Category: Clinical Guidance Statement (Interim Update)

Care in labour in the absence of pregnancy complications (C-Obs 31)

This statement has been developed by the C-Obs 31 Care in labour Statement Development Panel and was approved by the RANZCOG Women's Health Committee and Council in July 2023. An interim update to this statement was approved by the RANZCOG Women's Health Committee and Council in March 2024.

A list of the Women's Health Committee membership can be found in Appendix A: Women's Health Committee Membership. A list of the Statement Development Panel can be found in Appendix B: Statement Development Panel Membership.

Conflict of Interest disclosures have been received from all members of this committee (Appendix C).

Disclaimer: This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances (Appendix D).

Purpose:	To provide evidence-based guidance about intrapartum care (first, second and third stage of labour) of women, who commence labour without complications.
Target audience:	This statement was developed primarily for use by doctors who provide care to women[i] during labour and birth. See: RANZCOG's Interim statement on gendered language (below).
Background:	This statement was first developed by the RANZCOG Women's Health Committee in 2010 and updated in 2017. The statement was most recently updated by the Care in Labour Statement Development Panel, a working group of the Women's Health Committee in **July 2023**, followed by an interim update in **March 2024.**
Funding:	The development and review of this statement was funded by RANZCOG.

[i] *RANZCOG currently uses the term 'woman' in its documents to include all individuals needing obstetric and gynaecological healthcare, regardless of their gender identity. The College is firmly committed to inclusion of all individuals needing O&G care, as well as all its members providing care, regardless of their gender identity.*

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1. Purpose and scope

To provide evidence-based guidance on intrapartum care (first, second and third stages of labour) for women who commence labour without complications, where an obstetrician[ii] may be involved.

Out of scope: Vaginal birth after caesarean section (VBAC); indication and timing for administration of epidural analgesia (see Join RANZCOG/ANZCA Position Statement on the provision of obstetric analgesia services (WPI-14)); home births (see C-Obs 2- Home Births); fetal surveillance (See- RANZCOG Intrapartum Fetal Surveillance Clinical Guideline)

2. Introduction

Care during labour for women (wāhine), without known or identifiable risk factors at the start of labour at term, should ensure the wellbeing of the mother and baby, whilst providing a safe and fulfilling birth experience and minimising the risk of interventions. This Clinical Guidance Statement provides recommendations and Good Practice Points to support shared decision-making with women and their families (whānau) and collaborative care in labour provided by doctors and midwives.

3. Terminology

The following terms with definitions are used throughout the document. The World Health Organisation (WHO) definition was used to define the latent and active phases of labour.[1]

Latent phase of labour: The latent stage of labour is a period of time characterised by painful uterine contractions and variable changes of the cervix, including some degree of effacement and slower progression of dilation ≤4cm for first and subsequent labours.

Active phase of labour: Established (active) labour is when there are regular painful uterine contractions, a substantial degree of cervical effacement and more rapid cervical dilation ≥5cm until full dilation for first and subsequent labours.

Slow labour: Consensus-based definition. Slow labour is considered when there is less than a 2cm increase in cervical dilation in a four-hour period from 5cm dilation. Other features of the examination such as descent, rotation and application may inform the diagnosis.

4. List of recommendations

Planning for transfer

Good Practice Point 1
GPP: Registered health professionals providing care in labour should have an agreed and documented plan in place with the woman and her family for timely and safe maternal and perinatal transfer according to local policies, protocols, or pathways.[iii]

[ii] Includes GP obstetricians and trainees

[iii] RANZCOG acknowledges the te reo Māori terms for woman as *wahine* and family as *whānau*.

Care in the latent phase of the first stage of labour

Recommendation 1	Evidence-based recommendation

Conditional: Women having their first baby who are in the latent phase of the first stage of labour (≤4cm dilation) and assessed in a primary birthing unit/hospital may be offered discharge home or to remain in the birthing unit/hospital according to their preference.

Note: It is recommended that women who go home are given advice about when to return.

GRADE of evidence- Low

Timing of vaginal examinations

Good Practice Point 2

GPP: Clinicians should not plan to offer vaginal examinations more frequently than at four-hourly intervals in the first stage of labour. More frequent examinations may be recommended if there are concerns about the wellbeing of the mother or baby or in response to a woman's wishes.

Management of prolonged first stage

Recommendation 2a

Consensus-based recommendation: Women should be informed prior to labour that the length of labour varies widely. However, the duration of active first stage (≥5cm until full cervical dilation) usually does not extend beyond 18 hours in first labours, and usually does not extend beyond 12 hours in subsequent labours.

Recommendation 2b	Evidence-based recommendation

Conditional: When labour is progressing without complication, amniotomy should not be performed routinely. Combined early amniotomy with the use of oxytocin should not be used routinely. In women with slow labour, amniotomy with oxytocin augmentation may be considered for women with intact membranes, after explanation of the procedure and advice that is uncertain what effect this will have on the length of labour and mode of birth.

GRADE of evidence- Low

Safest length of time for second stage without intervention

Recommendation 3	Evidence based recommendation

Conditional: Decisions to expedite birth in the second stage of labour should not be based solely on specific time frames. Clinical decisions should be based on clinical assessment of the maternal and fetal condition, the progress of labour (including fetal descent) and on the woman's informed decisions.

GRADE of evidence- Low

Good Practice Point 3
GPP: In second stage, if nulliparous women have been pushing for two hours and parous women for one hour, escalation is recommended (within the guidance of local referral protocols). If maternal and fetal conditions permit and taking into account time to transfer and access to appropriate resources, it would be reasonable to support an additional hour of active pushing.

Management of prolonged second stage

Recommendation 4	Evidence-based recommendation
Conditional: An upright position in second stage for women should be recommended, as it is associated with a lower risk of assisted vaginal birth. The left lateral position may be recommended in second stage for women with epidural analgesia. GRADE of evidence- Low	

Recommendation 5
Consensus-based recommendation: Specific interventions for managing prolonged second stage of labour apart from expediting birth when indicated by the maternal and fetal condition, labour progress and/or the woman's wishes, are not recommended.

Cord clamping

Recommendation 6	Evidence-based recommendation
Conditional: Women who are giving birth could be offered delayed cord clamping for at least 60 seconds or until pulsation stops, as it may increase the haemoglobin concentration and iron stores of the infant. GRADE of evidence- Very low	

Good Practice Point 4
GPP: There may be clinical indications to cut the cord earlier if required. Resuscitation with an intact cord may be possible in some settings.

Management of third stage labour

Good Practice Point 5
GPP: During the antenatal period, the possibility of postpartum haemorrhage (PPH) and the management of the third stage of labour should be discussed with women (including risks and benefits), acknowledging that there are women who are low-risk for PPH where the benefit of active management is less certain.

Good Practice Point 6
GPP: Women may choose physiological management of the third stage without the use of an oxytocic. It is important that these women are adequately informed (including risks and benefits) so that they can make an informed choice about active or physiological management understanding that the events at the time of birth may change their risk profile.

Existing recommendation, as in C-Obs 43- Management of PPH	Evidence-based recommendation
Conditional[iv]**:** Active management of the third stage of labour (administration of prophylactic oxytocics and assisting birth of the placenta) should be recommended to all pregnant women as this reduces the risk of PPH and the need for blood transfusion. Prophylactic oxytocics should be recommended for the management of the third stage of labour, whether following vaginal or caesarean birth, as they reduce the risk of PPH by at approximately 50%. GRADE of evidence- Low (in low-risk women)	

Perineal care

Recommendation 7	Evidence-based recommendation
Strong: It is recommended that perineal care should be discussed with women during the antenatal period and documented in their care plan, as the use of a perineal care bundle is associated with a small reduction in severe perineal trauma. When elements of the bundle are considered individually, warm compresses may reduce severe perineal trauma and should be offered in the second stage of labour. GRADE of evidence- Moderate	

Recommendation 8
Consensus-based recommendation: Routine rectal examination may not be acceptable to all women although it will occasionally detect a buttonhole tear.

Additional practical advice- Diet in labour

Good Practice Point 7
GPP: It is safe for women to drink to remain hydrated and have a light diet in established labour unless risk factors develop that make a general anaesthetic more likely.

[iv] This recommendation is consistent with existing RANZCOG Clinical Guidance Statement: C-Obs 43- Management of PPH
This recommendation has been determined as Conditional, as this statement update only concerns low-risk women. The recommendation as made in C-Obs 43- Management of PPH, was assessed as Strong, as this statement included both low and high-risk women in its scope.

5. Background

Rationale

Teamwork between midwives and doctors is crucial for safe effective care of women in labour. This statement seeks to provide advice on the intrapartum and postpartum care of women at term without complications at the start of labour. It has been developed through the collaborative efforts of RANZCOG members and midwives with the objective of providing the best care for and improving the experience of women in labour.

Epidemiology

Most women who go into labour are healthy and have a straightforward pregnancy. While risk assessment is a continuous process and risk level can change throughout pregnancy and labour, almost 90% of women will give birth to a single baby with a cephalic presentation after 37 weeks of pregnancy.[2] 41% of women go into labour spontaneously. There are many clinical questions about care in labour, particularly around the benefits and risk of interventions in labour and this statement has sought to use evidence from well-designed research to answer those questions.

6. Methods

The statement was developed according to approved RANZCOG processes, available in the Manual for Developing and Updating Clinical Guidance Statements. Following these processes, including the development of nine clinical questions, the Research and Policy Team identified several local and international guidelines published within the past five years. These included:

- Intrapartum care for healthy women and babies, NICE 2014 (reviewed 2017, 2022).[3]
- WHO recommendations: Intrapartum care for a positive childbirth experience, World Health Organisation 2018.[1]

An additional literature search was conducted to identify any additional peer-reviewed studies published since previous guideline search dates. This search was applied to Cochrane database Central, retrieving publications and MEDLINE. Following screening, systematic reviews were critically appraised using the AMSTAR 2 tool.[4]

Assessment of the rigour, certainty and quality of evidence was performed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

The terms and phrases used in recommendations are dependent on the strength and certainty of the evidence body- further explanation of recommendation types and classifications can be found in the Manual.

Search strategy

Please refer to Appendix E for a comprehensive overview of the search strategy applied to identify peer-reviewed publications for each Clinical Question.

7. Clinical Questions and Recommendations

Detailed Evidence to Decision summaries for each clinical question, including the study results, absolute effect estimates and certainty of evidence for the reported outcomes, can be found in Appendix F.

Clinical Question 1

When birthing in a place where transfer may be necessary, what pre-labour planning should occur to facilitate a transfer?

There was no PICO.

Summary of evidence

As no studies were identified that directly reviewed the elements of pre-labour planning for transfer of care, indirect evidence informed the response to this clinical question. Five studies were identified describing the requirements and processes of facilitating transfers during labour for births occurring at a Primary Birthing Unit (PMU) or Midwifery Led Units. [4-9] It is noted transfers may also occur in a home birth; however, home birth was out of scope for this statement update.

A 2016 survey of 17 PMUs in small rural hospitals and 13 PMUs in Australia used the National Midwifery Guidelines for Consultation and Referral[5], however four PMUs had further modified the Guidelines for relevance to local context. The PMUs which did not use the guidelines reported local doctors conducted their own risk assessment to determine if referral to another service was indicated. When transfer was required, the average distance from PMUs to a tertiary facility was 56 kilometres over an average time of 49 minutes, and this was facilitated by road or less commonly, aeromedical emergency transport.[6] Another retrospective cohort study of transfers from a PMU in rural Queensland reported 42% of transfers in a three-year period (n = 138 women) occurred in the intrapartum period, mostly in the first stage of labour due to labour dystocia resulting in need for caesarean birth.[7]

A 2010 study of all national data in Aotearoa New Zealand reported a transfer rate of 12.6% of women who intended to give birth at a primary unit, with higher likelihood for women having their first baby requiring a transfer.[8] Another survey of women's experiences of transfer or change of care plan in the intrapartum period in Christchurch reported more women in the study were 'unbothered' by the change of plan than those who reported to be 'unhappy' or 'happy' about it. These respondents also knew transfer from PMU could be required and 'generally accepted it was appropriate'. Sense of control, communication with their care providers and support and information were identified as key factors associated with more positive experiences.[9]

A Western Australian study reported an intrapartum transfer rate of 34% (118/350) in 2013-2014 from a midwifery-led birthing centre to the co-located obstetric unit; primarily for analgesia (epidural) and other interventions for complicated labours.[10]

In summary, evidence suggests clinical discussions with women who plan to birth at a PMU or equivalent should include:

- Information about the limitations of services available and the implications for intrapartum and postpartum care, including the possibility antenatal transfer to a centre with more comprehensive services may be required.
- Following any collaborative formal systems already in place, to ensure the safe and timely transfer of women and/or their babies who require specialist treatment. The safety of the woman and baby should be the priority.
- The need to document all transfers for the purposes of future review, as such information is valuable for planning and resourcing improvements of those units requiring transfer capability.

Good Practice Point 1

GPP: Registered health professionals providing care in labour should have an agreed and documented plan in place with the woman and her family for timely and safe maternal and perinatal transfer according to local policies, protocols, or pathways. [iii]

Clinical Question 2

In nulliparous and parous women in latent stage of labour, does discharge home compared to ongoing monitoring in hospital, result in improved maternal and perinatal outcomes?

P[v]- Nulliparous women and parous women in latent phase <4cm cervical dilation with irregular contractions
I- Discharge, including provision of advice and when to re-present etc
C- Remain in hospital, including pain relief options and fetal monitoring
O- Maternal and perinatal outcomes, mode of birth (assisted, vaginal birth, CS, instrumental etc), length of labour, patient satisfaction.

Summary of evidence

The first stage of labour can be categorized into the "latent phase" and the "active phase". There is little agreement about the cervical dilation at which a woman's labour shifts from the "latent" to "active" phase- see Terminology.

One randomised control trial (RCT) included in the Cochrane review (McNiven et al., 1998) reported on the comparison of discharge or staying in hospital.[11] This study included nulliparous women at 37 weeks' gestation or greater who were deemed low-risk (n = 209) at a Canadian hospital who were randomised to early labour assessments with possible discharge or a control group who were sent immediately to the labour and birth unit, were admitted and received standard intrapartum care.

The early assessment group received the usual assessments of fetal and maternal well-being, such as fetal heart rate, blood pressure, and urine tests. A vaginal examination was conducted by a medical intern or the assessment area nurse. The determination of active labour was based on the presence of regular, painful contractions and cervical dilation greater than 3 cm. Women who were not found to be in active labour were given support, encouragement, advice, and were instructed to walk outside or return home until labour became more active. They were also instructed when to return to the hospital.

Women in the early labour assessment group:

- were **less likely** to use an epidural or other regional pain relief in labour compared to women in the direct admission group.
- were **less likely** to be treated with oxytocin to augment their labours than women in the direct admission group.
- There was **little to no difference** found in the proportion of women having caesarean birth between the two groups.
- There were **no differences** found in the rates of instrumental birth, or amniotomy between the two groups.
- were **more likely** to evaluate their experience positively than those who were admitted directly to the labour and birth unit.

[v] Please note, PICO is a framework for developing a focused clinical question. The letters represent Population, Intervention, Comparator, Outcome. See RANZCOG Manual on Developing and Updating Clinical Guidance Statements- pp. 10 for further detail.

- There was **little to no difference** found in the Apgar scores of infants born to women in the assessed and direct admission groups, and the frequency of infants requiring active resuscitation was also similar.
- There were no babies were born before hospital admission.

McNiven et al., 1998 did not report on the outcome of serious maternal morbidity of interest to the statement group, including postpartum haemorrhage (loss of more than 1000 mL of blood), postnatal fever, blood transfusion and maternal death.

No evidence was identified to inform a recommendation for parous women.

Recommendation 1	Evidence-based recommendation
Conditional: Women having their first baby who are in the latent phase of the first stage of labour (≤4cm dilation) and assessed in a primary birthing unit/hospital may be offered discharge home or to remain in the birthing unit/hospital according to their preference. *Note: It is recommended that women who go home are given advice about when to return.* GRADE of evidence- Low	

Clinical Question 3

For women in first stage of labour, does vaginal examination every four hours, compared to less frequent examinations, result in improved maternal and perinatal health outcomes?

P- Women in first stage of labour greater than or equal to 4cm dilation
I- VE <4 hourly
C- VE ≥4 hourly
O- Maternal and perinatal outcomes, mode of birth (assisted, vaginal birth, CS, instrumental etc), length of labour, patient satisfaction.

Summary of evidence

A single RCT of 150 women was identified in the Cochrane review (Abukhalil et al., 1996).[12] Participants were spontaneously labouring, nulliparous women at term were randomly allocated to receive either 2-hourly or 4-hourly vaginal examinations to assess the progress of labour at the specified intervals or at other times if indicated. Both groups were otherwise managed according to the standard labour ward protocol. Indications for vaginal examination outside of the specific intervals included: assessment prior to the administration of pethidine or epidural analgesia, if full dilation was suspected, the application of a fetal scalp electrode or if a fetal scalp blood sampling was necessary.

There were no significant differences in the cervical dilation at the start of labour or during all stages of labour. Little or no difference was found in any of the reported outcomes between women receiving 2-hourly examinations compared to women receiving 4-hourly examinations. One participant in the 4-hourly group had a persistent pyrexia (> 38°C at 1 day postpartum) but this did not reach diagnostic criteria for chorioamnionitis. No other maternal morbidity outcomes and no perinatal outcomes were reported.

Win et al., 2019 provides indirect evidence for maternal satisfaction.[13] This RCT compares vaginal examination 4-hourly with vaginal examinations only when indicated amongst women undergoing induction of labour with misoprostol. Little to no difference was found in maternal satisfaction scores between the two groups. When

surveyed postpartum, women in the vaginal examination when indicated group were more likely to prefer this method in a future pregnancy (88% vs 45%, p-value <0.001). Similarly, women in the vaginal examination when indicated group were more likely to recommend this method to a friend (87% vs 47%, p-value <0.001) (using Likert scale responses). This study also reported the induction to vaginal birth interval was shortened by 7 hours in the 4-hourly vaginal examination arm (mean 24 vs 31 hours, p-value 0.01), but no significant difference was found in the vaginal birth rate at 24 hours (27% in 4-hourly group vs 20% when indicated group, p-value 0.14).

Good Practice Point 2

GPP: Clinicians should not plan to offer vaginal examinations more frequently than at four-hourly intervals in the first stage of labour. More frequent examinations may be recommended if there are concerns about the wellbeing of the mother or baby or in response to a woman's wishes.

Clinical Question 4

When should augmentation and amniotomy be considered for women in first stage of labour?

P- Women in first stage of labour- measured by cervical dilation, length of cervix, descent of fetal head and other relevant parameters/assessments

I- Oxytocin augmentation and/or amniotomy

C- No oxytocin augmentation or no amniotomy

O- Maternal and perinatal outcomes, mode of birth (vaginal birth, assisted vaginal birth, caesarean birth etc), length of labour- first stage and second stage, length of hospital stay, pain relief, PPH, patient satisfaction

Summary of evidence

Background

Phases of labour are defined in Terminology. Contemporary studies of labour progress describe a wide variation in the duration of labour without complication, a non-linear curve of labour progress, and different criteria for transition to active phase. Evidence from a systematic review (Abalos et al., 2018) of seven studies of 99,712 low-risk women in spontaneous labour, who had a vaginal birth and no adverse perinatal outcomes, informed the WHO definitions of latent phase, active phase and slow progress in labour in the 2018 WHO Recommendations: Intrapartum care for a positive childbirth experience.[1, 14]

Studies reporting women with induction of labour, active management of labour or that included first stage caesarean birth were excluded from the systematic review (Abalos et al., 2018). This review reported that the acceleration of the rate of cervical dilation (to greater than 1cm/hr) occurred from 5cm, therefore, the WHO Intrapartum care document recommended the “active phase” be described as cervical dilation from 5cm to full dilation. The expected duration of the active phase of labour differs by the definition of “active phase” cervical dilation used, however, the 95th percentile values in the Abalos review of labour duration from 5cm to full dilation were 12 hours for women having their first labour, and 10 hours for subsequent labours. It should be noted there were limitations of the studies included in the Abalos et al., 2018 systematic review- specifically the inconsistency of method used to assess progress in labour.

The WHO recommended that a cervical dilation rate of 1cm/hr (commonly included in partograms) throughout the “active phase” of labour was unrealistically fast for some women and should not be used in isolation as an indication for obstetric intervention. A new WHO Labour Care Guide (a variation on the partogram) was developed in 2020 indicating new alert thresholds based on a non-linear labour curve accounting for the variability in the rates of progression between women.[15]

Of note to the development and use of this RANZCOG Clinical Guidance Statement, the Australian National Midwifery Guidelines for Consultation and Referral (2021) describe prolonged labour as "no cervical change in 4hrs" at 6cm or greater, consistent with more contemporary concepts of labour progress.[5] In Aotearoa New Zealand, Guidelines for Consultation with Obstetric and Related Medical Services (Referral Guidelines) (2023) define prolonged first stage of labour as <2cm in four hours for nulliparous women and 'slowing in the progress of labour… considering descent and rotation of fetal head, changes in strength, duration and frequency of contractions' for multiparous women.[16] Agreement on a definition of "slow" progress in labour is important in developing recommendations for the management of such labours.

Due to the heterogeneity of methods used to identify parameters for the length of first stage of labour, the SDP chose to define slow labour, including the duration, by consensus-based opinion. This is noted in 3-Terminology and reflected in Consensus-based Recommendation 2a.

RCT evidence for Recommendation 2b

This research question comprises two distinct populations of women in the first stage of labour and thus is presented in two parts:

1. The use of amniotomy and/or oxytocin augmentation for women in the first stage of labour whose labour is progressing without complication.
2. The use of amniotomy and/or oxytocin augmentation for women in the first stage of labour whose labour in "slow" to progress or who have a diagnosis of labour dystocia.

1. Women in the first stage of labour whose labour is progressing without complication or unselected populations

Amniotomy alone versus intention to preserve the membranes (no amniotomy)

A Cochrane review by Smyth et al., 2013 included one study, involving 39 women of amniotomy compared with no amniotomy in women with "labour dystocia". This study describes "labour dystocia" as a dilation of 3cm or more, having crossed the action line on a partogram, or having had no progress over two hours.

- There was no difference in caesarean birth, instrumental birth, or epidural/narcotic analgesia between the study groups.
- Maternal satisfaction with childbirth experience was higher in the amniotomy group (MD 22.00, 95% CI 2.74 to 41.26) [very low-quality evidence].
- None of the 39 participants had babies which were admitted to the SCBU/NICU.

Amniotomy alone versus intention to preserve the membranes (no amniotomy) for spontaneous labour

A Cochrane review authored by Smyth et al., 2013 included an unselected population of 15 studies, involving 5,583 women.[17] There was no consistency between trials regarding the timing of amniotomy during labour in terms of cervical dilation or labour progress. When comparing amniotomy versus control groups:

- There was **no clear statistically significant difference** found in length of the first stage of labour for nulliparous women (mean difference (MD) -57.93 minutes, 95% confidence interval (CI) -152.66 to 36.80) or parous women (mean difference (MD) 23.10 minutes, 95% confidence interval (CI) -50.89 to 97.09).
- There was a **small reduction** found in the length of the second stage for nulliparous women in the amniotomy compared to no amniotomy (mean difference (MD) -5.43 minutes, 95% confidence interval (CI) -9.98 to -0.89), however there was **no difference** found in length of second stage for parous women (mean difference (MD) -1.19 minutes, 95% CI -2.92 to 0.53).

- There was **no difference** found in caesarean birth, instrumental vaginal birth, or PPH >500mL, among nulliparous or parous women.
- There was **no difference** found in maternal satisfaction with childbirth experience (MD -1.10, 95% CI -7.15 to 4.95).
- No difference was found in admission to SCBU or NICU.

One additional study (Ruamsap et al., 2013) was identified published after the Cochrane review. This RCT (n = 120) compared effectiveness of early versus late amniotomy in women entering the active phase of labour.[18] Early amniotomy was defined as having a cervical dilation of 3- 5cm, whereas late was defined as membrane being left intact with amniotomy reserved for specific indications. The outcome of duration of first stage included a period of time at home before women were admitted in labour. There was **no difference** between groups for duration of first stage of labour and that rates of caesarean births were **significantly higher** in the early amniotomy group (43.3% vs 20%, p-value: 0.006).

Protocol of early amniotomy and early oxytocin (part of a package known as "active management of labour") vs routine care

The Cochrane review by Wei et al., 2013 included 14 trials including 8,033 women in labour.[19] Eleven of the trials enrolled women who were in spontaneous labour at randomization, allocating them either to early amniotomy and oxytocin if slow progress in labour ensued, or to expectant management.

- Early amniotomy and augmentation was associated with a small reduction in the CS rate (RR 0.87; 95% CI- 0.77 to 0.99; NNT 65).
- No difference was found in spontaneous vaginal birth, instrumental birth, and use of epidural analgesia.
- The length the first stage of labour was slightly reduced (mean difference (MD) -1.57 hours, 95% CI -2.15 to -1.0).

2. Women in the first stage of labour whose labour in "slow" to progress or who have a diagnosis of labour dystocia

Protocol of early amniotomy and early oxytocin known as "Active management of labour" vs routine care

Three of the trials in the Wei et al 2013 review included only women with an established delay in the progress of labour and were grouped as 'therapy' trials. These three trials differed in their definition of "slow labour". One defined slow labour as at least 3cm crossing action line on a partogram; one described dilation of less than 1cm/hr but lacked a minimum dilation for the beginning of "active phase"; and one included women with a cervical dilation of between 2- 4cm and a prolongation of "latent phase" of >20 hours for primiparous women and >14 hours for multiparous women. Results:

- There was **no difference** found in caesarean birth, spontaneous vaginal birth, instrumental birth, and use of epidural analgesia rates between the early amniotomy and augmentation and routine care groups.
- There was **no difference** found in the length of the first stage of labour (average MD -1.58 hours; 95% CI -4.27 to 1.10).

Oxytocin augmentation versus no treatment

The Cochrane review by Bugg et al., 2013 included eight studies with a total of 1,338 low-risk women in the first stage of spontaneous term labour.[20] Three trials (n= 138) compared the use of oxytocin versus placebo or no treatment. The definition of "slow" labour was not consistent across the included trials.

Oxytocin augmentation compared with placebo/no treatment groups:

- There were **no differences** in caesarean birth, spontaneous vaginal birth, and instrumental birth outcomes were reported between.

Early oxytocin augmentation group compared with delayed treatment group:

- There were **no significant differences** in caesarean birth, instrumental birth, or epidural analgesia rates.
- There was **no difference** in NICU admission rate.
- It was uncertain if serious neonatal morbidity and perinatal death was different between groups because of small numbers of patients.

Recommendation 2a
Consensus-based recommendation: Women should be informed prior to labour that the length of labour varies widely. However, the duration of active first stage (≥5cm until full cervical dilation) usually does not extend beyond 18 hours in first labours, and usually does not extend beyond 12 hours in subsequent labours.

Recommendation 2b	Evidence-based recommendation
Conditional: When labour is progressing without complication amniotomy should not be performed routinely. Combined early amniotomy with the use of oxytocin should not be used routinely. In women with slow labour, amniotomy with oxytocin augmentation may be considered for women with intact membranes, after explanation of the procedure and advice that is uncertain what effect this will have on the length of labour and mode of birth. GRADE of evidence- Low	

Clinical Question 5

What is the safest length of time for women to be in second stage labour without intervention?

P- Primiparous and multiparous women in second stage labour

I- Deliver early <2hrs

C- Deliver late >2hrs

O- Maternal and perinatal outcomes, mode of birth (vaginal birth, assisted vaginal birth, caesarean birth), length of labour- third stage, length of hospital stay, pain relief, PPH, third and fourth degree tear risk, shoulder dystocia.

Summary of evidence

RCT evidence

A RCT (n = 78) compared routine care or extending the duration of the second stage of labour by one hour (Girmovsky et al., 2016).[21, vi] Women in the study were randomly allocated to receive an additional hour (4 hours for women with epidural and 3 hours without) or usual labour length. Birth was expedited via caesarean birth or operative vaginal birth after the allocated timeframe had elapsed.

[vi] The American College of Obstetricians and Gynaecologists definition of prolonged second stage of labour at the time was 3 hours for women with epidural and 2 hours without and was taken as "usual labour length".

- Rates of caesarean births were **significantly higher** in women receiving usual labour length compared to receiving an extra hour (RR 2.22, 95% CI- 1.07-4.57) and rates of spontaneous vaginal birth were lower in women receiving usual labour length (RR 0.37, 95% CI- 0.18-0.77).
- There was **little to no difference** found between groups for maternal (operative vaginal birth, PPH, chorioamnionitis, third/fourth degree tears) or neonatal morbidity outcomes (NICU admission and length of NICU admission).
- No cases of perinatal death were reported in either group.
- One case of shoulder dystocia was reported in the extended labour group and none in the usual labour group, precluding a relative risk estimate.
- At 12-36 months postpartum, extending the length of labour in nulliparas with singleton gestations, epidural anaesthesia, and prolonged second stage **did not have an impact** on Pelvic Score Disability Index (PFDI-20) scores at 12–36 months postpartum (Gimovsky et al., 2021). Only 43% of participants completed the survey.

The authors conclude that extending the duration of the second stage of labour **significantly lowers** rates of caesarean births without impacting on maternal or neonatal morbidity.

Observational studies

A systematic review of 13 observational studies (Pergialiotis et al., 2020) included different definitions of prolonged labour, although studies conducted after 2009 were noted to converge around the ACOG definition.[22] Pooled meta-analysis of 13 included studies, each with different definition of prolonged second stage of labour, reported that:

- Prolonged second stage is associated with an **increased risk** of PPH (OR 2.15), chorioamnionitis (OR 3.77), endometritis (OR 3.05), postpartum fever (OR 1.88), and third/fourth degree tears for the mother (OR 2.29).
- **Increased risks** were also noted for shoulder dystocia (OR 1.80), NICU admission (OR 1.50), and sepsis for the baby (OR 2.28).

Recommendation 3	Evidence based recommendation
Conditional: Decisions to expedite birth in the second stage of labour should not be based solely on specific time frames. Clinical decisions should be based on clinical assessment of the maternal and fetal condition, the progress of labour (including fetal descent) and on the woman's informed decisions. GRADE of evidence- Low	

Good Practice Point 3
GPP: In second stage, if nulliparous women have been pushing for two hours and parous women for one hour, escalation is recommended (within the guidance of local referral protocols). If maternal and fetal conditions permit and taking into account time to transfer and access to appropriate resources, it would be reasonable to support an additional hour of active pushing.

Clinical Question 6

How should prolonged second stage of labour be managed for optimal outcomes?

P- Nulliparous women and parous women in second stage of labour (as defined by the NICE Guideline- Intrapartum care for healthy women and babies), which includes time until expected birth, diagnosis of delay (with clinical judgement) including malposition, such as deep transverse arrest

I- Oxytocin augmentation

C- Usual care, ARM, instrumental birth, prophylactic manual rotation to assist with descent and birth, peanut ball and other midwifery led management strategies (maternal position changes)
O- Maternal outcomes (including short and long-term gynaecological outcomes, such as prolapse and nerve damage), neonatal and perinatal outcomes, mode of birth (assisted, CS, instrumental etc), length of labour, shoulder dystocia

Summary of evidence

Oxytocin infusion vs placebo

A single RCT (Saunders et al., 1989) was identified, comparing oxytocin augmentation in the second stage to a placebo.[23] In this study, an oxytocin infusion was commenced at the diagnosis of full dilation, thus, the study does not entirely fit the specified population in the PICO for women with delayed second stage.

- The use of oxytocin **increased** the likelihood of a spontaneous vaginal birth in women with a fetus in the occiput anterior (OA) position but **little to no difference** was found for women with a fetus in the occiput transverse (OT) or occiput posterior (OP) position.
- **No difference** in NICU admission rates was noted between women receiving oxytocin infusion compared to placebo.

Indirect evidence not presented in evidence table, but summary may help to inform recommendation:

Prophylactic manual rotation vs sham/no treatment
A systematic review by Burd et al., 2022[vii] included six RCT with 1002 participants, and reported on manual rotations for both OP and OT positions of the fetal head.[24] The timing of manual rotation differed between studies, from at the start of second stage, to the start of pushing, or one hour after full dilation achieved.

- There was **little to no difference** found in length of second stage (MD -8.60 minutes, 95% CI -24.15 minutes to 6.95 minutes).
- There was **little to no difference** found in rates of spontaneous vaginal birth (RR 1.07 95% CI 0.95-1.20).
- There was **little to no difference** found in neonatal outcomes of NICU admission, five-minute Apgar score, or subgaleal haemorrhage between the manual rotation and sham groups.

Maternal position in second stage
Two Cochrane systematic reviews were identified; Gupta et al., 2017 and Walker et al., 2018.[25, 26]

- Women in an upright position without epidural analgesia had **reduced** rates of assisted vaginal birth (RR 0.75, 95% CI 0.66–0.86; 21 studies, 6841 women; GRADE- moderate quality).[26]
- There was **no significant difference** found between women in an upright position compared to a horizontal position on rates of caesarean birth.[26]
- During the second stage of labour with epidural analgesia, there was **no significant difference** in the overall effect for operative birth and duration of the second stage of labour between upright and horizontal positions.[25]

[vii] This review was published 6 months after another review by Bertholdt et al., 2022, but is used in preference to the Berthold review as it excluded one study which had additional interventions as part of a package in addition to purely consider the impact of manual rotation.

Peanut ball

A systematic review by Grenvik et al., 2018 was identified including 4 RCTs and 648 women.[27] This review included women with term pregnancies with babies in a cephalic presentation and epidural analgesia. The timing of starting the peanut ball intervention varied between included studies, often immediately or within 30 minutes of having the epidural commenced and ended at the diagnosis of full dilation.

- There was **little to no difference** found in the length of second stage between women using a peanut ball and those not using it (MD- 11.7minutes, 95% CI -33.6 minutes to 10 .2 minutes; two studies, 371 participants).
- There was **little to no difference** found in spontaneous vaginal birth (RR 1.1 95% 1.0-1.2; four studies, 648 participants), although was close to reaching statistical significance.
- There was **little to no difference** was found in operative vaginal birth, and in Apgar scores at one minute and 10 minutes.

Recommendation 4	Evidence-based recommendation
Conditional: An upright position in second stage for women should be recommended, as it is associated with a lower risk of assisted vaginal birth. The left lateral position may be recommended in second stage for women with epidural anaesthesia. GRADE of evidence- Low	

Recommendation 5
Consensus-based recommendation: Specific interventions for managing prolonged second stage of labour apart from expediting birth when indicated by the maternal and fetal condition, labour progress and/or the woman's wishes, are not recommended.

Clinical Question 7

In women who have just given birth vaginally does immediate cord clamping compared to delayed cord clamping achieve better neonatal outcomes?

P- Women who have given birth vaginally
I - Immediate cord clamping
C- Delayed cord clamping
O- Neonatal anaemia and wellbeing (including jaundice requiring phototherapy, Apgar, transfer to NICU/other care)

Summary of evidence

Gomersall et al., 2021 identified 33 studies comparing delayed cord clamping (cord clamping at least 30 seconds after birth) and early cord clamping (which the authors define as cord clamping within 30 seconds of birth).[28] This systematic review included late preterm pregnancies (>34 weeks) as well as term pregnancies. The complete study cohort (including late preterm births) is reported in the Appendix F- Evidence profiles. An analysis of only the term pregnancies only was performed. Apgar scores and severe neonatal morbidity (such as HIE) were not reported by any studies. This systematic review includes women who had caesarean birth (not included in the PICO), however, sensitivity analyses of the term pregnancies found no difference in the reported outcomes irrespective of mode of birth. The inclusion of a caesarean birth cohort therefore does not significantly alter the interpretation of the results.

Among term pregnancies only:

Sensitivity analysis of these results by gestational age at birth reported:

- Delayed cord clamping of at least 30 seconds **may increase** haemoglobin concentrations within 24 hours of birth (MD 1.39g/dL, 95% CI 0.57-2.21 g/dL; GRADE- Very low) among term neonates.
- Delayed cord clamping of at least 30 seconds **increased** hyperbilirubinemia requiring phototherapy when compared to early cord clamping (RR 1.54; 95% CI 1.01-2.34; GRADE- Very low). Due to very low quality of included studies, we are uncertain where the real effect lies and must interpret this result with caution.

Additional RCTs:

Ofojebe et al., 2021 conducted an RCT including 204 singleton, term pregnancies in Nigeria.[29] Participants were randomly assigned to delayed cord clamping (60 seconds after birth) or immediate cord clamping (0-15 seconds after birth).

- At 48 hours, mean haemoglobin concentrations were **significantly higher** in the delayed clamping group than the immediate cord clamping group (16.51 +/- 1.71 g/dL vs 15.16 +/ - 2.27 g/dL; p value 0.001).
- Total mean bilirubin concentrations were **not significantly different** between the groups.
- There was **little to no difference** found in PPH rate, diagnosis of neonatal jaundice, or need for phototherapy.

Seliga-Siwecka et al., 2020 conducted an RCT in Poland including 307 singleton, term pregnancies.[30] This study was significantly underpowered for their primary outcome of neonatal jaundice requiring phototherapy, recruiting less than one third of the required sample size due to funding constraints. Eligible participants were randomised in a 1:1:1 ratio to one of three groups: 106 to early cord clamping (<40 secs after birth), 106 to delayed cord clamping (1-2 mins after birth), or 97 to cord milking (4 times towards the neonate). Cord milking is outside of the scope of this clinical question.

- There was **little to no difference** in jaundice requiring phototherapy found between the delayed cord clamping (29%) and early cord clamping groups (23%) (RR 1.29, 95% CI 0.82 - 2.05).

Recommendation 6	Evidence-based recommendation
Conditional: Women who are giving birth could be offered delayed cord clamping for at least 60 seconds or until pulsation stops, as it may increase the haemoglobin concentration and iron stores of the infant. GRADE of evidence- Very low	

Good Practice Point 4
GPP: There may be clinical indications to cut the cord earlier if required. Resuscitation with an intact cord may be possible in some settings.

Clinical Question 8

For women who have just delivered and not received augmentation, does active management compared to physiological management of third stage labour achieve better maternal outcomes?

P- Women who have given birth and not had augmentation and are at low risk of bleeding

I - Active management bundle

C- Physiological, expectant management

O- PPH, maternal mortality and morbidity, length of hospital stay

Summary of evidence

The third stage of labour is defined as the period of time between the birth of the baby and the birth of the placenta. The package of care referred to as "Active Management" of the third stage includes:

- Administration of an intramuscular or IV uterotonic
- Controlled cord traction
- Timing of clamping and cutting of cord varies according to local policies/definitions.

Physiological or expectant management of the third stage refers to the birth of the placenta without the components of active management.

Sources: The Cochrane Review (Begley et al., 2019) reported on the evidence for women at low-risk of bleeding.[31] The included studies identified low-risk women as those with no previous PPH, singleton pregnancy, cephalic, parity <5, at term, first stage of labour < 15 hours, no APH and no previous caesarean birth. The evidence suggested that for women at low-risk of bleeding:

- it is **uncertain** whether active management compared with expectant management reduces the risk of severe primary PPH (< 1000 mL) (RR 0.31, 95% CI 0.05 to 2.17, 2 studies, 2941 women), maternal haemoglobin (Hb) less than 9 g/dL following birth, maternal Hb less than 9 g/dL at 24 to 72 hours (RR 0.17, 95% CI 0.02 to 1.47, 1 study, 193 women). GRADE: Very low quality.
- Active management **probably reduced** therapeutic uterotonics during the third stage and/or within the first 24 hours compared with expectant management (average RR 0.15, 95% CI 0.11 to 0.21, 3 studies, 3134 women).
- Postnatal maternal mean Hb **probably increased** with active management (outcome not pre-specified) (MD in g/dL 0.50, 95% CI 0.41 to 0.59, 2 studies, 2683 women. GRADE: Moderate quality.
- Active management **may reduce** primary blood loss 500 mL or more, clinically estimated or measured at time of birth, compared with expectant management (average RR 0.33, 95% CI 0.20 to 0.56, 2 studies, 2941 women.
- Active management **may reduce** mean maternal blood loss (mL) (MD −78.80, 95% CI −95.96 to−61.64, 2 studies, 2941 women.
- Active management **may reduce** maternal blood transfusions (average RR 0.30, 95% CI 0.10 to 0.88, 3 studies, 3134 women). GRADE- low quality.
- No studies report any cases of maternal mortality.
- No studies reported on the length of stay for women.

Side effects were more common in all women (not limited to women at low-risk of bleeding) receiving active management (vomiting RR 2.09, 95% CI 1.59-2.74, NNT 20; and hypertension (diastolic BP >90mmHg) (RR 4.10 95% CI 1.63-10.30, 3 studies, 4636 women; GRADE: Moderate quality), however, it should be noted that studies reporting this outcome gave oxytocin and ergometrine as their prophylactic uterotonic rather than the IM or IV oxytocin commonly used in Australia and Aotearoa New Zealand.

There are cultural considerations for Māori and Pacific Islands women relevant to the third stage of labour. For example, to some women the whenua (placenta) is tapu (sacred) and may need to stay with wahine

(woman) and/or her whānau (family). It is suggested that clinicians seek to understand any cultural preferences and plans wāhine (women) and whānau may have for the immediate care of the whenua to ensure appropriate cultural needs are respected. This practice has now been adopted well beyond Māori and Pacific Islands communities.

Good Practice Point 5
GPP: During the antenatal period, the possibility of postpartum haemorrhage (PPH) and the management of the third stage of labour should be discussed with women (including risks and benefits), acknowledging that there are women who are low-risk for PPH where the benefit of active management is less certain.

Good Practice Point 6
GPP: Women may choose physiological management of the third stage without the use of an oxytocic. It is important that these women are adequately informed (including risks and benefits) so that they can make an informed choice about active or physiological management, understanding that the events at the time of birth may change their risk profile.

Existing recommendation, as in C-Obs 43- Management of PPH	Evidence-based recommendation
Conditional[viii]**:** Active management of the third stage of labour (administration of prophylactic oxytocics and assisting birth of the placenta) should be recommended to all pregnant women as this reduces the risk of PPH and the need for blood transfusion. Prophylactic oxytocics should be recommended for the management of the third stage of labour, whether following vaginal or caesarean birth, as they reduce the risk of PPH by at approximately 50%. GRADE of evidence- Low (in low-risk women)	

Clinical Question 9

Does use of a perineal care bundle, compared with usual care, improve the health outcomes in women having a vaginal birth?

P- Women in second stage of labour giving birth via vaginal birth
I- Perineal care bundle- The Perineal Protection Bundle (AUS) or OASI (NZ)
C- Usual care
O- Third- and fourth-degree tears; blood loss; requirement for suturing by specialist; length of stay; pain management; ongoing gynaecological pain; sexual function

Summary of evidence

Background

The Australian Perineal Protection Bundle© was developed by a multidisciplinary panel including midwives, obstetricians, urogynaecologists and consumer representatives.[32]

The elements of the perineal care bundle are as follows:

- Care Element 1- Warm compress. Apply a warm compress during second stage at the commencement of perineal stretching.

[viii] This recommendation is consistent with existing RANZCOG Clinical Guidance Statement: C-Obs 43- Management of PPH
This recommendation has been determined as Conditional, as this statement update only concerns low-risk women. The recommendation as made in C-Obs 43- Management of PPH, was assessed as Strong, as this statement included both low and high-risk women in its scope.

- Care Element 2- Encouraging a slow controlled birth. Perineal support with a hands-on technique - slow controlled birth, counter pressure of fetal head, gentle traction to release anterior shoulder if not delivered spontaneously, allow posterior shoulder to be released following the curve of Carus.
- Care Element 3- Technique when performing an episiotomy. When an episiotomy is indicated, an episiotomy should be performed at the crowning of the fetal head; using a medio-lateral incision; at a minimum 60-degree angle. For women having their first birth by forceps or ventouse, an episiotomy should also be offered.
- Care Element 4- Assessment for perineal tears - routine genito-anal examination (PR).
- Care Element 5- Grading severity of perineal tears – graded according to the RCOG grading guideline and reviewed by a second clinician.

The Obstetric Anal Sphincter Injury Care Bundle (OASI-CB) is used in New Zealand. This bundle of care was developed by a multidisciplinary team in the UK in response to rising rates of 3rd and 4th degree tears. The elements of this perineal care bundle are as follows:

- Information about OASI and what can be done to mitigate risk.
- Document manual perineal protection.
- Mediolateral episiotomy when indicated.
- Perineal examination after birth - including routine PR examination.

The individual components of these perineal care bundles have varying levels of evidence to support them. A Cochrane review of perineal care techniques (Aasheim et al., 2017) reports on comparisons of hands off (or poised) compared to hands on; warm compresses compared to control; and Ritgen manoeuvre compared to standard care.

- Hands off (or poised): included five trials (7317 women) testing the effect of 'hands off' or 'poised' versus 'hands on'. There was also no effect of perineal protection on 3rd and 4th degree tears (RR 0.68 95% CI 0.21–2.26, GRADE- very low quality).
- Warm compresses: included four trials (1799 women) testing the effect of warm compresses showing fewer third- or fourth-degree perineal tears were reported in the warm-compress group (average RR 0.46, 95% CI 0.27 to 0.79; GRADE- moderate quality).

Evidence summary

A step-wedge cluster trial was conducted by Gurol-Urganci et al., 2020 evaluating the impact of the Obstetric Anal Sphincter Injury Care Bundle (OASI-CB) quality improvement project in four regions in the UK.[33] Implementation of the care bundle was through a stepwise regional roll-out every 3 months starting in January 2017 and was led locally by midwives and obstetrician champions from each maternity unit. A total of 55 060 singleton live vaginal births were included (79% spontaneous vaginal births and 21% operative vaginal births).

- The OASI rate amongst all women **decreased** from 3.3% before to 3.0% after care bundle implementation (adjusted OR 0.80, 95% CI 0.65-0.98, p-value = 0.03, GRADE- moderate quality). Risk difference is 0.3%, NNT 333.
- The OASI rate amongst nulliparous women **decreased** on sensitivity analyses (5.2% to 4.9%), however, the confidence interval includes the null effect (adjusted OR 0.81, 95% CI 0.65-1.00, p-value = 0.05, GRADE- moderate quality), and multiparous women (1.7% to 1.5%) (adjusted OR 0.78, 95% CI 0.61-1.01, p-value = 0.06, GRADE- moderate quality).
- Sensitivity analyses by mode of birth found the OASI rate among women who had a spontaneous vaginal birth **decreased** from 2.6% before to 2.2% after care bundle implementation (adjusted OR 0.75, 95% CI 0.60-0.92, p-value = 0.03, GRADE- moderate quality).

- There was **little to no difference** found between OASI rate before and after implementation of the care bundle among women having a forceps birth (7.6% unchanged) (adjusted OR 0.88, 95% CI 0.69-1.14, p-value = 0.34, GRADE- moderate quality), or a ventouse birth (2.7% to 2.6%) (adjusted OR 0.82, 95% CI 0.54-1.25, p-value = 0.36, GRADE- moderate quality).

The NICE evidence update, published in 2022 on rectal examination, further reported the following:

- One RCT (Ozyurt et al., 2015) was identified that compared the number of sphincter injuries in nulliparous women (n= 201, SVD with mediolateral episiotomy after 36-weeks' gestation) who had a physical examination, with women who had transvaginal sonography (TVS).[34]
- Physical examination classified 194/201 cases as not involving the sphincter (second degree tears) while TVS classified 171/201 tears as causing 'no defect to the sphincter.'
- There were 23 cases (11.5%) of 'occult tears' for example, tears undetected by physical examination but detected by TVS. The injuries resulting from these occult tears were classified by TVS operators as external sphincter partial defects at the lower end of injury severity.

Recommendation 7	Evidence based recommendation
Strong: It is recommended that perineal care should be discussed with women during the antenatal period and documented in their care plan, as the use of a perineal care bundle is associated with a small reduction in severe perineal trauma. When elements of the bundle are considered individually, warm compresses may reduce severe perineal trauma and should be offered in the second stage of labour. GRADE of evidence- Moderate	

Recommendation 8
Consensus-based recommendation: Routine rectal examination may not be acceptable to all women, although it will occasionally detect a buttonhole tear.

Additional practical advice

Diet in labour

Evidence summary

A Cochrane review (Singata et al., 2013) found no significant difference in outcomes associated with restricting or permitting fluid and food intake in labour for women at low-risk of pregnancy complications. Outcomes measured included rates of Caesarean birth, operative vaginal birth, and Apgar scores.[35]

The last NICE guidelines to include a literature review on this subject were in 2014 and found that comparing light diet to starvation in labour, women who had light diet vomited twice as frequently but had lower ketone levels.[3] Further studies comparing carbohydrate drinks showed no significant differences in the majority of outcomes. One study showed women with carbohydrate supplementation in labour had a higher rate of caesarean birth,[36] but this was not corroborated in other studies from the same group (Scheepers et al., 2002).[37]

A more recent review of oral carbohydrate supplementation showed no increase in vomiting or in labour outcomes.[38]

Good Practice Point 7

GPP: It is safe for women to drink to remain hydrated and have a light diet in established labour unless risk factors develop that make a general anaesthetic more likely.

8. Legal and ethical implications

Shared decision making while planning and during labour should respectfully acknowledge the right of the consumer to be well informed. It is the clinician's responsibility to ensure informed consent is obtained for any assessment or treatment undertaken. This is an interactive process between the woman, her family, her doctor, and midwife.

Adverse outcomes may occur at any time during labour, even in women who commence labour without identified risk factors for adverse pregnancy outcomes. Labour is a dynamic process and previously obtained consent may be reviewed or withdrawn.

9. Recommendations for future research

- Comparative studies of different planned frequencies of vaginal examinations in labour for improving birth outcomes.
- Comparative studies of different oxytocin regimes/protocols for inducing or augmenting labours for improving birth outcomes.
- Comparative studies of different criteria for intervention or obstetric review in the second stage of labour for improving birth outcomes.
- Further studies evaluating maternal and perinatal outcomes following transfer from a rural/regional location to tertiary level care.
- Studies that specifically assess women's birth experiences including traumatic birth experience.
- Comparative studies of different methods of assessing labour progress for improving birth outcomes.
- More randomised trials assessing timing of umbilical cord-clamping in term and late preterm births for improving birth outcomes.
- Comparative studies of different methods of preventing perineal trauma in pregnancy for improving birth outcomes.

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39. Moncrieff G, Gyte GM, Dahlen HG, Thomson G, Singata-Madliki M, Clegg A, et al. Routine vaginal examinations compared to other methods for assessing progress of labour to improve outcomes for women and babies at term. Cochrane Database Syst Rev. 2022;3(3):Cd010088.

11. Links to relevant College Statements and Guidelines

- Instrumental vaginal birth (C-Obs 16)
- Consent and provision of information to patients in Australia regarding proposed treatment (C-Gen 2a)
- Consent and provision of information to patients in Aotearoa New Zealand regarding proposed treatment (C-Gen 2b)
- Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)

12. Links to relevant Consumer resources

- Labour and birth- RANZCOG Patient Information Pamphlet (Resource hub - RANZCOG)

13. Links to RANZCOG learning modules

- RANZCOG Fetal Surveillance Education Program

14. Useful links/support groups

Appendices

Appendix A: Women's Health Committee Membership

Name	Position on Committee
Dr Scott White	Chair
Dr Anna Clare	Deputy Chair (Gynaecology) and Councillor
Associate Professor Amanda Henry	Deputy Chair (Obstetrics) and Councillor
Dr Samantha Scherman	Member and Councillor
Dr Marilla Druitt	Member and Councillor
Dr Kasia Siwicki	Member and Councillor
Associate Professor Jared Watts	Member and Councillor
Dr Victoria Carson	Member and Councillor
Dr Nisha Khot	Vice President, Specialist International Medical Graduate (SIMG) Representative
Dr Marilyn Clarke	Aboriginal and Torres Strait Islander Representative
Dr Angela Beard	He Hono Wāhine Representative
Dr Martina Mende	DRANZCOG Representative
Dr Pallavi Desai	SIMG Representative
Professor Kirsten Black	Sexual and Reproductive Health Committee Representative
Dr Frank Clark	State Representative- TAS
Dr Elizabeth Gallagher	Territory Representative- ACT
Dr James Brown	State Representative- VIC
Dr Kathy Saba	State Representative- QLD
Dr Divya Viswanathan	Trainee Representative
Adrienne Priday	Midwifery Representative, Aotearoa New Zealand
Dr Angela Brown	Midwifery Representative, Australia

Appendix B: Statement Development Panel Membership

Name	Position on Committee
Dr Anna Clare	Chair and Councillor
Dr Bradley De Vries	Member
Dr Riki Anderson	Member
Dr Liam Dunn	Member
Dr Letitia McGinness	Member
Dr Britt Haller	Member
Dr Liz Newnham	Member, Australian midwifery representative
Ms Sharon Rance	Member, Australian midwifery representative
Ms Adrienne Priday	Member, Aotearoa New Zealand midwifery representative
Ms Teresa Krishnan	Member, Aotearoa New Zealand midwifery representative
Research & Policy Team	**Position**
Professor Cindy Farquhar	Dean of Research & Policy
Ms Jinty Wilson	Head of Research & Policy
Ms Katie Coulthard	Senior Coordinator, Research & Policy
Research preparation	
Professor Cindy Farquhar	Dean of Research & Policy
Dr Karyn Anderson	Researcher, University of Auckland

Appendix C: Overview of the development and review process for this statement

i. Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of RANZCOG Women's Health Committee or working groups.

A declaration of interest form specific to guidelines and statements (approved by the RANZCOG Board in September 2012). All members of the Statement Development Panels, Statement and Guideline Advisory Group (SaGG) and Women's Health Committee were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this statement.

ii. Steps in developing and updating this statement

This statement was developed in July 2022- May 2023 by the C-Obs 31 Care in Labour Statement Development Panel, a working group established by the Women's Health Committee. It was most recently reviewed by the Women's Health Committee and RANZCOG Council in July 2023. The Women's Health Committee carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all members prior to reviewing this statement.
- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the July 2023 meeting of the Women's Health Committee, the existing consensus-based recommendations were reviewed and updated (where appropriate) based on the available body of evidence and clinical expertise, as set out in the Methodology section below.

RANZCOG statements are developed according to the standards of the Australian National Health and Medical Research Council (NHMRC), which includes the use of GRADE methodology. The Evidence to Decision framework embedded within the MAGIC (Making GRADE the Irresistible Choice) digital platform (https://magicevidence.org) is used to publish the updated statement recommendations. The recommendations published by RANZCOG are approved by the RANZCOG Women's Health Committee, Council and Board respectively. The processes used to develop RANZCOG clinical guidance statements are described in detail at: https://ranzcog.edu.au/wp-content/uploads/2022/08/Manual-for-developing-and-updating-clinical-guidance-statements.pdf

iii. Developing recommendations using GRADE methodology

The relevant GRADE assessments for each recommendation are presented within the online platform used to structure the clinical guidance statement (MAGICapp; https://magicevidence.org/magicapp/).

Appendix D: Full Disclaimer

Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning care in labour (first, second and third stage of labour) for women who do not have identified pregnancy complications and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any person. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual person and the particular circumstances of each case.

Quality of information

The information available in this statement is intended as a guide and provided for information purposes only. The information is based on the Australian/New Zealand context using the best available evidence and information at the time of preparation. While the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has endeavoured to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available. The use of this information is entirely at your own risk and responsibility.

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this statement being in any way inaccurate, out of context, incomplete or unavailable for all expenses, losses, damages and costs incurred.

These terms and conditions will be constructed according to and are governed by the laws of Victoria, Australia.

Appendix E – Search Strategy

Search completed by RANZCOG

CQ2. Primary evidence source: Cochrane review Kobayashi et al., 2017 "Assessment and support during early labour for improving birth outcomes".

- Terms and Boolean operators: "early labour" OR "latent phase" AND admission OR discharge OR home.
- Years of publication: 2016 – 2022
- Other limitations: nil

Results: N = 57. No additional studies were identified for inclusion.

CQ3. Primary evidence source: Cochrane systematic review (Moncrieff et al., 2022)- *Routine vaginal examinations compared to other methods for assessing progress of labour to improve outcomes for women and babies at term*.[39]

No additional searches undertaken due to recency of Cochrane review.

CQ4. Primary evidence sources: Cochrane review Wei et al., 2013- *Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care*; Cochrane review Smyth, Markham, & Dowswell 2013- *Amniotomy for shorting spontaneous labour*; and Cochrane review Bugg, Siddiqui, & Thornton 2013- *Oxytocin versus no treatment or delayed treatment for slow progress in the first stage of spontaneous labour.*

- Terms and Boolean operators: "spontaneous labour" OR "labour NOT induced" OR "labour NOT induction".
- AND "amniotomy" OR "augmentation" OR "oxytocin"
- Years of publication: 2013 – 2022
- Other limitations: nil

Results: 407 results screened, 9 retrieved for full text review. None of the identified studies were included.

CQ5.

- Terms and Boolean operators: mesh heading – "labour, second stage" OR "2nd stage" AND "delay*" OR prolonged OR length
- Years of publication: unrestricted
- Other limitations: studies in humans, systematic reviews or RCT

Results: N = 55 studies identified, 8 retrieved for full text review and 1 RCT included.

CQ6. A Cochrane review Costley & East 2013- *Oxytocin augmentation of labour in women with epidural analgesia for reducing operative deliveries* – this review included one study (Sauders et al., 1989) considered oxytocin use at full dilation.

- Terms and Boolean operators: MeSH heading labor stage, second OR "2nd stage" AND oxytocin OR augmentation
- Years of publication: unrestricted
- Other limitations: human studies

Results: N = 147 results, 7 were reviewed in full text, none were suitable for inclusion.

Additional literature searches were undertaken to identify systematic review evidence for each of the listed comparators in the PICO given limited evidence meeting the PICO was identified.

- Terms and Boolean operators: mesh heading – "labor stage, second" OR "2nd stage" AND…
- ARM OR "rupture of membranes" - 20 studies identified - none were selected for inclusion.
- Instrumental OR Vacuum Extraction, Obstetrical/ OR Obstetrical Forceps/ OR ventouse OR "assisted birth" limited to RCTs or systematic reviews - 40 studies identified - 2 retrieved for full text review, neither selected for inclusion.
- "Manual rotation" limited to humans - 20 studies identified - 2 systematic reviews and 1 RCT identified for inclusion. Systematic review by Burd et al., 2022 included in preference to systematic review by Bertholdt et al., 2022 as the former review excluded one study which had additional interventions as part of a package in addition to purely consider the impact of manual rotation. An RCT de Varies et al., 2022 was published after the literature searches for the above reviews.
- "peanut ball" limited to humans - 1 RCT identified (Mercia et al., 2018). This study was cited in a systematic review of peanut ball use on the length of labour (Grenvik et al., 2019) - a summary of the findings from this review including 4 RCTs of 648 women.

CQ7. Primary evidence source: Systematic review Gomersall et al., 2021; Cochrane review McDonald 2013 et al., "Effect of timing of umbilical cord clamping of term infants on maternal and neonatal outcomes"

- Terms and Boolean operators: Mesh term – "Umbilical cord" AND clamp OR clamping OR clamped OR ICC OR DCC OR ECC AND mesh term – "infant, newborn" OR newborn OR baby*
- Years of publication: 2019 – 2022
- Other limitations: human studies, RCTs

Results: N = 52 of which 6 were retrieved for full text review. 2 were included in the evidence table

CQ8. No evidence search undertaken – signposting

CQ9.

- Terms and Boolean operators: "perineal" OR mesh term "perineum" AND mesh term - "Patient care bundles"
- Years of publication: unrestricted
- Other limitations: nil

Results: N = 10, all of which were retrieved for full text review. One was included in the evidence table.

Additional supporting evidence of components of perineal bundle: Cochrane review Aasheim et al., 2017 "Perineal techniques during the second stage of labour for reducing perineal trauma"

Appendix F- Evidence profiles and evidence to decision tables

Clinical Question 1 - Planning for transfer in labour

If delivering in a place of birth where transfer may be necessary (e.g., primary birthing/midwifery led units or home birth), what pre-labour planning should occur to facilitate a transfer?

Please view the narrative summary for the evidence profile for this clinical question.

Evidence to Decision

Benefits and harms	Substantial net benefits of the recommended alternative

There no direct evidence identified that informed this recommendation.

As no studies were identified that directly reviewed the elements of pre-labour planning for transfer of care, indirect evidence informed the response to this clinical question. Five studies were identified describing the requirements and processes of facilitating transfers during labour for births occurring at a Primary Birthing Unit (PMU) or Midwifery Led Units. 4-9 It is noted transfers may also occur in a home birth; however, home birth was out of scope for this statement update. C-Obs 2 Home Births.

A 2016 survey of 17 PMUs in small rural hospitals and 13 PMUs in Australia used the Australian College of Midwives Guidelines for Consultation and Referral[5], however four PMUs had further modified the Guidelines for relevance to local context. The PMUs which did not use the guidelines reported local doctors conducted their own risk assessment to determine if referral to another service was indicated. When transfer was required, the average distance from PMUs to a tertiary facility was 56 kilometres over an average time of 49 minutes, and this was facilitated by road or less commonly, aeromedical emergency transport.[6] Another retrospective cohort study of transfers from a PMU in rural Queensland reported 42% of transfers in a three-year period (n = 138 women) occurred in the intrapartum period, mostly in the first stage of labour due to labour dystocia resulting in need for caesarean birth.[7]

A 2010 study of all national data in Aotearoa New Zealand reported a transfer rate of 12.6% of women who intended to give birth at a primary unit, with higher likelihood for women having their first baby requiring a transfer.[8] Another survey of women's experiences of transfer or change of care plan in the intrapartum period in Christchurch reported more women in the study were 'unbothered' by the change of plan than those who reported to be 'unhappy' or 'happy' about it. These respondents also knew transfer from PMU could be required and 'generally accepted it was appropriate'. Sense of control, communication with their care providers and support and information were identified as key factors associated with more positive experiences.[9]

A Western Australian study reported an intrapartum transfer rate of 34% (118/350) in 2013-2014 from a midwifery-led birthing centre to the co-located obstetric unit; primarily for analgaesia (epidural) and other interventions for complicated labours. [10]

In summary, evidence suggests clinical discussions with women who plan to birth at a PMU or equivalent should include:

- Information about the limitations of services available and the implications for intrapartum and postpartum care, including the possibility antenatal transfer to a centre with more comprehensive services may be required.
- Following any collaborative formal systems already in place, to ensure the safe and timely transfer of women and/or their babies who require specialist treatment. The safety of the woman and baby should be the priority.

- The need to document all transfers for the purposes of future review, as such information is valuable for planning and resourcing improvements of those units requiring transfer capability.

Features of the protocols for transfer for home birth have been used as indirect evidence to inform the good practice point. Requirements included maximum time and distance to hospital, access to ambulance service and attendance of another midwife in second stage of labour.

Benefits relate to timely and safe transfers. There were no identified harms. Eight percent of women were very unhappy about transfer from the primary maternity unit to hospital. (Grigg et al., 2015)

Certainty of the Evidence

Very low

Values and preferences

No substantial variability expected

Research evidence

Mixed methods small cohort study - Women's experiences of transfer from primary maternity unit to tertiary hospital in New Zealand: part of the prospective cohort Evaluating Maternity Units study (Grigg et al., 2015).

407 low-risk women (defined as not having any level 2 or 3 referral criteria in the New Zealand College of Midwives Referral Guidelines) planned to give birth in a PMU in 2010-2012. 238 (58%) experienced any type of birthplace change of plan or transfer, however only 174 responded to survey.

- 55% transferred antenatally
- 31% transferred prior to admission in labour
- 12% transferred after admission to PMU
- 1% transferred in postnatal period

Study found majority of women who transferred at any stage were ‘unbothered’ by the decision to transfer, particularly if transfer had occurred after admission to PMU. A smaller proportion (8%) were ‘very unhappy’ or ‘neutral’ and 7% ‘very happy’.

Summary

The qualitative evidence shows while transfer was not wanted or planned, all women knew of this potential and the experience was less likely to be negative where effective communication and support and information from their midwife were provided.

Resources

Factor not considered

Out of scope

Equity

Important issues, or potential issues not investigated

Rural and remote women are generally unable to have births at home or in PMUs as there is no guarantee that they can access transfers.

Acceptability

Important issues, or potential issues not investigated

Birth at home or in a PMU is only acceptable (too strong) for regions with < 35 mins of the hospital with a publicly funded home birth service or a PMU. There are only 14 publicly funded home birth programs in

Australia (women can also seek a private midwife to attend a home birth, can also have birth collaborative arrangement of care with a hospital)

Feasibility	Important issues, or potential issues not investigated

Ideally, transfers would be feasible when there is a suitable transfer service available.

Clinical Question 2 – Care in the latent stage of labour

In primiparous and multiparous women in latent stage of labour, does discharge home compared to ongoing monitoring in hospital, result in improved maternal and perinatal outcomes?

Population: Primiparous and multiparous women in latent phase <4cm cervical dilation with irregular contractions
Intervention: Discharge, including provision of advice and when to re-present etc.
Comparator: Remain in hospital, including pain relief options and fetal monitoring

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Plain language summary**
		Remain in hospital	Discharge		
Early labour assessment vs direct admission - Rate of caesarean birth	Relative risk: 0.72 (CI 95% 0.3 - 1.72) Based on data from 209 participants in 1 study[1]	**106** per 1000	**76** per 1000	**Very low** Due to serious risk of bias, Due to very serious imprecision[2]	Cochrane review Kobayashi 2017 We are uncertain whether discharge increases or decreases early labour assessment vs direct admission - rate of caesarean birth
		Difference: **30 fewer per 1000** (CI 95% 74 fewer - 76 more)			
Early labour assessment vs direct admission - Rate of instrumental vaginal birth	Relative risk: 0.86 (CI 95% 0.58 - 1.26) Based on data from 209 participants in 1 study[3]	**356** per 1000	**306** per 1000	**Very low** Due to serious risk of bias, Due to very serious imprecision[4]	Cochrane review Kobayashi 2017 We are uncertain whether discharge to home increases or decreases rate of instrumental vaginal birth
		Difference: **50 fewer per 1000** (CI 95% 150 fewer - 93 more)			
Early labour assessment vs direct admission - Baby born before arrival at hospital or unplanned home birth	(CI 95% -) Based on data from 209 participants in study[5]	**0.0**			Cochrane review Kobayashi 2017 - outcome not reported
		Difference: **fewer**			
Early labour assessment vs direct admission - Augmentation of labour	Relative risk: 0.57 (CI 95% 0.37 - 0.86) Based on data from 209 participants in 1 study[6]	**404** per 1000	**230** per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[7]	Cochrane review Kobayashi 2017 Discharge home may decrease augmentation of labour
		Difference: **174 fewer per 1000** (CI 95% 255 fewer - 57 fewer)			
Early labour assessment vs direct admission - Use of epidural or any regional anaesthesia	Relative risk: 0.87 (CI 95% 0.78 - 0.98) Based on data from 209 participants in 1 study[8]	**904** per 1000	**786** per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[9]	Cochrane review Kobayashi 2017 Discharge home may decrease use of epidural or any regional anaesthesia slightly
		Difference: **118 fewer per 1000** (CI 95% 199 fewer - 18 fewer)			
Early labour assessment vs direct admission - Apgar score < 7 at 5 minutes	Relative risk: 2.97 (CI 95% 0.12 - 72.12) Based on data from 209 participants in 1 study[10]	**0** per 1000	**0** per 1000	**Very low** Due to serious risk of bias, Due to very serious imprecision[11]	Cochrane review Kobayashi 2017 We are uncertain whether discharge home increases or decreases apgar score < 7 at 5 minutes
		Difference: **0 fewer per 1000** (CI 95% 0 fewer - 0 fewer)			
Early labour assessment vs	Measured by: hours	**20.5** Mean	**18.6** Mean	**Low**	Discharge home may decrease total

direct admission - Total length of 1st stage of labour (hours)	Scale: - Lower better Based on data from 209 participants in 1 study[12]	Difference: **MD 1.9 lower**		Due to serious risk of bias, Due to serious imprecision[13]	length of 1st stage of labour slightly
Early labour assessment vs direct admission - Total length of 2nd stage of labour (hours)	Measured by: hours Scale: - Lower better Based on data from 209 participants in 1 study	**1.58** Mean	**1.29** Mean	**Low** Due to serious risk of bias, Due to serious imprecision[14]	Discharge home may decrease total length of 2nd stage of labour slightly
		Difference: **MD 0.29 lower**			
Early labour assessment vs direct admission - Total length of labour (1st and second stage, home and hospital) (hours)	Measured by: hours Scale: - Lower better Based on data from 209 participants in 1 study	**22.1** Mean	**19.9** Mean	**Low** Due to serious risk of bias, Due to serious imprecision[15]	Discharge home may decrease total length of labour (including 1st and second stage, and home and hospital) slightly
		Difference: **MD 2.2 lower**			
Early labour assessment vs direct admission - Maternal satisfaction (score)	Measured by: Scale: - Based on data from 201 participants in 1 study[16]	**142** Mean	**158** Mean	**Low** Due to serious risk of bias, Due to serious imprecision[17]	Cochrane review Kobayashi 2017 Discharge home may increase maternal satisfaction (score) slightly
		Difference: **MD 16.0 higher** (CI 95% 7.53 higher - 24.47 higher)			

1. Systematic review [33] with included studies: McNiven 1996 **Baseline/comparator** Control arm of reference used for intervention.
2. **Risk of Bias: serious.** No blinding; **Imprecision: very serious.** Wide confidence intervals, Only data from one study;
3. Systematic review [33] with included studies: McNiven 1996 **Baseline/comparator** Control arm of reference used for intervention.
4. **Risk of Bias: serious.** No blinding; **Imprecision: very serious.** Wide confidence intervals, Only data from one study;
5. Systematic review [33] with included studies: McNiven 1996 **Baseline/comparator** Control arm of reference used for intervention.
6. Systematic review [33] with included studies: McNiven 1996 **Baseline/comparator** Control arm of reference used for intervention.
7. **Risk of Bias: serious.** No blinding; **Imprecision: serious.** Only data from one study;
8. Systematic review [33] with included studies: McNiven 1996 **Baseline/comparator** Control arm of reference used for intervention.
9. **Risk of Bias: serious.** No blinding; **Imprecision: serious.** Only data from one study;
10. Systematic review [33] with included studies: McNiven 1996 **Baseline/comparator** Control arm of reference used for intervention.
11. **Risk of Bias: serious.** No blinding; **Imprecision: very serious.** due to few events, Only data from one study, Wide confidence intervals;
12. Systematic review [33] with included studies: McNiven 1996 **Baseline/comparator** Control arm of reference used for intervention.
13. **Risk of Bias: serious.** No blinding; **Imprecision: serious.** Only data from one study;
14. **Risk of Bias: serious.** No blinding; **Imprecision: serious.** Only data from one study;
15. **Risk of Bias: serious.** No blinding; **Imprecision: serious.** Only data from one study;
16. Systematic review [33] with included studies: McNiven 1996 **Baseline/comparator** [35]
17. **Risk of Bias: serious.** No blinding; **Imprecision: serious.** Only data from one study;

References

[33] Kobayashi S, Hanada N, Matsuzaki M, Takehara K, Ota E, Sasaki H, Nagata C, Mori R: Assessment and support during early labour for improving birth outcomes. Cochrane Database of Systematic Reviews 2017;
[35] Scotland GS, McNamee P, Cheyne H, Hundley V, Barnett C : Women's preferences for aspects of labor management: results from a discrete choice experiment. Birth (Berkeley, Calif.) 2011;38(1):36-46.

Evidence to Decision

Benefits and harms	Substantial net benefits of the recommended alternative

One RCT was included in the Cochrane review (McNiven et al., 1998) for this comparison. This study included women who were nulliparous, at 37 weeks' gestation or greater, and were deemed low-risk (n = 209) at a Canadian hospital.

Women allocated to the early labor assessment group received the usual assessments of fetal and maternal well-being, such as fetal heart rate, blood pressure, and urine tests. A vaginal examination was conducted by a medical intern or the assessment area nurse. The determination of active labor was based on the presence of regular, painful contractions and cervical dilation greater than 3 cm. Women who were not found to be in active labor were given support, encouragement, and advice, and were instructed to walk outside or return home until labor became more active. They were also instructed when to return to the hospital. Women allocated to the control group were sent immediately to the labor and birth unit and were admitted and received standard intrapartum care.

Women in the assessment group were less likely to use an epidural or other regional pain relief in labour compared to women in the direct admission group. Women in the assessment group were more less to be treated with oxytocin to augment their labors than women in the direct admission group. Little to no difference was found in the proportion of women having cesarean birth between the two groups. No differences occurred in the rates of instrumental birth, or amniotomy between the two groups.

Women in the assessment group were more likely to evaluate their experience positively than those who were admitted directly to the labor and birth unit.

Little to no difference was found in the Apgar scores of infants born to women in the assessed and direct admission groups, and the frequency of infants requiring active resuscitation was also similar. No babies were born before hospital admission.

McNiven et al., (1996) did not report on the outcome of serious maternal morbidity of interest to the statement group, including postpartum haemorrhage (loss of more than 1000 mL of blood), postnatal fever, blood transfusion and maternal death.

No evidence was identified to inform a recommendation for multiparous women.

Certainty of the Evidence	Low

Downgraded for a lack of blinding and only a single study included in the systematic review.

Values and preferences	Substantial variability is expected or uncertain

Additional considerations

A study conducted by Scotland et al., (2011) attempted to quantify women's preferences of labour management.

The researchers sent a questionnaire to 1,251 women who had recently given birth to their first child at one of 14 maternity units in Scotland. Discrete choice questions were used to measure women's preferences for five attributes of care: number of visits (assessments) before admission to the labor ward, time spent on the labor ward before birth, mobility during labor, pain relief required, and mode of birth. 58.4% of questionnaires were returned.

Women expressed a preference for fewer visits before admission, shorter times on the labor ward before birth, mobility during labor, spontaneous vaginal deliveries, and moderate forms of pain relief (Entonox and opiates).

The authors concluded that “Women appear to dislike being turned away from the labor ward before admission for birth. Extra visits before admission only appear to be a price worth paying if they result in

reductions in the duration of time spent on the labor ward, reductions in the chance of being immobilized in hospital during labor, or a lower chance of requiring an instrumental or operative birth".

Summary

Satisfaction was a reported outcome in the Cochrane review. Women in the assessment group were more likely to evaluate their experience positively than those who were admitted directly to the labor and birth unit. This finding is in contrast to results from a patient preferences survey by Scotland et al., (2011). In this survey women valued fewer visits to the hospital before admission for birth. However, for women who participated in the survey, extra visits before admission appear to be acceptable if they are balanced by reductions in the duration of time spent on the labor ward, reductions in the chance of being immobilized in hospital during labor, or a lower chance of requiring an instrumental or operative birth

Resources	No important issues with the recommended alternative

Full economic evaluation is outside of the scope of this evidence review.

While resources are required to assess women in latent phase reduced labour ward admission time may be cost saving.

Equity	Important issues, or potential issues not investigated

Reduced equity for women who may not live close to a hospital/birthing facility or do not have ready access to transportation.

Acceptability	No important issues with the recommended alternative

Feasibility	No important issues with the recommended alternative

Clinical Question 3- Timing of vaginal examinations (VE)

For women in 1st stage of labour, does vaginal examination every 4 hours, compared to less frequent examinations, result in improved maternal and perinatal health outcomes?

Population: Women in the 1st stage of labour greater than or equal to 4cm dilation
Intervention: Routine vaginal examinations 4-hourly
Comparator: Routine vaginal examination <4-hourly

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Plain language summary**
		Routine vaginal examination <4-hourly	Routine vaginal examinations 4-hourly		
Augmentation of labour (sub-group of women who have not had a baby before)	Relative risk: 0.97 (CI 95% 0.6 - 1.57) Based on data from 109 participants in 1 study[1]	**382** per 1000	**371** per 1000	**Very low** Due to very serious risk of bias, Due to serious imprecision[2]	Cochrane review - Moncrieff et al., 2022 We are uncertain whether routine vaginal examinations 4-hourly increases or decreases augmentation of labour
		Difference: **11 fewer per 1000** (CI 95% 153 fewer - 218 more)			
Caesarean birth	Relative risk: 1.3 (CI 95% 0.61 - 2.78) Based on data from 150 participants in 1 study[3]	**133** per 1000	**173** per 1000	**Very low** Due to very serious risk of bias, Due to serious imprecision[4]	Cochrane review - Moncrieff et al., 2022 We are uncertain whether routine vaginal examinations 4-hourly increases or decreases caesarean birth
		Difference: **40 more per 1000** (CI 95% 52 fewer - 237 more)			
Operative vaginal birth	Relative risk: 0.69 (CI 95% 0.32 - 1.52) Based on data from 150 participants in 1 study[5]	**173** per 1000	**119** per 1000	**Very low** Due to very serious risk of bias, Due to serious imprecision[6]	Cochrane review - Moncrieff et al., 2022 We are uncertain whether routine vaginal examinations 4-hourly increases or decreases operative vaginal birth
		Difference: **54 fewer per 1000** (CI 95% 118 fewer - 90 more)			
Epidural for pain relief	Relative risk: 1.3 (CI 95% 0.65 - 2.6) Based on data from 109 participants in 1 study[7]	**200** per 1000	**260** per 1000	**Very low** Due to very serious risk of bias, Due to serious imprecision[8]	Cochrane review - Moncrieff et al., 2022 We are uncertain whether routine vaginal examinations 4-hourly increases or decreases epidural for pain relief
		Difference: **60 more per 1000** (CI 95% 70 fewer - 320 more)			
Spontaneous vaginal birth (primary outcome) - Primiparous	Relative risk: 1.02 (CI 95% 0.83 - 1.26) Based on data from 150 participants in 1 study[9]	**693** per 1000	**707** per 1000	**Very low** Due to very serious risk of bias, Due to serious imprecision[10]	Cochrane review - Moncrieff et al., 2022 We are uncertain whether routine vaginal examinations 4-hourly increases or decreases spontaneous vaginal birth in primiparous women
		Difference: **14 more per 1000** (CI 95% 118 fewer - 180 more)			
Length of labour (in hours)	Measured by: hours Scale: - Lower better Based on data from 109 participants in 1 study[1]	**6.66** Mean	**6.76** Mean	**Very low** Due to very serious risk of bias, Due to serious imprecision[12]	Cochrane review - Moncrieff et al., 2022 We are uncertain whether routine vaginal examinations 4-hourly increases or decreases length of labour (in hours)
		Difference: **MD 0.10 higher** (CI 95% 1.28 lower - 1.48 higher)			

18. Systematic review [32] with included studies: Abukhalil 1996 **Baseline/comparator** Control arm of reference used for intervention .
19. **Risk of Bias: very serious.** No blinding, incomplete outcome data - 27% of women in the 2-hourly arm and 28% of women in the 4-hourly arm were withdrawn because they developed exclusion criteria after randomisation.
20. **Imprecision: serious.** Only 1 small study with 150 women;
21. Systematic review [32] with included studies: Abukhalil 1996 **Baseline/comparator** Control arm of reference used for intervention .
22. **Risk of Bias: very serious.** No blinding, incomplete outcome data - 27% of women in the 2-hourly arm and 28% of women in the 4-hourly arm were withdrawn because they developed exclusion criteria after randomisation.; **Imprecision: serious.** Only data from one study;
23. Systematic review [32] with included studies: Abukhalil 1996 **Baseline/comparator** Control arm of reference used for intervention .
24. **Risk of Bias: very serious.** No blinding, incomplete outcome data - 27% of women in the 2-hourly arm and 28% of women in the 4-hourly arm were withdrawn because they developed exclusion criteria after randomisation.; **Imprecision: serious.** Only data from one study;
25. Systematic review [32] with included studies: Abukhalil 1996 **Baseline/comparator** Control arm of reference used for intervention .
26. **Risk of Bias: very serious.** No blinding, incomplete outcome data - 27% of women in the 2-hourly arm and 28% of women in the 4-hourly arm were withdrawn because they developed exclusion criteria after randomisation.; **Imprecision: serious.** Only data from one study;
27. Systematic review [32] with included studies: Abukhalil 1996 **Baseline/comparator** Control arm of reference used for intervention .
28. **Risk of Bias: very serious.** No blinding, incomplete outcome data - 27% of women in the 2-hourly arm and 28% of women in the 4-hourly arm were withdrawn because they developed exclusion criteria after randomisation.; **Imprecision: serious.** Only data from one study;
29. Systematic review [32] with included studies: Abukhalil 1996 **Baseline/comparator** Control arm of reference used for intervention .
30. **Risk of Bias: very serious.** No blinding, incomplete outcome data - 27% of women in the 2-hourly arm and 28% of women in the 4-hourly arm were withdrawn because they developed exclusion criteria after randomisation.; **Imprecision: serious.** Only data from one study;

References

[32] Moncrieff G, Gyte G, Dahlen H, Thomson G, Singata-Madliki M, Clegg A, Downe S : Routine vaginal examinations compared to other methods for assessing progress of labour to improve outcomes for women and babies at term. Cochrane Database of Systematic Reviews 2022.

Evidence to Decision

Benefits and harms	Small net benefit, or little difference between alternatives

Summary

A single RCT of 150 women was identified in the Cochrane review (Abukhalil et al., 1996). Participants were spontaneously labouring, nulliparous women at term were randomly allocated to receive either 2-hourly or 4-hourly vaginal examinations to assess the progress of labour at the specified intervals or at other times if indicated. Both groups were otherwise managed according to the standard labour ward protocol. Indications for vaginal examination outside of the specific intervals included: assessment prior to the administration of pethidine or epidural analgesia, if full dilation was suspected, the application of a fetal scalp electrode or if a fetal scalp blood sampling was necessary.

There were no significant differences in the cervical dilation at the start of labour or during all stages of labour. Little or no difference was found in any of the reported outcomes between women receiving 2-hourly examinations compared to women receiving 4-hourly examinations. One participant in the 4-hourly group had a persistent pyrexia (> 38°C at 1 day postpartum) but this did not reach diagnostic criteria for chorioamnionitis. No other maternal morbidity outcomes and no perinatal outcomes were reported.

Win et al., (2019) provides indirect evidence for maternal satisfaction. This RCT compares vaginal examination 4-hourly with vaginal examinations only when indicated amongst women undergoing induction of labour with misoprostol. Little to no difference was found in maternal satisfaction scores between the two groups. When surveyed postpartum, women in the vaginal examination when indicated group were more likely to prefer this method in a future pregnancy (88% vs 45%, p=<0.001). Similarly, women in the vaginal examination when indicated group were more likely to recommend this method to a friend (87% vs 47%, p=<0.001) (using Likert scale responses). This study also reported the induction to vaginal birth interval was shortened by 7 hours in the 4-hourly vaginal examination arm (mean 24 vs 31 hours, p=0.01), but no significant difference was found in the vaginal birth rate at 24 hours (27% in 4-hourly group vs 20% when indicated group, p=0.14).

Certainty of the Evidence	Very low

Values and preferences	Substantial variability is expected or uncertain

Additional considerations

A recent qualitative survey (Keedle, Keedle and Dahlen 2022) on Australian women's experiences of 'obstetric violence' in past five years (n = 626) found poor experiences having intrapartum vaginal examinations were the second largest reported 'obstetric violence' category (124 comments). Women reported not being asked for consent for a VE, feeling violated/assaulted and having multiple HCPs conducting VEs throughout labour. The study referred to the Cochrane Systematic Review (Moncrieff et al., 2022) showing uncertain evidence around timing of routine VEs and recommended further research be conducted to determine if any 'external physiological and behavioural signs to display progress in labour can be used in place of routine VE'. The Cochrane Review also did not identify any eligible studies comparing physiological/behavioural changes to routine VE.

This study also found a need to ensure informed consent and clear communication between clinician-patient is obtained for VEs and efforts made to ensure women are aware of what the procedure requires.

This study had a high risk of bias and would receive a Very Low GRADE.

Summary

Pregnant women across all settings are likely to place a high value on minimal labour interventions, including less invasive procedures such as vaginal examinations. Women are unlikely to accept frequent vaginal examinations in the absence of any clinical maternal or fetal indication. [WHO]

Resources	No important issues with the recommended alternative

Implementation and adherence to this recommendation is likely to save costs related to staff time and materials that would be required to perform vaginal examinations at intervals more frequent than every four hours. However, as the authors of the included study point out even when the intended interval is 4-hourly, examinations will tend to be performed more frequently than this.

Equity	Important issues, or potential issues not investigated

Consideration of the preferences of women who have experienced previous sexual assault who may find vaginal examination difficult to cope with.

Acceptability	Important issues, or potential issues not investigated

The 4 hourly vaginal examination time interval is the most commonly used examination interval in most Australian and New Zealand hospital

Feasibility	No important issues with the recommended alternative

Clinical Question 4- Management of prolonged 1st stage labour

When should augmentation and amniotomy be considered for women in 1st stage of labour?

Population: Primiparous and multiparous women in 2nd stage labour
Intervention: Oxytocin augmentation
Comparator: Usual care, ARM, instrumental birth, manual rotation, peanut ball, other midwifery management strategies

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Plain language summary**
		Usual care, ARM, instrumental birth, manual rotation, etc	Oxytocin augmentation		
Oxytocin infusion commenced in second stage vs placebo - OA position - spontaneous vaginal birth [RCT] SAUNDERS 1989	Relative risk: 1.47 (CI 95% 1.05 - 2.06) Based on data from 226 participants in 1 study[1]	**430** per 1000	**632** per 1000	**Moderate** Due to serious indirectness[2]	Oxytocin augmentation commenced in second stage probably increases spontaneous vaginal birth in women with fetuses in the OA position compared to placebo.
		Difference: **202 more per 1000** (CI 95% 22 more - 456 more)			
Oxytocin infusion commenced in second stage vs placebo - OT position - spontaneous vaginal birth [RCT] SAUNDERS 1989	Relative risk: 0.59 (CI 95% 0.21 - 1.62) Based on data from 226 participants in 1 study	**400** per 1000	**236** per 1000	**Low** Due to serious indirectness, Due to serious imprecision[3]	Oxytocin augmentation commenced in the second stage may have little or no difference on spontaneous vaginal birth for women with fetuses in the OT position compared to placebo.
		Difference: **164 fewer per 1000** (CI 95% 316 fewer - 248 more)			
Oxytocin infusion commenced in second stage vs placebo - OP position - spontaneous vaginal birth [RCT] SAUNDERS 1989	Relative risk: 1.42 (CI 95% 0.5 - 4.04) Based on data from 226 participants in 1 study	**240** per 1000	**341** per 1000	**Low** Due to serious indirectness, Due to serious imprecision[4]	Oxytocin augmentation commenced in the second stage may have little or no difference on spontaneous vaginal birth for women with fetuses in the OP position compared to placebo.
		Difference: **101 more per 1000** (CI 95% 120 fewer - 730 more)			
Oxytocin infusion commenced in second stage vs placebo - admission to NICU [RCT] SAUNDERS 1989	Relative risk: 0.55 (CI 95% 0.1 - 2.92) Based on data from 226 participants in 1 study	**34** per 1000	**19** per 1000	**Low** Due to serious indirectness, Due to serious imprecision[5]	Oxytocin augmentation commenced in the second stage may have little or no difference on NICU admission compared to placebo.
		Difference: **15 fewer per 1000** (CI 95% 31 fewer - 65 more)			

31. Primary study . **Baseline/comparator** Control arm of reference used for intervention. Supporting references [72]. [73]. [65]. [67]. [66]. [69].
32. **Indirectness: serious.** Differences between the population of interest and those studied - participants not restricted to prolonged second stage;
33. **Indirectness: serious.** Differences between the population of interest and those studied; **Imprecision: serious.** Wide confidence intervals;
34. **Indirectness: serious.** Differences between the population of interest and those studied; **Imprecision: serious.** Wide confidence intervals;
35. **Indirectness: serious.** Differences between the population of interest and those studied; **Imprecision: serious.** Wide confidence intervals;

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Evidence to Decision

Benefits and harms

Certainty of the Evidence

The Cochrane reviews included in this evidence summary comment that amniotomy is virtually impossible to mask, and oxytocin was not blinded in the included trials. Therefore, in all the studies, the participants and clinicians were not blinded to the treatment, hence the risks of bias were high. Studies were also downgraded for wide confidence intervals or high statistical heterogeneity.

Studies ranged from moderate to very low quality evidence using GRADE methodology.

Values and preferences

Additional considerations

Kempe (2020) - 1380 nulliparous women in Sweden reported on their satisfaction with their birth experience correlated with clinical records. Satisfaction with the birthing experience was significantly related to mode of birth, oxytocin augmentation, epidural anaesthesia and to duration of labour. Duration of labour and mode of birth had independent significant statistical effect on the satisfaction with the birthing experience.

Summary

There is likely substantial variation in what women value with regards to management of spontaneous and “slow” labour.

A systematic review of 25 studies (Alòs-Pereñíguez et al., 2022) found women's views and experiences of augmentation of labour were shaped by their knowledge, and beliefs, and the support they received during labour. Irrespective of the context, women consistently associated augmentation of labour with pain. The decision to augment women's labour was often performed without their informed consent.

A systematic review of qualitative studies (Downe et al., 2018) looking at what matters to women during labour found that most pregnant women would prefer a shorter labour. Most women want a spontaneous vaginal birth with good outcomes for mother and baby but acknowledged that medical intervention may sometimes be necessary.

Resources

Economic analysis falls outside of the scope of this statement. The WHO note in the development of their recommendations defining spontaneous labour that any cost savings from reducing interventions such as amniotomy and oxytocin augmentation may be offset by increased costs associated with pain relief and care provision for longer labours.

Equity

No evidence on the impact on equity was found.

Acceptability

Evidence from a 2017 survey of Obstetric specialists working in Australia (White et al., 2017) indicates a wide variation in criteria used to define spontaneous labour, and the diagnosis and management of prolonged labour.

Feasibility

Healthcare staff provision of care may be limited by local and National protocols/ referral guidelines setting mandatory limitations on practice and when to refer.

Clinical Question 5

What is the safest length of time for women to be in 2nd stage labour without intervention?

Population: Primiparous and multiparous women in 2nd stage labour
Intervention: Deliver early <2hrs
Comparator: Deliver late >2hrs

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the Evidence (Quality of evidence)	Plain language summary
		Deliver late >2hrs	Deliver early <2hrs		
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous women - spontaneous vaginal birth [RCT] GIRMOVSKY 2016	Relative risk: 0.37 (CI 95% 0.18 - 0.77) Based on data from 78 participants in 1 study[1]	**512** per 1000	**189** per 1000	**Moderate** Due to serious risk of bias[2]	Deliver >2hrs (Extended labour by 1hr) probably increases spontaneous vaginal birth for nulliparous women compared to deliver <2hrs (usual care)
		Difference: **323 fewer per 1000** (CI 95% 420 fewer - 118 fewer)			
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous women - operative vaginal birth [RCT] GIRMOVSKY 2016	Relative risk: 1.29 (CI 95% 0.69 - 2.43) Based on data from 78 participants in 1 study	**293** per 1000	**378** per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[3]	We are uncertain whether deliver >2hrs (extended labour by 1hr) has an effect on operative vaginal birth for nulliparous women compared to deliver <2hrs (usual care)
		Difference: **85 more per 1000** (CI 95% 91 fewer - 419 more)			
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous women - Caesarean birth [RCT] GIRMOVSKY 2016	Relative risk: 2.22 (CI 95% 1.07 - 4.57) Based on data from 78 participants in 1 study	**195** per 1000	**433** per 1000	**Moderate** Due to serious risk of bias[4]	Deliver >2hrs (Extended labour by 1hr) probably decreases caesarean birth for nulliparous women compared to deliver <2hrs (usual care)
		Difference: **238 more per 1000** (CI 95% 14 more - 696 more)			
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous women - PPH [RCT] GIRMOVSKY 2016	Relative risk: 0.42 (CI 95% 0.11 - 1.45) Based on data from 78 participants in 1 study	**195** per 1000	**82** per 1000	**Moderate** Due to serious risk of bias[5]	Deliver >2hrs (extended labour by 1hr) probably has little or no difference on PPH for nulliparous women compared to deliver <2hrs (usual care)
		Difference: **113 fewer per 1000** (CI 95% 174 fewer - 88 more)			
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous	Relative risk: 0.18 (CI 95% 0.02 - 1.46) Based on data from 78	**146** per 1000	**26** per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[6]	We are uncertain whether deliver >2hrs (extended labour by 1hr) has an effect on third/fourth degree

women - third/fourth degree tear [RCT] GIRMOVSKY 2016	participants in 1 study	Difference: **120 fewer per 1000** (CI 95% 143 fewer - 67 more)			tears for nulliparous women compared to deliver <2hrs (usual care
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous women - chorioamnionitis [RCT] GIRMOVSKY 2016	Relative risk: 1.31 (CI 95% 0.67 - 2.56) Based on data from 78 participants in 1 study	**268** per 1000	**351** per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[7]	We are uncertain whether deliver >2hrs (extended labour by 1hr) has an effect on chorioamnionitis for nulliparous women compared to deliver <2hrs (usual care)
		Difference: **83 more per 1000** (CI 95% 88 fewer - 418 more)			
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous women - shoulder dystocia [RCT] GIRMOVSKY 2016	(CI 95% -) Based on data from 78 participants in 1 study	**24** per 1000	**0** per 1000	**Moderate** Due to serious risk of bias[8]	There were too few who experienced shoulder dystocia, to determine whether birth >2hrs (extended labour by 1hr) made a difference
		Difference: **fewer per 1000**			
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous women - NICU admission [RCT] GIRMOVSKY 2016	Relative risk: 1.19 (CI 95% 0.65 - 2.2) Based on data from 78 participants in 1 study	**317** per 1000	**377** per 1000	**Moderate** Due to serious risk of bias[9]	Deliver >2hrs (extended labour by 1hr) probably has little or no difference on NICU admission for nulliparous women compared to deliver <2hrs (usual care)
		Difference: **60 more per 1000** (CI 95% 111 fewer - 380 more)			
Usual labour vs extended labour (1hr beyond upper limit recommendation) in nulliparous women - NICU length of stay [RCT] GIRMOVSKY 2016	Measured by: days Scale: - Lower better Based on data from 78 participants in 1 study	**2.66** Mean	**4.03** Mean	**Moderate** Due to serious risk of bias[10]	Deliver >2hrs (extended labour by 1hr) probably has little or no difference on length of NICU admission for nulliparous women compared to deliver <2hrs (usual care)
		Difference: **MD 1.37 lower** (CI 95% 3.16 lower - 0.42 higher)			

36. Primary study. **Baseline/comparator** Control arm of reference used for intervention. Supporting references [71]. [64]. [68]. [70].
37. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.
38. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Wide confidence intervals.
39. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.
40. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias;
41. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Wide confidence intervals;
42. **Risk of Bias: serious.** Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias, Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias; **Imprecision: serious.** Wide confidence intervals;
43. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias;

44. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias;
45. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias;

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Evidence to Decision

Benefits and harms

Evidence sources include:

- NICE Intrapartum care for healthy women and babies (2017) NICE guideline CG190 (including 2019 surveillance report).
- WHO recommendations: Intrapartum care for a positive childbirth experience (2018)

Primary literature searches conducted on 24/02/2023 in CENTRAL using search term "second stage labour" (47 studies identified) and MEDLINE using search terms “mesh heading” labor, second stage" OR “2nd stage” AND “delay*” OR prolonged OR length limited to humans and RCT or systematic reviews (55 studies identified, 8 retrieved for full text review and 1 RCT included).

Multiple cohort studies were pertaining to this question were identified through the reference list of a systematic review of the maternal and neonatal impacts of prolonged second stage (Pergialiotis et al., 2020). These are summarized in an appendix table.

Summary

RCT evidence:

Girmovsky et al., (2016) conducted an RCT (n = 78) examining the effect of extending the duration of the second stage of labour by 1hr. The American College of Obstetricians and Gynaecologists definition of prolonged second stage of labour is 3 hours for women with epidural and 2 hours without was taken as "usual labour length". Women in the study were randomly allocated to receive an additional hour (4 hours for women with epidural and 3 hours without) or usual labour length. Birth was expedited via caesarean birth or operative vaginal birth after the allocated timeframe had elapsed. Rates of caesarean births were significantly higher in women receiving usual labour length compared to receiving an extra hour (RR 2.22 95% CI 1.07-4.57) and rates of spontaneous vaginal birth were lower in women receiving usual labour length (RR 0.37 95% CI 0.18-0.77). Little to no difference was found between groups for maternal (operative vaginal birth. PPH, chorioamnionitis, third/fourth degree tears) or neonatal morbidity outcomes (NICU admission and length of NICU admission). No cases of perinatal death were reported in either group. One case of shoulder dystocia was reported in the extended labour group and none in the usual labour group precluding a relative risk estimate.

The authors conclude that this evidence suggests that extending the definition of the duration of the second stage of labour significantly lowers rates of caesarean births without impacting on maternal or neonatal morbidity.

This study group followed up their RCT cohort at 12-36 months postpartum. Only 43% of the initial cohort completed the survey follow-up. Extending the length of labor in nulliparas with singleton gestations, epidural anesthesia, and prolonged second stage did not have an impact on PFDI-20 scores at 12–36 months postpartum (Gimovsky et al., 2021).

Observational studies:

Observational studies included in the Pergialiotis et al., 2020 systematic review are heterogenous in their definition of prolonged labour, although studies conducted after 2009 were noted to converge around the ACOG definition of >2hrs without an epidural and >3hrs with an epidural for nulliparous women, and >1hr without an epidural and >2hrs with an epidural for parous women. Pooled meta-analysis of 13 included studies, using each papers own definition of prolonged second stage of labour, indicates that prolonged second stage is associated with an increased risk of PPH (OR 2.15), chorioamnionitis (OR 3.77), endometritis (OR 3.05), postpartum fever (OR 1.88), and third/fourth degree tears (OR 2.29) for the mother. Increased risks were also noted for shoulder dystocia (OR 1.80), NICU admission (OR 1.50), and sepsis (OR 2.28) for the baby.

A summary table of cohort studies provide as an appendix document to the SDP indicates that a dose response relationship is often observed between these adverse outcomes and the length of second stage beyond 3hrs, with increasing risk as second stage length increases. Caesarean birth and instrumental birth rates increase with increasing length of second stage, with associated decrease in spontaneous vaginal birth.

Certainty of the Evidence

Girmovsky et al., 2016 graded as moderate quality - downgraded due to lack of blinding as to the intervention. Some outcomes further downgraded to low quality due to wide confidence intervals.

Systematic review Pergialiotis et al., 2020 - AMSTAR moderate

Values and preferences

Substantial variability is expected or uncertain

No observational studies reported on women's satisfaction with longer lengths of second stage. It is likely that women's values and preferences would differ.

Resources

Although economic evaluation is outside of the scope of this statement, a costs effectiveness evaluation of extending the second stage of labor in nulliparous women with epidural analgesia conducted in the US was identified (Schmidt et al., 2020).

This theoretical model evaluated expectant management to 4 h compared to birth at 3 h in the setting of a prolonged second stage of labor in nulliparous women with epidural analgesia. Expectant management to 4 h was the dominant strategy in the model. Sensitivity analysis indicated that expectant management until 4 h was cost-effective as long as the probability of cesarean birth at 4 h was below 41.8%.

It is likely that these findings would also apply to the Australian and New Zealand context, as a longer accepted length of second stage may reduce the use of costly obstetric interventions to hasten birth.

Equity

No specific evidence on equity was identified. It could be considered inequitable if options for intervening or continuing labour were not discussed for women with longer labours.

Clinical Question 6- Management of prolonged 2nd stage labour

How should prolonged 2nd stage of labour be managed for optimal outcomes?

Population: Primiparous and multiparous women in 2nd stage labour
Intervention: Oxytocin augmentation
Comparator: Usual care, ARM, instrumental birth, manual rotation, peanut ball, other midwifery management strategies

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Plain language summary**
		Usual care, ARM, instrumental birth, mannual rotation, etc	Oxytocin augmentation		
Oxytocin infusion commenced in second stage vs placebo - OA position - spontaneous vaginal birth [RCT] SAUNDERS 1989	Relative risk: 1.47 (CI 95% 1.05 - 2.06) Based on data from 226 participants in 1 study[1]	**430** per 1000	**632** per 1000	**Moderate** Due to serious indirectness[2]	Oxytocin augmentation commenced in second stage probably increases spontaneous vaginal birth in women with fetuses in the OA position compared to placebo.
		Difference: **202 more per 1000** (CI 95% 22 more - 456 more)			
Oxytocin infusion commenced in second stage vs placebo - OT position - spontaneous vaginal birth [RCT] SAUNDERS 1989	Relative risk: 0.59 (CI 95% 0.21 - 1.62) Based on data from 226 participants in 1 study	**400** per 1000	**236** per 1000	**Low** Due to serious indirectness, Due to serious imprecision[3]	Oxytocin augmentation commenced in the second stage may have little or no difference on spontaneous vaginal birth for women with fetuses in the OT position compared to placebo.
		Difference: **164 fewer per 1000** (CI 95% 316 fewer - 248 more)			
Oxytocin infusion commenced in second stage vs placebo - OP position - spontaneous vaginal birth [RCT] SAUNDERS 1989	Relative risk: 1.42 (CI 95% 0.5 - 4.04) Based on data from 226 participants in 1 study	**240** per 1000	**341** per 1000	**Low** Due to serious indirectness, Due to serious imprecision[4]	Oxytocin augmentation commenced in the second stage may have little or no difference on spontaneous vaginal birth for women with fetuses in the OP position compared to placebo.
		Difference: **101 more per 1000** (CI 95% 120 fewer - 730 more)			
Oxytocin infusion commenced in second stage vs placebo - admission to NICU [RCT] SAUNDERS 1989	Relative risk: 0.55 (CI 95% 0.1 - 2.92) Based on data from 226 participants in 1 study	**34** per 1000	**19** per 1000	**Low** Due to serious indirectness, Due to serious imprecision[5]	Oxytocin augmentation commenced in the second stage may have little or no difference on NICU admission compared to placebo.
		Difference: **15 fewer per 1000** (CI 95% 31 fewer - 65 more)			

46. Primary study. **Baseline/comparator** Control arm of reference used for intervention. Supporting references [72]. [73]. [65]. [67]. [66]. [69].
47. **Indirectness: serious.** Differences between the population of interest and those studied - participants not restricted to prolonged second stage;
48. **Indirectness: serious.** Differences between the population of interest and those studied; **Imprecision: serious.** Wide confidence intervals.

49. **Indirectness: serious.** Differences between the population of interest and those studied; **Imprecision: serious.** Wide confidence intervals.
50. **Indirectness: serious.** Differences between the population of interest and those studied; **Imprecision: serious.** Wide confidence intervals.

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Evidence to Decision

Benefits and harms

Research evidence

A Cochrane review (Costley & East 2013) was identified which considered oxytocin augmentation for women with epidural anaesthesia. Only one study included in this review (Saunders et al., 1989) considered oxytocin use at full dilation, and this study restricted inclusion to primiparous women with term, singleton pregnancies and epidural anaesthesia.

NICE Guidelines published in 2017 indicated their literature search revealed no studies with oxytocin augmentation as the intervention in second stage.

A primary literature search was undertaken on 23/02/23 of CENTRAL using the search term “second stage” which returned 47 results. None included oxytocin augmentation as an intervention. A search of MEDLINE using terms: mesh heading labor stage, second OR “2nd stage” AND oxytocin OR augmentation - restricted to human studies - yielded 147 results, 7 were reviewed in full text, none were suitable for inclusion.

Following a discussion with SDP Chair Anna Clare and the technical team a decision was made to broaden the search to any of the comparators listed in the PICO to usual care or placebo/sham. Furthermore, studies of these comparators listed in the PICO in any women in second stage would meet inclusion criteria, not only women with diagnosed delay in second stage. Only RCTs and systematic review evidence will be presented for each of the comparators listed in the PICO to limit the search to a manageable amount of evidence.

Additional literature searches were undertaken on 02/03/23 in MEDLINE using the mesh heading: labor stage, second OR “2nd stage” AND…

- ARM OR “rupture of membranes” - 20 studies identified - none were selected for inclusion.
- Instrumental OR Vacuum Extraction, Obstetrical/ OR Obstetrical Forceps/ OR ventouse OR “assisted birth” limited to RCTs or systematic reviews - 40 studies identified - 2 retrieved for full text review, neither selected for inclusion.
- "Manual rotation" limited to humans - 20 studies identified - 2 systematic reviews and 1 RCT identified for inclusion. Systematic review by Burd et al., 2022 included in preference to systematic review by Bertholdt et al., 2022 as the former review excluded one study which had additional interventions as part of a package in addition to purely consider the impact of manual rotation. An RCT de Varies et al., 2022 was published after the literature searches for the above reviews.
- “peanut ball” limited to humans - 1 RCT identified (Mercia et al., 2018). This study was cited in a systematic review of peanut ball use on the length of labour (Grenvik et al., 2019) - a summary of the findings from this review including 4 RCTs of 648 women.

Evidence for maternal position obtained by a search of CENTRAL which identified two Cochrane systematic reviews: Gupta et al., 2017 and Walker et al., 2018.

Despite receiving the suggestion of including “Spinning Babies” as a midwifery led technique no published peer-reviewed studies regarding this technique were identified.

A search of MEDLINE for “rebozo”, a midwifery positioning technique used for correction of fetal malposition yielded 4 studies, none of which were comparative in nature and suitable for inclusion.

Summary

Presented in evidence table:

Oxytocin infusion vs placebo

A single RCT (Saunders et al., 1989) was identified which compares oxytocin augmentation in the second stage to placebo. In this study an oxytocin infusion was commenced at the diagnosis of full dilation, thus, the study does not entirely fit the specified population in the PICO for women with delayed second stage. The use of oxytocin increased the likelihood of a spontaneous vaginal birth in women with a fetus in the OA position but little to difference was found for women with a fetus in the OT or OP position. No difference in NICU admission rates was noted between women receiving oxytocin infusion compared to placebo.

Indirect evidence not presented in evidence table, but summary may help to inform recommendation:

Prophylactic manual rotation vs sham/no treatment

A systematic review by Bund et al., 2022 was identified to inform this comparison. This review was published 6 months after another review by Bertholdt et al., 2022, but is used in preference to the Berthold review as it excluded one study which had additional interventions as part of a package in addition to purely consider the impact of manual rotation. The Bund et al., review includes 6 RCTs with a total of 1002 participants, including manual rotations for both occipital posterior and transverse positions of the fetal head. The timing of manual rotation differed between studies, from at the start of second stage, to the start of pushing, or 1hr after full dilation achieved. Little to no difference was found in length of second stage (MD -8.60 minutes 95% CI -24.15 minutes to 6.95 minutes). Little to no difference was found in rates of spontaneous vaginal birth (RR 1.07 95% CI 0.95-1.20). Little to no difference was found in neonatal outcomes of NICU admission, 5 minute Apgar, or subgaleal haemorrhage between the manual rotation and sham groups.

Maternal position in second stage

Two Cochrane systematic reviews identified which consider this comparison; Gupta et al., 2017 and Walker et al., 2018. During the second stage of labor without epidural analgesia (Gupta 2017), women in an upright position showed significant reduction in rates of assisted vaginal birth (RR 0.75 95% CI 0.66–0.86; 21 studies, 6841 women; moderate quality evidence). However, no significant differences were found between women in an upright position compared to a horizontal position on rates of caesarean birth. During the second stage of labor with epidural analgesia (Walker 2018), the odds of having an operative birth were increased for women in an upright compared to a horizontal position (high quality studies only: RR 1.11 95% CI 1.03-1.20; 3 studies of 3,609 women, high quality). ODDS of caesarean birth were also increased among women in an upright position compared to a horizontal position (high quality studies only: RR 1.29 95% CI 1.05-1.57; 3 studies of 3,609 women, high quality)

Peanut ball

A systematic review by Grenvik et al., 2018 was identified including 4 RCTs and 648 women. This review included women with term pregnancies with babies in a cephalic presentation and epidural analgesia. The timing of starting the peanut ball intervention varied between included studies, often immediately or within 30 minutes of having the epidural commenced and ended at the diagnosis of full dilation. Little to no difference was found in the length of second stage between women using a peanut ball and those not using it (MD -11.7minutes 95% CI -33.6 minutes to 10 .2 minutes; 2 studies, 371 participants). Little to no difference was found in spontaneous vaginal birth (RR 1.1 95% 1.0-1.2; 4 studies, 648 participants), although this came close

to reaching statistical significance. Little to no difference was found in operative vaginal birth, nor Apgar scores at 1minute and 10 minutes.

One-to-one support in labour

Although one-to-one continuous support in labour was considered in a Cochrane review Bohren et al., 2017 and was found to reduce total length of labour (MD - 0.69 hours 95% CI -1.04 to -0.34 hours) compared to usual care, the length of second stage was not reported so this intervention does not fit criteria to form part of the recommendation for strategies to prevent prolonged second stage.

Certainty of the Evidence

Values and preferences

Preference regarding interventions for (prolonged) second stage are likely to vary among women. Whilst many women value a spontaneous childbirth, they recognise that intervention is sometimes necessary. For some women a shorter length of labour is of value and these interventions that may shorten the length of the second stage may be preferred.

Resources

Economic evaluation falls outside of the scope of this statement development group.

Acceptability

A survey of obstetricians in Australia and New Zealand published in 2012 (Phipps et al.,) was identified relating to the acceptability of one of the comparator techniques specified in the PICO for this question among clinicians. Of 1077 respondents 97% thought that manual rotation at full dilation was a valid intervention, although only 41% of practising obstetricians had performed a manual rotation in the last year.

Clinical Question 7 – Optimal time for cord clamping

In women who have just given birth (vaginal), does immediate cord clamping compared to delayed cord clamping achieve better neonatal outcomes?

Population: Women who have given birth to a term baby
Intervention: Delayed cord clamping
Comparator: Immediate cord clamping

(Please note: not all absolute effect estimates have a published baseline risk. These data have been extracted as published in the corresponding study).

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Plain language summary**
		Immediate cord clamping	Delayed cord clamping		
Later delayed cord clamping (>30secs) vs Early cord clamping (<30 secs) - neonatal mortality - term pregnancies - [SR] GOMERSALL 2021	Relative risk: 1.0 (CI 95% 0.07 - 14.45) Based on data from 304 participants in 2 studies	Difference: **fewer**		**Very low** Due to serious risk of bias, Due to very serious imprecision[1]	We are uncertain whether delayed cord clamping (>30secs) increases or decreases neonatal mortality for term pregnancies compared to early cord clamping (<30 secs)
Later delayed cord clamping (>30secs) vs Early cord clamping (<30 secs) - Hyperbilirubinaemia requiring phototherapy - term pregnancies - [SR] GOMERSALL 2021	Relative risk: 1.54 (CI 95% 1.01 - 2.34) Based on data from 2691 participants in 13 studies	**24** per 1000	**37** per 1000	**Low** Due to serious risk of bias, Due to serious inconsistency[2]	Delayed cord clamping (>30secs) may increase hyperbilirubinaemia requiring phototherapy in term pregnancies compared to early cord clamping (<30 secs)
		Difference: **13 more per 1000** (CI 95% 0 fewer - 32 more)			
Later delayed cord clamping (>30secs) vs Early cord clamping (<30 secs) - neonatal resuscitation at birth - late preterm (>34wks) and term pregnancies - [SR] GOMERSALL 2021	Relative risk: 5.08 (CI 95% 0.25 - 103.58) Based on data from 329 participants in 3 studies	**0** per 1000	**10** per 1000	**Very low** Due to serious risk of bias, Due to serious indirectness, Due to serious imprecision, Due to very serious imprecision[3]	We are uncertain whether delayed cord clamping (>30 secs) increases or decreases neonatal resuscitation at birth in late preterm (>34wks) and term pregnancies compared to early cord clamping (<30 secs)
		Difference: **10 more per 1000** (CI 95% 20 fewer - 40 more)			
Later delayed cord clamping (>30secs) vs Early cord clamping (<30 secs) - admission to NICU - late preterm (>34wks) and term pregnancies - [SR] GOMERSALL 2021	Relative risk: 1.16 (CI 95% 0.69 - 1.95) Based on data from 1968 participants in 10 studies	**29** per 1000	**29** per 1000	**Very low** Due to serious risk of bias, Due to serious imprecision, Due to very serious risk of bias[4]	We are uncertain whether delayed cord clamping (>30secs) increases or decreases admission to NICU in late preterm (>34wks) and term pregnancies compared to early cord clamping (<30 secs)
		Difference: **0 more per 1000** (CI 95% 10 fewer - 20 more)			
Later delayed cord clamping (>30secs) vs Early cord clamping (<30 secs) - PPH - late preterm (>34wks) and term	Relative risk: 0.89 (CI 95% 0.7 - 1.13) Based on data from 2675	**91** per 1000	**81** per 1000	**Low** Due to serious risk of bias, Due to serious indirectness[5]	Delayed cord clamping (>30 secs) may have little or no difference on PPH for late preterm (>34wks) and term pregnancies compared t
		Difference: **10 fewer per 1000** (CI 95% 27 fewer - 12 more)			

pregnancies - [SR] GOMERSALL 2021	participants in 10 studies			to early cord clamping (<30 secs)
Later delayed cord clamping (1-2minutes) vs Early cord clamping (<30 secs) - Hyperbilirubinaemia requiring phototherapy - late preterm (>34wks) and term pregnancies - [SR] GOMERSALL 2021	Relative risk: 0.86 (CI 95% 0.41 - 1.79) Based on data from 517 participants in 4 studies	Difference: **fewer**	**Low** Due to serious risk of bias, Due to serious imprecision[6]	Delayed cord clamping (1-2 minutes) may have little or no difference hyperbilirubinaemia requiring phototherapy in late preterm (>34wks) and term pregnancies compared to early cord clamping (<30 secs)
Later delayed cord clamping (>2mins) vs Early cord clamping (<30 secs) - Hyperbilirubinaemia requiring phototherapy - late preterm (>34wks) and term pregnancies - [SR] GOMERSALL 2021	Relative risk: 1.39 (CI 95% 0.75 - 2.57) Based on data from 747 participants in 5 studies	Difference: **fewer**	**Low** Due to serious risk of bias, Due to serious imprecision[7]	Delayed cord clamping (>2 minutes) may have little or no difference hyperbilirubinaemia requiring phototherapy in late preterm (>34wks) and term pregnancies compared to early cord clamping (<30 secs)
Later delayed cord clamping (1-2mins) vs Early cord clamping (<30 secs) - PPH - late preterm (>34wks) and term pregnancies - [SR] GOMERSALL 2021	Relative risk: 0.66 (CI 95% 0.32 - 1.36) Based on data from 486 participants in 2 studies	Difference: **fewer**	**Low** Due to serious risk of bias, Due to serious imprecision[8]	Delayed cord clamping (1-2mins) may have little or no difference on PPH for late preterm (>34wks) and term pregnancies compared to early cord clamping (<30 secs)
Later delayed cord clamping (>2mins) vs Early cord clamping (<30 secs) - PPH - late preterm (>34wks) and term pregnancies - [SR] GOMERSALL 2021	Relative risk: 1.11 (CI 95% 0.71 - 1.76) Based on data from 458 participants in 2 studies	Difference: **fewer**	**Low** Due to serious risk of bias, Due to serious imprecision[9]	Delayed cord clamping (>2mins) may have little or no difference on PPH for late preterm (>34wks) and term pregnancies compared to early cord clamping (<30 secs)
Delayed cord clamping (>60 secs) vs immediate cord clamping (0-15 secs) - PPH >500mL - [RCT] OFOJEBE 2021	Relative risk: 0.67 (CI 95% 0.11 - 3.91) Based on data from 204 participants in 1 study	**30** per 1000 / **20** per 1000 Difference: **10 fewer per 1000** (CI 95% 27 fewer - 87 more)	**Low** Due to serious risk of bias, Due to serious imprecision[10]	We are uncertain whether delayed cord clamping (>60 secs) increases or decreases PPH >500mL compared to immediate cord clamping (0-15 secs)
Delayed cord clamping (>60 secs) vs immediate cord clamping (0-15 secs) - neonatal jaundice - [RCT] OFOJEBE 2021	Relative risk: 1.06 (CI 95% 0.59 - 1.89) Based on data from 204 participants in 1 study	**176** per 1000 / **187** per 1000 Difference: **11 more per 1000** (CI 95% 72 fewer - 157 more)	**Moderate** Due to serious risk of bias[11]	Delayed cord clamping (>60 secs) may have little or no difference on neonatal jaundice compared to immediate cord clamping (0-15 secs)

Delayed cord clamping (>60 secs) vs immediate cord clamping (0-15 secs) - need for phototherapy - [RCT] OFOJEBE 2021	Relative risk: 2.0 (CI 95% 0.18 - 21.71) Based on data from 204 participants in 1 study	**10** per 1000	**20** per 1000	**Very low** Due to very serious imprecision, Due to serious risk of bias[12]	We are uncertain whether delayed cord clamping (>60 secs) increases or decreases need for phototherapy compared to immediate cord clamping (0-15 secs)
		Difference: **10 more per 1000** (CI 95% 8 fewer - 207 more)			
Delayed cord clamping (1-2mins) vs early cord clamping (<40 secs) - need for phototherapy in first week of life - [RCT] SELIGA-SIWECKA 2020	Relative risk: 1.29 (CI 95% 0.82 - 2.05) Based on data from participants in 1 study	**226** per 1000	**292** per 1000	**Moderate** Due to serious risk of bias[13]	Delayed cord clamping (1-2 mins) may have little or no difference on neonatal jaundice requiring phototherapy compared to early cord clamping (<40 secs)
		Difference: **66 more per 1000** (CI 95% 41 fewer - 237 more)			
Later delayed cord clamping (>30secs) vs Early cord clamping (<30 secs) - Haemoglobin concentration (g/dL) within 24hrs of birth - term pregnancies - [SR] GOMERSALL 2021	Measured by g/dL Scale: - High better Based on data from 866 participants in 6 studies			**Very low** Due to serious risk of bias, Due to very serious risk of bias, Due to serious inconsistency[14]	We are uncertain whether delayed cord clamping (>30secs) increases or decreases haemoglobin concentration (g/dL) within 24hrs of birth in term pregnancies
		Difference: **MD 1.39 higher** (CI 95% 0.57 higher - 2.21 higher)			
Later delayed cord clamping (1-2mins) vs Early cord clamping (<30 secs) - Haemoglobin concentration (g/dL) within 24hrs of birth - late preterm (>34 weeks) and term pregnancies - [SR] GOMERSALL 2021	Measured by g/dL Scale: - High better Based on data from 782 participants in 3 studies			**Very low** Due to very serious risk of bias, Due to serious inconsistency[15]	We are uncertain whether delayed cord clamping (1-2mins) increases or decreases haemoglobin concentration (g/dL) within 24hrs of birth in term pregnancies, furthermore the clinical significance of this degree of increase is likely to be negligible
		Difference: **MD 0.91 higher** (CI 95% 0.03 higher - 1.80 higher)			
Later delayed cord clamping (>2mins) vs Early cord clamping (<30 secs) - Haemoglobin concentration (g/dL) within 24hrs of birth - late preterm (>34 weeks) and term pregnancies - [SR] GOMERSALL 2021	Measured by g/dL Scale: - High better Based on data from 273 participants in 3 studies			**Very low** Due to very serious risk of bias, Due to serious inconsistency[16]	We are uncertain whether delayed cord clamping (>2mins) increases or decreases haemoglobin concentration (g/dL) within 24hrs of birth in term pregnancies
		Difference: **MD 2.47 higher** (CI 95% 1.82 higher - 3.12 higher)			
Delayed cord clamping (>60 secs) vs immediate cord clamping (0-15	Measured by: Scale: - High better Based on data from 204	**15.16** Mean	**16.51** Mean	**Moderate** Due to serious risk of bias[17]	Delayed cord clamping (>60 secs) may increase haemaglobin concentrations (g/dL) at 48hrs after birth compared to immediate
		Difference: **MD 1.35 higher** (CI 95% 0.80 higher - 1.90 higher)			

secs) - mean haemaglobin at 48hrs (g/dL) - [RCT] OFOJEBE 2021	participants in 1 study				cord clamping (o-15 secs)
Delayed cord clamping (>60 secs) vs immediate cord clamping (0-15 secs) - mean bilirubin at 48hrs (mg/dL) - [RCT] OFOJEBE 2021	Measured by mg/dL Scale: - Lower better Based on data from 204 participants in 1 study	**3.71** Mean	**3.88** Mean	**Moderate** Due to serious risk of bias[18]	Delayed cord clamping (>60 secs) may have little or no difference on bilirubin concentration compared to immediate cord clamping (0-15 secs)
		Difference: **MD 0.17 higher** (CI 95% 0.55 higher - 0.21 lower)			
Later delayed cord clamping (>30secs) vs Early cord clamping (<30 secs) - ferritin concentration at 3-6 months after birth - late preterm (>34 weeks) and term pregnancies - [SR] GOMERSALL 2021	Measured by µg/L Scale: - High better Based on data from 126 participants in 2 studies	µg/L	µg/L	**Very low** Due to serious risk of bias, Due to very serious risk of bias, Due to serious imprecision[19]	We are uncertain whether delayed cord clamping (>30secs) increases or decreases ferritin concentration (µg/L) within3-6 months of birth
		Difference: **MD 32.38 higher** (CI 95% 13.72 higher - 51.05 higher)			
Later delayed cord clamping (>30secs) vs Early cord clamping (<30 secs) - ASQ-3 total score at 4 years - late preterm (>34 weeks) and term pregnancies - [SR] GOMERSALL 2021	Measured by: Scale: - High better Based on data from 245 participants in 1 study			**Very low** Due to serious risk of bias, Due to very serious imprecision[20]	We are uncertain whether delayed cord clamping (>30secs) increases or decreases ASQ-3 scores (a measure of neurodevelopmental impairment) at 4 years
		Difference: **MD 3.4 higher** (CI 95% 2.86 lower - 9.66 higher)			
Delayed cord clamping (>1 minute) vs early cord clamping (<30 secs) - ASQ-3 total score at 4 months - term pregnancies - [CR] MCDONALD 2013	Measured by: Scale: - High better Based on data from 365 participants in 1 study			**Low** Due to serious risk of bias, Due to serious imprecision[21]	Delayed cord clamping may have little or no difference on ASQ-3 total score among term pregnancies compared to early cord clamping at 4 months
		Difference: **MD 1.40 lower** (CI 95% 7.31 lower - 4.51 higher)			

51. **Risk of Bias: serious.** Selective outcome reporting; **Imprecision: very serious.** Wide confidence intervals, due to few events;
52. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: 71 %.; **Imprecision: no serious.** Wide confidence intervals.
53. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias, Selective outcome reporting unclear; **Indirectness: serious.** due to no definition of resuscitation; **Imprecision: very serious.** Wide confidence intervals, due to few events.
54. **Risk of Bias: very serious.** Selective outcome reporting unclear, Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Imprecision: serious.** Wide confidence intervals.
55. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Indirectness: serious.** due to no definition of PPH.
56. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Imprecision: serious.** Wide confidence intervals.
57. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Imprecision: serious.** Wide confidence intervals.
58. **Risk of Bias: serious. Imprecision: serious.** Wide confidence intervals.

59. **Risk of Bias: serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Imprecision: serious.** Wide confidence intervals.
60. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Wide confidence intervals.
61. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.
62. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: very serious.** Wide confidence intervals.
63. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.
64. **Risk of Bias: very serious.** Selective outcome reporting, Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: 89 %.
65. **Risk of Bias: very serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias, Selective outcome reporting; **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: 89 %.
66. **Risk of Bias: very serious.** Inadequate concealment of allocation during randomization process, resulting in potential for selection bias, Selective outcome reporting; **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2:... %.
67. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.
68. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.
69. **Risk of Bias: very serious.** due to high attrition bias in 1 study, protocol violations in the other; **Imprecision: serious.** Wide confidence intervals.
70. **Risk of Bias: serious.** due to lack of clarity around reporting and losses to follow-up; **Imprecision: very serious.** Wide confidence intervals crossing null effect, only data from one study.
71. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, due to neurodevelopmental outcome only reported in a subset of participants in the study; **Imprecision: serious.** Only data from one study.

Evidence to Decision

Benefits and harms	Small net benefit, or little difference between alternatives

Research evidence

Systematic review (Gomersall et al., 2021) used as the primary source of evidence for this PICO. The searches for this review were up to date to July 2019.

A search of MEDLINE for additional RCTs published since July 2019 was conducted on 16/03/2023 using search terms:

- Mesh term - Umbilical cord AND
- clamp OR clamping OR clamped OR ICC OR DCC OR ECC AND
- mesh term - infant, newborn OR newborn OR baby*

limited to humans, 2019-current, RCTs

Returned 52 results of which 6 were retrieved for full text review. 2 were included in the evidence table

Summary

Gomersall et al., (2021) identified 33 studies comparing delayed cord clamping (cord clamping at least 30 seconds after birth) and early cord clamping (which they define as cord clamping within 30 seconds of birth). This systematic review included late preterm pregnancies (>34 weeks) as well as term pregnancies. A sensitivity analysis of the term pregnancies was performed. Pre-specified neonatal outcomes from the PICO are included in the evidence table as well as the rate of PPH as this has been postulated to be increased in delayed cord clamping. Apgar and severe neonatal morbidity (such as HIE) were not reported by any studies. This systematic review includes women who delivered by caesarean birth (not included int he PICO), however, sensitivity of results by mode of birth found no difference in outcomes between modes of birth so we believe that this does not significantly alter the interpretation of the results.

Among combined late preterm (out of scope) and term pregnancies:

Delayed cord clamping of at least 30 seconds may increase haemoglobin concentrations within 24hrs of birth (MD 1.17g/dL, 95% CI 0.48-1.86 g/dL; very low quality) without an increase in hyperbilirubinaemia requiring phototherapy (RR 1.28, 95% CI 0.90-1.82; very low quality), however, due to very low quality of included studies we are uncertain where the real effect lies. We are uncertain if delayed cord clamping of at least 30 seconds impacts on NICU admission (RR 1.16, 95% CI 0.69-1.95; very low quality), and need for neonatal resuscitation (RR 5.08, 95% CI 0.25-103.58; very low quality). Delayed cord clamping may have little or no effect on PPH (RR 0.89; 95% CI 0.70-1.13; low quality) or retained placenta.

Longer term, delayed cord clamping of at least 30 seconds was associated with higher ferritin stores at 3-6 months (MD 32.38 µg/L higher 95% CI 13.72 to 51.05 higher). Neurodevelopmental delay was reported by both the Cochrane review (ASQ total score at 4 months MD -1.40 95% CI -7.31 to 4.51) and Gomersall et al., systematic review (ASQ total score at 4 years MD 3.40 higher 95% CI 2.86 lower to 9.66 higher).

Sensitivity analysis of Gomersall et al., systematic review results by length of delay in cord clamping found higher haemoglobin concentrations with a longer duration of delayed cord clamping (1-2mins delay: MD 0.91, 95% CI 0.03-1.80; >2mins delay: MD 2.47, 95% CI 1.82-3.12) when compared to early cord clamping (<30 secs). No difference in hyperbilirubinaemia requiring phototherapy was found in either the 1-2min delay group or the >2min delay group when compared to early cord clamping (<30 secs). No difference in PPH risk was found between either the 1-2min and more than 2 min delay groups and the early cord clamping group.

Among term pregnancies only:

Sensitivity analysis of these results by gestational age at birth found similarly that delayed cord clamping of at least 30 seconds may increase haemaglobin concentrations within 24hrs of birth (MD 1.39g/dL, 95% CI 0.57-2.21 g/dL; very low quality) among term neonates. However, among term neonates delayed cord clamping of at least 30 secs was found to increase hyperbilirubinaemia requiring phototherapy when compared to early cord clamping (RR 1.54; 95% CI 1.01-2.34; very low quality). Due to very low quality of included studies we are uncertain where the real effect lies,and must interpret this result with caution.

Additional RCTs:

Ofojebe et al., 2021 conducted an RCT including 204 singleton, term pregnancies in Nigeria. Participants were randomly assigned to delayed cord clamping (60 secs after birth) or immediate cord clamping (0-15 secs after birth). At 48hrs mean haemoglobin concentrations were significantly higher in the delayed clamping group than the immediate cord clamping group (16.51 +/- 1.71 g/dL vs 15.16 +/ - 2.27 g/dL; p value 0.001). Total mean bilirubin concentrations were not significantly different between the groups. Little to no difference was found in PPH rate, diagnosis of neonatal jaundice, or need for phototherapy.

Seliga-Siwecka et al., 2020 conducted an RCT in Poland including 307 singleton, term pregnancies. This study was significantly underpowered for their primary outcome of neonatal jaundice requiring phototherapy, recruiting less than ⅓ of the required sample size due to funding constraints. Eligible participants were randomised in a 1:1:1 ratio to one of three groups: 106 to early cord clamping (<40 secs after birth), 106 to delayed cord clamping (1-2 mins after birth), or 97 to cord milking (4 times towards the neonate). Cord milking is outside of the scope of this clinical question. Little to no difference in jaundice requiring phototherapy was found between the delayed cord clamping (29%) and early cord clamping groups (23%) (RR 1.29, 95% CI 0.82 - 2.05).

Certainty of the Evidence	Low

GRADE assessment performed by Gomersall et al., 2021 authors scored as low to very low - studies down graded for risk of bias due to unclear allocation concealment, lack of blinding, and selective outcome reporting. Some outcomes downgraded for inconsistency, indirectness, or imprecision.

Gomersall et al., 2021 systematic review AMSTAR moderate.

RCTs by Ofojebe et al., 2021 and Seliga-Siwecka et al., 2020 were both GRADEd as moderate.

Values and preferences	No substantial variability expected

Maternal satisfaction scores were recorded as part of an RCT of early (less than 60secs) and delayed (after pulsation ceases at more than 60secs) for women having a vaginal birth in Spain (The CORDON Study - *not included in evidence summary as no English language version available*). A separate analysis of these scores was published by Orenga-Orenga et al., 2022. Women reported their satisfaction with their birth experience using the Mackey Childbirth Satisfaction Rating Scale. There was no relationship found between the time of cord clamping and satisfaction with the birth experience.

Resources

Economic evaluation falls outside of the scope of this statement

Acceptability	No important issues with the recommended alternative

Feasibility	No important issues with the recommended alternative

Delayed cord clamping forms part of physiological management of the third stage - a management strategy practiced by almost half of independent midwives in New Zealand for women having a spontaneous birth (Dixon 2013).

Clinicians have previously raised concerns regarding the practicality of performing neonatal resuscitation without the cord being cut. Although this has been demonstrated as feasible in centres with appropriate experience and equipment under study conditions not all facilities will have such resources available. Thus, delayed cord clamping for the term neonate requiring resuscitation may not be feasible.

Clinical Question 8- Management of third stage labour

For women who have just delivered and not received augmentation, does active management compared to physiological management of third stage labour achieve better maternal outcomes?

Evidence to Decision

Benefits and harms

The third stage of labour is defined as the period of time between the birth of the baby and the birth of the placenta. The package of care referred to as "Active Management" of the third stage includes:

- Administration of an intramuscular or IV uterotonic
- Controlled cord traction
- Timing of clamping and cutting of cord varies according to local policies/definitions.

Physiological or expectant management of the third stage refers to the birth of the placenta without the components of active management.

Sources: The Cochrane Review (Begley et al., 2019)[31] reported on the evidence for women at low risk of bleeding. The included studies identified low-risk women as those with no previous PPH, singleton pregnancy, cephalic, parity <5, at term, first stage of labour < 15 hours, no APH and no previous caesarean birth.
The evidence suggested that: for women at low risk of bleeding,

- it is uncertain whether active management compared with expectant management reduces the risk of severe primary PPH (< 1000 mL) (RR 0.31, 95% CI 0.05 to 2.17, 2 studies, 2941 women), maternal haemoglobin (Hb) less than 9 g/dL following birth, maternal Hb less than 9 g/dL at 24 to 72 hours (RR 0.17, 95% CI 0.02 to 1.47, 1 study, 193 women). GRADE: very low quality)
- active management probably reduces therapeutic uterotonics during the third stage and/or within the first 24 hours compared with expectant management (average RR 0.15, 95% CI 0.11 to 0.21, 3 studies, 3134 women)
- postnatal maternal mean Hb was probably increased (outcome not pre-specified) (MD in g/dL 0.50, 95% CI 0.41 to 0.59, 2 studies, 2683 women. (GRADE: moderate-quality evidence)
- active management may reduce primary blood loss 500 mL or more, clinically estimated or measured at time of birth, compared with expectant management (average RR 0.33, 95% CI 0.20 to 0.56, 2 studies, 2941 women;
- mean maternal blood loss (mL) (MD −78.80, 95% CI −95.96 to−61.64, 2 studies, 2941 women;
- maternal blood transfusions (average RR 0.30, 95% CI 0.10 to 0.88, 3 studies, 3134 women). (low quality evidence)
- No studies report any cases of maternal mortality.
- No studies reported on the length of stay for women.

Side effects were more common in all women (not limited to women at low-risk of bleeding) receiving active management (vomiting RR 2.09 95% CI 1.59-2.74, NNT 20; and hypertension (diastolic BP >90mmHg) RR 4.10 95% CI 1.63-10.30, 3 studies, 4636 women; GRADE: moderate), however, it should be noted that studies reporting this outcome gave oxytocin and ergometrine as their prophylactic uterotonic rather than the IM or IV oxytocin commonly used in Australia and New Zealand.

Certainty of the Evidence

The quality of the evidence included in the evidence table ranged from moderate to very low. Studies were downgraded for a lack of blinding, and low adherence to the intervention in the physiologic management group. Some outcomes were downgraded for wide confidence intervals.

Values and preferences

Substantial variability is expected or uncertain

Qualitative research was conducted by Reed et al., 2019, in Australia with 20 women, 11 women of whom had expectant management, eight who had active management and one who was unsure. Most of the women who had expectant management considered a physiological birth of the placenta to be an intrinsic element of

natural birth, and active management was considered to be an intervention used if complications occurred. In contrast, women who chose active management did not consider the placenta to be an important element of natural birth and chose active management in order to prevent complications.

It is likely that women's preferences for active or physiological management of the third stage vary.

Resources	Important issues, or potential issues not investigated

Additional considerations

The only additional cost of active management when compared to physiological management of the third stage is the cost associated with the administration of prophylactic uterotonic (usually oxytocin IM). A midwife/doctor would be present regardless of management strategy, so no additional staffing costs are generated.

Summary

Economic evaluation is outside of the scope of this statement.

Equity	No important issues with the recommended alternative

Acceptability

Additional considerations

Peberdy et al., 2021: 129 Australian maternity healthcare professionals responded to a 2018 survey of their knowledge, attitudes and practices relevant to cord blood banking, donation and clamp timing. Midwives considered the practice of informing parents of cord clamp timing options as very important, compared to their obstetric counterparts (94.1% vs 50%, p<.001), and thus midwives were significantly more likely than obstetricians to discuss cord clamp timing with all clients (79.6% vs 20.8%, p<.001), support parental preferences for cord clamp timing (99% vs 78.3%, p<.001), and clamp the cord after pulsations ceased (82.7% vs 72.7%, p<.001).

Summary

Active management and prophylactic management strategies are both already practiced in Australia and New Zealand. A modified active management strategy has emerged with variation in the timing of cord clamping and uterotonic administration in order to facilitate a move toward delayed cord clamping for all births.

The occurrence of side effects associated with active management (specifically the administration of prophylactic uterotonics) is likely to be a consideration for women in terms of their birth experience.

Feasibility

All trials included in the two systematic reviews presented were conducted in a hospital setting. The risks and benefits of the two management strategies in primary birth unit or home birth settings have not been evaluated in this evidence.

Clinical Question 9- Perineal care

Does use of a perineal care bundle, compared with usual care, improve the health outcomes in women having a vaginal birth?

Population: Women in the 2nd stage of labour giving birth via vaginal birth
Intervention: Perineal care bundle - Perineal Protection Bundle (Aus) or OASI-CB (NZ)
Comparator: Usual care

Outcome Timeframe	**Study results and measurements**	**Absolute effect estimates**		**Certainty of the Evidence** (Quality of evidence)	**Plain language summary**
		Usual care	Perineal care bundle		
OASI-CB use vs prior to bundle introduction - third/fourth degree tears - all women - [STEP-WEDGE TRIAL] GUROL-URGANCI 2020	Odds ratio: 0.8 (CI 95% 0.65 - 0.98) Based on data from 55060 participants in 1 study[1]	**33** per 1000	**30** per 1000	**Moderate** Due to serious risk of bias[2]	Introduction of the OASI-CB perineal care bundle probably decreases third/fourth degree tears in all women compared to prior to its introduction
		Difference: **3 fewer per 1000** (CI 95% 12 fewer - 1 fewer)			
OASI-CB use vs prior to bundle introduction - third/fourth degree tears - nulliparous women - [STEP-WEDGE TRIAL] GUROL-URGANCI 2020	Odds ratio: 0.81 (CI 95% 0.65 - 1.0) Based on data from 55060 participants in 1 study[3]	**52** per 1000	**49** per 1000	**Moderate** Due to serious risk of bias[4]	Introduction of the OASI-CB perineal care bundle probably decreases third/fourth degree tears in nulliparous women compared to prior to its introduction, however the confidence interval includes the null hypothesis
		Difference: **3 fewer per 1000** (CI 95% 18 fewer - 0 fewer)			
OASI-CB use vs prior to bundle introduction - third/fourth degree tears - multiparous women - [STEP-WEDGE TRIAL] GUROL-URGANCI 2020	Odds ratio: 0.78 (CI 95% 0.61 - 1.01) Based on data from 55060 participants in 1 study[5]	**17** per 1000	**15** per 1000	**Moderate** Due to serious risk of bias[6]	Introduction of the OASI-CB perineal care bundle probably has little or no difference on third/fourth degree tears in multiparous women compared to prior to its introduction
		Difference: **2 fewer per 1000** (CI 95% 7 fewer - 0 more)			
OASI-CB use vs prior to bundle introduction - third/fourth degree tears - spontaneous vaginal birth - [STEP-WEDGE TRIAL] GUROL-URGANCI 2020	Odds ratio: 0.75 (CI 95% 0.6 - 0.93) Based on data from 55060 participants in 1 study[7]	**26** per 1000	**22** per 1000	**Moderate** Due to serious risk of bias[8]	Introduction of the OASI-CB perineal care bundle probably decreases third/fourth degree tears in women having spontaneous vaginal deliveries compared to prior to its introduction
		Difference: **4 fewer per 1000** (CI 95% 10 fewer - 2 fewer)			
OASI-CB use vs prior to bundle introduction - third/fourth degree tears - forceps birth - [STEP-WEDGE TRIAL] GUROL-URGANCI 2020	Odds ratio: 0.88 (CI 95% 0.69 - 1.14) Based on data from 55060 participants in 1 study[9]	**76** per 1000	**76** per 1000	**Moderate** Due to serious risk of bias[10]	Introduction of the OASI-CB perineal care bundle probably has little or no difference on third/fourth degree tears in women having a forceps birth compared to prior to its introduction
		Difference: **0 fewer per 1000** (CI 95% 24 fewer - 11 more)			

OASI-CB use vs prior to bundle introduction - third/fourth degree tears - ventouse birth - [STEP-WEDGE TRIAL] GUROL-URGANCI 2020	Odds ratio: 0.82 (CI 95% 0.54 - 1.25) Based on data from 55060 participants in 1 study[11]	**27** per 1000	**26** per 1000	**Moderate** Due to serious risk of bias[12]	Introduction of the OASI-CB perineal care bundle probably has little or no difference on third/fourth degree tears in women having a ventouse birth compared to prior to its introduction
		Difference: **1 fewer per 1000** (CI 95% 12 fewer - 7 more)			

72. Primary study. **Baseline/comparator** Control arm of reference used for intervention. Supporting references [75]. [77]. [74]. [76]. [80].
73. **Risk of Bias: serious.** due to inability to measure the coverage and fidelity of the intervention.
74. Primary study. **Baseline/comparator** Control arm of reference used for intervention. Supporting references [76].
75. **Risk of Bias: serious.** due to inability to measure the coverage and fidelity of the intervention.
76. Primary study. **Baseline/comparator** Control arm of reference used for intervention. Supporting references [76].
77. **Risk of Bias: serious.** due to inability to measure the coverage and fidelity of the intervention.
78. Primary study. **Baseline/comparator** Control arm of reference used for intervention. Supporting references [76].
79. **Risk of Bias: serious.** due to inability to measure the coverage and fidelity of the intervention.
80. Primary study. **Baseline/comparator** Control arm of reference used for intervention. Supporting references [76].
81. **Risk of Bias: serious.** due to inability to measure the coverage and fidelity of the intervention.
82. Primary study. **Baseline/comparator** Control arm of reference used for intervention. Supporting references [76].
83. **Risk of Bias: serious.** due to inability to measure the coverage and fidelity of the intervention.

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Evidence to Decision

Benefits and harms	Small net benefit, or little difference between alternatives

Research evidence

Evidence to support the individual elements of the perineal care bundles have been summarised by both NICE in NG190 Intrapartum care for healthy women and babies (2017) and WHO in WHO recommendations Intrapartum care for a positive childbirth experience (2018). Neither document addresses evidence of the impact of introduction of a perineal care bundle (either the Perineal Protection Bundle or the OASI-CB) on outcomes.

MEDLINE search - “perineal” OR mesh term “perineum” AND mesh term “Patient care bundles” - 10 studies identified - all retrieved for full text review - 1 referenced a quality improvement review of the OASI-CB not identified in primary search - this study (Gurol-Urganci et al., 2020) was retrieved and included in the evidence table for this PICO.

Additional studies identified in this literature search were used to inform elements of the evidence to decision framework.

Summary

A step-wedge cluster trial was conducted by Gurol-Urganci et al., 2020 evaluating the impact of the OASI-CB quality improvement project in four regions in the UK. Implementation of the care bundle was through a stepwise regional roll-out every 3 months starting in January 2017 and was led locally by midwives and obstetrician champions from each maternity unit. A total of 55 060 singleton live vaginal births were included (79% spontaneous vaginal births and 21% operative vaginal births).

The OASI rate amongst all women **decreased** from 3.3% before to 3.0% after care bundle implementation (adjusted OR 0.80, 95% CI 0.65-0.98, p value = 0.03, moderate certainty). Risk difference is 0.3% , NNT 333. A similar trend was seen on sensitivity analyses including nulliparous women (5.2% to 4.9%), however, the confidence interval includes the null effect (adjusted OR 0.81, 95% CI 0.65-1.00, p value = 0.05, moderate certainty), and multiparous women (1.7% to 1.5%) (adjusted OR 0.78, 95% CI 0.61-1.01, p value = 0.06, moderate certainty).

Sensitivity analyses by mode of birth found the OASI rate among women who had a spontaneous vaginal birth **decreased** from 2.6% before to 2.2% after care bundle implementation (adjusted OR 0.75, 95% CI 0.60-0.92, p value = 0.03, moderate certainty). However, little to no difference was found between OASI rate before and after implementation of the care bundle among women having a forceps birth (7.6% unchanged) (adjusted OR 0.88, 95% CI 0.69-1.14, p value = 0.34, moderate certainty), or a ventouse birth (2.7% to 2.6%) (adjusted OR 0.82, 95% CI 0.54-1.25, p value = 0.36, moderate certainty).

Harms should not be minimised as in some centres there have been 'blanket roll outs' for little benefit. A rectal examination for all women may be harmful. No studies were identified in the NICE 2022 evidence update literature searches comparing routine with restricted rectal examination and there is no evidence to suggest that restricted rectal examination increases the risk of poor outcomes.

Certainty of the Evidence	Moderate

The step wedge trial by Gurol-Urganci et al., 2020 was GRADED as moderate quality evidence. This study was downgraded for risk of bias due to the studies inability to measure the coverage and fidelity of the intervention.

Values and preferences	Substantial variability is expected or uncertain

Research evidence

Rare outcomes may not justify the rectal examination. The numbers needed to be examined compared with benefit of picking one additional hidden tear - no studies of the incidence of an isolated button-hole tear in an intact perineum have been reported - 9 case reports identified in a search conducted by Roper et al., 2020.

Additional considerations

Nineteen women were interviewed to learn about their experiences with the OASI-CB as part of the step-wedge trial (Bidwell et al., 2021). This study indicated that interviewed women did not experience any of the care bundle components as an intrusion of their physical integrity. Additionally, an urgent need was identified for more information about perineal trauma, in terms of risk, prevention and recovery.

Anecdotally woman do not like the rectal examinations to be done routinely when the perineum is intact.

Summary

Both care bundles in the PICO include the routine use of per rectal examination for all women. This may be perceived as invasive by some women although it is likely that preferences vary.

Resources	Important issues, or potential issues not investigated

Economic evaluation is outside of the scope of this statement.

Equity	No important issues with the recommended alternative

Additional considerations

If it made mandatory, then it is not equitable for all women as women may not feel empowered to decline the examination.

Summary

Consent needs to be given prior to the bundle being used.

Acceptability	Important issues, or potential issues not investigated

Research evidence

Warm compresses (likely means hands on also) have been shown to be helpful in the Cochrane review (reduced the rate of third/fourth degree tears) - and anecdotally women seem to like it.

Additional considerations

Bidwell et al., 2021:

Thematic analysis of patient experiences with the OASI-CB identified three themes:

1. Memories of touch, whereby women reported that a “hands-on” approach to perineal protection was a positive experience

2. Midwife as a supportive guide, where women reported that good communication facilitated a calm birth and enabled post-birth diagnosis

3. Education: women need more information about perineal trauma

Summary

Focus group discussions were held with local clinical champions (of varying health professions) at the end of the implementation phase of the OASI-CB step-wedge trial in the UK to understand barriers and enablers to implementation (Jurczuk et al., 2021). The main barriers that surfaced were a lack of perineal management skills, resistance to change/ standardisation, and a reluctance to discuss perineal trauma with women in the antenatal period, as this was perceived to cause anxiety to women.

Nineteen women were interviewed to learn about their experiences with the OASI-CB as part of the step-wedge trial (Bidwell et al., 2021). This study indicated that interviewed women did not experience any of the care bundle components as an intrusion of their physical integrity. Additionally, an urgent need was identified for more information about perineal trauma, in terms of risk, prevention and recovery.

Allen et al., (2022) conducted a qualitative study of midwives’ views of the Australian Perineal Protection Bundle introduction and how it has affected their practice. Twelve midwives were interviewed from five hospitals in one state in Australia. Many midwives expressed that they felt that the introduction of a perineal care bundle policy impacted their autonomy in their practice and that standardized cared did not respect women's differing preferences in birth. Many expressed concerns about the evidence base for the items included in the bundle.

Feasibility	No important issues with the recommended alternative

Additional considerations

The OASI-CB does not include warm compresses as a standardised component partly because of variation in availability and use, and partly because of clinical practicalities such as the feasibility of safely heating/reheating compresses.

Similar practical issues were raised in the implementation notes for the Australian Perineal Protection Bundle as it was identified that the temperature of hot tap water varied substantially between birth units and receptacles used to contain water for warm compresses were inadequate at maintaining the ideal temperature.

Summary

A perineal care bundle is probably feasible in most centres. However, issues with warm compresses have been raised within the implementation of both the Australian Perineal Protection Bundle and the OASI-CB.

Version	Date of Version	Pages revised / Brief Explanation of Revision
V3.1	March/ 2024	Interim update approved by RANZCOG Women's Health Committee and Cpuncil .
V3	July/ 2023	Full update and retitling of statement. Approved by RANZCOG Women's Health Committee and Council.
V2.0	July/ 2017	Update.
v1.0	March/ 2010	First endorsed by RANZCOG.

Policy Version:	Version 3.1
Policy Owner:	Women's Health Committee
Policy Approved by:	RANZCOG Women's Health Committee and Council
Review of Policy:	July / 2028