effects: maternal hypotension (6 studies): RR 58.49 [95% CI 21.29 to 160.66], maternal fever >38 ºC (2 studies): RR 4.37 [95% CI 2.99 to 6.38] and urinary retention during labour (3 studies) RR 17.05 [95% CI 4.82 to 60.39]. No significant differences were found between groups in relation to nausea, vomiting or somnolence. In addition it was observed that epidural analgesia was associated with a significant increased in the duration of the second stage of labour (10 studies): WMD 16,24 minutes [95% CI 6.71 to 25.78 minutes] and an increase in the use of oxytocin (10 studies): RR 1.19 [95% CI 1.02 to 1.38].

SR of RCTs 1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

These SR did not evaluate the effectiveness of performing maternal examinations on women in labour that use epidural analgesia. However, the NICE (10) guideline concludes that mothers must be observed and their blood pressure, degree of analgesia and sensory block controlled.

CEFM (Continuous Electronic Fetal Monitoring) with neuraxial analgesia

In order to respond to this question the NICE (10) guideline includes studies that assess the effect of neuraxial analgesia on abnormalities in FHR. On the one hand the use of epidural analgesia in high and low doses is compared to non epidural analgesia and on the other, the use of intradural opioids with or without a local anaesthetic compared to not using intradural opioids.

Epidural analgesia versus non epidural analgesia

(low doses: defined as less than 0.25% bupivacaine or equivalent)

The guideline describes two studies (342-344), both conducted in the USA. The epidural analgesia dose was bupivacaine 0.125% (344) or 0.0625% (342;343) with 2 mcg/ml of fentanyl following 0.25% of bupivacaine, compared with 10 mg (344) or 15 mg (342;343) of meperidine every 10 minutes after 50mg of meperidine. The studies were of good quality.

One of the studies (344) (n=715 nulliparous and multiparous) published in 1997 did not show any differences in the incidence of abnormal FHR RR 1.07 [95% CI 0.27 to 4.21]. In the other study (343) (n=459 nulliparous women), published in 2002, it was observed that women with epidural analgesia showed less variability in FHR: RR 0.23 [95% CI 0.15 to 0.30] and more accelerations: RR 1.42 [95% CI 1.24 to 1.63], although there was no evidence of differences in the incidence of decelerations: p= 0.353. RCTs 1+

Use of intradural opioids

The NICE (10) guideline includes a SR (345) and two relatively new studies, 2003 and 2004 (346;347). The SR (345) performed a meta-analysis of 3,513 women from 24 studies, in which an evaluation is performed of the effect of three opioids administered intrathecally or intradurally: sufentanyl, fentanyl and morphine, with or without several doses of intrathecal or epidural bupivacaine. The RCT carried out in the USA in 2003 included 108 women (346). This study compares, for combined epidural-intradural analgesia, six different doses (0, 5, 10, 15, 20, 25 µg) of intrathecal fentanyl combined with 2.5 mg of bupivacaine.

The last study (347) took place in Singapore in 2004, and included 40 women, evaluating intrathecal administration of 2.5 mg levobupivacaine only or associated with 25 µg of fentanyl, followed by epidural infusion (10 ml/ bolus) of 0.125% levobupivacaine and 2 µg/mol of fentanyl.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The SR meta-analysis showed that in women that were administered opioids intradurally there was a greater incidence of fetal bradycardia in the first hour of analgesia than the control group that had not received opioids: RR 1.81 [95% CI 1.04 to 3.14]. Although there was no evidence of a difference in the incidence of other abnormalities in fetal heart rate (345-347), there is overwhelming evidence that intrathecally administered opioids increase the incidence of pruritus, compared with groups of women who had not been administered opioids: RR 29.6 [13.6 to 64.6]. SR/MAof RCTs 1+

The first text showed that the women who were administered 15 µg or more of fentanyl or more had a score on the VAS scale of less than 20 mm (on a scale of 0 to 100 mm), whilst those who received less than 15 µg did not (346). There was no evidence of differences in the incidence of nausea and vomiting, or alternations in FHR. The other RCT (347) showed a significantly greater analgesic effect (less women required a supplement) in the group of women with combined analgesia consisting of 25 µg de fentanyl and 2.5 mg levobupivacaine, compared to analgesia with levobupivacaine only. The study was not sufficiently powered to allow the assessment of adverse events. RCTs 1+

Summarising, there was evidence that intrathecally administered opioids increase the incidence of fetal bradycardia in the first hour of establishing analgesia (345-347). It is thus suggested that if there were to be abnormalities in FHR, this would be more probable during the establishment of neuraxial analgesia.

Furthermore it is observed that the combination of local anaesthesia with intradural fentanyl has a greater and more lasting analgesic effect than levobupivacaine alone (346; 347).

Update (2006 to July 2008)

No new studies have been selected so that the evidence is that given in the NICE (10) guideline.

The GDG considers that the results observed in relation to the adverse effects of neuraxial analgesia may help to determine the need for the type of surveillance and observations to be carried out on healthy women in labour who use neuraxial analgesia. (See Appendix 2.4.2)

Summary of Evidence

Epidural analgesia produces a significant increase in hypotension, maternal fever, urinary retention (310; 341).	1+

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The incidence of abnormalities in FHR is similar in women with epidural analgesia in comparison to women administered meperidine (344). Women with epidural analgesia showed less variability in FHR, more acceleration although the incidence of decelerations was similar (343).	1+
There is an increased incidence of fetal bradycardia during intrathecal opiod analgesia establishment (345-347).	1+

Recommendations

√	Blood pressure should be taken while neuraxial analgesia is becoming established and after each new dose is administered.
√	CEM of fetal heart rate should be carried out within 30 minutes of establishing neuraxial analgesia and after each bolus of 10 ml or more is administered.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.4.8. Local anaesthetic in epidural analgesia

- What effect does the use of local anaesthetic influence obstetric neuraxial analgesia?

In our field there are several local anaesthetics that are regularly used in obstetric analgesia. In addition to the traditionally used bupivacaine, the past few years have seen the use of ropivacaine and levobupivacaine, to which less toxicity and motor block have been attributed. However, it is important to assess the advantages and drawbacks of these drugs in the clinical context we are dealing with.

Scientific Evidence

To respond to this question the NICE (10) guideline uses a total of good quality 36 RCTs, LE=1+. These studies studied the comparison between the following local anaesthetics: bupivacaine, ropivacaine and levobupivacaine. Analgesic, maternal and neonatal effects were measured.

A comparison of *bupivacaine vs ropivacaine* was studied in 29 RCTs used to perform meta-analyses. Three of these studies used combined analgesia (intradural-epidural), while the rest of the studies used epidural analgesia.

There was evidence of less motor block in the women who received ropivacaine although the analgesic effect was also shorter, with no differences in the onset of the analgesic effect, maternal hypotension, nausea, vomiting or abnormalities in FHR. SR/MA of RCTs 1+

Women who were administered bupivacaine had a shorter second stage of labour. No significant differences were observed in relation to the women's satisfaction with pain relief. SR/MA of RCTs 1+

With regards to the neonate, it was found that there was a greater percentage with a neurologic and adaptive capacity score (NACS) of more than 35 at two hours after birth, although this difference was not significant after 24 hours.

A subgroup analysis was also conducted, including only the studies that used epidural analgesia. The results were consistent with the global meta-analysis.

Six studies compared the administration of *bupivacaine versus levobupivacaine*. Women in the levobupivacaine group experienced a shorter lasting analgesic effect although there were no differences in the rest of the clinical, maternal and neonatal results. SR/MA of RCTs 1+

When an analysis of subgroups was performed with 3 epidural analgesia studies, there were no differences in any of the results, including duration of analgesic effect

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

Seven studies compared the administration of *levobupivacaine versus ropivacaine*, 3 of them used combined analgesia (intradural-epidural) and the rest, epidural analgesia.

No differences in clinical results were found, except in relation to the incidence of vomiting in the epidural subgroup, which was greater in the ropivacaine group. In the analysis of the epidural-only subgroups, there was a reduction in the duration of analgesia in the levobupivacaine group and less nausea and vomiting. The rest of the results were similar in all of the groups.

RS-MA de RCTs
1+

Update (2006 to July 2008)

No new studies were selected and hence the recommendations of the GDG are based on the evidence provided by the NICE (10) guideline.

Summary of Evidence

Compared to levobupivacaine and ropivacaine, bupivacaine achieves a longer-lasting analgesic effect (10).	1+
Ropivacaine produces less motor block and a longer second stage of labour than bupivacaine and a greater incidence of vomiting compared to levobupivacaine (10).	1+
Epidurally administered levobupivacaine has a shorter analgesic duration than ropivacaine (10).	1+
There are no important differences in other results (maternal and neonatal) with the use of bupivacaine, ropivacaine and levobupivacaine (10).	1+

Recommendations

A	There are no substantial differences that make it possible to recommend one local anaesthetic over another.

More than 5 years have passed since the publication of this ClinicalPracticeGuideline, and its validity has not been reviewed

9.4.9. Opioids in epidural analgesia

- How does use of opioids and neuraxial coadjuvants influence labour and its outcomes?

The use of opioids in neuraxial analgesia enables a reduction in the doses of local anaesthetics used, as well as in the maternal motor block. However, they seem to increase pruritus and produce a certain degree of neonatal depression which may interfere with the start of breast feeds. For this reason there is a need to evaluate and update the evidence concerning the benefits and drawbacks of the use of opioids in neuraxial analgesia.

Scientific Evidence

Epidural analgesia with opioids

The NICE (10) guideline assesses the effect of adding opioids in epidural analgesia compared to the use of a local anaesthetic only.

Two studies (348; 349) compare administration of *bupivacaine 0.125% vs bupivacaine* 0.125% plus 2-3 µg /ml of fentanyl.

The two studies had a good quality and homogeneity and for that reason a meta-analysis that included 93 women was carried out.

With regards to the results of analgesia, there were no differences in the onset of analgesia, the total dose of bupivacaine used or the incidence of adverse effects, including hypotension, pruritus, urinary retention, nausea, vomiting and motor block. SR/MA of RCTs 1++

Furthermore, no differences were observed in neonatal or maternal outcomes (type of labour and duration of the second stage). As for maternal satisfaction, an aspect that was only examined in the second study, the women who received fentanyl showed a slightly greater degree of satisfaction with pain relief in the first stage of labour. SR/MA of RCTs 1++

Fives studies (350-354) compared administering *bupivacaine 0.125% vs. bupivacaine 0.0625% plus 2-3 µg/ml of fentanyl*. Due to their homogeneous nature, a meta-analysis was performed, with a LE=1++, in which 667 women were included.

The analysis showed that the women in the group with opioids needed less dose of bupivacaine and experienced less motor block, with a greater duration of the analgesic and more pruritus, there being no differences in other adverse effects. SR/MA of RCTs 1++

There were no differences in neonatal or maternal results (type of labour, duration of second stage and satisfaction).

Effects on breastfeeding

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The NICE (10) guideline identified two studies published in 2005 that investigated the effects of epidural fentanyl on breastfeeding: one good-quality RCT conducted in the United States of America (355) and a retrospective cross-sectional study conducted in the United Kingdom (356).

The United States RCT (355) (2005) enrolled women who had previously breastfed and who requested epidural anaesthesia in labour. The women were randomly assigned to one of the following three groups: *epidural without fentanyl (n = 60), epidural with an intermediate dose of fentanyl (1-150 µg) (n = 59) and epidural with a high dose of fentanyl* (> 150 µg) (n = 58). The demographic and labour characteristics (>95% vaginal deliveries in each group) were similar between the groups. The women filled in a questionnaire that asked for details of breastfeeding problems and they were also assessed by a breastfeeding specialist 24 h after delivery. Six weeks later another follow-up questionnaire was filled in.

The results of the questionnaire showed that within 24 hours of childbirth there were no statistically significant differences between the three groups in terms of the number of women who reported breastfeeding problems: group without fentanyl and group with an intermediate dose of fentanyl: n = 6 (10%), compared to the group with high doses of fentanyl: n= 12 (21%), p= 0.09. Furthermore no differences were observed in the results evaluated by breastfeeding specialists. Statistically significant differences were detected in the neurologic and adaptive capacity score of the baby, with average scores of 35, 34 and 32 in the groups without fentanyl, intermediate doses and high doses of fentanyl, respectively, although the researchers indicated that the clinical significance of this fact is not known. Among the 157 women who responded to the follow-up questionnaire after six weeks, 14 (9 %) had not continued breastfeeding: one woman in the group without fentanyl, three in the group with intermediate doses of fentanyl and ten in the group with high doses of fentanyl, p= 0,002. When the women reported a breastfeeding problem within 24 hours of childbirth there was a greater probability of their not continuing to breastfeed in the sixth week, compared to women who did not have problems with breastfeeding: 29% compared to 6%, p= 0,004. Furthermore neonates (with concentrations of more than 200 pg/ml of fentanyl in umbilical cord blood) of mothers in the high dose fentanyl group had less probabilities of continuing to be breastfed in the sixth week after birth than neonates (with a concentration of < 200 pg/ml of fentanyl in umbilical cord blood) of mothers who had received high doses of fentanyl in epidurals), p= 0.02.

RCTs
1+

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

The cross-sectional study (356) was conducted with the aim of examining the impact of fentanyl, administered during labour, on breastfeeding at the time of hospital discharge. For this purpose the clinical records of 425 women, randomly selected from the year 2000 birth register of a British hospital, were examined.

Almost half of the women (45%) used formula milk to feed their babies at the time of discharge. Approximately one out of 5 had attempted to breastfeed. The proportion of bottle-fed neonates varied depending on the analgesia received by the woman during labour: 32% of neonates of mothers who received nitrous oxide only during labour, 42% in the group with IM opioids plus nitrous oxide, 44% with neuraxial analgesia that contained local anaesthetic and 54% with neuraxial analgesia with an opioid, fentanyl or diamorphine. These are associated with a greater frequency of bottle feeding. The use of antiemetics during labour is associated with bottle feeding and also with an operative birth. No significant associations were observed between feeding methods with prenatal oxytocin, duration of hospital stay, duration of labour, maternal body weight, infant body weight or neonates in special care units.

Cross-sectional study 3

The study performed a logistic regression to identify the predictive variables for breastfeeding at discharge from hospital. The analysis revealed that the main determinants for bottle feeding were: maternal age (by year): OR 0.90 [CI 95%: 0.85 to 0.95], occupation (for each category of unemployed, manual work, non-manual work): OR 0.63 [CI 95%: 0.40 to 0.99], prenatal infant feeding intention (for the categories of bottle feeding, undecided and breastfeeding): OR 0.12 [95% CI 0.08 to 0.19], caesarean section (caesarean or vaginal birth): OR 0.25 [95% CI 0.13 to 0.47] and the dose of fentanyl administered: OR 1.0004 [CI 95%: 1.000 to 1.008] for each microgram administered in the range from 8 to 500 µg. This dose-response relationship between bottle feeding and fentanyl has not previously been documented. When well-established determining factors of infant feeding are considered, it seems that administering fentanyl during labour, especially in high doses, can make onset of breast feeds more difficult.

Cross-sectional study 3

A weak association between the dose of fentanyl administered during labour and the duration and success of breatfeeding is proposed, although there are other variables such as maternal age, occupation, etc.

Effects on FHR

Studies evaluating the influence of regional analgesia on FHR have been summarised in the CEFM with neuraxial analgesia section, in the question regarding maternal monitoring with neuraxial analgesia, which includes five good-quality studies (342; 344-347; 357).

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In short, there is evidence that intrathecal opioid administration increases the incidence of fetal bradycardia in the first hour of onset of analgesia and that it produces pruritus (345-347), and hence it is suggested that if there are abnormalities in FHR these will most probably occur during the establishment or onset of neuraxial analgesia. It is furthermore observed that the combination of a local anaesthetic with fentanyl administered intradurally has a more effective and longer lasting analgesic effect than fentanyl only (346; 347). RCTs 1+

Other effects

The NICE (10) guideline identified a SR (358) that included seven studies comparing three opioids (morphine, fentanyl and sufentanyl) with bupivacaine o lidocaine.

The meta-analysis performed showed a comparable analgesic effect 15-20 minutes after administration, although it also revealed greater incidence of pruritus: RR 14.10 [95% CI 13.39 to 14.80]. There was no evidence of differences between the different analgesic treatments in terms of nausea: RR 0.94 [95% CI 0.01 to 1.88] or spontaneous vaginal delivery: RR 1.10 [95% CI 0.34 to 1.85]. SR/MA of RCTs 1+

Update (2006 to July 2008)

New studies were not found and hence the GDG has based recommendations on the evidence provided in the NICE (10) guideline.

In short, similar results are observed with the use of bupivacaine 0.125% with or without opioids. However, lower doses of bupivacaine (0.0625%) associated with opioids provide a longer lasting analgesic effect with lower total doses of local anaesthetic, less motor block and more pruritus.

Furthermore, in relation to the effects on breastfeeding, a weak association is suggested between the dose of fentanyl administered during labour and the duration and success of breastfeeding, although there are other variables such as maternal age, occupation, etc.

Summary of Evidence

The association of epidurally administered fentanyl and bupivacaine 0.0625% reduces the total dose of local anaesthetic used; it produces less motor block, longer lasting analgesia and more pruritus (350-354).	1++

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

The number of women still breastfeeding in the 6th week postpartum is greater when there have been no problems with breastfeeding at 24 hours and when the concentration of fentanyl in umbilical cord blood is <200pg/ml (355).	1+
Administration of fentanyl during labour, particularly in high doses, can make the establishment of breast feeds more difficult (356).	3
In the establishment of analgesia with intrathecally administered opioids there may be an increase in the incidence of fetal bradycardia and the incidence of pruritus (345).	1+
The combination of a local anaesthetic and intradural fentanyl is more effective than local anaesthetic alone (346; 347).	1+

Recommendations

A	Low doses of local anaesthetic alongside opioids should be used for epidural anaesthesia.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

9.4.10. Maintaining Epidural Analgesia During the Second Stage of Labour

- Should epidural anaesthesia be maintained during the second stage of labour?

Epidural analgesia provides effect pain relief during labour. However, it is associated with certain adverse obstetric effects which include an increase in the risk of an operative delivery.

Frequently the administration of analgesia is reduced or discontinued when the last stage of labour is near in order to improve the woman's capacity to push and reduce the percentage of operative deliveries. However, with modern analgesic regimens (with low doses of epidural), less motor block is experienced and the woman's capacity to actively push should not be affected.

Scientific Evidence

The evidence that responds to this question in the NICE (10) guideline is an SR with a meta-analysis (359), that includes five RCTs and 462 women with spontaneous and induced deliveries. The SR assessed the impact of interrupting epidural analgesia during the final stages of labour (cervical dilatation > 8 cm) on the type of labour and pain relief, comparing it with the standard practice without interruptions.

In the meta-analysis the discontinuation in the administeration of epidural analgesia before the second stage of labour did not reduce the incidence of operative deliveries: RR 0.84 [95% CI 0.61 to 1.15], nor the rate of caesarean sections: RR 0.98 [95% CI 0.43 to 2.25]. Furthermore, the duration of the second stage of labour was similar in both groups. SR/MA of RCTs 1+

In relation to neonatal results (Apgar score at one minute and umbilical artery pH) no significant differences were found.

The only significant difference found was the inadequate analgesia reported by women in whom epidural analgesia was interrupted in the final phase of the first stage of labour: RR 3.68 [95% CI 1.99 to 6.80].

Update (2006 to July 2008)

No new studies were selected.

Summary of Evidence

The interruption of epidural analgesia in the final phase of labour does not improve the rate of spontaneous deliveries or other clinical results (359).	1+

Recommendations

A	Epidural anaesthesia should be maintained during the the second stage, delivery and during perineal repair if this is necessary

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

10. Fetal Monitoring

The idea that the technification of labour control should improve neonatal outcomes has led to fetal monitoring. The aim of fetal monitoring is to detect situations of fetal hypoxia during the labour and birth process in order to be able to intervene and prevent fetal deterioration.

This chapter examines which method is most appropriate for controlling fetal well-being in childbirth in healthy women, when and how to use fetal monitoring and how to interpret it. The following methods of fetal control will be assessed: intermittent auscultation (IA), intermittent electronic fetal monitoring (CEFM), analysis of the ST segment of the fetal ECG (STAN), fetal pulse oximetry, fetal blood sample (FBS) and fetal scalp stimulation.

10.1. Continuous electronic fetal monitoring (CEFM) versus intermittent fetal auscultation (IA)

- How effective are the following methods of fetal monitoring: continuous electronic fetal monitoring (CEFM) vs intermittent fetal auscultation (Pinard stethoscope or Doppler)?

Fetal heart rate can be monitored intermittently using a Pinard fetal stethoscope or a manual Doppler device. Continuous recording of fetal heart rate can also be obtained using cardiotocography equipment (CTG). This method is known as electronic Fetal monitoring (EFM) and provides a continuous recording of the fetal heat rate and uterine contractions during labour.

Although continuous CTG has certain advantages, such as providing a written recording that can be analysed at any moment during or after labour, which gives more quantifiable parameters in relation to fetal heart rate patterns, it also has certain drawbacks, amongst which are the difficulty of standardizing CTG interpretations due to the complex nature of fetal heart rate patterns, limitations with regard to mobility and the fact that that the attention of nursing staff, the woman and the person accompanying her tends to be diverted towards the electronic fetal monitor during labour.

Furthermore, although it has been suggested that certain specific abnormalities in fetal heart rate patterns in the CTG are associated with a greater risk of cerebral palsy, the specificity of the CTG to predict cerebral palsy is low, with a false positive rate of up to 99.8%, even with multiple late decelerations or reduced variability (360)

These facts have led to concerns being expressed in relation to the efficacy and the routine use of continuous CTG in labour (361). The obvious contradiction between generalized use of continuous CTG and the recommendations to limit its habitual use (362) indicate that it is necessary to carry out a new assessment of this technique.

Scientific Evidence

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

To respond to the question of the effectiveness of continuous electronic Fetal monitoring compared to intermittent auscultation, the NICE (10) guideline built on a good quality SR (363), LE=Ia that compared the effectiveness of CEFM during labour vs IA or vs IEFM.

In *relation to the comparison of CEFM with intermittent auscultation*, three of the 12 studies included 37,000 low-risk women; the studies were conducted in the USA, Ireland and Australia and their quality was between moderate and good.

The outcomes of all of the women as a whole were assessed and those of low-risk women were assessed separately. The data obtained from the high and low-risk subgroups were compatible with the general results.

In *women with low-risk* births evidence was found that women with CEFM had a greater possibility of requiring a caesarean section due to abnormal fetal heart rate: RR 2.31 [95% CI 1.49 to 3.59], operative vaginal delivery: RR 1.29 [95% CI 1.02 to 1.62] and any type of instrumental delivery (caesarean section, instrumental vaginal delivery): RR 1.35 [95% CI 1.09 to 1.67], compared to those who underwent intermittent auscultation. SR of RCTs and CCTs II

No differences in perinatal mortality were observed between the two groups of women, RR 1.02 [95% CI 0.31 to 3.31]. However, it was observed that women with CEFM were less likely to have infants with neonatal seizures, RR 0.36 [95% CI 0.16 to 0.81] and more likely to have infants who have to be admitted to neonatal units, RR 1.37 [95% CI 1.01 to 1.87] in comparison with the intermittent auscultation group. SR of RCTs and CCTs II

When the overall results of *high and low-risk women* are analysed, nine studies that included 32,386 women found that neonatal seizures were reduced by half with CEFM: RR 0.50 [95% CI 0.31 to 0.80] although in two studies with 13,252 women no significant differences in cerebral palsy were detected: RR 1.74 [95% CI 0.97 to 3.11]. SR of RCTs and CCTs II

The NICE (10) guideline also examines the use of Doppler ultrasonography versus the Pinard stethoscope. It is a small study (364), conducted in 1994 in a low-income country with 1,255 high and low-risk women, in which it is observed that with the use of Doppler there are less spontaneous vaginal births: RR 0.83 [ÎC 95% 0.76 to 0.91] and more caesarean sections: RR 1.95 [95% CI 1.47 to 2.60], less probability of the infant being admitted to a neonatal unit: RR 0.65 [95% CI 0.46 to 0.94] and /or of suffering hypoxic encephalopathy: RR 0.12 [95% CI 0.02 to 0.88]. The NICE (10) guideline development group considers that this evidence is not solid enough to allow a differentiation to be made between the two techniques. RCTs II

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In summary there is a high level of evidence that CEFM reduces the rate of neonatal seizures but it does not have an impact on the rates of cerebral palsy. There is a high level of evidence that it increases the number of caesarean sections and instrumental deliveries.

Update (2006 to July 2008)

No new studies have been located in the update but the CPB ICSI (Institute for Clinical Systems Improvement), 2007 (365) has been reviewed and classed as recommended after assessment with AGREE. It analyses the effectiveness of using CEFM compared to intermittent auscultation.

To respond to this question this guideline uses an SR with seven RCTs that included both high and low-risk women.

No differences were observed in fetal mortality and most of the studies showed an increase in the number of caesarean sections in the groups with CEFM. The most recently published RCT of those included in the review indicated a significant reduction in perinatal mortality due to asphyxia in the group with CEFM, although the reason for these differences in relation to the other RCTs is not clear. SR of RCTs II

The ICSI guideline considers that the presence of trained, motivated midwives who perform auscultations adds quality to healthcare process and improves outcomes.

See Appendix 3.1. Technique of intermittent auscultation of the fetal heart

Summary of Evidence

CEFM compared to IA reduces the rate of seizures but does not have an impact on the rates of cerebral palsy (363). CEFM increases the number of caesarean sections and instrumental deliveries (363).	II
There is not enough evidence to differentiate between the effectiveness of intermittent auscultation with a Doppler device or a Pinard stethoscope (364).	II

Recommendations

B	Both CEFM and IA are valid and recommended methods for checking fetal well-being during labour.
√	IA can be performed using either Doppler ultrasound or a stethoscope.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

10.2. CEFM versus Intermittent electronic fetal monitoring (IEFM)

- How effective are the following methods of fetal monitoring: CEFM vs intermittent electronic fetal monitoring (IEFM)?

IEFM has been suggested to try to obtain the best of each method. The aim is to keep the pregnant woman free of monitoring equipment for most of the time but to still be able to assess the variables given by the continuous cardiotocographic recording, such as variability or reactivity that are impossible to assess using auscultation procedures.

Scientific Evidence

The NICE (10) guideline does not answer this question but included in the SR that the NICE guideline (363) contains, is an RCT conducted in Sweden (366), with LE=Ib, CE (363) that addresses the comparison between CEFM and IEFM. This study includes 4,044 women in labour with a low risk of suffering loss of fetal well-being.

The group with intermittent electronic monitoring were monitorised for 10 to 30 minutes every 2 or 2 and a half hours during the first stage of labour and fetal heart rate was auscultated every 15-30 minutes between recording periods. If complications arose intermittent monitoring was changed to continuous monitoring. During the second stage of labour continuous monitoring was used in all of the cases.

No significant differences were observed between the two groups for any of the variables analysed: ominous or suspicious fetal heart rate, caesarean section due to suspected loss of fetal well-being, umbilical pHl, Apgar values or admittance to Neonatal Intensive Care Units (NICU). RCTs Ib

Use of electronic intermittent fetal monitoring at regular intervals (with intermittent auscultation between these intervals) seems to be as safe as continuous electronic fetal monitoring in low-risk childbirth.

Update (to May 2008)

No new studies were found in the update.

Summary of Evidence

The use of *IEFM* at regular intervals (with *intermittent auscultation* between *intervals*) seems to be as safe as *continuous electronic fetal monitoring* in low-risk childbirths (366).	Ib

Recommendations

A	Both CEFM and IEFM accompanied by IA are valid and recommended methods for checking fetal well-being during labour.

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

10.3. CEFM with or without pulse oximetry

- How effective are the following methods of fetal monitoring: CEFM with or without pulse oximetry when there are alterations in fetal hear rate?

Pulse oximetry is a continuous way of determining arterial oxygen saturation of fetal haemoglobin by optical means. Oxygen saturation values above 30% ensure a normal fetal acid-base balance. Arterial oxygen saturation would seem to have a relationship with cardiotocographic alterations and hence could improve the specificity of intrapartum fetal surveillance.

The aim is to discover if its use together with continuous monitoring can provide benefits in the event of pathological cardiotocographic recordings.

Scientific Evidence

The NICE (10) guideline does not respond to this question since this is not a technique used in the United Kingdom.

Update (to May 2008)

In the new search performed, a Cochrane review (367) published in 2007 has been recovered. The review comprised five RCTs with a total of 7,424 women. This review compared fetal pulse oximetry and CTG versus CTG alone or with the pulse oximetry values blinded.

Four of the five studies did not report any significant differences in the general rate of caesarean sections. In the remaining study with less population, a significant reduction in caesarean sections was observed in the group with pulse oximetry and CTG. — SR of RCTs Ia

In two of the four studies it was observed that there was a significant reduction in caesarean sections due to risk of loss of fetal well-being in the group with pulse oximetry and CTG: Caesarean section rate in the cases without fetal blood sampling prior to inclusion in the study, RR 0.68 [95% CI 0.47 to 0.99] and, in the cases in which a fetal blood sample was required prior to inclusion in the study, RR 0.03 [95% CI 0.00 to 0.44]. — SR of RCTs Ia

No significant differences were observed in instrumental deliveries or caesarean sections in relation to dystocia when pulse oximetry and CTG are performed, nor were there any significant differences in neonatal results or maternal satisfaction. — SR of RCTs Ia

More than 5 years have passed since the publication of this Clinical Practice Guideline and its validity has not been reviewed

In summary, evidence consistency for this question derives exclusively from this Cochrane SR in which it is observed that the data come from studies with limitations and provide a limited support for the use of fetal pulse oximetry when it is used in the presence of CTG, to reduce caesarean sections due to risk of loss of fetal well-being. It was also observed that adding fetal pulse oximetry to an abnormal CTG does not reduce the general rate of caesarean sections.

The guideline development group considers that the evidence provides only limited support for the use of pulse oximetry in the presence of a non-reassuring CTG for the routine use of fetal pulse oximetry to be recommended, and, given the limitations of the study methods, the strength of the recommendation is further reduced.

Summary of Evidence

The evidence provides limited support for the use of fetal *pulse oximetry* in the presence of an abnormal CTG to reduce caesarean sections due to risk of loss of fetal well-being. However, the general caesarean section rate is not reduced (367).	Ia

Recommendations

A	Fetal pulse oximetry should not be used routinely

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

10.4. CEFM with or without ST segment analysis (STAN) of the fetal ECG with a pathological CTG recording

- How effective are the following methods of fetal monitoring: CEFM with or without analysis of the ST (STAN) segment of the fetal ECG when there is an abnormal cardiotocography reading (CTGR)?

ST segment analysis (STAN) of the fetal ECG by means of an electrode attached to the Fetal scalp provides information on the capacity of the fetal myocardium to respond to hypoxia during labour. The aim is to assess the fetal myocardial function which represents an indirect measurement of the state of oxygenation of the foetus's brain.

During acute hypoxemia a mature foetus reacts physiologically with a rise in the ST segment and a progressive increase in the height of the T wave (T/QRS ratio). Depression of the ST segment and a negative T wave show a myocardium which does not respond adequately to hypoxic stress.

The purpose of this question is to determine whether or not the combined use of ST segment analysis (STAN) of the fetal ECG with continuous monitoring in the presence of pathological cardiotocographic recordings affords benefits compared to the use of cardiotocography alone.

Scientific Evidence

The NICE (10) guideline used a Cochrane SR (368) published 2005 and a randomised controlled clinical trial published in 2006 (369).

The SR compared the effectiveness of the ST segment analysis of the fetal ECG compared to other alternative methods of fetal monitoring during childbirth in high risk women and evaluated the use of fetal ECG associated with CEFM. The three studies included in the SR were of good quality. Two of them assessed the ST segment and in the other, the PR interval.

The RCT published in 2006 (369) was conducted in Finland and it assessed the effectiveness of ST segment analysis of the fetal ECG. The consistency between the two studies included in the SR and the new study enabled a meta-analysis to be performed to study the effectiveness of performing an ST segment analysis of the fetal ECG.

The meta-analysis showed evidence that ST segment analysis of the fetal ECG significantly reduced the rate of:

SR/MA of RCTs
Ia

- Instrumental vaginal deliveries RR 0.87 [95% CI 0.78 to 0.96]
- Any type of instrumental delivery RR 0.89 [95% CI 0.82 to 0.96]
- Need for fetal blood samples RR 0.69 [95% CI 0.48 to 1.00]

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

- Number of neonates who develop neonatal encephalopathy RR 0.33 [95% CI 0.11 to 0.95]
- Acidosis in umbilical cord blood (pH less than 7.05, base excess less than −12 mmol/l), RR 0.53 [95% CI 0.33 to 0.85]

There was no evidence of differences in other neonatal outcomes such as perinatal mortality, RR 2.16 [95% CI 0.48 to 9.58], Apgar test scores <7 after 5 minutes, RR 0.80 [95% CI 0.56 to 1.14] or admittance to neonatal units, RR 0.90 [95% CI 0.75 to 1.08]. When perinatal mortality and neonatal encephalopathy were combined, no differences were found, RR 0.60 [95% CI 0.27 to 1.34].

SR/MA of RCTS Ia

The evidence is of good quality but these are studies conducted in high-risk women so that this must be taken into account when they are interpreted and applied to low-risk women.

Update (2006 to May 2008)

In the update search the studies detected were rejected for not fulfilling inclusion criteria but an SR (370) with LE=II, located in a literature search for another question, has been taken into consideration.

This SR includes four RCTs (2 of which are already included in the NICE (368) SR, three observational studies and a non-randomised prospective study. The aim of the SR is to evaluate the pathophysiology of the ST segment of the fetal ECG, its role in monitoring during labour and the practical use of this technology.

SR of RCTSs and observational studies 2

The SR (370) concludes that with the incorporation of the ST segment analysis of the fetal ECG in the CTG, there has been a reduction in the rates of neonatal metabolic acidosis and moderate and severe neonatal encephalopathy, which has led to an improvement in perinatal outcomes. This is achieved thanks to improved detection of fetal hypoxia which reduces the number of unnecessary interventions. There was also a significant reduction of instrumental deliveries due to fetal hypoxia.

This is indirect evidence as it comes from studies involving high and low risk women, undergoing a wide range of circumstances and interventions.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

Summary of Evidence

The incorporation of ST segment analysis of the fetal ECG to the pathological CTG has been shown to reduce the need for fetal blood sampling FBS, instrumental vaginal deliveries, neonatal encephalopathy and metabolic acidosis in the studies that included low and high-risk women. Although there are no differences in the number of caesarean sections, in an Apgar score of less than seven after five minutes, nor in admissions to neonatal care units. (368-370)	II

Recommendations

A	Routine analysis of the ST segment of fetal ECG is not recommended for normal labour.
B	In hospital births when analysis of the ST segment of fetal ECG is available, it should only be used in women with an abnormal CTG.

More than 5 years have passed since the publication of this Clinical Practice Guideline, and its validity has not been reviewed

10.5. CEFM with or without fetal scalp blood sampling (FBS)

- How effective are the following methods of fetal monitoring: CEFM with or without fetal scalp blood sampling (FBM)?

Fetal blood sampling is a procedure in which a small amount of the foetus's blood is taken, generally from the scalp. Fetal blood sampling and measuring of acid-base balance parameters (pH, base excess/deficit, etc) have been introduced for the purpose of identifying foetuses that are genuinely at risk and which must be delivered immediately from those that are not really at risk. It is important to underline the value of this test as a complement to CTG, to the extent that it has been recommended that cardiotocography should not be performed if this procedure is not available.

Scientific Evidence

To respond to the questions the NICE (10) guideline used an SR (363) that comprises 12 studies (37,000 women) in which CEFM was compared to IA, also evaluating the effect of FBS on a CEFM subgroup. It also uses the results of an observational cohort study with historic controls that compares the effectiveness of FBS and CEFM vs CEFM alone, (371) LE=II. The two studies were of reasonable quality although in the SR neither a statistical nor subgroup analysis was conducted and hence the findings are suggestive only.

The SR included *high risk and low risk women*, revealing an increase in instrumental vaginal deliveries in the CEFM and FBS group:

SR of RCTs and CCTs
II

CEFM and FBS versus IA: RR 1.47 [95% CI 1.11to 1.93] CEFM

CEFM without FBS versus IA: RR 1.10 [95% CI 0.87 to 1.40]

And a reduction in neonatal seizures:

CEFM and FBS versus IA: RR 0.49 [95% CI 0.29 to 0.83]

CEFM without FBS compared to IA: RR 0.54 [95% CI 0.20 to 1.44].

When *low-risk women* only were included in the meta-analysis, the results were consistent: there were less neonatal seizures in the CEFM and FBS groups when compared to IA: RR 0.37 [95% CI 0.15 to 0.87] and in the groups of CEFM without FBS compared to IA, the differences were not significant: RR 0.54 [95% CI 0.03 to 3.22]). No differences were found either in the results for other variables.

SR of RCTs and CCTs
II

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The cohort study (371) compared CEFM with CEFM and FBS and revealed evidence that the use of FBS reduces the incidence of instrumental deliveries due to fetal suffering: RR 0.33; (p=0,007), although no differences were observed in caesarean sections due to fetal suffering: RR 0.5; (p=0,5) nor in the Apgar test score of less than 7 at one minute: RR 0.50, (p=0.15) or at five minutes; (p=0.25).

Cohort study II

The evidence provided by NICE (10) is limited due to the fact that there are no direct comparisons in randomised studies, but the evidence obtained from indirect comparisons suggests that FBS prevents some instrumental deliveries and caesarean sections.

The GDG of the NICE (10) guideline also highlights the contraindications to FBS:

- Maternal infection: HIV, hepatitis, herpes.
- Fetal blood disorders: haemophilia
- Prematurity: less than 34 weeks.

Update (2006 to May 2008)

In the update search no new studies were found meeting the criteria for inclusion.

See Appendix 3.2. Decision algorithm according to fetal pH results.

Summary of Evidence

Evidence coming from indirect comparisons suggests that FBS prevents some instrumental deliveries and caesarean sections. The procedure that has been shown to be most useful in reducing false positives of CEFM is FBS (363;371).	II

Recommendations

B	FBM should be performed when there is an abnormal CTG reading.

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10.6. CEFM with or without fetal scalp stimulation in the presence of FHR alterations

- How effective are the following methods of fetal monitoring: CEFM with or without fetal stimulation test when there are alterations in fetal hear rate?

Many sites have reduced the use of FBS to determine pH (372) and have not experienced a negative impact on neonatal morbidity-mortality. This has been possible thanks to an increase in the use of the Fetal stimulation test which is a technique that has arisen as a less invasive alternative, allowing less dependence on FBS.

Scientific Evidence

To respond to this question the NICE (10) guideline used an SR with a meta-analysis published in 2002 (373) that assessed the usefulness of the stimulation test in predicting fetal acidemia. The review assessed the predictive value of four fetal stimulation tests amongst among which were puncture of fetal scalp (six studies) and digital stimulation (2 studies). The studies provide the results of the effectiveness of these methods separately and compared with FBS, the baseline test for determining fetal pH.

Reactivity of FHR after stimulation defines a negative result that predicts the absence of fetal acidemia. The meta-analysis that was republished (374) after corrections were made to the magnitude of the estimates analysed, on the one hand, six studies that assessed *stimulation by puncture* of the fetal scalp, showing a combined likelihood ratio or a combined Lr for a negative acidemia test (Lr-) of: 0.22 [95% CI 0.05 to 1.05] and a combined likelihood ratio for a positive test (Lr+) of 2.3 [95% CI 1.53 to 3.48]. On the other hand, the combination of the two studies that assess *digital stimulation* of the fetal scalp resulted in Lr- :0.08 [95% CI 0.02 to 0.41] and Lr+: 1.93 [95% CI 1.48 to 2.52].

SR/MA of cross-sectional studies

The very low value of negative Lr (<0.1) means that a negative test result practically rules out an acidemia diagnosis, and a positive Lr >1 increases the likelihood of acidemia existing.

In this meta-analysis the puncture results, with a statistically non-significant negative likelihood ratio, do not give confidence that the pre-test likelihood is altered after performing scalp puncture stimulation.

SR/MA of cross-sectional studies III

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In relation to digital stimulation, an Lr- of 0.08 indicates that a negative result of said test would generate a considerable change in pre-test likelihood, reducing the likelihood of having acidemia and practically ruling out such a diagnosis. The Lr+ 1.93 only indicates a slight increase in post-test likelihood (in relation to the estimated 11% pre-test likelihood in the study) of having acidemia. Thus the evidence shows that digital stimulation of the fetal scalp has a high negative predictive value for the diagnosis of fetal acidemia.

SR/MA of cross-sectional studies III

Update (2006 to May 2008)

The search did not find any new studies that met the inclusion criteria.

Summary of Evidence

Digital stimulation of the fetal scalp has a poor positive predictive value but a high negative predictive value for the diagnosis of fetal acidemia (374).	III

Recommendations

√	*Digital fetal stimulation test* should be used as an additional diagnostic method when there is an abnormal CTG reading.

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10.7. Application of a CEFM categorisation system

- How does the use of a CEFM classification system influence neonatal outcomes?

There is a great disparity of criteria when classifying fetal heart rate patterns and, what is more, criteria are not applied across the board. It would be expected that the use of strict classification criteria would improve CTG monitoring capacities to obtain an appropriate indication for interventions.

Additionally, adopting uniform classification criteria for fetal heart rate recordings should afford benefits with regards to reproducibility of the research results.

Scientific Evidence

This question is not answered by the NICE (10) guideline.

Update (2006 to May 2008)

A literature search of systematic reviews, meta-analyses and assessment reports has been carried out to respond to this question.

The search has not found any review comparing the two interventions proposed: application of classification systems of continuous CTG recordings in different risk categories compared to assessment of the CTG recording without using these classifications.

Appendix 3.3 contains the classification of CTG recordings for each of the different risk categories. This table has been drawn up using two documents: the NICE (10) guideline and a review used in the update of one of the questions (370).

Summary of Evidence

There are no *categorisation systems*, validated by trials, that demonstrate the effectiveness of applying a system for the classification of continuous CTG recordings in different risk categories (370).	II

Recommendations

√	The CTG classification system shown in Appendix 3.3.2. is recommended.

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11. Dissemination and implementation

11.1. Dissemination and implementation strategy

Clinical practice guidelines are useful for improving the quality of healthcare and patient outcomes. Currently, the main challenge is to achieve compliance by healthcare practitioners with the recommendations made by these guidelines. It is hence of essential importance to put in place an implementation strategy aimed at overcoming existing barriers in the medium in which it is to be applied.

The implementation plan for the Clinical Practice Guideline on Care in Normal Childbirth includes the action outlined below:

1. Official presentation of the guideline to the different scientific societies and mass media, in collaboration with the Quality Agency of the Ministry of Health and Social Policy.
2. Presentation of the guideline to Primary Care and Specialised Care management in the different Health Services.
3. The information prepared for women will be highlighted at all of the presentations to encourage its distribution.
4. Distribution to the groups of professionals involved (doctors, midwives and nurses) to facilitate its dissemination.
5. Posting of the guideline in electronic format on the websites of the Ministry of Health and Social Policy, GuíaSalud, OSTEBA, Avalia-t and other evaluation agencies and societies involved in the project.
6. Publication of the guideline in scientific journals.
7. Establishment of criteria for good care in the programme and clinical management contracts, as provided for in the guideline.
8. Evaluation of the effectiveness of implementation, establishing clinical decision support systems, integrating the guideline and the indicators selected in the software used in PC.

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11.2. Implications for implementation in clinical practice

Care during childbirth

Care by Professionals and Those Accompanying

In the current Spanish Health System it is widespread practice for a non-professional person to accompany women during labour. Women should be aware of the importance of the role of the accompanying person (partner, relative, close friend...) and the qualities that such a person should have and they must feel free to choose this person. Maternity units should try to ensure that accompaniment is as effective as possible and accept the woman's choice of person.

First Stage of Labour

Care on Admission: Amnioscopy and CTG

It is a widespread practice to perform a CTG when a pregnant woman arrives at hospital with suspected labour. In spite of available evidence, it will be difficult not to continue with this practice especially when women are not in the active phase of labour and are not admitted.

Second stage of Labour

Definition of the second stage of labour

There is an identified need to further better knowledge amongst professionals with regards to the existence of the latent phase in the second stage of labour.

Woman's position during the second stage of labour

There is an identified need for maternity units to be equipped with furniture that allows women in labour to adopt different positions during the second stage of labour.

Delivery: third stage of labour

Managing delivery

The admission sheet should inform about active and physiological management.

The definitions of the stages of labour should be clear, in order to ensure that both women and professionals share the same ideas, making communication easier.

Care for neonates

Skin-to-Skin contact

Professionals are unaware of the skin-to-skin contact procedure and this is an obstacle when putting it into practice. It is thus considered that a good explanation on what it means

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and how to perform it are necessary.

Breastfeeding

There is a need for information on techniques to help with breastfeeding, directed at both professionals and women.

The posture of women in the 3rd period should be suitable to facilitate breastfeeding or suction.

Means of administration of prophylaxis with vitamin K

Oral vitamin K packs have 6 doses when only 3 are necessary

Pain Relief during Labour

Pain, Analgesia and Maternal Satisfaction

It would be advisable for birth preparation classes to include the recommendations and changes described in this guideline.

Birth preparation could increase the level of maternal satisfaction, teaching physiological aspects of childbirth and the conditions that favour them, the resources available, providing techniques to improve personal skills and information so that women's expectations for childbirth are closer to the real situation.

Non-pharmacological methods of pain relief Immersion in water

All birthing tubs or pools must adhere to the cleanliness protocol established by the microbiology department and be in line with the manufacturer's guidelines.

When dilatation or labour takes place in water the temperature of the water and that of the woman should be checked every hour to ensure comfort and that the woman is not running a temperature.

The mother's abdomen should be covered by the water for it to be effective. The recommendation is for the water temperature to be kept below 37.5ºC so hyperthermia is not caused. Furthermore opioids should not be administered to women who wish to use immersion in hot water. There are no data that permit us to recommend the suitable time for immersion nor the period of time that women should remain in the birthing pool.

Massage

Midwives and nurses should consider massage as a means of alleviating pain in labour.

The recommendation has a B grade because it requires training. The possible implications in our context should be appraised as the person will not be required to have training. Mere physical contact has been shown to be beneficial in relieving pain.

Sterile water injection

Provide experiences on the use of sterile water injections.

The action mechanism of this analgesic method is not known. It consists of applying 4 intradermal injections of 0.05-0.1 ml of sterile water, forming small blebs two of them at the posterior iliac spines and the other two 3 cm below and 1 cm medial to the previous

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injection site. It is advisable to give the first two injections simultaneously and on both sides because in this way a certain analgesic effect can be obtained. The injection sites do not have to be exact in order to be effective.

These injections are painful and to reduce the discomfort they cause they can be administered during a contraction and simultaneously by two professionals. Women should be warned that they will experience a burning sensation and that this will disappear in the time that a contraction lasts, as some women find them so uncomfortable that they do not wish to continue.

Pharmacological methods of pain relief

Nitrous oxide

Every hospital maternity unit should establish the required mechanisms for the renewal of ambient air when N2O is used in order to prevent the risks of being continually exposed to said gas.

Opioids

Every hospital maternity unit should provide continuous monitoring of SaO2 for the women it is going to be used on, as well as oxygen therapy and close supervision by an anaesthetist.

Neuraxial Analgesia

Administration of neuraxial analgesia via PCEA

There are factors favouring the use of PCEA: less staff is needed, less use of local anaesthetics and greater satisfaction of women.

The obstacle for PCEA is its high cost.

Fetal monitoring

Greater dissemination of current evidence is needed, showing its strength, both among midwives and in particular obstetricians. Without this first step the rest of the actions will not be effective. The first step to be taken is to provide information followed by training staff that assists births in the techniques of intermittent monitoring.

When **intermittent procedures** are used individualised attention is needed from the moment the woman is admitted. Staff need to be trained to perform this type of childbirth monitoring and there should be a better midwife/pregnant woman ratio, ideally 1:1. Hence health authorities committed to this policy must be aware of their responsibility in dealing with the difficulties involved in applying it. There must be a reduction in the workload to encourage implementation, within the framework of a Humanisation Plan for perinatal care

Fetal pulse oximetry is a procedure that at the current time has very limited use in clinical practice, such as for example in the case of fetal arrhythmia and it is used more in the field of research. It therefore does not seem to be necessary to implement policies aimed at furthering the dissemination of this procedure.

With regards to **ST segment analysis** of the fetal ECG it is important to facilitate access

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to this technology as it has been shown to improve neonatal outcomes. However, the recommendation for implementation cannot include a recommendation, by the clinical practice guideline, for it to be acquired by all maternity units, even though we are aware that it is useful in units dealing with more complicated cases. It is in these maternity units where this technology should be implemented, but bearing in mind that the benefits of using this diagnosis equipment are directly related to the training of the professionals that use it.

Analysis of fetal blood samples to determine fetal well-being should be available, especially in maternity units dealing with high-risk births. Again correct training of professionals is required since the capacity to obtain quick, reliable results depends on this to a great extent.

Current knowledge of the usefulness of **fetal scalp stimulation** must be disseminated given that it is a technique that is easy to perform and prevents a considerable number of FBS analyses which is a more invasive test.

Disseminate the use of **standardized classifications of fetal heart rate patterns**. Include the classifications in the specialty training programme.

Interventions in relation to Professionals

- Dissemination of electronic intermittent monitoring methodology as well as intermittent fetal auscultation (Pinard stethoscope or Doppler)
- Specific training for professionals on the use and interpretation of fetal heart rate recordings.
- Fetal heart rate interpretation varies among different observers. Standardised classifications must be used.
- Training in other fetal monitoring procedures: Pulse oximetry, ST segment analysis of fetal ECG, fetal blood sample analysis and fetal scalp stimulation.

Interventions in relation to organisations

- Aimed at Professionals: Adapting of human resources devoted to care in childbirth in accordance with the recommendations of current evidence.
- Aimed at Women: Preparation of a section in the CPG aimed at pregnant women in which the information provided in the CPG is presented in a summarised, understandable, factual way and which allows pregnant women be the most important party in the decisions to be taken in controlling childbirth.

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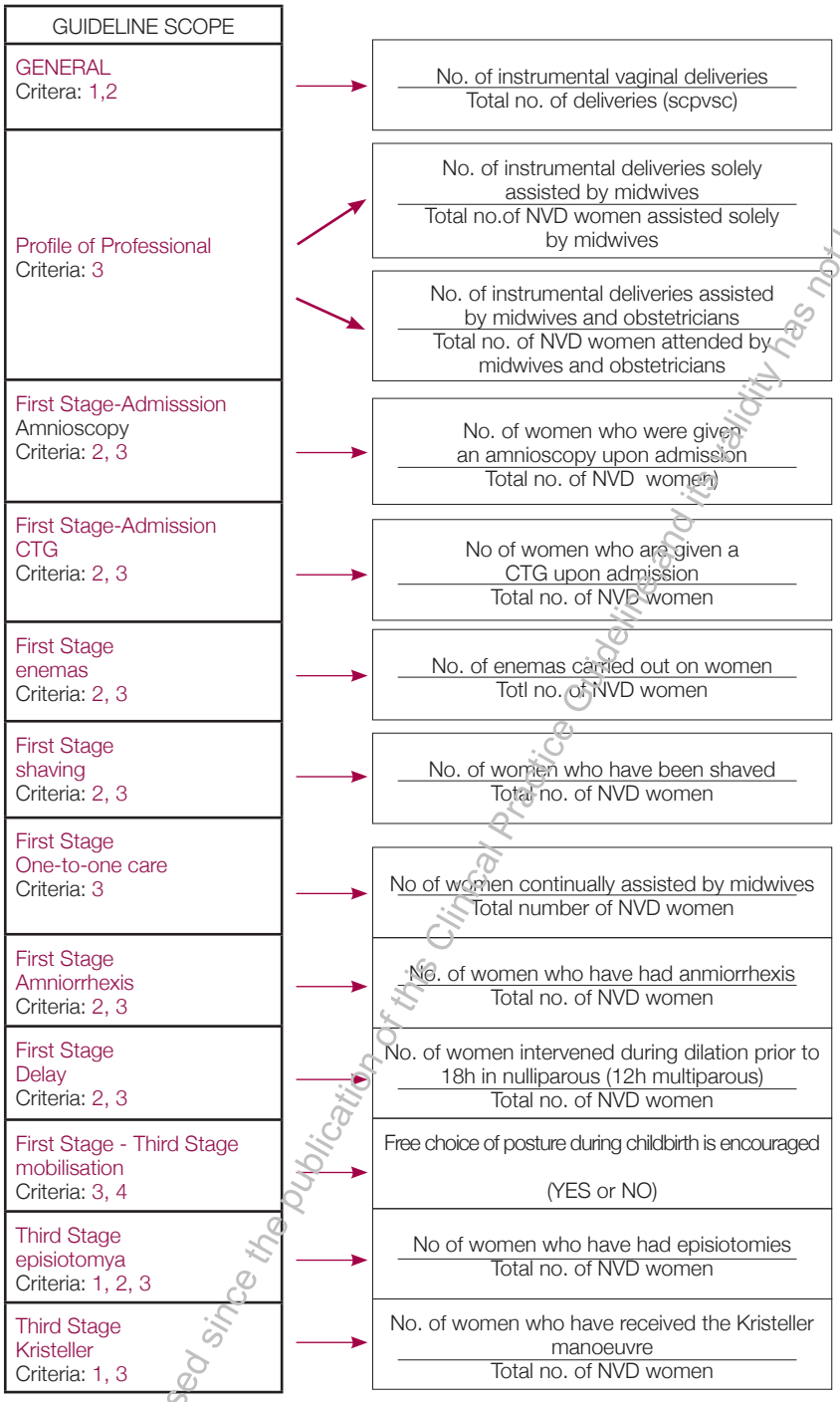
11.3. Proposed indicators

At the same time that the guideline has been prepared, a set of indicators has had to be designed. These indicators have to be measureable using healthcare information systems in order to evaluate both the care given during childbirth and the potential impact of the implementation of the guideline. The purpose is not to create a comprehensive and detailed design involving the use of all of the proposed indicators, but rather to provide a tool for the healthcare practitioners and managers involved, which can be used for the specific design of assessments of care in normal childbirth

The indicators have been grouped together according to the field of application of the guideline and taking into account the fact that they measure different aspects or criteria for improving the quality of care and maternal and neonatal health:

1. Security, prevention of maternal and/or neonatal risks
2. Reduction of instrumentation
3. Driving effective practices
4. Encouraging the woman to have the lead role and ensure her satisfaction.

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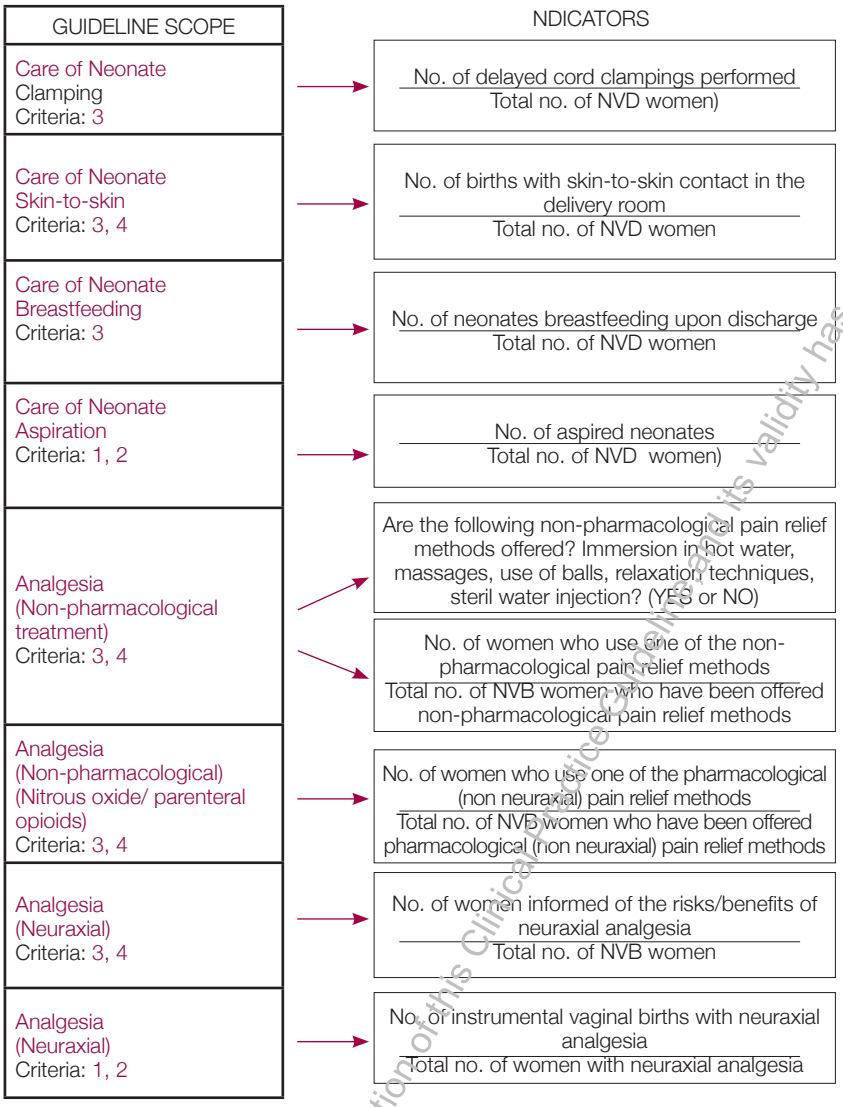


Criteria

1. Security, prevention of maternal and/or neonatal risks
2. Reduction of instrumentation
3. Driving effective practices
4. Encouraging the woman to have the lead role and ensure her satisfaction.

NVD: Normal vaginal delivery

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Criteria

1. Security, prevention of maternal and/or neonatal risks
2. Reduction of instrumentation
3. Driving effective practices
4. Encouraging the woman to have the lead role and ensure her satisfaction.

NVD: Normal vaginal delivery

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12. Future lines of research

Care during childbirth

Care from professionals and those accompanying

- Conduct new research that sheds light on the influence of how the woman feels (her feeling of security and trust) on outcomes during childbirth.
- New studies with validated tools for assessing maternal satisfaction with the birth experience.
- Conduct controlled trials that compare being accompanied by relatives or a person close the woman who have been trained to take on the role of a physical and emotional support, versus accompaniment by people who have not received this training.

Restriction of fluids and solids

- Sufficiently powered trials to assess the safety of intake of solids during labour.

First stage of labour

One-to-one care

- Studies that assess perinatal mortality and the long-term well-being of women and their children.
- Studies that assess whether or not the profile of the person offering continuous support affects clinical outcomes.

Delay treatment

- Studies on the effectiveness of high doses versus low doses of oxytocin in the treatment of the delay in the first stage.

Second stage of labour Duration

- Studies on the influence that prolonging the second stage of labour has on the pelvic floor.

Third stage of labour

Management of delivery

- There is a proposal for new research to be carried out on the cord clamping time and its effects on the mother and child.

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Use of uterotonics

- A need is detected to investigate the use of carbetocin during delivery in women with low-risk labours.

Dose of oxytocin for actively managed delivery

- There is the need to conduct studies that compare the use of oxytocin 2-3 UI versus 5 UI-10UI and studies that investigate the effects of the quick or slow method of administration on maternal and neonatal results.

Care of neonates

Clamping umbilical cord

- New studies are required to clarify the appropriate time for cord clamping (1', 2', after respiration or after pulsing) and the risk-benefit balance for the child and mother.

Breastfeeding

- Future research is called for to examine outcome variables such as the duration of the third stage of labour, need of therapeutic oxytocin, manual removal of placenta rate, haemorrhages, rates of short and long-term breastfeeding and mother-child bonding.

More effective product for neonate ophthalmic prophylaxis

- High quality studies are required to provide firmer recommendations.

Pain relief during labour

Pain, analgesia and maternal satisfaction

- There is a need for new studies that investigate the factors related to satisfaction and include results on emotional and psychological maternal well-being.
- Studies that assess the different models childbirth preparation.

Immersion in water

- New research is required on the effectiveness and most suitable means of using immersion in hot water as a method of pain relief.

Sterile water injection

- Additional research is required on the effect of repeated doses, variations in doses, number and sites of the injections and the possibility of reducing the pain in their application.

Nitrous oxide

- Studies that assess the effect of nitrous oxide on breastfeeding.

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Effectiveness of non-pharmacological pain relief techniques

- Studies that compare the effectiveness of neuraxial techniques versus non-pharmacological pain relief techniques.

Prerequisites for neuraxial analgesia

- Studies that assess the effectiveness of coagulation studies and platelet count.

Intravenous fluid preload prior to neuroaxial analgesia

- Study with a suitable sample number to assess if more modest changes in blood pressure (< 20%) compromise placental blood flow and alter FHR.

When opioids are used

- Studies that assess the effect of the use of opioids in neuaxial analgesia on breastfeeding.

Fetal monitoring

- Additional studies are recommended to assess the usefulness of complementary methods to cardiotocography (fetal pH, pulse oximetry, ST segment analysis of the ECG) to assess fetal well-being.
- The recommendation is to carry out for long-term monitoring of the impact that AI and continuous EFM have on the neuropsychological outcomes in neonates.
- Computer analysis of fetal heart rate is beginning to show promising results which should be taken into account in new research developments.
- Studies that estimate the predictive value of fetal heart rate recording classifications on neonate outcomes should be conducted. Based on these, studies testing the use of a uniform categorisation to improve the effectiveness of cardiotocography should be designed.

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Appendices

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Appendix 1: Abbreviations

AGREE: Appraisal of Guidelines, Research and Evaluation for Europe
CCT: Controlled clinical trial
CEFM: Continuous electronic fetal monitoring
CI: Confidence interval
CPG: Clinical practice guideline
CSE: Combined spinal-epidural
CTG: Cardiotocography
CTGR: Cardiotocographic recording
EFM: Electronic fetal monitoring
EL: Evidence level
FHR: Fetal heart rate
IA: Intermittent auscultation
ICU: Intensive care unit
IEFM: Intermittent electronic fetal monitoring
IM: Intramuscular
IV: Intravenous
NHS: National Health Service
NICE: National Institute for Health and Clinical Excellence
NN: Neonate
OR: Odds ratios
PCEA: Patient-controlled epidural analgesia
PICO: Patient/Intervention/Comparison/Outcome
PPH: Postpartum haemorrhage
RCT: Randomised controlled trial
RR: Relative risk-risk ratio
SD: Standard deviation
SD: Standard deviation
SEGO: Sociedad Española de Ginecología y Obstetricia
SHS: Spanish Healthcare System
SIGN: Scottish Intercollegiate Guidelines Network

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SPSS: Statistical Package for the Social Sciences

SR/MA: Systematic review/meta-analysis

SR: Systematic review

TENS: Transcutaneous electrical nerve stimulation

UL: Upper limit

USA: United States of America

WHO: World Health Organisation

WMD: Weighted mean difference

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Appendix 2: Glossary

Active management of delivery: This includes the administration of prophylactic uterotonics, controlled traction of the umbilical cord and uterine massage after delivery of the placenta.

Amnioscopy: Direct observance of colour and amount of amniotic fluid using an amnioscope.

Birth partner: (The presence of) a person chosen by the woman for the whole of the labour and childbirth process, from the moment she is admitted to the maternity ward (relative, partner, person close to her,…)

Carbohydrate solutions: In general sugar solutions.

Cardiotocography (CTG): Cardiotocography is a type of fetal assessment that simultaneously records fetal heart rate, fetal movements and uterine contractions. The procedure can be carried out through the skin (external cardiotocography) or by placing at electrode directly on the scalp of the foetus through the cervix (internal cardiotocography).

Case Series: Analysis of a series of patients with the disease.

Case-control study: A study that identifies people with a disease (cases), for example, lung cancer and compares them with a group without the disease (control). The relationship between one or several factors (for example tobacco) related to the disease is examined, comparing frequency of exposure to it or other factors among the case individuals and the control individuals.

Categorisation: Procedure for the classification of cardiotocographic recordings, establishing fetal wellbeing risk categories.

Chorioamnionitis: Infection of placental membranes or amniotic fluid. It is also known as intraamniotic infection or amnionitis.

Clear fluids: Water, pulpless fruit juices, carbonated drinks, coffee and tea without milk, isotonic drinks.

Cochrane Library: A database on effectiveness produced by the Cochrane Collaboration. It consists of the organisation's original systematic reviews and other items

Cohort study: This consists of monitoring one or more cohorts of individuals with varying levels of exposure to a risk factor, in whom the onset of the illness or condition being studied is measured.

Combined analgesia: Intradural analgesia + epidural analgesia

Confidence interval (CI): The interval within which the actual effect size (never known exactly) is found with a pre-established level of security or confidence. We often speak of a "95% confidence interval" (or "95% confidence limits"). This means that the actual value would be within this interval in 95% of cases.

Cross-sectional study: This type of study describes the frequency of an event or an

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exposure at a given time (one sole measurement). It allows the relationship between a risk factor (or exposure) and an effect (or result) in a defined population and at a determined moment (cohort) to be examined. It is also known as prevalence studies.

Dehiscence: Separation of more than 0.5 cm of the edges of a sutured surgical wound.

Delayed pushing: Until the woman feels like pushing or the head of the foetus reaches the pelvic floor.

Diagnosis delay: Possibility of an atresia (rectal or oesophageal) going unnoticed, causing undue delay in treatment.

Dispareunia or coitalgia: is painful sexual intercourse. It ranges from postcoital vaginal irritation to severe pain. It is defined as pain or discomfort before, after or during sexual intercourse. The pain women experience may be a burning sensation, contraction or stabbing pain which may be located inside or outside the vagina, in the pelvic region or in the abdomen.

Doula: Doulas are women, mostly mothers, who accompany other women during gestation, labour, delivery and the postnatal period offering physical and emotional support.

Dystocia: Labour or delivery that occurs in an abnormal way or with difficulties.

Early onset vitamin K deficiency haemorrhagic disease: It can occur during the first 15 days of life.

Embase: European (Dutch) database produced by Excerpta Médica with clinical medicine and pharmacological contents.

Encopresis: Faecal incontinence.

Epidural analgesia: Type of neuraxial analgesia in which an anaesthetic is introduced near to the spinal cord (epidural space), without perforating the dura mater.

Episiotomy: Performing a surgical incision in the area of the woman's perineum which includes skin, muscle layer and vaginal mucosa, the purpose of which is to widen the "soft" channel in order to shorten the duration of childbirth and facilitate the delivery of the foetus.

Fetal scalp stimulation test: A technique in which the foetus is stimulated by applying pressure to the fetal scalp during vaginal examination or by puncture of the fetal scalp. The test is considered to be negative if there is acceleration in the FHR of at least 15 beats per minute lasting 15 seconds. A positive test is defined as the absence of acceleration of the FHR or an acceleration of less than 15 beats per minute or for a duration of less than 15 seconds.

First degree perineal tear: Laceration that affects the fourchette, perineal skin and vaginal mucosa.

Fourth degree perineal tear: It includes laceration of anal mucosa and can reveal the rectal lumen.

Immediate pushing: Immediately after reaching full dilatation.

Informed decision: It is the ability to decide on a procedure or therapeutic action after having received true, comprehensible information.

Intermittent auscultation (IA): Auscultation of fetal heart rate using a Pinard stetho-

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scope or Doppler ultrasounds for 1 minute after a contraction, every 15-30 minutes during the active phase of the first stage of labour and every 5-15 minutes in the second stage of labour.

Intermittent electronic fetal monitoring (IEFM): Cardiotocographic recording of fetal heart rate for a period of 15-30 minutes every 2 hours with intermittent auscultation every 15-30 minutes between the periods of electronic monitoring.

Intradural analgesia: This is a type of neuraxial analgesia in which the dura mater and arachnoid mater are perforated and an anaesthetic is introduced in the subarachnoidal space where it mixes the cephalorachidian fluid.

Isotonic drinks: Drinks that have a great rehydrating capacity. Their composition includes low doses of sodium, normally in the form of sodium chloride or sodium bicarbonate, sugar or glucose and usually potassium and other minerals.

Kappa index: Proportion of potential agreement above randomness that different measurements of the same fact obtain.

Ketosis: Metabolic state of the body caused by a deficit of carbohydrates which induces the catabolism of fats to obtain energy, generating compounds known as ketone bodies.

Kristeller manoeuvre: The Kristeller manoeuvre consists of exerting pressure on the uterine fundus for 5 to 8 seconds, synchronously with the uterine contraction, with a pause of 0.5 to 3 minutes to facilitate final progress and delivery of the fetal head.

Late onset vitamin K deficiency haemorrhagic disease: It can occur from 2 weeks up to 2-3 months after birth and appears in otherwise healthy infants.

Lithotomy: Position in which the woman is placed in the supine position with hips and knees flexed and thighs abducted and external rotation.

Medline: Predominantly clinical database produced by the USA National Library of Medicine available in CD-Rom and Internet (PubMed).

Meta-analysis: A statistical technique that allows the results of several different studies (studies of diagnostic tests, clinical trials, cohort studies, etc.) to be combined in a single estimate which lends more weight to the results of larger studies.

Modern regimen of neuraxial analgesia (low dose regimen): Neuraxial analgesia that uses neuraxial anaesthetics (e.g.: bupivacaine) in a concentration < 0.25%, generally associated with opioids. It can be given as an epidural or combined (intradural-epidural).

Morbidity: Disease or frequency in which a disease arises in a population.

Mortality: Rate of deaths or number of deaths due to a certain disease in a group of persons and in a certain period.

Neonatal bradycardia: Heart rate of less than 100 bpm.

Neonatal prophylaxis with vitamin K: Early onset haemorrhagic disease due to vitamin K deficiency: it spans the first 15 days of life.

Neuraxial analgesia: Pain relief achieved by blocking painful impulses at spinal cord level.

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NICE (National Institute for Clinical Excellence): It forms part of the UK's NHS. Its role is to provide doctors, patients and the general public with the best available evidence, mainly in the form of clinical guidelines.

Nulliparous: A woman who has not previously given birth to a viable infant.

Partogram: Visual graphical representation of values and events related to the course of labour. The action line is traced to the right of the line showing the progress of cervical dilatation, at a rate of l cm per hour. A 2-hour action line is displaced 2 hours to the right of the progress line and if progress slows down so that the line crosses the action line, a diagnosis of delayed dilatation is given.

Perineal dose – high concentrations: Bupivacaine-levobupivacaine 0.25% or greater; ropivacaine 0.2% or greater and lidocaine 1.5% or greater.

Perineal massage: To and fro movement accompanied by pressure on the vulva fourchette.

Perineal shaving: The practice of removing perineum hair by shaving it.

Physical management of delivery: Management of delivery without administering uterotonics and delivery of the placenta by gravity and maternal pushing.

Placebo: A substance administered to the control group in a clinical trial, ideally having an identical appearance and taste as the experimental treatment and thought to have no specific effect for the disease in question. In the context of non-pharmacological interventions, the placebo is usually known as a simulated treatment.

Post-traumatic stress: Is a late or deferred response to a stressful event or an exceptionally threatening or catastrophic situation that would, in itself, cause general ill effects in any person.

Pushing: Force in addition to that carried out by the uterine muscle when it contracts so that it can be more effective.

Qualitative research (Q): This is a method that comprises a plurality of theoretical approaches, methods and techniques and which is characterised by the fact that it studies phenomena in their natural context, attempting to find the meaning or interpretation of them from the meanings that people give them. For this purpose it uses empirical material (interviews, observations, texts, etc.) that can best describe both routine and problematic situations and what they mean in individuals' lives.

Randomised clinical trial (RCT): It is a study design in which individuals are randomly allocated to two groups: one (experimental group) receives the treatment being tested and the other (comparison or control group) receive a standard (or sometimes placebo) treatment. The two groups are monitored to observe any difference in outcomes and in this way the efficacy of the treatment is assessed.

Respiratory distress: A situation of unstable breathing which requires special surveillance, monitoring, oxygen therapy or admission for observation or treatment.

Second degree perineal tear: In addition to the previously described lacerations it affects the skin and mucosa, the aponeurosis and perineal muscles, but not the anal sphincter.

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SIGN (Scottish Intercollegiate Guidelines Network): A multidisciplinary Scottish agency that publishes evidence-based clinical practice guidelines and methodological documents on guideline design.

Specificity: Probability that a measurement correctly classifies a healthy person.

Spontaneous pushing: Instinctive, without saying how or when to carry it out.

STAN: ST segment analysis of the fetal electrocardiogram.

Systematic review (SR): A review in which the evidence on a particular subject has been systematically identified, assessed and summarised according to a pre-established set of criteria. It may or may not include meta-analysis.

TENS: Transcutaneous electrical nerve stimulation is a non-invasive analgesic technique based on the electrical stimulation of afferent nerve fibres through the skin by means of applying electrodes. The way it acts is based on stopping painful impulses in the spinal cord, releasing endorphins, participating in central mechanisms and blocking peripheral nerves. This is a simple method with few side effects and for this reason its use in obstetric analgesia has been studied.

Therapeutic oxytocin: Used to treat a possible haemorrhage due to delivery problems (not as a product aimed at facilitating actively managed deliveries).

Third degree perineal tear: It extends to all the aforementioned and the anal sphincter.

To direct pushing: Directing the way and time that pushing is carried out during labour.

Traditional regimen (high-dose regimen): Analgesia performed with local anaesthetics (e.g.: bupivacaine) in a concentration ≥0.25%.

Types of suturing material:

* **ABSORBABLE**: Materials that the tissue in which they are placed can degrade. Absorption depends on the tissue, the type of suture, the age and general state of health of the patient. There is a variety of sutures:

NON SYNTHETIC

Catgut. Made from collagen. Can be plain or chromic. They are used in tissues that heal quickly. It is widely used in gynaecological and urogenital surgery.

SYNTHETIC ABSORBABLE

Made of synthetic polymers. It causes less inflammatory reaction and is easier to handle and has greater tensile strength. Dexon®: is a polymer and Vicryl®: lactic acid or lactate.

Uterine hyperdynamia: Intense contractions of the uterus.

Walking-epidural (WE): Walking epidural is the name given to the analgesic technique that allows the pregnant woman to remain mobile during the first stage of labour, while at the same time maintaining a good quality of pain relief. A walking epidural basically consists of reducing the amount of neuraxial anaesthetic by using low concentration local anaesthetics and associating them with opioids so that only the sensory fibres are blocked, maintaining the quality of the analgesic, and the function of the motor fibres that control movement is preserved.

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Appendix 3: Effective communication between professionals and women in labour.

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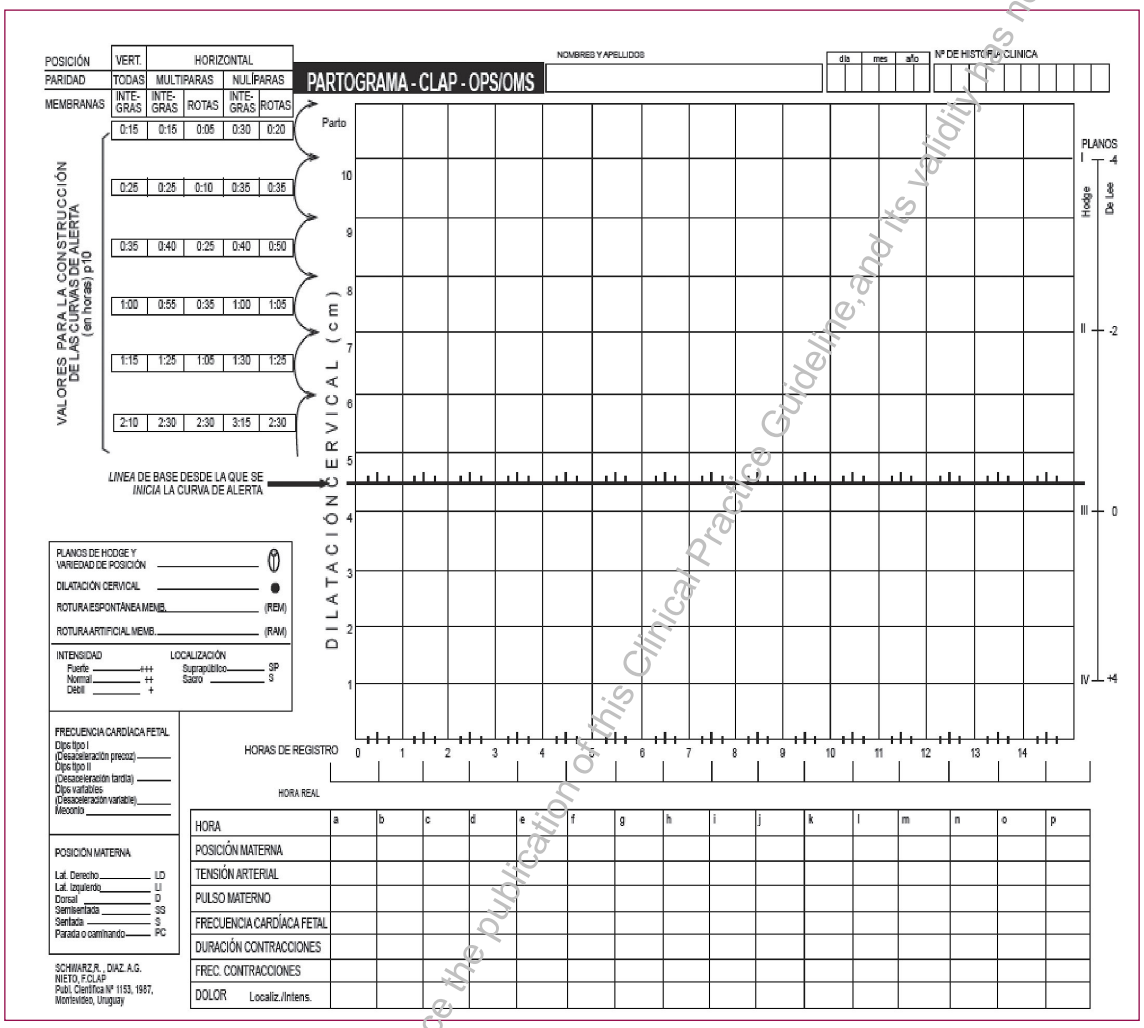
To establish effective communication the following attitudes and behaviours have been shown to be useful and to be highly valued:

- Greet the woman personally and welcome her with a smile.
- Check if there are any language barriers and explain the role that you are going to play in caring for her.
- Behave in a calm way and transmit security and confidence which will reduce the anxiety, fear and stress that many women experience.
- Consider the room as a personal and private space. Knock on the door and wait for an answer before entering and ask the rest of the staff to do the same. Avoid the presence of any unnecessary staff at all times. Encourage the woman to adapt the room's ambience to her individual needs, lights, temperature, music, personal objects, etc.
- Employing open, undirected questions to find out how she feels, what her needs are and what can help to contribute to her comfort and wellbeing. Ask if there is anything she is worried or concerned about. If she has a specific childbirth plan, go over it with her. In all cases it is important to be aware of a woman's expectations regarding the development of labour and the birth of her baby. Allow her to move freely, to express her emotions, to drink fluids and respect her need not to feel observed or judged.
- Provide understandable, relevant information, clarify any false ideas and always act in a supportive, understanding way, showing confidence in the woman's ability to deal with childbirth. It is advisable to check how much the woman knows about pain relief methods to offer the information and advice she needs to be able to choose the method that best suits her.
- Professionals' attention must be focused on the woman and not on the cardiotocograph or the clinical documentation.
- Get the woman's verbal consent before carrying out any procedure or examination and explain or ask permission if you propose an examination for teaching purposes or if it is going to be repeated by trainees. Ask for permission for trainee staff to remain in attendance during childbirth.
- Help the accompanying person to provide calm, considerate encouragement, show confidence, willingness to help and maximum respect for the woman's decisions. Show the person how to make the woman in labour comfortable and to give pain-relieving massages if she so requests.

- When leaving the room let the woman and the person accompanying her know when you will be returning and any change in staff or that other specialists have been asked to intervene. Said professionals should introduce themselves and explain why they are there.
- Provide a calm, quiet environment respecting each woman's need for seclusion, privacy and concentration.

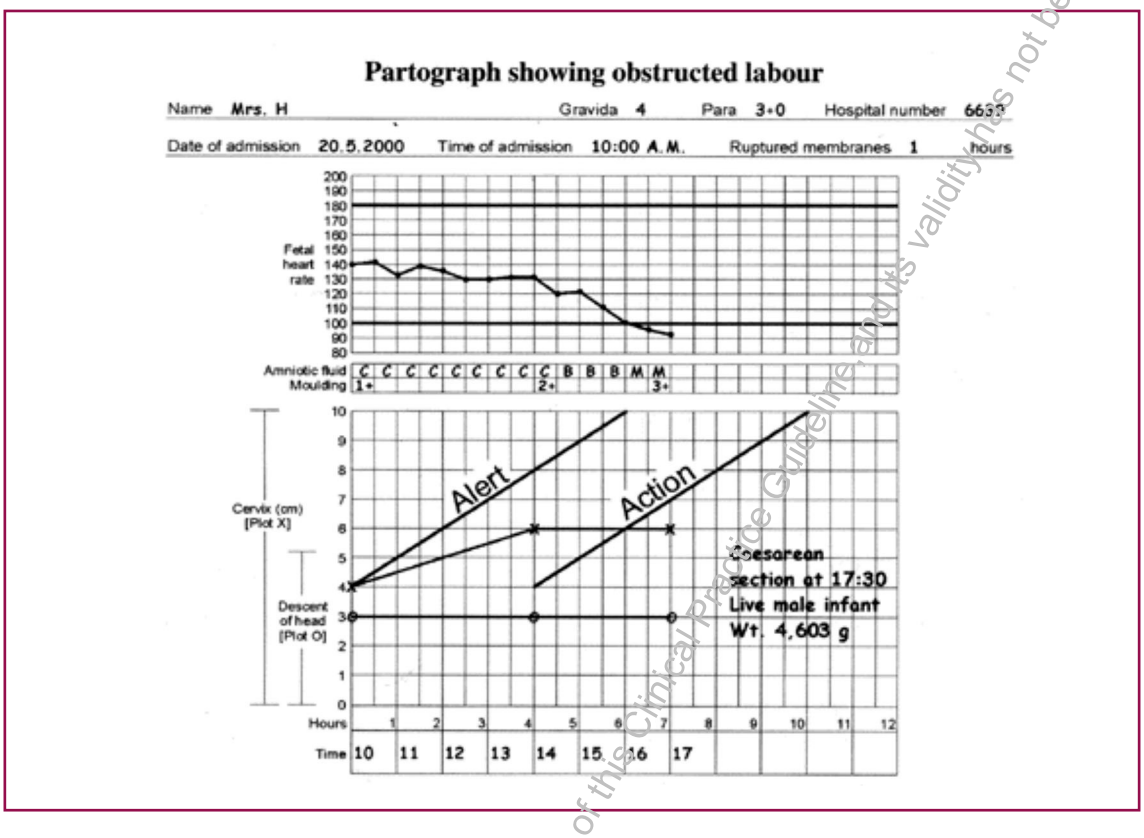
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Appendix 4: Partogram



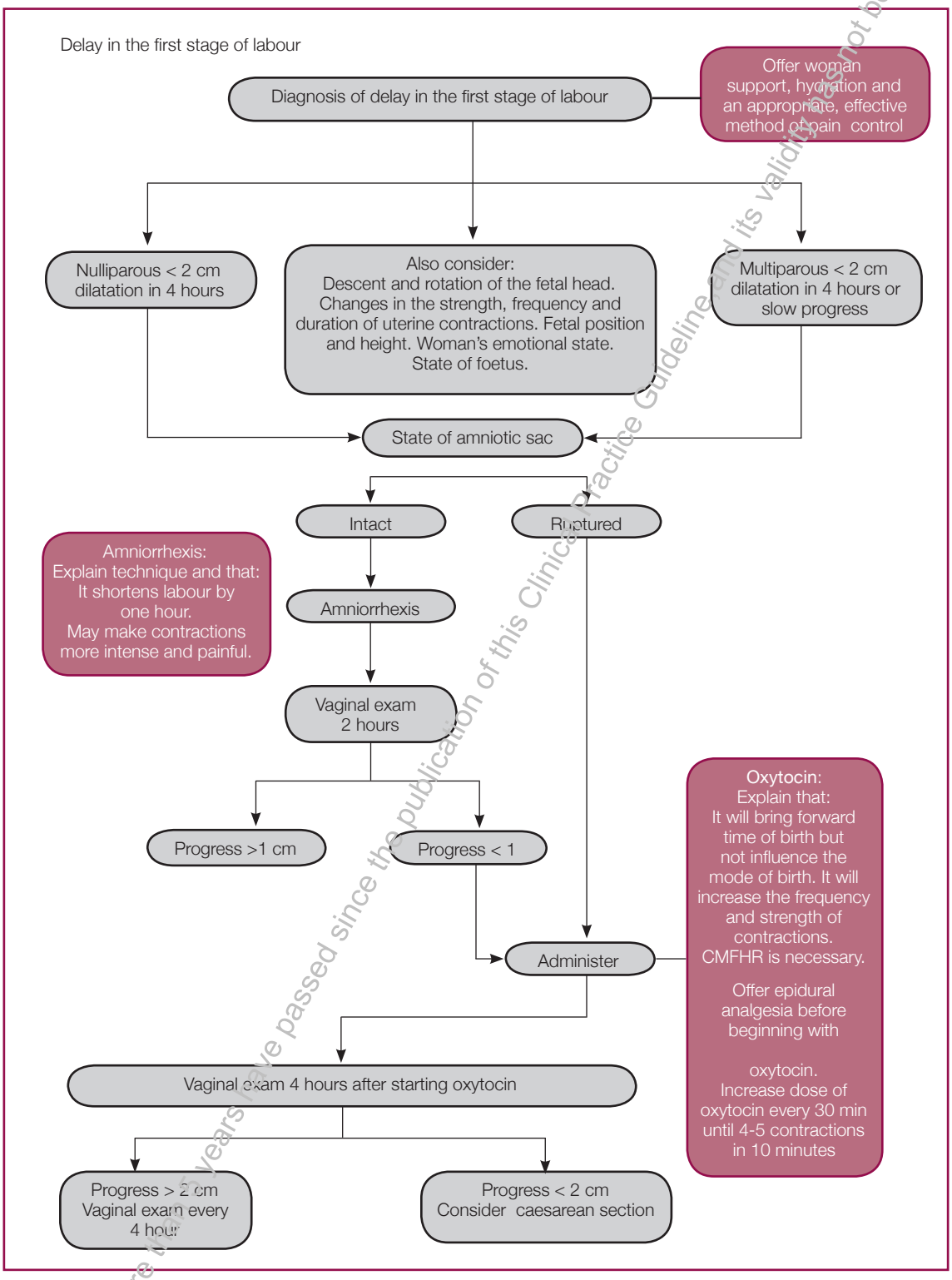
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Example: Partogram recording



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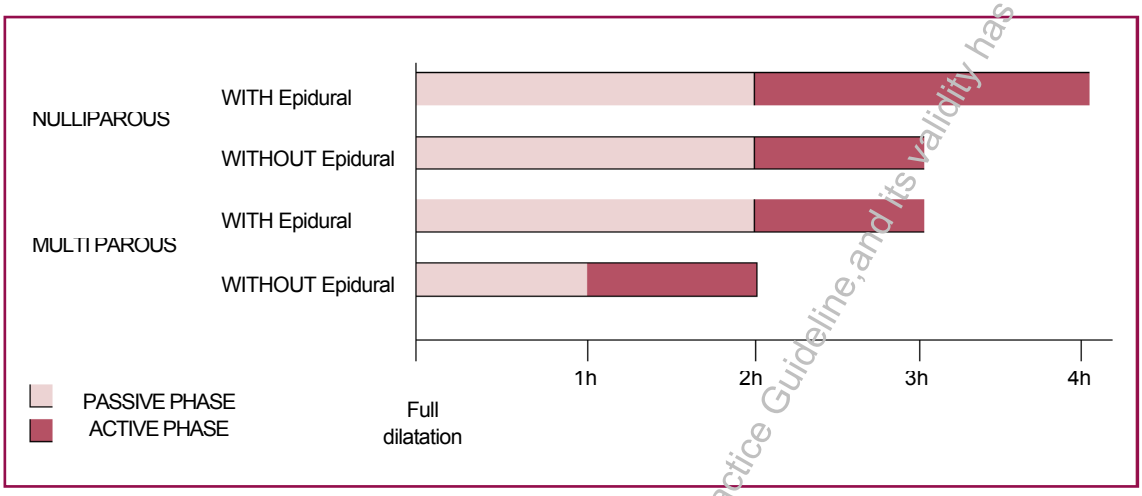
Appendix 5. Algorithm for Diagnosing the Delay in the First Stage of Labour



CMFHR : continuous monitoring of fetal heart rate

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Appendix 6. Duration of the second stage of labour with and without neuraxial analgesia



		Duration of the second stage of labour		
		Passive phase	Active phase	TOTAL Second Stage
Nulliparous	With epidural	2 h	2 h	4 h
	Without epidural	2 h	1 h	3 h
Multiparous	With epidural	2 h	1 h	3 h
	Without epidural	1 h	1 h	2 h

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Appendix 7. Skin-to-skin contact

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Neonates eligible for skin-to-skin contact.

Skin-to-skin contact can be carried out without restriction, provided that the procedure is supervised, in the following cases:

- Full term neonates (or late preterm)
- Neonates that are considered suitable for this by competent personnel.

Non-urgent procedures and medical measures should not be performed immediately after birth, as they can be postponed and otherwise interfere with skin-to-skin contact.

Procedure for carrying out skin-to-skin contact.

- Inform the mother during the first stage of labour about the benefits and procedure for skin-to-skin contact and the possibility of doing this with her son or daughter immediately after birth. Answer her questions and respond to her needs personally, respecting her decision at all times.
- Maintain a suitable temperature in the delivery room (22-24ºC).
- Prepare cloths, cotton fleece covers, hats and warm nappies.
- The delivery room environment should be silent, warm with dim lighting and a person to accompany the mother if she wants. There should not be an excessive number of health care professionals in the room.
- In the last minutes of the second stage of labour, ask the woman who wishes to experience skin-to-skin contact to uncover her abdomen/chest and help her to do so if necessary, covering it with a warm cotton fleece cover.
- Remove the cotton fleece cover at the time of birth.
- Place the neonate directly on the woman's skin, gently drying the neonate's back with a pre-heated cloth. Check that he/she is breathing without difficulty, with good thoracic movements and that the neonate has good muscle tone.
- Remove the cloth used to dry the baby and cover mother and baby with a dry, warm cotton fleece cover which does not come above the baby's shoulders, allowing visual contact.
- Place the mother in a semi-recumbent position, cradling her baby.

a Mother close to 45º with neonate in a prone position between her breasts.

b Neonate with open, flexed extremities and head to one side and slightly spread out, resting on mother's chest, avoiding flexion and hyperextension of neck.

- Encourage visual contact between mother and baby, aiding this by placing a pillow behind the mother.

- Place a pre-warmed cotton hat on neonate
- Carry out Apgar test after one and five minutes with neonate resting on mother's body.
- Perform late clamping of umbilical cord (after two minutes or when it stops pulsing).
- Placing of cord clamp without interfering with skin-to-skin contact.
- Collect blood from umbilical cord following the usual procedure (fetal Rh blood group, gases...).
- Skin-to-skin contact must not interfere with performing directed delivery.
- Put a nappy on the neonate, if the mother wants you to, without interrupting skin-to-skin contact.
- During the whole process ensure the well being of the mother and neonate, checking colour, breathing and muscle tone.
- Accompany the mother in the postpartum period, helping her to find a comfortable position (bed at 45º with pillow) that enables her to interact and look at her baby, encourage her to touch and caress him/her, respecting her desires and privacy.
- Identify the neonate before leaving the delivery room.
- If the mother wishes, let the neonate latch onto her breast spontaneously without forcing the first feed. Access to the breast may be made easy but it is preferable for the baby to latch on spontaneously.
- Keep the neonate with skin-to-skin contact whilst the mother gets into bed.
- Whenever possible the mother and neonate should remain in the delivery room until the first feed has been completed, noting down when and how it occurs.
- Check the mother's well being immediately after leaving the delivery area.

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Appendix 8: Technical aspects of use of nitrous oxide (375)

Administering nitrous oxide for pain relief during childbirth requires connecting apparatus and equipment to gas points and instructing women on how to use the device for self-administration of analgesia by inhalation.

Standardised procedure for administration of nitrous oxide by midwives

I. Background

A. *Establish "Standard procedure"*

B. *Supervision*

After a period of training and supervision to establish competence, continuous direct supervision is not required. However, the anaesthetist must be available for consultation or assistance.

C. *Indications*

Women experiencing painful childbirth or with perineal pain during suturing after a vaginal birth, who request nitrous oxide analgesia.

D. *Precautions / Contraindications*

In women:

1. Who cannot sustain a mask
2. With deteriorated consciousness or an intoxication
3. Who have received significant amounts of intravenous opioids
4. Who are being treated with vitamin B12 or have a deficit of vitamin B12
5. Who suffer a deterioration in oxygenation
6. With altered haemodynamics
7. With fetal compromise
8. With clinical contraindications such as intracranial hypertension, gastrointestinal distention, pneumothorax, bullous emphysema, lack of cooperation or understanding of use.

II. Materials

Kalinox® machine

III. Start up and administration of nitrous oxide for women in labour

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A. *Pre-assessment of treatment*

Assessment of the suitability of the user (mother and foetus) and that there are no contraindications. Vital signs such as blood pressure, heart rate, oxygen saturation and controlling fetal heart rate.

B. *Start up (if applicable*)

Ensure that the equipment is connected and functions correctly.

C. *Preparing the woman*

1. Inform the woman of the moderate analgesic effect and possible side effects: nausea, vomiting, light-headedness and alteration of recollection.
2. Instruct the woman on self-administration: how to place the mask correctly to create an airtight seal or the nozzle and rate of breathing to achieve the maximum analgesic effect.

D. *Procedure*

The woman holds the nozzle in her mouth or keeps the mask over mouth and noise creating a sufficiently airtight seal to activate a second stage of opening of the regulator that controls the flow of nitrous oxide (50%) in oxygen (50%).

The health care professional in charge will be instructed and confirm in writing the order that additional opioids must not be administered without the direct supervision of the anaesthetist or the medical staff whilst the woman continues using nitrous oxide analgesia.

E. *Termination of treatment*

Use of nitrous oxide will be interrupted if the woman so requests or if pain relief is not necessary or if there are any undesirable side effects.

IV. Documentation

The midwives will record on the woman's medical record, as part of the progress of labour, the use of nitrous oxide, its efficacy and any side effects or complications that have occurred.

V. Assessment of competence

A. *Initial competence*

1. Midwives attend training sessions on nitrous oxide given by obstetric anaesthetists. After the training sessions they will have to demonstrate that they:

a) Understand of the equipment

b) Are capable of correctly configure the equipment

c) Understand the indications and contraindications

d) Have knowledge of the possible side effects

e) Skills to offer informed consent and instructions to women who request this method of analgesia.

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2. Furthermore, midwives will have to repeat start up and administration of nitrous oxide to women three times under the observation of a member of the anaesthesia team or already qualified trained staff before they are deemed competent.

B. Continuous competence

Midwives will receive updates on the use of nitrous oxide by the obstetric anaesthesia team and will pass yearly assessments to guarantee continued continuous competence.

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Appendix 9: Information for women who choose neuraxial analgesia.

Before choosing epidural analgesia the woman must be informed of the risks and benefits and the implications for childbirth. This information on epidural pain relief must include the facts that:

- It provides greater pain relief than opioids. A
- It is not associated with a longer 1st stage of labour or with a greater percentage of caesarean sections. A
- It is associated with a longer 2nd stage of labour and a greater risk of an instrumental vaginal delivery. A
- It requires more intense monitoring and invasive procedures. √
- It is not associated with long-term back pain. A

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Appendix 10: Maternal supervision

Blood pressure should be measured during establishment of neuraxial analgesia every 5 minutes for the first 15 minutes and after each bolus when administered intermittently.

If the patient is not pain-free 30 minutes after each administration of local anaesthetic and/or opioid, she should be reassessed by the anaesthesia professional.

Hourly assessments of the level of sensory block and degree of motor block should be carried out.

CEM or FHR is recommended for the first 30 minutes of establishment of neuraxial analgesia and after the administration of each of the following boluses of 10 ml or more.

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Appendix 11: Intermittent Fetal Auscultation Technique

- Before initiating any fetal monitoring method the woman must be informed of the benefits and risks of each of the techniques.
- Auscultation can be performed using Doppler ultrasound equipment or with a Pinard stethoscope.
- Fetal heart auscultation is recommended in the first antenatal assessment and then after each examination to determine the establishment of labour.
- During the active phase of labour, intermittent auscultation is performed as follows:

— Auscultation of fetal heart at least every 15-30 minutes during the second stage of labour.

— Auscultation will be performed for at least 30-60 seconds after a contraction.

— The mother's pulse rate must also be known to differentiate the mother's rate and the fetal heart beat.

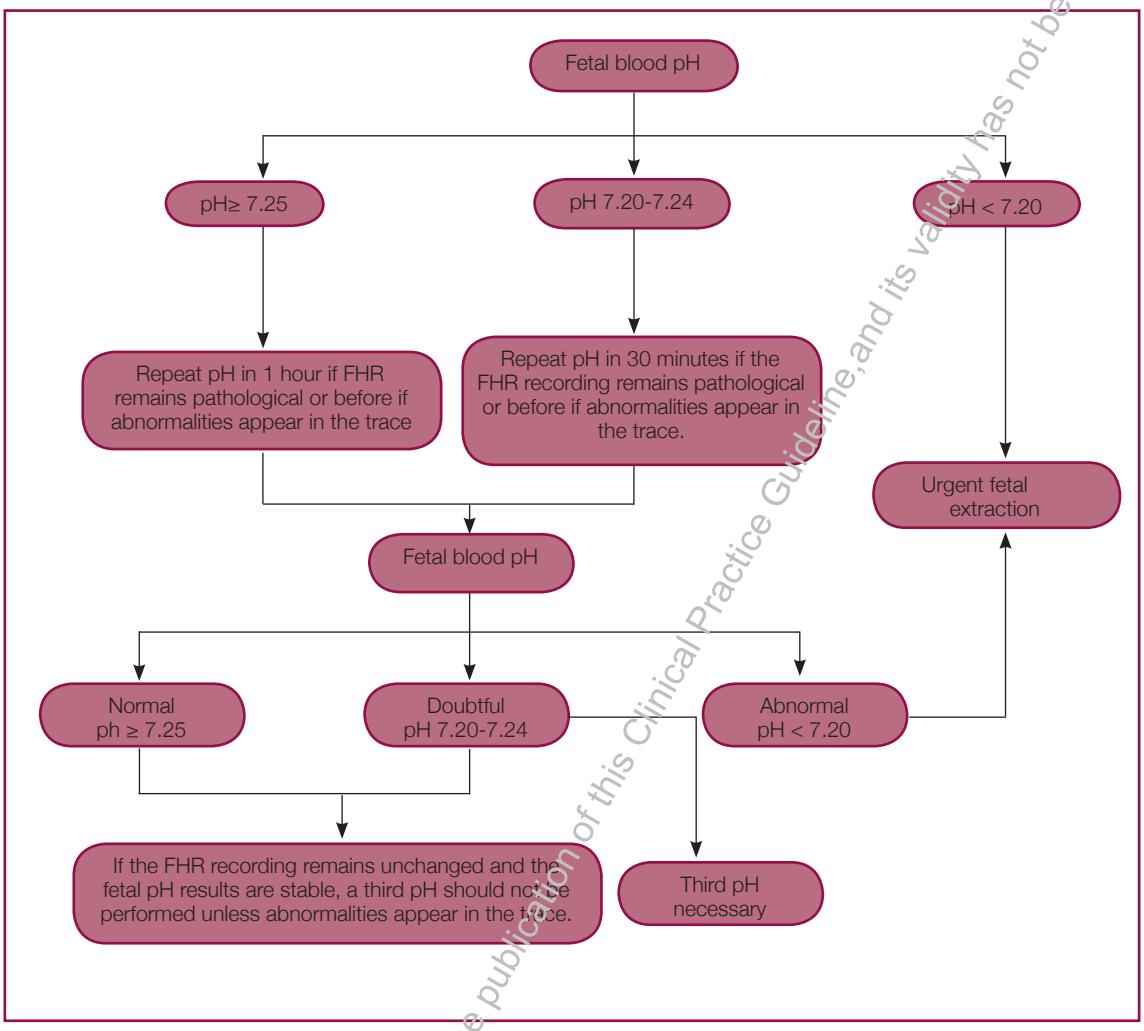
— It must be recorded on the partogram the time when auscultation was performed, fetal heart beat, the presence or absence of accelerations and decelerations and the duration of auscultation.

Intermittent auscultation or IEFM must be changed to CEFM in low-risk women in the following situations:

- Presence of stained amniotic liquid.
- Alteration in feat heart beat by auscultation.
- Maternal fever.
- Bleeding during labour.
- Use of oxytocin.
- At the request of the woman.
- For a period of 30 minutes after establishment of epidural anaesthesia or after the administration of each additional bolus.

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Appendix 12: Decision algorithm according to fetal pH results



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Appendix 13. Cardiotocographic recordings

Cardiotocographic recording

- The date and time must be correctly set on the cardiotocograph.
- The recording must be correctly identified, with the name of the woman and the date.
- Any intrapartum event that may affect the FHR must be written down on the recording, indicating the date and time at which it occurs and signing it (for example: vaginal examination, micro sampling, or adopting a sitting position to receive epidural).
- Members of staff who are asked to give an opinion on a recording should write down their conclusions on the recording as well as on the woman's medical history, along with the date, time and signature.
- After birth, the date, time and type of birth must be written down on the recording.

CTG classification according to fetal heart rate

Classification	Heart rate (l/m)	Variability (l/m)	Decelerations	Accelerations
Reassuring CTG	110-160 l/m	≥5	None	Present
Non-reassuring CTG	100-109 l/m 161-180 l/m	< 5 for 40-90 minutes	• Typical variable decelerations with more than 50% of contractions (for approx. 90 minutes). Prolonged one-off deceleration (of up to 3 minutes)	The absence of transitory accelerations in a recording that is otherwise normal has an uncertain meaning
Abnormal CTG	The combination of several non-reassuring observations give rise to an abnormal CTG			
	<100 l/m >180 l/m Sinusoidal pattern ≥ 10 minutes	< 5 for more than 90 minutes	Atypical variable decelerations with more than 50% of contractions or delayed decelerations (DIPII), for for more than 30 minutes Prolonged one-off deceleration of > 3 minutes	
Preterminal CTG	Total absence of variability and reactivity with or without decelerations or bradycardia			

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Definition of cardiotocographic recording categories

- Normal recording: FHR recording in which the 4 reading criteria are classed as reassuring.
- Suspicious recording: FHR recording with one criterion classed as non-reassuring and the rest as reassuring.
- Pathologic recording: FHR recording with 2 or more non-reassuring criteria or 1 or more classed as abnormal.

Further information on the classification of FHR recordings

- An FHR trace with reduced variability and repeated accelerations should be considered to be reassuring.
- Early decelerations are rare and benign and hence, not significant.
- Most decelerations that take place during labour are variable.
- Fetal bradycardia of more than 3 minutes requires urgent measures and to initiate preparations for rapid extraction of the foetus, which should take place if fetal recovery has not occurred within 9 minutes. If the FHR recovers before 9 minutes the decision to extract the foetus must be reconsidered.
- Fetal tachycardia of 160-180 bpm, with accelerations and no other adverse parameter, should not be considered suspicious. However an increase in baseline heart rate, even in the normal range, with other abnormal or non-reassuring characteristics, should trigger an increase in surveillance.
- In woman with continuous monitoring, a systematic assessment should be carried out each hour, documented on the basis of these definitions and classifications.
- When there are abnormal FHR patterns the follow aspects must be considered:
    1. Change in maternal position to a lateral position, preferably on the left side.
    2. Vaginal examination to rule out prolapsed cord or quick evolution of labour. At this time fetal scalp stimulation could be performed as an additional method of diagnosis.
    3. In the case of women who are administered oxytocin: if there is a suspicious FHR trace, the obstetrician should be consulted. If the FHR trace is classed as pathological, oxytocin should be stopped and a complete assessment of the foetus's condition should be carried out by an obstetrician before resuming administration of oxytocin.
    4. Monitoring of maternal blood pressure to rule out material hypotension.
    5. If the abnormal pattern is associated with hyperdynamia not secondary to oxytocin, the use of tocolysis should be considered.
    6. Prolonged use of oxygen therapy in mothers can be detrimental for the foetus and should be avoided. There are no studies that assess the benefits or risks associated with the short-term use of maternal oxygen therapy in cases of presumed fetal compromise.

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Characteristics of atypical variable decelerations

Atypical variable decelerations are defined as those that present one or several of the following characteristics:

- Loss of initial transient rise.
- Slow return of FHR to baseline.
- Loss of secondary transient rise.
- Prolonged secondary transient rise.
- Biphasic deceleration.
- Loss of variability during deceleration.
- Subsequent continuation of baseline at a lower level.

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Appendix 14. Conflict of interest statement

The following people have stated that they have no conflicts of interest:

Idoia Armendariz Mántaras, Gerardo Atienza Merino, M.ª Pilar de la Cueva Barrao, Jose Luis de Pablo Lozano, Itziar Etxeandia Ikobaltzeta, Marian Fernández Bao, Luis Fernández-Llebrez del Rey, Isabel Fernandez del Castillo Sainz, Rosario Fernández Fontanill, Manuel Fillol Crespo, José Manuel García Adanez, José Ángel García Hernández, Blanca Herrera Cabrerizo, Raquel Jiménez Calahorra, María del Carmen Maceira Rozas, Juan Carlos Melchor Marcos, Juan Manuel Odriozala Feu, José María Paricio Talayero, Yolanda Olivares Saralegui, Alberto Puertas Prieto, Charo Quintana Pantaleón, Rosa Rico Iturrioz, Justino Rodríguez Alarcón, Ángel Salgado Barreira, Marta Sancha Naranjo, Olivia Santiago Soriana, Rafael Ucieda Som

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