

Appendix A: Summary of evidence from surveillance

2019 surveillance of <u>Intrapartum care for healthy women and</u> babies (2014) NICE guideline CG190

Summary of evidence from surveillance

Studies identified in searches are summarised from the information presented in their abstracts.

Feedback from topic experts who advised us on the approach to this surveillance review, was considered alongside the evidence to reach a final decision on the need to update each section of the guideline.

A full list of guideline recommendations can be found on the website at the following link: www.nice.org.uk/guidance/cg190

1.1 Place of birth

A systematic review of 15 studies (1) (n = 215,257) examined the proportion of transfers from a planned home birth setting to hospital and the reasons behind the transfers. Results indicated that the proportion of transfers varied from 9.9% to 31.9%, with the most common reason for transfer being dystocia (5.1-9.8%). Other reasons for transfer included fetal distress (1-3.6%) and postpartum haemorrhage (0-0.2%).

A meta-analysis (2) of 991 studies (n = 9,094,443) examined the association between smoking during pregnancy and placenta previa. Results indicated that smoking during pregnancy was significantly associated with an increased risk of placenta previa.

Intelligence gathering

No intelligence was identified for this section of the guideline.

Impact statement

New evidence was identified that highlighted the most common reasons for transfer to a hospital setting from a planned home birth setting were dystocia, fetal distress, and postpartum haemorrhage. The rates of transfers from this setting were found to be lower than those reported in table 3 in the guideline recommendations which states that the rates of transfer from home is approximately 45%. Table 5 in the guideline states that the most common reason for transfer from a home setting is delay in the first or second stage of labour

(32.4%), followed by other factors which do include dystocia and postpartum haemorrhage. Respiratory problems are listed as a medical condition indicating increased risk leading to planned birth at an obstetric unit (table 6).

The new evidence suggests that rates of transfer from a home birth setting may be lower than the guideline currently states, and that reasons for transfer might differ slightly from the information in the tables. However, the new evidence includes one systematic review including studies from outside the UK so the applicability of the findings may be lower than the Birthplace study used to inform guideline development. Furthermore, the authors were unable to perform a meta-analysis of the data so the ranges of the rates and reasons for transfer may be misleading. Therefore, due to the uncertainties around the data in the new evidence, it is unlikely that the guideline will be affected.

Results from a large meta-analysis indicate that smoking during pregnancy is significantly associated with an increased risk of placenta previa. Smoking is not currently listed in Table 7 as a factor indicating increased risk, suggesting planned birth in an obstetric unit. However, placenta previa is listed in this table, so women in this group are likely to be covered by the table already. Importantly, NICE guideline CG62 on antenatal care for uncomplicated pregnancies covers assessment of smoking status and offering lifestyle advice to quit at an earlier point in pregnancy (before the intrapartum period). As NICE guideline CG62 and CG190 appear in a common interactive flowchart, guidance in this area is sufficient and no impact on the guideline is expected.

New evidence is unlikely to change guideline recommendations.

1.2 Care throughout labour

Support

A systematic review of 31 quantitative and qualitative studies (n = not reported) (3) examined the factors that influence paternal support during pregnancy and childbirth. For the purposes of this surveillance review, only the findings relating to childbirth were considered. Results indicated that fathers showed a desire to be involved in the intrapartum period, however there were several barriers to them doing so. These barriers were found to be related to informational support, attitudes towards involvement,

qualities of marital relationship, relations with their own parents and sociodemographic factors.

Hygiene measures

An updated Cochrane review (4) of 3 studies (n = 3012) examined the effectiveness and side effects of chlorhexidine vaginal douching during labour in reducing maternal and neonatal infections (excluding group B β -hemolytic streptococcus). The results indicate that chlorhexidine vaginal douching during labour had no significant impact on maternal and neonatal infections.

Intelligence gathering

No intelligence was identified for this section of the guideline.

Impact statement

Support

New evidence was identified which suggests there may be barriers to fathers providing support during childbirth.

Recommendation 1.2.4 in the guideline states: "Encourage the woman to have support from birth companion(s) of her choice." This recommendation serves to ensure that any birthing partner chosen by the mother is accepted by healthcare staff. Other barriers such as marital relationship qualities and relations with parents are beyond the remit of NICE guideline

CG190. Therefore the guideline is unlikely to be affected.

Hygiene measures

New evidence suggested that chlorhexidine vaginal douching during labour had no impact on maternal and neonatal infection. This is in line with guideline which states that tap water may be used if cleansing is required (recommendation 1.2.5), so it is unlikely that the recommendation will be affected by this new evidence.

New evidence is unlikely to change guideline recommendations.

1.3 Latent first stage of labour

Pain relief

An updated Cochrane review (5) of 10 studies (n = 1055) examined whether massage, reflexology and other manual therapies would help with reducing pain and improve women's experiences of childbirth (stage of labour not reported in the abstract). Results indicated that that massage, warm pack and thermal manual methods significantly reduced pain, length of labour and improved women's sense of control and emotional experience of labour. However the authors note that the quality of the evidence was low which makes the conclusion uncertain.

Acupressure

Two RCTs were identified which examined the effect of acupressure at point L14 on pain outcomes during the first stage of labour (6,7). Both studies found pain scores were significantly lower in the acupressure group compared to control (7) (n = 88), (6) (n = 149). One study also found a significant reduction in duration of labour and women reporting it was not sufficient to control pain (7).

Breathing

One RCT (8) (n = 140) found that breathing patterns had no significant impact on anxiety, pain, fatigue or maternal satisfaction, compared to a usual care

control. One RCT (8) (n = 140) found that breathing patterns during the first stage of labour had no significant impact on anxiety, pain, fatigue or maternal satisfaction, compared to a usual care control.

Aromatherapy

Two RCTs were identified on the use of aromatherapy interventions on maternal outcomes during the first stage of labour. One found that rose oil and a footbath significantly reduced anxiety scores in mothers compared to a control (9) (n = 120). However this study was limited by differences in baseline anxiety scores between groups prior to treatment. The second study found that aromatherapy with citrus aurantium (bitter orange) significantly reduced pain scores in the first stage of labour compared to control (10) (n = 126).

Position

An RCT (11) (n = 439) found that adopting the hand-and-knees position for at least 10 minutes during the first stage of labour had no significant effect in facilitating the rotation of the fetus to the occiput anterior position, compared to control. However, women adopting the hands-and-knees position reported significantly higher comfort levels.

Immersion in water

A Cochrane review (12) of 15 trials (n = 3663) evaluated the effects of water immersion during labour and/or birth (first, second and third stage of labour) on women and their infants. There were 13 trials that included women in the first stage of labour which are summarised here (n = not reported in the abstract). Results indicated that immersion in water seemed

to have no significant impact on rates of instrumental vaginal birth, caesarean section, blood loss or perineal tears. However, there was a small reduction in the risk of using regional analgesia for women immersed in water. The comparator in all cases was no immersion in water.

Intelligence gathering

No intelligence was identified for this section of the guideline.

Impact statement

Pain relief

A Cochrane review was identified which suggests the use of massage, warm pack and thermal manual methods may have beneficial effects during labour. Recommendation 1.3.9 in the guideline states "Advise the woman and her birth companion(s) that breathing exercises, immersion in water and massage may reduce pain during the latent first stage of labour." The new findings are partially in line with the guideline, although it does not currently mention thermal manual methods or warm packs. Given the uncertainty around the evidence, this discrepancy is unlikely to impact the guideline. There are various recommendations on respecting the woman's wishes regarding pain relief (see recommendation 1.8.1) so it is likely that use of warm packs would be encouraged should the woman wish to use them.

Acupressure

Evidence was found to suggest that acupressure significantly lowered pain scores in women, though it was insufficient to control their pain. This is in line with recommendation 1.3.10 which

states "Do not offer or advise aromatherapy, yoga or acupressure for pain relief during the latent first stage of labour. If a woman wants to use any of these techniques, respect her wishes." Therefore it is unlikely that the guideline will be affected.

Breathing

Evidence from one trial was identified to suggest that breathing patterns had no significant impact on anxiety, pain, fatigue or maternal satisfaction, compared to a usual care control in the first stage of labour. This is partially in line with the evidence reviewed during original guideline development, which showed no impact of breathing exercises on intrapartum pain (with the exception of women who were highly anxious during pregnancy). Originally, the committee decided to recommend supporting the woman if she chooses to use breathing exercises (recommendation 1.3.9), therefore it is unlikely that the recommendation will be impacted by the new evidence.

Aromatherapy

Evidence was identified to suggest that aromatherapy may decrease pain scores and anxiety scores in the first stage of labour. The guideline does not currently recommend offering aromatherapy to women, however it does state that their wishes should be respected if they wish to use it (recommendation 1.3.10). Given the limitations of one of the studies, the

recommendation is still valid and it is unlikely that the guideline will be affected by the new evidence.

Position

Evidence was identified to suggest that adopting the hand-and-knees position in the first stage of labour increased comfort levels. The guideline does not make any recommendations on the optimal position for the first stage of labour, however recommendation 1.2.3 does state "Encourage and help the woman to move and adopt whatever positions she finds most comfortable throughout labour". This is in line with the new evidence and therefore no impact on the guideline is expected.

Immersion in water

Evidence was identified to suggest that there was no significant impact of immersion in water (in the first stage of labour) on rates of instrumental vaginal birth, caesarean section, blood loss or perineal tears. However, there was a small reduction in the risk of using regional analgesia for women immersed in water. This is generally supportive of recommendation 1.3.9 which states that immersion in water may reduce pain, therefore the guideline is unlikely to be impacted.

New evidence is unlikely to change guideline recommendations.

1.4 Initial assessment

An updated Cochrane review (13) of 6 studies (n = 12,604) examined the effect of assessment and support interventions for women during early labour. When comparing early assessment with direct admission to hospital, duration of labour was significantly shorter in the early assessment group. This comparison showed no further impact on caesarean section rates or instrumental vaginal births, however the early assessment group were less likely to have an epidural or oxytocin for labour augmentation and have increased satisfaction with their care.

When comparing home assessment and midwife support to telephone triage, there were no clear differences in duration of labour, caesarean section rates, instrumental birth, epidural use, serious maternal morbidity, Apgar scores or neonatal intensive care unit admission. A comparison of one-to-one structured care with usual care also showed no significant differences between groups for the same outcomes. This was also the case for a labour diagnosis tool used by midwives.

Intelligence gathering

No intelligence was identified for this section of the guideline.

Impact statement

A Cochrane review was identified that suggested when compared to direct hospital admission, an early assessment reduced the duration of labour and rates of caesarean and epidural, as well as increasing maternal satisfaction. This is in line with the guideline, which currently recommends an initial assessment, giving recommendations on what this should include (see recommendations 1.4.1-1.4.5). The guideline does not specify where the initial assessment should take place, due to it covering different birth settings, however this is unlikely to be affected by the new evidence because this was not the focus of the Cochrane review.

New evidence is unlikely to change guideline recommendations.

1.5 Ongoing assessment

Surveillance decision

No new information was identified at this surveillance review.

1.6 General principles for transfer of care

Surveillance decision

No new information was identified at any surveillance review.

1.7 Care in established labour

Support in labour

A Cochrane review (14) of 27 studies (n = 15,858) examined the effects of continuous, one-to-one intrapartum support compared with usual care in women and babies across all settings. Results indicated that women with continuous support are significantly more likely to have a spontaneous vaginal birth and shorter labour. They were also less likely to report a negative childbirth experience, use intrapartum analgesia or have a baby with a low 5 minute Apgar score.

An RCT (15) (n = 2314) examined the effect of caseload midwifery on women's satisfaction with care throughout pregnancy, labour and the postpartum period. Caseload care consisted of care provided by a primary midwife throughout pregnancy and labour. Women receiving caseload care were compared to those receiving standard care (midwife-led care with varying levels of continuity). For the purposes of this surveillance review, only the results relating to intrapartum care were considered. Results indicated that compared to standard care, women receiving caseload care had higher ratings of satisfaction with intrapartum care.

Intelligence gathering

Better Births is the report of the National Maternity Review, published in February 2016. It contains recommendations to improve outcomes for maternity services and has led to the launch of the government's Maternity Transformation Programme which is currently underway in the NHS. There are several recommendations on ensuring continuity of care which relate to this guideline, these include: ensuring every woman has a midwife who is part of a small team of 4 to 6 midwives, each team should have an identified obstetrician, and the midwife care should be joined up with the care she is receiving in the community.

Impact statement

A Cochrane review was identified which highlights the benefits of continuous one-to-one intrapartum support of women during childbirth. Results from a further trial also supported the use of a continuity of care caseload model for midwives. Both pieces of evidence are in line with the guideline, which supports a continuity of care approach by linking to the NHS guideline on patient experience in adult NHS services (see recommendation 1.7.3). This is also in line with the Maternity Transformation Programme, which is currently underway to ensure continuity of care in maternity services.

New evidence is unlikely to change guideline recommendations.

1.8 Pain relief in labour: non-regional

Pain-relieving strategies

The following table includes a summary of 18 studies which examined the effect of non-pharmacological pain relief interventions during labour.

| Study type (n) | Intervention | Comparator(s) | Outcomes for intervention in relation to comparator |
|---|--|-------------------|--|
| Comparison of all relaxatio | n techniques throug | hout labour | |
| Cochrane meta-analysis (19 studies, n = 2519) (5) | Mind-body relaxation techniques: relaxation, yoga, music, audio analgesia and mindfulness. | Usual care | Relaxation, yoga, and music groups had significantly lower pain scores. No pain outcomes reported for trials on audio analgesia or mindfulness. Greater satisfaction with pain relief for relaxation, yoga and music groups. |
| Acupuncture | | | |
| RCT (n = 303), stage of labour not reported. (16) | 40 Minutes of manual acupuncture or electronic acupuncture | No acupuncture | No difference between groups for pain scores. Women receiving electronic acupuncture were significantly less likely to use epidural analgesia |
| RCT (n = 63), stage of labour not reported. (17) | Acupuncture at points LI-4 and SP-6 | Control | No significant effect on pain scores or serum cortisol. Duration of labour was significantly decreased in the acupuncture group. |
| Birth ball | | | |
| RCT (n = 90), latent first to established first stage of labour. (18) | Birth ball or heat therapy | Control | Heat therapy group had significantly lower mean pain scores compared to control. Birth ball group had significantly lower scores at each measurement point, compared to control. |

| Meta-analysis including 3 RCTs (n = 220), stage of labour not reported. (19) | Birth ball | Control | Significantly reduced pain during labour for birth ball group. |
|---|--|----------------------------------|--|
| Hypnosis | | 1 | |
| Cochrane (9 studies, n = 2954), stage of labour not reported. (20) | Hypnosis | Control | No pain score outcomes reported. Hypnosis groups had a significantly lower overall use of analgesia. No difference between groups for satisfaction with pain relief, sense of coping with labour or spontaneous vaginal birth. |
| Breathing and relaxation | | | |
| RCT (n = 250), second stage of labour. (21) | Breathing exercises | Control | - Significantly reduced pain scores and duration of the second stage of labour. There were no differences between groups for the first-minute Apgar scores |
| Aromatherapy | l | 1 | |
| RCT (n = 156), throughout labour. (22) | Salvia | Jasmine or a control | Significantly reduced pain severity 30 minutes after the intervention but not at 60 minutes in the salvia group. No differences in Apgar scores. |
| RCT (n = 120), stage of labour not reported. (23) | Breathing techniques with lavender | Breathing techniques alone | Pain scores were significantly lower in the later stages of labour with lavender. |
| RCT (n = 104), stage of labour not reported. (24) | Aromatherapy | Control | Pain scores in the latent and early active phases of labour were significantly lower, but not for late active phase. Other perinatal outcomes (painkiller use, duration of labour, adverse effects, delivery method, Apgar scores) were not significantly different between groups. |
| RCT (n = 100), stage of labour not reported. (25) | Orange oil | Control | Anxiety scores were significantly lower with orange oil. No differences observed in physiological measures such as systolic and diastolic blood pressure, respiration and pulse rates. |
| Acupressure | | | |

| RCT (n = 150), stage of labour not reported. (26) | Acupressure | Supportive care, control. | Significant difference between groups for pain severity scores (further details not reported in the abstract). Rates of vaginal delivery were significantly higher in both the supportive care and acupressure groups. Rates of caesarean section were significantly higher in the control group. |
|---|---|------------------------------------|---|
| Meta-analysis of 13 studies (n = not reported), stage of labour not reported. (27) | Acupressure | Control | Acupressure significantly increased the chance of vaginal delivery and significantly reduced the duration of both the active phase of labour and the second stage of labour. |
| RCT (n = 156), stage of labour not reported. (28) | Acupressure at the sanyinjiao point | Placebo, control | No significant impact on average pain scores compared to placebo and control groups. |
| Music therapy | | • | |
| RCT (n = 90), stage of labour not reported. (29) | Music therapy | Hoku ice point massage or control. | Pain scores decreased in all groups after the intervention, with no significant differences between groups. |
| RCT (n = 156), stage of labour not reported. (30) | Music therapy | Control | Significantly lower scores of pain and anxiety with music. Postpartum analgesia required was also significantly reduced. |
| Reflexology | | • | |
| RCT (n = 80), stage of labour not reported. (31) | Foot reflexology | Control | Significantly reduced pain scores, anxiety scores and duration of the first stage of labour. Significant increase in Apgar scores. |
| Water immersion | | | |
| A Cochrane review of 15 trials (2 trials of women in the second stage of labour (n = 320) and 4 trials of women immersed in both the first and second stages of labour (n = 386) (12) | Water immersion during labour and/or birth | Control | - No clear differences between groups for the following outcomes: instrumental vaginal birth, caesarean section, and admission to neonatal intensive care unit. |

Pharmacological pain relief

The following table includes a summary of 7 studies which examined the effect of non-regional pharmacological pain relief interventions during labour.

| Study type (n) | Intervention | Comparator(s) | Outcomes for intervention in relation to comparator. | |
|---|---|---|---|--|
| Intravenous and intramuscular opioids | | | | |
| Cochrane review (70 studies, n >60,000), stage of labour not reported. (32) | Opioid (only pethidine mentioned in the abstract) | Placebo | Lower pain scores with opioid (pethidine) Fewer women requesting any additional analgesia in the opioid group. Increased side effects of drowsiness, nausea, and vomiting. | |
| Cochrane (20 studies, n = 3569), stage of labour not reported. (33) | Remifentanil intravenous patient-controlled analgesia | Epidural, other opioid, remifentanil (IV), remifentanil intravenous patient-controlled analgesia (different regimen). | Stronger pain relief at one hour compared to other opioids, but reduced pain relief when compared to epidural. Lower risk for the requirement of additional analgesia when compared to other opioids, but higher risk than epidural. Greater satisfaction than with other opioids. But lower satisfaction when compared to epidural. No evidence that remifentanil was associated with increased risk of: maternal respiratory depression, increased risk for newborns with Apgar scores less than 7 at 5 minutes. | |
| RCT (n = 188), stage of labour not reported. (34) | 1mg/kg pentazocine (IM) | 15mg/kg paracetamol (IM) | Paracetamol group significantly lower pain scores after first hour. No difference thereafter. | |
| RCT (n = 105), women in the early stage of labour. (35) | 10ml Bupivacaine 0.08mg with fentanyl 100µg | 10ml Bupivacaine 0.08mg with fentanyl 50µg or 20mg | Median time to onset of analgesia significantly faster in the 100μg group compared to 20mug, but not 50μg. No difference between groups for maternal side effects, mode of delivery, patient satisfaction, or neonatal Apgar scores. | |
| RCT (n = 120), stage of labour not reported. | 0.1% bupivacaine with | 0.1% bupivacaine | Pain scores significantly lower in the non-morphine group. | |

| (36) | 2μg/ml fentanyl and 2mg morphine in 15ml saline | with 2μg/ml fentanyl | Total dose of bupivacaine and duration of second stage of labour were significantly smaller in the morphine group. |
|---|--|---|--|
| Meta-analysis (8, n = 2351), stage of labour not reported. (37) | Remifentanil (dosage not reported) | Epidural analgesia (dosage not reported) | No differences between groups for pain scores at 2 and 3 hours. Pain scores at 1 hour were significantly higher with remifentanil. Pruritis was significantly lower with remifentanil. No differences between groups for maternal satisfaction, nausea, vomiting, need for caesarean section, respiratory depression, neonatal Apgar scores |
| Inhalational analgesia | | | |
| RCT (n = 120), stage of labour not reported. (38) | Entonox | Oxygen | Significantly lower pain scores in the Entonox group. Significantly shorter duration of labour and higher dizziness in the Entonox group. No significant differences between groups for maternal blood pressure and neonatal Apgar scores. |

Pain relief in labour: non-regional

Intelligence gathering

An ongoing trial was identified in this area. The <u>POOL</u> study is examining the safety of water births for mothers and babies at low risk. This study will be monitored and the impact of the results on the guideline will be assessed when they are available.

Impact statement

Pain relieving strategies

Evidence was identified to support the use of breathing and relaxation techniques, birth ball, reflexology, yoga, aromatherapy and music to help with deal with pain during labour. Acupuncture was not found to have an impact on pain relief. The benefits of acupressure on pain scores were unclear, but increased chances of vaginal delivery were also reported. Hypnosis was found to be associated with significantly lower use of analgesia but no

benefit was observed for pain relief satisfaction.

The guideline currently states that the woman should be supported in the use of breathing and relaxation techniques (recommendation 1.8.2) and music therapy (recommendation 1.8.9) which is in line with the new evidence. The guideline also states that women's wishes should be respected if she wishes to use aromatherapy, yoga or acupressure however these should not be offered by the healthcare team (recommendation 1.3.10). The guideline also states that acupuncture, acupressure or hypnosis should not be offered, but women should not be prevented from using these techniques (recommendation 1.8.8). There are no recommendations on the use of a birth ball or reflexology, however recommendation 1.8.1 states "Healthcare professionals should think about how their own values and beliefs inform their attitude to coping with pain in labour and ensure their care supports the woman's choice" which suggests if the woman wishes to use these techniques then her wishes should be respected.

A Cochrane review was identified on the effect of water immersion during labour and/or birth, with results showing no clear differences between groups for maternal and neonatal outcomes. The guideline currently recommends offering the woman the opportunity to labour in water for pain relief (recommendation 1.8.4). The new evidence is unlikely to impact the guideline at this point, as no evidence has been identified to indicate any risk of harm from immersion in water. An ongoing trial has been identified in this area and the results will be assessed for impact on the guideline when they are available.

New evidence is unlikely to change guideline recommendations.

Intravenous and intramuscular opioids

Results from a Cochrane review suggest significant benefits of opioids for pain relief compared to placebo. However side effects of drowsiness, nausea and vomiting were noted. This is in line with the guideline, which recommends that opioids should be available in all birth settings and that the woman should be informed of their side effects (recommendation 1.8.12).

Results from a recent Cochrane review suggest that the opioid remifentanil may be more effective than other opioids in relieving pain and have significantly higher satisfaction ratings. The guideline currently only names pethidine and diamorphine but it does mention "other opioids" should be available (recommendation 1.8.12). This is an update of a Cochrane review, where the original was considered during guideline development. Therefore many of the trials have already been considered by the committee when recommendation 1.8.12 was written. Furthermore, the authors note that the evidence was very low quality and not sufficient to inform changes in practice. Therefore, the new evidence is unlikely to impact the guideline at this point.

There was mixed evidence on the effect of adding morphine to a combination of epidural and opioid (bupivacaine with fentanyl or sufentanil). One study showed no significant impact on duration of analgesia and another showed significantly lower pain scores without the morphine addition. This is in line with the guideline which currently advises bupivacaine with

fentanyl solution and no dose of morphine (recommendations 1.9.15 and 1.9.16).

Other trials were identified which compared different dosages of opioids, however these were not considered to impact the guideline as it does not currently make any recommendations on the dosages of opioids.

New evidence is unlikely to change guideline recommendations.

Inhalational analgesia

There was evidence to support the use of Entonox over oxygen for managing pain through inhalational analgesia. This is in line with the guideline which recommends ensuring Entonox is available in all birth settings (recommendation 1.8.11).

New evidence is unlikely to change guideline recommendations.

Other non-regional pharmacological pain relief

There was evidence to suggest that paracetamol may be initially more effective at reducing pain than pentazocine. The guideline does not make any recommendations on either of these treatments therefore impact on the guideline is unlikely.

New evidence is unlikely to change guideline recommendations.

1.9 Pain relief in labour: regional analgesia

The following table includes a summary of 12 studies which examined the effect of different types of regional analgesia for use during labour.

| Study type (n) | Intervention | Comparator(s) | Outcomes for intervention in relation to comparator. |
|--|---|---|--|
| Patient-controlled epidura | al | | |
| RCT (n = 50), stage of labour not reported. (39) | 10ml 0.1% ropivacaine (with 2ng/ml fentanyl) | 10ml 0.1% bupivacaine (with 2ng/fentanyl) | Significant decrease in pain scores for both groups. No difference between groups. No significant differences between groups for: duration of labour, adverse events and maternal satisfaction. |

| RCT (n = 51), stage of labour not reported. (40) | Patient-controlled epidural analgesia (5ml bolus of 0.08% bupivacaine and 2mg/ml fentanyl. Lockout interval 15 minutes) | Continuous epidural (10ml. per hour of 0.08% bupivacaine and 2mg/ml fentanyl) | Significantly lower pain scores in the second and fourth hours for the patient-controlled analgesia compared to continuous. Motor block was significantly lower in the patient-controlled epidural analgesia group. |
|--|---|---|---|
| Combined spinal-epidura | | 1 | |
| RCT (n = 60), stage of labour not reported. (41) | Combined spinal- epidural with epidural volume extension (10ml saline). | Combined spinal- epidural only. | No significant differences between groups for pain scores. |
| RCT (n = 60), stage of labour not reported. (42) | Combined spinal- epidural | Low dose epidural | - Mean total drug consumption during labour was significantly less in the combined spinal-epidural group, who also had a significantly faster onset of analgesia. |
| Epidural analgesia | . I | 1 | <u> </u> |
| A Cochrane review of 52 studies (n>11,000), stage of labour not reported. (43) | All types of epidural analgesia. | Non-epidural or no pain relief | Pain intensity scores and need for additional pain relief were lower in those with epidural compared to opioids. Higher satisfaction with pain relief with epidural. Overall, women receiving epidural experienced more assisted vaginal birth, however a subgroup analysis showed this only to be the case in trials predating 2005. No differences between groups for caesarean rates, backache, neonatal outcomes, admission to neonatal intensive care unit or Apgar scores. |

| RCT (481), women throughout first and second stage of labour. (44) | 0.125% ropivacaine plus 0.3μg/ml sufentanil | 0.125% ropivacaine | Significant decrease in pain score for intervention group compared to comparator in first stage of labour. No difference in second stage of labour, side effects, |
|--|---|--|---|
| RCT (n = 60), stage of labour not reported. (45) | Ropivacaine epidural analgesia | Ropivacaine 0.1% with fentanyl 2µg/ml | Pain significantly lower in pain scores between groups. No significant differences between groups for caesarean section or need for oxytocin in first stage of labour. |
| Meta-analysis (8 studies, n = 18,832), women in the second stage of labour. (46) | Routine epidural. | Analgesia on request. | Pain significantly lower in the epidural group, including hypertension and longer second stage of labour. No differences between groups for caesarean section or need for oxytocin in first stage of labour. |
| RCT (n = 400), women in the first and second stage of labour. (47) | 1 st and 2 nd stage of labour: 0.08% ropivacaine with 0.4mg/ml sufentanil | 1 st stage of labour only: 0.08% ropivacaine with 0.4mg/ml sufentanil | No significant differences in pain scores between groups. No significant differences between groups for duration of second stage of labour or spontaneous vaginal delivery rate. Maternal satisfaction significantly higher in the |
| Meta-analysis (15 studies, n = 2097), stage of labour not reported. (48) | Bupivacaine 0.10% ± 0.03 with fentanyl | Ropivacaine 0.12% ± 0.04 with fentanyl | - No significant differences between groups for pain scores. - No significant differences between groups for rates of instrumental or caesarean delivery, Apgar scores, maternal satisfaction, duration of labour, onset or duration of analgesia, oxytocin use. - Ropivacaine group had a significantly lower incidence of motor blocks. |

| RCT (n = 237), stage of labour not reported. (49) | Bupivacaine (0.0625%, 0.1%, 0.125%) | Levobupivacaine (0.0625%, 0.1%, 0.125%) | - Pain breakthrough significantly different between groups but direction of effect not reported. |
|---|--|---|---|
| | | | Rate of caesarean section was significantly lower in the bupivacaine 0.1% compared to levobupivacaine 0.1%, 0.125% and bupivacaine 0.125%. No significant differences between groups for maternal and fetal side effects. |
| RCT (n = 94), women were reported to be in early labour. (50) | 2ml 0.125% bupivacaine with 5mug fentanyl, plus patient-controlled analgesia and intermittent bolus with background infusion. | 2ml 0.125% ropivacaine with 5mug fentanyl, plus patient-controlled analgesia and intermittent bolus with background infusion. | No significant difference between groups for pain scores Duration of analgesia was significantly shorter in the ropivacaine group but press frequency of the patient-controlled analgesia was significantly higher in the bupivacaine group. |

Pain relief in labour: regional analgesia

Patient-controlled epidural

There was mixed evidence on the use of patient-controlled epidural compared to continuous administration. One study found there were no differences between groups for pain scores, whereas another found patient-controlled epidural was associated with significantly lower pain scores in the second and fourth hours. The new evidence is broadly consistent with the guideline, which recommends either

patient-controlled epidural analgesia or intermittent bolus given by healthcare professionals (<u>recommendation 1.9.19</u>).

New evidence is unlikely to change guideline recommendations.

Combined spinal-epidural

Evidence was identified on the use of combined spinal-epidural. Results suggest that there was no difference in fetal outcomes (heartrate and Apgar scores) when comparing combined epidural with standard epidural. There was also no difference in pain scores when comparing combined spinal-epidural with epidural volume extension with no volume extension. However, there was evidence to suggest that overall drug consumption was lower and onset of analgesia is faster with combined spinal-epidural compared to low dose epidural. This is in line with the guideline which currently recommends using either epidural or combined spinal-epidural for establishing regional analgesia (recommendation 1.9.13).

New evidence is unlikely to change guideline recommendations.

Epidural analgesia

Evidence was identified to suggest that addition of an opioid to epidural analgesia significantly lowered pain scores in the first but not the second stage of labour. More side effects were associated with the opioid addition. This is consistent with the guideline, which currently suggests using a combination of epidural with opioid solution to establish regional analgesia (recommendation 1.9.16) and also to inform women of the side effects of taking opioids (recommendation 1.8.12).

Other trials compared specific analgesic agents. The new evidence suggests that there may be no difference in effect of bupivacaine, ropivacaine and levobupivacaine for various pain-related outcomes and adverse effects. The guideline does not currently recommend a specific local anaesthetic, however it does list bupivacaine as an example (recommendations 1.9.16-1.9.18).

In terms of dosages, the evidence was unclear around which dosage of bupivacaine or levobupivacaine was more effective as the direction of effect was not reported in the abstract for the one study identified in this area. Therefore the guideline is unlikely to be impacted at this point.

Evidence comparing the length of time the epidural is delivered was also identified in one trial. When comparing epidural use in both first and second stages of labour with use in just the first stage, there were no differences in pain scores or duration of second stage of labour between the 2 groups. However satisfaction scores were significantly higher in the group receiving epidural in the first stage only. This is not fully in line with the guideline, which states "Once established, continue regional analgesia until after completion of the third stage of labour and any necessary perineal repair". It is not clear what the satisfaction ratings are referring to and how they are measured is not reported in the abstract. Because of this uncertainty and given there are no differences between groups for the other outcomes, it is unlikely that the new evidence will impact the guideline recommendations.

Evidence was identified comparing all types of epidural with non-epidural pain relief and no pain relief at all. Results indicated that women with epidural had lower pain intensity scores and higher satisfaction with pain relief compared to those receiving just opioids. There was evidence to suggest that overall, women receiving epidural experienced more assisted vaginal birth, however a subgroup analysis showed this only to be the case in trials pre-dating 2005, suggesting that modern analgesic methods may not carry

this association. The following side effects were also significantly more likely in women with epidural: hypotension, motor blockade, fever, urinary retention, longer first and second stages of labour and oxytocin augmentation. The new evidence is not fully in line with recommendation 1.9.2 in the guideline, which recommends providing specific information about epidural analgesia. For example, the fourth bullet point states there may be "increased chance of vaginal instrumental birth" with epidural, which is an association not found in recent trials. Bullet 4 also states "It is not associated with a longer first stage of

labour" which is not in line with the new evidence. Other side effects missing from recommendation 1.9.2 which can be found in the new evidence include: increased risk of hypotension, motor blockade, fever, urinary retention and oxytocin augmentation. In light of the new evidence, the information provided on the risks associated with epidural may need to be reviewed.

New evidence identified that may change current recommendations.

1.10 Monitoring during labour

Measuring fetal heart rate

A meta-analysis (51) of 6 RCTs (n = 26,529) examined the effectiveness of intrapartum fetal monitoring using cardiotocography (CTG) plus ST waveform analysis compared with CTG alone. The primary outcome was a composite measure of neonatal outcome which considered the following: intrapartum fetal death, neonatal death, Apgar score of 3 or less at 5 minutes, neonatal seizure. metabolic acidosis, intubation for ventilation at delivery, or neonatal encephalopathy. Results indicated that there was no significant difference between groups for the composite neonatal outcome.

Interpretation of CTG traces

Two RCTs were identified which examined the effectiveness of central fetal

monitoring with computer analysis (52)(53):

- One study found that continuous central fetal monitoring by computer analysis did not significantly reduce rates of metabolic acidosis or obstetric intervention, compared to monitoring by visual analysis. (53) (n = 7730).
- One pilot study found that a computerised decision support system used alongside CTG significantly reduced rates of hypoxia, acidemia, caesarean section and admission to the neonatal intensive care unit compared to standard cardiotocography. (52) (n = 720).

Conservative measures

A Cochrane review (54) of 8 studies (n = 734) examined the effect of acute tocolysis during labour for uterine tachysystole or suspected fetal distress, or both, on fetal, maternal and neonatal

outcomes. All of the trials used a selective beta₂-adrenergic agonist in one arm, however the specific drug used varied between trials, as did the comparator. Because each study compared a different intervention (each with sample sizes too small to detect an effect), the authors concluded that there was insufficient evidence to determine the effects of tocoytic drugs for uterine tachysystole or suspected fetal distress during labour.

Intrauterine resuscitation

A Cochrane review (55) examined the effect of amnioinfusion for meconium stained liquor to prevent meconium aspiration syndrome. The review included 14 studies (n = 4435). Results indicated that amnioinfusion had no significant impact on occurrence of meconium aspiration syndrome, perinatal and maternal death or severe morbidity. A subgroup analysis for settings with limited peripartum surveillance showed that amnioinfusion led to a significant reduction in caesarean sections, meconium aspiration syndrome, perinatal ventilation or neonatal intensive care unit admission.

Intelligence gathering

A topic expert highlighted that CTG and fetal blood sampling practices vary across the country, emphasising the importance of up to date guidance in this area. They also highlighted that the CTG classification table from The International FIGO may be easier to interpret than the tables in NICE guideline CG190. The expert called for the NICE tables to be simplified, highlighting that CTG misinterpretation is a large factor in intrapartum care problems and stating that many leading units in the UK prefer to use the FIGO tables.

An ongoing trial was identified in this area which will be monitored and results assessed when published:

 Comparing second-line tests in labour to assess fetal well-being: this trial is comparing the effectiveness of Fetal Scalp Stimulation (FSS) versus Fetal Blood Sampling (FBS) to assess fetal wellbeing in labour.

Impact statement

Measuring fetal heart rate

Evidence was identified which showed no difference in outcomes when comparing CTG with and without ST waveform analysis. This is in line with the guideline, which currently has no recommendations on the use of ST waveform analysis, or any other type of additional ECG analysis, with CTG. During guideline development, the committee considered whether a lack of effect could warrant a 'do not use' recommendation for this area of the guideline, however they concluded this was not justified by the evidence.

Therefore, it is unlikely that the guideline will be affected.

Automated interpretation of CTG traces

There was mixed evidence to support the use of automated computer software to interpret CTG traces, with one study showing no difference in outcomes such as metabolic acidosis or obstetric intervention and another suggesting a beneficial effect on rates of hypoxia, acidemia, caesarean section and admission to the neonatal intensive care unit. Given that the trial showing a benefit was a pilot study, more evidence is required on automated interpretation before any impact on the guideline can be assessed.

Conservative measures

Results from a recent Cochrane review suggest that the evidence is insufficient to determine the effects of tocolytic fetal distress during labour. The guideline currently recommends offering a tocolytic drug to reduce contraction frequency in the event of there being concerns about the baby's wellbeing (see recommendation 1.10.34). During guideline development, the committee noted the small sample sizes of the studies in this area and stated that they were unable to recommend any particular tocolytic over any other, although they proceeded to recommend their use as a conservative measure. As no harm issues were raised by the new evidence, more evidence may be required before any impact on the guideline can be assessed.

Intrauterine resuscitation

A Cochrane review was identified which supports recommendation 1.10.37 in the guideline which states "Do not offer amnioinfusion for intrauterine fetal resuscitation". The new evidence found

that amnioinfusion had no significant impact on occurrence of meconium aspiration syndrome, perinatal and maternal death or severe morbidity. A subgroup analysis showed a benefit of amnioinfusion in settings where facilities for perinatal surveillance are limited, however this is not applicable to the UK. As the evidence is in line with the guideline, it is unlikely to impact on recommendations.

User-friendly CTG classification tables

A topic expert highlighted that clinicians may find tables 10 and 11 in the guideline hard to follow. They advised that the tables provided in other national guidance may be more user-friendly. This issue was also raised by several stakeholders, who requested that the tables be simplified. In light of these concerns and to avoid the risk of CTG misinterpretation, we will amend the tables accordingly.

New evidence identified that may change current recommendations.

1.11 Prelabour rupture of membranes at term

Surveillance decision

No new information was identified at any surveillance review.

1.12 First stage of labour

Observations during the established first stage

Formal charting

An updated Cochrane review (56) of 11 studies (n = 9475) examined the effectiveness and safety of partograph use on perinatal and maternal morbidity and mortality. Outcomes were not consistently reported between studies and each compared different intervention features, therefore the authors concluded that the effects of routine use of the partograph as part of standard labour management are uncertain. Three trials (n = 1813) compared the use of partograph with no partograph and found no difference in outcomes such as caesarean section rates, oxytocin augmentation or duration of the first stage of labour. Four trials (n = 5051) compared a four-hour action line to a twohour action line and found that women in the four-hour group were significantly more likely to receive oxytocin augmentation.

Possible routine interventions in the first stage

Amniotomy

One RCT (57) (n = 120) compared effectiveness of early versus late amniotomy in women entering the active phase of labour. 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. Results indicated that there was no difference between groups for duration of first stage of labour and that rates of caesarean section were

significantly higher in the early amniotomy group.

Intelligence gathering

No intelligence was identified for this section of the guideline.

Impact statement

Observations during the established first stage

Formal charting

A Cochrane review was identified which provided mixed evidence on the effectiveness and safety of partograph use during intrapartum care. They identified some evidence to suggest that there is no benefit to using a partograph on outcomes such as caesarean section rate, oxytocin augmentation or duration of first stage of labour. Other evidence showed that use of the 4-hour action line was associated with significantly higher use of oxytocin augmentation. The guideline currently recommends using the partograph for charting observations during the first stage of labour (recommendation 1.12.5), specifically stating that the 4-hour action line should be used according to World Health Organisation (WHO) recommendations (recommendation 1.12.6). As the evidence is reported to be considerably uncertain and the WHO have not changed their recommendation on the use of the 4-hour action line, it is unlikely that the guideline will be affected at this point.

New evidence is unlikely to change guideline recommendations.

Possible routine interventions in the first stage

Amniotomy

Evidence was identified to suggest that there is no impact of performing early routine amniotomy on duration of the first stage of labour, compared to late amniotomy (reserved for specific indications). Furthermore, early amniotomy was significantly associated with higher rates of caesarean section. The guideline does not currently recommend routine amniotomy (see recommendation 1.12.11)

but it does suggest discussing it if there is a suspected delay in the first stage of labour (see recommendation 1.12.15) or advising the women to have it if the delay is established and there is confirmation that the membranes are still intact (recommendation 1.12.17). The new evidence is in line with the guideline as it supports the use of late amniotomy (if required) over early routine amniotomy.

New evidence is unlikely to change guideline recommendations.

1.13 Second stage of labour

The woman's position and pushing in the second stage

Position without epidural

An updated Cochrane review (58) of 32 studies (30 included in the analysis, n = 9015) examined the benefits and risks of the use of different birth positions during the second stage of labour in women without epidural anaesthesia. The results indicated that compared to supine positions, upright positions were associated with a significantly reduced duration of the second stage of labour. The authors note this finding should be interpreted with caution due to the low quality of evidence and high variability between the trials. A subgroup analysis excluding high risk of bias trials found that this effect disappeared. Other findings from the main analysis indicated that upright positions were associated with a

reduction in episiotomies and fewer abnormal fetal heart rate patterns. However, there was also a small increase in second degree perineal tears and increased blood loss more than 500ml. There were no differences between groups for rates of caesarean section, 3rd or 4th degree perineal tears, and admissions to neonatal intensive care unit.

Position with epidural

An updated Cochrane review (59) of 8 studies (n = 4464) examined the benefits and risks of the use of different birth positions (upright or recumbent) during the second stage of labour in women with epidural anaesthesia. Results indicated that there may be little or no difference between upright and recumbent positions for the following outcomes: incidence of operative births, caesarean section, instrumental vaginal birth, duration of the second stage of labour, postpartum haemorrhage. Maternal satisfaction was significantly lower in women adopting the

upright position. Results from the sensitivity analysis on trials with a low risk of bias (3 trials, n = 3609) indicate that upright positions significantly increase the chance of operative births (driven by the increase in caesarean sections in this group).

One RCT (60) (n = 102) examined the effect of women adopting a squatting position using bars compared to a supine position at a 45 degree angle using the semi-fowler. The abstract does not report whether the women had epidural or not. Results indicated that women adopting the squatting positon experienced a significantly shorter duration of labour, lower pain scores and less likely to be induced. There were no significant differences between groups for postpartum blood loss, neonatal birth weight, Apgar score at 1 and 5 minutes, or admission to the neonatal intensive care unit.

Pushing techniques

An updated Cochrane review (61) of 21 studies (n = 3763) examined the effect of different maternal pushing/breathing techniques during the expulsive stage of labour on maternal and fetal outcomes. Women included in the studies were either with or without epidural. Results indicated that when spontaneous pushing was compared to directed pushing, there were no significant differences between groups for the following outcomes: duration of the second stage of labour, 3rd or 4th degree perineal tears, episiotomy, duration of pushing, Apgar scores and neonatal intensive care unit admissions. No effect was seen on other maternal outcomes. However, delayed pushing was associated

with significantly increased incidence of low umbilical cord blood pH.

An RCT (n = 2414) (62) examined the effect of immediate versus delayed pushing during the second stage of labour on rates of spontaneous vaginal delivery among nulliparous women receiving neuraxial analgesia. Women in the delayed group were instructed to wait 60 minutes after they reached complete cervical dilation. Results indicated that there were no differences between groups for rates of spontaneous vaginal delivery, neonatal morbidity or perineal lacerations. Women who were instructed to push immediately had significantly lower rates of postpartum haemorrhage and shorter duration of the second stage.

Duration of the second stage and definition of delay

An RCT (n = 78) (63) examined the effect of extending the duration of the second stage of labour. 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. Women in the study were randomly allocated to receive an additional hour or care as usual (expedited delivery via caesarean section or operative vaginal birth after timeframe had elapsed). Results indicated that rates of caesarean sections were significantly lower in women receiving an extra hour compared to usual care. There were no significant differences between groups for maternal or neonatal morbidity outcomes. Authors noted the study may have been underpowered to detect clinically important differences.

Intrapartum interventions to reduce perineal trauma

The following table includes a summary of 10 studies examining the effect of different interventions for reducing perineal trauma.

| Study type (n) | Intervention | Comparator(s) | Outcomes for intervention in relation to comparator |
|--|---|---------------------------------|--|
| Position | | | |
| RCT (n = 1400) Epidural status unknown (64) | Hands-and- knees position | Lying down | Rates of episiotomy and second degree perineum laceration were significantly lower in the intervention group. Rates of first degree perineum laceration and longer duration of the second stage of labour were significantly higher in the intervention group. |
| General perineal to | echniques | | |
| Cochrane review of 22 trials (n = 15,181) (65) | Perineal massage, warm or cold compresses, and perineal management techniques | Control | Perineal massage and warm compresses had no significant impact on incidence of perineal trauma requiring suturing or second degree tears. Perineal massage was significantly associated with an increased incidence of intact perineum and, with less certainty, lower rates of episiotomy. Warm compresses showed no effect on these outcomes. Incidence of third and fourth-degree tears were significantly less frequent with either warm compress or perineal massage. Low quality evidence suggests that a 'handsoff' technique may reduce episiotomy, but this technique had no clear impact on other outcomes. |
| RCT (n = 335) (66) | Disposable semi-soft vacuum extraction cup during assisted vaginal delivery | Re-sterilisable metallic cup | The primary outcome was a composite measure of cup dysfunction, requirement of other instruments, caesarean section, cephalohaematoma, episiotomy and perineal tears. - There was no difference between groups for the primary outcome. - Failed instrumental delivery was more common in the intervention group, however this group also experienced significantly fewer perineal tears. |
| RCT (n = 150) (67) | Warm compress | Standard care | Significantly higher frequency of intact perinea and lower incidence of episiotomy. |

| Meta-analysis of 5 RCTs (n = 6647) and 7 non-randomised studies (n not reported) (68) RCT (n = 650) | 'Hands on' perineal support Primary | 'Hands poised' poised approach Primary delivery | - Rates of ruptures were significantly higher in the warm compress group. 'Hands on' position did not significantly reduce the risk of obstetric and anal sphincter injury, whereas the non-randomised trials did show a significant risk reduction. Frequency of any perineal trauma did not differ |
|--|---|---|--|
| (69) | delivery of the anterior shoulder. | of the posterior shoulder. | between the two groups. |
| Episiotomy | | | |
| Cochrane review of 12 studies (n = 6177) (70) | Selective episiotomy | Routine episiotomy | Selective episiotomy resulted in significantly fewer women experiencing severe perineal trauma. No significant impact on blood loss, Apgar scores, perineal infection, moderate or severe perineal pain. Long term outcomes were also inconclusive |
| Meta-analysis of 15 observational studies (n = not reported) (71) | Mediolateral episiotomy during vacuum- assisted delivery | Lateral episiotomy during vacuum- assisted delivery | Both types of episiotomy significantly reduced the risk of obstetric and anal sphincter injury. |
| RCT (n = 309) (72) | no episiotomy | routine episiotomy | No difference between groups for advanced perineal tears, however the authors state that this may have been because a large proportion of patients in the no episiotomy group received an episiotomy. |
| Meta-analysis of 16 non- randomised studies (n = 651,114) (73) | mediolateral episiotomy | no episiotomy | Mediolateral episiotomy significantly reduced the risk of obstetric and anal sphincter injury. |

Intelligence gathering

We sought advice from topic experts and stakeholders about the new evidence on

delayed versus immediate pushing in women with epidural in the second stage of labour. The majority confirmed that delayed pushing is generally adhered to in practice, as advised in recommendation 1.9.9. However, in light of the new evidence indicating that delayed pushing may be associated with an increased risk of postpartum haemorrhage, topic experts recommended that this area be reviewed. Stakeholders were only asked about adherence to recommendation 1.9.9, so did not comment on the new evidence summarised here.

Impact statement

The woman's position and pushing in the second stage

Position without epidural

Results from an updated Cochrane review indicated that compared to supine positions, upright positions were associated with a significantly reduced duration of the second stage of labour in women without epidural. However, a sensitivity analysis on low risk of bias trials did not find this effect. Upright positions were also associated with a reduction in episiotomies and fewer abnormal fetal heart rate patterns. Currently the guideline advises discouraging the woman from lying supine or semi-supine, but encouraging her to adopt any position that feels comfortable (recommendation 1.13.9), although the recommendations do not distinguish between woman with or without epidural. Given the uncertainty around which position is most beneficial, the current recommendation may still be appropriate for this population as it promotes free choice for the woman. However, changes may need to be made to the wording of this recommendation to clarify that this applies to women without epidural.

New evidence identified that may change current recommendations.

Position with epidural

Results from an updated Cochrane review indicated that there may be little or no difference between upright and recumbent positions for the following outcomes: incidence of operative births, caesarean section, instrumental vaginal birth, duration of the second stage of labour, postpartum haemorrhage. However, results from a sensitivity analysis on trials with a low risk of bias (3 trials, n = 3609) indicate that upright positions significantly increase the chance of operative births (driven by the increase in caesarean sections in this group). This result was mostly driven by a large UK-based RCT which suggests supine or semi-supine positions are more beneficial for women with epidural. As discussed above, the guideline currently advises discouraging the woman from lying supine or semisupine, but encouraging her to adopt any position that feels comfortable (recommendation 1.13.9), although the recommendations do not distinguish between woman with or without epidural. As the new evidence does not support the guideline, it may be necessary to review the recommendations in this area.

New evidence identified that may change current recommendations.

Pushing techniques

Results from an updated Cochrane review indicated that there are no differences in outcomes when comparing spontaneous pushing to directed pushing (in women with and without epidural). Delayed pushing in women with an epidural was

associated with a significant increase in the duration of the second stage of labour but a decrease in the duration of pushing and an increase in spontaneous vaginal delivery. The new evidence is broadly in line with the current recommendations throughout the guideline on pushing techniques, which advise delayed pushing in women with epidural (recommendation 1.9.9) and informing the woman "in the second stage she should be guided by her own urge to push" (recommendation 1.13.10). Therefore, no impact on the guideline is expected.

Further evidence was identified comparing the effect of immediate versus delayed pushing on rates of spontaneous vaginal birth. Results indicated that there were no differences between groups in spontaneous vaginal birth, however women who delayed pushing were found to have significantly more postpartum haemorrhages. This is not in line with the Cochrane review discussed above or with the guideline, which states delayed pushing should be recommended for women with epidural after full dilation (recommendation 1.9.9). After seeking further advice from topic experts and stakeholders on this issue, it is decided that no impact on the guideline is expected at this point. Given the inconsistencies with previous studies and in the absence of other reports measuring postpartum haemorrhage, further evidence in this area is required before impact on the guideline can be assessed.

New evidence is unlikely to change guideline recommendations.

Duration of the second stage and definition of delay

Evidence was identified to suggest that extending the definition of the duration of the second stage of labour significantly lowered rates of caesarean sections yet did not impact on maternal or neonatal morbidity. The authors note that the study is likely to have been underpowered, therefore until there is further evidence in this area, an impact on the guideline is unlikely.

New evidence is unlikely to change guideline recommendations.

Intrapartum interventions to reduce perineal trauma

Position

There was evidence to suggest that adopting a hand-and-knees positon during the second stage of labour may reduce rates of episiotomy and second degree lacerations, however rates of first degree perineum laceration and longer duration of the second stage of labour were also reported with this intervention. The guideline does not currently make any recommendations on the best position for reducing perineal trauma. As the new evidence provides mixed results on the benefits of adopting the hands-and-knees position, more research in this area is needed before any impact on the guideline can be assessed.

New evidence is unlikely to change guideline recommendations.

Other perineal techniques

Mixed evidence was identified on the use of massage and heat/cold therapy to reduce perineal trauma. Collectively, the results suggest some positive benefits to perineal massage and warm compress, with significant associations found with the following outcomes: higher rates of intact perineum, fewer incidences of third and fourth-degree tears (but not second degree), and fewer incidences of episiotomy. The evidence on the use of 'hands on' or 'hands poised' was inconclusive. One study examined the use of a disposable cup device for use during vacuum-assisted delivery, with results indicating no meaningful difference with usual care.

There was evidence to suggest that different manoeuvres for shoulder delivery had no impact on perineal trauma. The guideline does not currently make any recommendations on delivery manoeuvres to reduce perineal trauma so it is unlikely that the guideline will be affected.

The guideline currently has a 'do not use' recommendation for perineal massage (recommendation 1.13.12) which may need reviewing in light of the new evidence. Recommendation 1.13.13 in the guideline advises the use of either 'hands on' or 'hands poised', which is consistent with the new evidence where one technique cannot be recommended over another.

New evidence identified that may change current recommendations.

Episiotomy

Evidence was identified to support the use of selective episiotomy over routine episiotomy, with results indicating significant reductions in women experiencing severe perineal trauma. This is in line with the guideline recommendations which do not recommend routine episiotomy (recommendations 1.13.15 and 1.13.17).

There was also evidence to suggest that there are no difference in outcomes when comparing mediolateral episiotomies with lateral episiotomies during vacuumassisted delivery. Currently the guideline recommends using the mediolateral episiotomy technique (recommendation 1.13.20), however it does not specify the type of delivery. As the new evidence is specific to women undergoing vacuumassisted delivery and because there appear to be no differences between groups, it is unlikely that the guideline will be impacted. Furthermore, results of a metaanalysis support the use of mediolateral episiotomies over no episiotomy, which is in line with the guideline.

New evidence is unlikely to change guideline recommendations.

1.14 Third stage of labour

Active and physiological management of the third stage

An updated Cochrane review (74) of 7 studies (n = 8247) compared the effectiveness of active versus expectant management of the third stage of labour. Results indicated that active management of the third stage may reduce the risk of haemorrhage greater than 1000 mL and 500ml in women at mixed risk of excessive bleeding. However the following side effects were noted: increased maternal diastolic blood pressure, vomiting, afterpains, use of analgesia from birth up to discharge from the labour ward and more women returning to hospital with bleeding.

Delayed cord clamping

Four trials were identified which examined the effect of delayed cord clamping in the third stage of labour. The delay in clamping varied from 2 minutes post birth to 5 minutes. Results indicated that delayed cord clamping had the following effect on neonates:

- Significantly increased haematocrit and ferritin levels. (75) (RCT, n = 73).
- Significantly lower residual placental blood volume, higher haemoglobin levels at 24 and 48 hours, and no difference in bilirubin levels. (76) (RCT, n = 73).
- No significant effect on number of red blood cells, haemoglobin or haematocrit 48 hours after birth. (77) (RCT, n = 97).
- Significantly greater haematocrit at 2 hours but no effect on Apgar scores or duration of the third stage of labour. (78) (RCT, n = 56).

One RCT (79) (n =546) examined whether gravity affects volume of placental transfusion during the delay period before cord clamping. For babies born in the intervention group, the baby was handed straight to the mother and held for 2 minutes on her chest before the cord was clamped. In the usual care group, babies were held for 2-minutes at the vagina level before the cord was clamped. Volume of placental transfusion was measured by weighing the baby immediately after birth and after cord clamping. Results indicated that there were no significant differences between groups for mean weight change. No adverse events were observed.

Controlled cord traction

A meta-analysis (80) of 5 studies (n = 30,532) examined the effect of controlled cord traction for prevention of postpartum haemorrhage. Results indicated that controlled cord traction significantly reduced overall incidence of postpartum haemorrhage, manual removal of the placenta and duration of the third stage of labour. However, there was no significant impact of controlled cord traction on incidence of severe postpartum haemorrhage, the need for blood transfusion or therapeutic uterotonics.

Active management with uterotonics

An updated Cochrane review (81) of 8 studies (n = 2031) examined the effectiveness and safety of prophylactic use of ergot alkaloids (e.g. ergometrine) in the third stage of labour by any route compared with no uterotonic agents, for the prevention of postpartum haemorrhage. Results indicated that the use of ergot alkaloids was associated with a significant decrease in mean blood loss, decreased postpartum haemorrhage of at

least 500ml, increased maternal haemoglobin concentration and decreased use of therapeutic uterotonic drugs. However, ergot alkaloids were also associated with significantly increased risk of high blood pressure and pain after birth requiring analgesia. The effect on risk of retained placenta was inconsistent and there were no differences between groups for vomiting, headache or eclamptic fit. Most of the studies (7/8) delivered the ergot alkaloid via the intravenous or intramuscular route.

An updated Cochrane review (82) used a network meta-analysis to compare the most effective uterotonic agents to prevent postpartum haemorrhage with the least side effects (196 studies, n = 135,559). Results indicated that carbetocin was significantly more effective than oxytocin in the prevention of postpartum haemorrhage, however when low quality trials were removed from the analysis the results showed carbetocin was comparable to oxytocin. Other uterotonic agents were found to be more clinically effective than oxytocin, these included: ergometrine (with and without oxytocin) and misoprostol with oxytocin. However, these agents were found to have significantly more side effects such as nausea, vomiting, hypertension, headache and shivering. Carbetocin and oxytocin each had the most favourable side effect profiles.

One RCT (83) (n = 29,645) compared the effectiveness of heat-stable carbetocin against oxytocin to prevent postpartum haemorrhage (CHAMPION trial). Both carbetocin and oxytocin were administered via intramuscular injections. Results indicated that heat-stable carbetocin was non-inferior to oxytocin for

the prevention of postpartum blood loss of at least 500ml but not for blood loss of at least 1000ml.

One RCT (84) (n = 200) examined the effect of prophylactic use of carboprost compared to oxytocin during active management. The intervention group received 125µg carboprost and were compared to a control group who received oxytocin (10 units). Results indicated that the carboprost group showed a significantly larger reduction in the duration of the third stage of labour and blood loss, compared to the oxytocin control. The only side effect reported with carboprost was diarrhoea.

One RCT (85) (n = 200) compared the efficacy of oral misoprostol with intramuscular oxytocin. Results indicated that there were no differences between groups for occurrence of postpartum haemorrhage and mean postpartum blood loss. Shivering, pyrexia and diarrhoea were all significantly more common in women receiving misoprostol.

One RCT (86) (n = 600) examined the optimum timing and route of oxytocin administration. Women were randomised into 4 groups: intravenous after delivery, intravenous after anterior shoulder seen, intramuscular after delivery and intramuscular when anterior shoulder seen. Results indicated that postpartum blood loss and need for additional uterogenics were similar across groups. However those receiving oxytocin intravenously after anterior shoulder was seen had a significantly shorter third stage of labour and changes in haemoglobin and haematocrit were significantly reduced.

One RCT (87) (n = 1075) compared intravenous oxytocin with intramuscular

oxytocin as part of active management in the third stage of labour. Results indicated that the incidence of severe postpartum haemorrhage (blood loss measured ≥1000 ml) was significantly lower in the intravenous group compared to the intramuscular group. Also, the need for blood transfusion and admission to a high dependency unit was significantly lower in the intravenous group. There were no differences between groups for rates of postpartum haemorrhage (measured blood loss ≥500 mL) or side effects.

Retained placenta

A Cochrane review (88) of 3 studies (n = 244) examined the effectiveness and safety of prostaglandins for the management of retained placenta. Results indicated that when compared to placebo, prostaglandins showed no significant impact on the following: rate of manual removal of the placenta, severe postpartum haemorrhage, need for blood transfusion, mean blood loss and mean time from injection to placental removal. All side effects were similar between groups, apart from shivering which was significantly more common with prostaglandin.

A Cochrane review (89) including 3 RCTs (n = 175) examined the effect of nitroglycerin as a tocolytic, either alone or in addition to uterotonics, in the management of retained placenta. Results suggest that nitroglycerin did not reduce the need for manual placenta removal or increase the incidence of severe postpartum haemorrhage.

Postpartum haemorrhage

Pharmacological management

A Cochrane review (90) of 10 studies (n = 4052) examined the effectiveness and safety of any intervention used for the treatment of primary postpartum haemorrhage. The authors noted that all of the trials included in the review were not adequately powered to assess the impact on postpartum haemorrhage. The results indicate that oxytocin may be more effective than misoprostol for the treatment of postpartum haemorrhage, with significantly fewer side effects. However, when used after prophylactic uterotonic drugs, there were no significant differences between groups when comparing misoprostol and oxytocin.

A Cochrane review (91) of 3 studies (n = 20,412) examined the effectiveness and safety of antifibrinolytic drugs (in this case, tranexamic acid) for treating primary postpartum haemorrhage. This review is an update of the Cochrane review about treatment for postpartum haemorrhage (90), however, both are included in this summary because the update only includes antifibrinolytic drugs (whereas the previous version includes any intervention). Results indicated that when compared to placebo or standard care alone, women receiving tranexamic acid had a significantly reduced risk of maternal death from bleeding, this effect was only found in women given treatment between 1-3 hours after birth (with no effect found after this time). Use of tranexamic acid was also found to be associated with the following outcomes: significantly fewer maternal deaths from all causes and reduced blood loss of more than 500ml. No effect was found on serious maternal morbidity, need for hysterectomy to

control bleeding or blood transfusion. In terms of adverse outcomes of tranexamic acid, there was a significant increase in the use of brace sutures but no indication of increased thromboembolic events.

One RCT (92) (n = 100) examined the effectiveness of carbetocin compared to oxytocin for the management of atonic postpartum haemorrhage. The intervention group received 100mg carbetocin and were compared to a control group who received oxytocin (dosage not reported). Results indicated that the amount of blood loss and the need for further uterotonic drugs was significantly lower in the carbetocin group. There was no significant difference between groups regarding incidence of major postpartum haemorrhage, the need for blood transfusion, or side effects including nausea, vomiting and shivering.

One RCT (93) (n = 150) examined the effect of tranexamic acid compared to placebo to reduce postpartum blood loss. Both groups received a prophylactic intramuscular injection of oxytocin. Results indicated that there were no significant differences between groups regarding blood loss in the first 2 hours.

Surgical or mechanical interventions

An RCT (94) (n = 66) examined the effectiveness of condom-loaded Foley's catheter compared to a Bakri Balloon to treat postpartum haemorrhage. Results indicated both interventions successfully stopped uterine bleeding, with no significant difference between groups. The time to stop the uterine bleeding was significantly shorter in the Bakri Balloon group. There were no significant differences between groups for maternal

complications, vital signs, urine output, haemoglobin and haematocrit levels.

Breastfeeding

A Cochrane review (95) of 4 trials (n = 4608) examined the effect of breastfeeding or nipple stimulation for reducing postpartum haemorrhage in the third stage of labour. Only 2 trials contributed to the analysis (n = 4472) and only one trial (n = 4385) reported on the primary outcomes of interest (severe postpartum haemorrhage ≥ 1000 mL, maternal death or severe morbidity). Results indicated that there were no significant differences between nipple stimulation and no treatment in relation to maternal death, the incidence of postpartum haemorrhage, blood loss in the third stage of labour, retained placenta, perinatal deaths or maternal readmission to hospital.

Intelligence gathering

Two ongoing trials were identified in this area which will be monitored and results assessed when published:

- The <u>IMox</u> trial: comparing syntocinon (oxytocin), syntometrine (oxytocin with ergometrine) and carbetocin for prevention of postpartum haemorrhage.
- The <u>HOLDS</u> trial: comparing high or low dose syntocinon® for delay in labour.

Impact statement

Active and physiological management of the third stage

Active versus physiological management

Results from an updated Cochrane review support the guideline by confirming that active management is associated with a

lower risk of postpartum haemorrhage of more than 1 litre (recommendation 1.14.7). However, there were some side effects of active management highlighted in the review that are not mentioned in the guideline, these being: increased maternal diastolic blood pressure, after-pains, use of analgesia from birth up to discharge from the labour ward and more women returning to hospital with bleeding. Recommendation 1.14.7 currently references nausea and vomiting but may need to be reviewed in light of the other side effects highlighted in the review.

New evidence identified that may change current recommendations.

Delayed cord clamping

New evidence was identified which supports the use of delayed cord clamping as part of active management. Collectively, the results suggested benefits to haematocrit levels and residual placental blood volume. There were mixed results around the effect on haemoglobin levels and no impact was seen on Apgar scores and labour duration. The new evidence is broadly in line with the guideline, which recommends delaying cord clamping 1 minute from the birth of the baby as part of active management of the third stage of labour (recommendation 1.14.14).

Evidence was also identified on whether gravity is required during the delay in cord clamping. Results from an RCT indicated that volume of placental transfusion were similar in babies that were given straight to the mother compared to being held at vagina level for 2-minutes (as is standard practice). The guideline does not currently make any recommendations on where the baby should be held during the delay in

cord clamping. Further advice was sought from topic experts on what is standard practice in the UK. Feedback suggests that both practices are used, however it was confirmed that holding the baby at vagina level was difficult and may result in low compliance of delayed cord clamping. It was agreed that recommendations in this area would be beneficial and that the guideline should be reviewed in light of the new evidence.

New evidence identified that may change current recommendations.

Controlled cord traction

Evidence was identified which suggests that controlled cord traction may reduce the overall incidence of postpartum haemorrhage, need for manual removal of the placenta and duration of the third stage of labour. Although no impact was found on incidence of severe postpartum haemorrhage, the need for blood transfusion or therapeutic uterotonics. This is in line with the guideline, which currently recommends controlled cord traction as part of active management (recommendation 1.14.15).

New evidence is unlikely to change guideline recommendations.

Uterotonics

Results from an updated Cochrane review suggest that compared to no utertonics, ergot alkaloids were associated with a significant decrease in mean blood loss, decreased postpartum haemorrhage of at least 500ml, increased maternal haemoglobin concentration and decreased use of therapeutic uterotonic drugs. The guideline currently recommends using

oxytocin to prevent postpartum haemorrhage as it is associated with fewer side effects than oxytocin plus ergometrine (an ergot alkaloid) (recommendation 1.14.13). However, it does recommend the use of ergometrine for both first and second-line treatment for postpartum haemorrhage (recommendations 1.14.32 and 1.14.33). The comparison tested in the review (ergot alkaloid versus no uterotonic) is therefore not applicable to the guideline and is unlikely to impact recommendations.

Further evidence was found in an updated Cochrane review comparing and ranking the effectiveness of different uterotonic drugs for the prevention of postpartum haemorrhage. When low quality trials were excluded, findings suggested that carbetocin was just as effective as oxytocin in the prevention of postpartum haemorrhage as well as having a similar favourable side-effect profile. Combinations containing ergometrine and misoprostol were found to have the worst side effect profile. This is partially in line with the guideline, which recommends using oxytocin without ergometrine due to side effects (recommendation 1.14.13). However, there are no recommendations on the use of carbetocin. The authors conclude that the evidence on carbetocin is uncertain and they highlight two trials which were ongoing at the time of publication. One of the trials, the CHAMPION trial has now published and the results have been considered in this surveillance review. The results from the CHAMPION trial indicate that carbetocin is non-inferior to oxytocin for prevention of blood loss of at least 500ml but not for blood loss of at least 1000ml. The other trial highlighted in the Cochrane review is

the <u>IMox</u> trial which is still ongoing and discussed above. Given the uncertainty around the effectiveness of carbetocin in comparison to oxytocin, we will wait for the results of the IMox trial to publish before assessing impact on guideline recommendations. As stated above, we are monitoring this trial and will assess the results as soon as they are available.

Evidence was also found comparing carboprost with oxytocin for active management, with results suggesting carboprost was associated with a significantly larger reduction in the duration of the third stage of labour and blood loss. Another trial compared oral misoprostol with intramuscular oxytocin, finding no difference between groups for postpartum haemorrhage but significantly more side effects with misoprostol. This is not fully in line with the guideline, which currently only recommends using oxytocin during active management (recommendation 1.14.13). Whilst there is evidence to suggest carboprost may be more effective than oxytocin during active management, more information is needed on the maternal outcomes and side effects before any impact on the guideline can be assessed. There is an ongoing trial in this area which may shed more light on which uterotonic drug is preferable for use as part of active management.

Evidence was identified on the optimal administration route for oxytocin as part of active management. One RCT comparing intramuscular with intravenous delivery found that intravenous oxytocin was associated with significantly lower rates of severe postpartum haemorrhage, the need for blood transfusion and admission to high dependence unit. Another trial found that intravenous oxytocin delivered after

the birth of the anterior shoulder resulted in a significantly shorter duration of labour, but did not affect postpartum blood loss. No differences in side effects were reported. The guideline currently recommends intramuscular administration of oxytocin with the birth of the anterior shoulder or immediately after the birth of the baby and before the cord is clamped and cut (recommendation 1.14.13). This is not supported by the new evidence which suggests that intravenous delivery of oxytocin may be more beneficial for maternal outcomes. This recommendation may need to be reviewed in light of the new evidence.

New evidence identified that may change current recommendations.

Retained placenta

Results from a Cochrane review indicated that prostaglandins were no different from placebo for the management of retained placenta. This is in line with the guideline, which does not have any recommendations on the use of prostaglandins for this condition.

Another Cochrane review focussed on the effect of nitroglycerin in the management of retained placenta. Results suggest that nitroglycerin did not reduce the need for manual placenta removal or increase the incidence of severe postpartum haemorrhage. This is in line with the guideline, which does not have any recommendations on the use of nitroglycerin for this condition.

New evidence is unlikely to change guideline recommendations.

Postpartum haemorrhage

Pharmacological management

Results from a Cochrane review indicated that there was no difference in outcomes when comparing misoprostol with oxytocin for treating postpartum haemorrhage. This is not fully consistent with the guideline, which currently only recommends the choice of either oxytocin, ergometrine or a combination of the two (recommendation 1.14.32) for first line treatment. However it is in line with the recommendation on second-line treatment, which states "No particular uterotonic drug can be recommended over any other" (recommendation 1.14.33). The authors point out that all of the included studies were underpowered to detect differences, so it is unlikely that there will be an impact on guideline recommendations.

Evidence was identified to suggest that carbetocin may be more effective than oxytocin in the management of atonic postpartum haemorrhage, with results showing significantly less blood loss and the need for further uterotonic drugs. There were no significant differences between groups for adverse events. The guideline does not currently have any recommendations on the use of carbetocin for the management of postpartum haemorrhage. Further studies are required to confirm these results before impact on the guideline can be assessed.

Another Cochrane review found that tranexamic acid given 1-3 hours after birth may be effective at reducing risk of maternal death from bleeding, maternal deaths from all causes and blood loss of more than 500ml. Currently the guideline only recommends tranexamic acid as

treatment for significant continuing postpartum haemorrhage (recommendation 1.14.34) rather than as first line treatment. The new evidence suggests that tranexamic acid is more effective when given as early as possible in the event of postpartum haemorrhage, which may need to be reflected in a change to the guideline recommendations.

New evidence identified that may change current recommendations.

Surgical or mechanical management

Evidence was identified comparing the effect of different mechanical techniques to manage postpartum haemorrhage. Both a condom-loaded Foley's catheter and Bakri Balloon were effective at stopping bleeding, with the balloon being significantly quicker. This is in line with the guideline which currently recommends considering a balloon tamponade before surgery (recommendation 1.14.36). Furthermore, both FIGO and the

International Confederation of Midwives have approved the balloon as one of the primary support tools in treating postpartum haemorrhage.

New evidence is unlikely to change guideline recommendations.

Breastfeeding

Findings from a Cochrane review suggest that there is insufficient evidence to test the effect of breastfeeding or nipple stimulation to treat postpartum haemorrhage. Results indicated that there were no significant differences between nipple stimulation and no difference in relation to maternal and neonatal outcomes. The guideline does not make any recommendations in this area and is therefore unlikely to be affected by the new evidence.

New evidence is unlikely to change guideline recommendations.

1.15 Care of the newborn baby

Initial assessment of the newborn baby and mother-baby bonding

Three RCTs were identified which examined the effect of skin-to-skin contact of mother and baby. The results of the trials were as follows:

 Breast feeding self-efficacy and rates of successful breastfeeding were significantly higher in women who undertook skin-to-skin contact with their baby immediately after birth, compared to routine care. Also, time to

- initiate breastfeeding was significantly shorter in the skin-to-skin group compared to routine care. (96) (n = 114)
- Suckling competence and number of babies being exclusively breastfed at 6 week follow-up was significantly higher in women who performed skin-to-skin contact with their babies immediately after birth, compared to a control. Skinto-skin contact was also associated with significantly higher maternal satisfaction rates, neonatal temperature gains, less weight loss at discharge and 6-week follow-up, and lesser morbidity. (97) (n = not stated)

The number of babies being exclusively breastfed at 6 week follow-up was significantly higher in women who performed skin-to-skin contact with their babies immediately after birth, compared to a control. The control group in this case had their babies placed under a radiant warmer for 45 minutes while the mother underwent management of the third stage of labour and episiotomy repair. Further results showed that maternal pain scores during the episiotomy repair were significantly lower in the skin-toskin group compared to the control. (98) (n = 200)

Care of babies in the presence of meconium

An RCT (99) (n = 175) examined the effect of endotracheal suction on the incidence of meconium aspiration syndrome and/or mortality on non-vigorous neonates born through meconium stained amniotic fluid. The comparator group received no endotracheal suction. Results indicated that there was no significant difference between groups for incidence of meconium aspiration syndrome or mortality.

Intelligence gathering

No intelligence was identified for this section of the guideline.

Impact statement

Initial assessment of the newborn baby and mother-baby bonding

Evidence was identified to support advising skin-to-skin contact of mother and baby immediately after birth. Results indicated skin-to-skin contact benefited breastfeeding outcomes, maternal satisfaction, neonatal temperature and weight gain outcomes and pain outcomes during episiotomy repair. This is in line with the guideline, which currently recommends encouraging the woman to have skin-to-skin contact with their babies as soon as possible after birth (recommendation 1.15.6)

Care of babies in the presence of meconium

Evidence was identified on the use of endotracheal suction for meconium aspiration syndrome. Results suggest that endotracheal suctioning was no different from the control group on outcomes of meconium aspiration syndrome incidence or mortality. The guideline does not currently recommend suctioning either before birth or if the baby has normal respiration (recommendation 1.15.19). It also recommends using nationally accredited guidance on suctioning in the presence of significant meconium (recommendation 1.15.20). The evidence is therefore broadly in line with the guideline.

New evidence is unlikely to change guideline recommendations.

1.16 Care of the woman after birth

Perineal care

Pain relief

An RCT (100) (n = 81) examined the effect of hydrocortisone cream to reduce perineal pain after vaginal birth. The intervention was compared to a placebo cream and a no treatment control. Results indicated that the women receiving hydrocortisone cream or placebo cream had significantly lower pain scores than the no treatment control.

An RCT (101)(n = 140) examined the effect of either Achillea millefolium or Hypericum perforatum ointment for episiotomy wound healing. Treatments were compared to a placebo ointment and a no treatment control. Results indicated that pain level, redness, edema and ecchymosis were significantly less in both ointment groups compared to controls. There were no differences between groups for discharge rates or dehiscence incidence.

Suturing

A systematic review (102) of 4 RCTs and 2 quasi-randomised trials (n = 2922) compared the effect of sutures, skin adhesives or non-suturing on pain and discomfort after second degree perineal tear or episiotomy. Results indicated that non-suturing and skin adhesives caused less pain than suturing in both the short-and long term and had fewer complaints, yet both methods are associated with an increased rate of skin separation.

Intelligence gathering

No intelligence was identified for this section of the guideline.

Impact statement

Perineal care

Pain relief

Evidence was identified on treatment for perineal pain and wound healing. One trial showed that hydrocortisone cream was no more effective than a placebo cream in reducing pain scores, however both creams were more effective than a no treatment comparison. Results from another trial indicated that ointments containing either Achillea millefolium or Hypericum perforatum were both more effective than no treatment in reducing pain and other related outcomes. The guideline currently recommends offering rectal non-steroidal anti-inflammatory drugs after perineal repair of first or second degree trauma (recommendation 1.16.21) however there are no recommendations on treatment for general perineal wound healing or pain relief. The extent of the perineal damage is not clear for the abstract of the studies, however it is unlikely that the evidence will impact the guideline as these treatments are not licenced for this use in the UK.

Suturing

Evidence was identified on the effectiveness of skin suturing compared with adhesives and non-suturing for repairing second degree perineal tears or episiotomy. Non-suturing and skin adhesives were found to cause less pain than suturing in both the short- and long term and had fewer complaints, yet both methods were associated with an increased rate of skin separation. Therefore the new evidence indicates that suturing led to significantly higher rates of

successful repair. This is consistent with the guideline, which recommends suturing for perineal repair (recommendations 1.16.16-1.16.22).

New evidence is unlikely to change guideline recommendations.

Areas not currently covered in the guideline

In surveillance, evidence was identified for areas not covered by the guideline. This new evidence has been considered for possible addition as a new section of the guideline.

Does the use of ultrasound reduce the risk of incorrect diagnosis of the fetal head position during instrumental delivery?

Surveillance decision

This section should not be added.

Use of ultrasound during instrumental delivery

2018 surveillance summary

An RCT (n = 514) (103) examined whether use of ultrasound at instrumental delivery reduced the risk of incorrect diagnosis of fetal head position. The ultrasound group also received clinical assessment and were compared to a usual care group who received clinical assessment only. Results indicated that rates of incorrect diagnosis of fetal head position was significantly lower in the ultrasound group, however there were no significant differences between groups in terms of maternal and neonatal complications, failed instrumental delivery and rates of caesarean sections.

Intelligence gathering

No intelligence was identified in this area.

Impact statement

Evidence was identified to suggest that use of ultrasound during instrumental delivery significantly improved diagnosis of head position. Ultrasound use during instrumental delivery is not currently covered in the guideline recommendations. However, as there were no impacts on other outcomes such as maternal or neonatal complications, failed instrumental delivery rates, or rates of caesarean sections it is unlikely that the guideline will be impacted.

New evidence is unlikely to impact on the guideline.

Does the routine use of antibiotic prophylaxis before or immediately after incision or repair of episiotomy or perineal tear prevent maternal infection and improve outcomes?

Surveillance decision

This section should not be added.

Use of routine antibiotic prophylaxis with episiotomy or perineal tears

2018 surveillance summary

Episiotomy

A Cochrane review (104) of 1 quasirandomised controlled trial (n = 73) examined whether routine antibiotic prophylaxis before or immediately after incision or repair of episiotomy prevents maternal infectious morbidities and improves outcomes. The intervention was compared to no prophylaxis or placebo. Results indicated that antibiotics had no impact on wound dehiscence with or without infection and no other infections were observed.

Perineal tears

A Cochrane review (105) of one study (n = 147) examined the effectiveness of antibiotic prophylaxis for reducing maternal morbidity and side effects in third- and fourth-degree perineal tear during vaginal birth. Results indicated that incidence of perineal wound complications were significantly lower in the antibiotic group compared to the control after 2

weeks however the authors state this finding should be interpreted with caution because loss to follow-up in this study was very high.

Intelligence gathering

No intelligence was identified in this area.

Impact statement

Two Cochrane reviews were identified which examined the use of prophylactic antibiotics for women with episiotomy or perineal tears. Prophylactic antibiotics were found to have no effect on wound dehiscence or infection rates for women with episiotomy. However they were found to reduce incidence of perineal wound complications in women with perineal tears. The authors note that loss to follow-up for this study was very high, which limits the conclusions that can be drawn from this review. Therefore it is unlikely that the new evidence will have an impact on the guideline, which currently makes no recommendations in this area.

New evidence is unlikely to impact on the guideline.

What is the effectiveness and safety of antibiotic prophylaxis in reducing infectious puerperal morbidities in women undergoing operative vaginal deliveries?

Surveillance decision

This section should not be added.

Prophylactic antibiotics for operative vaginal delivery

2018 surveillance summary

A Cochrane review (106) of 1 study (n = 393) examined the effectiveness and safety of antibiotic prophylaxis in reducing infectious puerperal morbidities in women undergoing operative vaginal deliveries including vacuum or forceps deliveries, or both. Results indicated that prophylactic antibiotics had no significant effect on rates of endomyometritis or length of hospital stay.

Intelligence gathering

No intelligence was identified in this area.

Impact statement

Results from a Cochrane review indicate that prophylactic antibiotics were found to have no effect on rates of endomyometritis or length of hospital stay in women undergoing operative vaginal deliveries. Given this lack of effect, it is unlikely that the new evidence will impact the guideline, which currently makes no recommendations in this area.

New evidence is unlikely to impact on the guideline.

Is the use of fundal pressure effective in achieving spontaneous vaginal birth in the second stage of labour?

Surveillance decision

This section should not be added.

Fundal pressure

2018 surveillance summary

A Cochrane review (107) of 9 studies (n = 891) examined whether fundal pressure is

effective in achieving spontaneous vaginal birth, and preventing prolonged second stage or the need for operative birth. The review considered manual fundal pressure and fundal pressure by an inflatable belt separately. Results indicated that when compared to no pressure, manual pressure was not associated with any changes in spontaneous vaginal birth, caesarean births, instrumental births, operative births, duration of the second stage of labour or Apgar scores less than 7 at 5 minutes. However, cervical tears were significantly more frequent with manual pressure compared to no pressure.

Compared to no pressure, fundal pressure by the inflatable belt did not appear to have an impact on instrumental births, operative births, caesarean sections or Apgar scores. The duration of second stage of labour was significantly shorter with inflatable belt, however 3rd degree perineal tears were higher in this group.

Intelligence gathering

No intelligence was identified in this area.

Impact statement

Results from a Cochrane review suggest that manual pressure showed no benefit on outcomes compared to no pressure at all. Fundal pressure was also found to have little benefit, although results did suggest that the duration of the second stage of labour was significantly shorter. In terms of adverse events, cervical tears were more common with manual pressure and perineal tears were more common in with fundal pressure. Given the lack of effect of these interventions and taking into account the adverse events, it is unlikely that there will be an impact on the guideline, which currently makes no recommendations in this area.

New evidence is unlikely to impact on the guideline.

Is tranexamic acid effective and safe for preventing postpartum haemorrhage?

Surveillance decision

This section should not be added.

Tranexamic acid for the prevention of postpartum haemorrhage

2018 surveillance summary

A Cochrane review (108) of 12 studies (n = 3285) examined whether tranexamic acid is effective and safe for preventing postpartum haemorrhage in comparison to placebo or no treatment (with or without uterotonic co-treatment), or to uterotonic agents. For the purposes of this

surveillance review, only the results from women not undergoing elective caesarean section are considered (3 trials, n = 832). Results indicated that tranexamic acid was associated with a significant decrease in the incidence of blood loss greater than 500ml or 400ml. Also, mean blood loss (from delivery until 2 hours postpartum) was significantly lower in women who received tranexamic acid compared to placebo or no intervention. There was no effect of the intervention on the incidence

of blood loss greater than 1000ml. The following side effects were significantly more common for women receiving tranexamic acid: nausea, vomiting, dizziness. The effect of tranexamic acid on maternal mortality, severe morbidity and thromboembolic events is uncertain due to the low quality of the evidence.

Intelligence gathering

An ongoing trial was identified in this area, the <u>WOMAN2</u> trial. This trial is examining the effect of tranexamic acid for the prevention of postpartum bleeding in women with anaemia.

Impact statement

A Cochrane review was identified which examined the effect of tranexamic acid on the prevention of postpartum haemorrhage. This has a different objective to the previously mentioned Cochrane review (91) which focussed on the effect of tranexamic acid for the management of existing postpartum haemorrhage. The results suggest that tranexamic acid may reduce blood loss up to a point, but not for levels over 1000ml. Nausea, vomiting and dizziness were also reported as side effects. Given the uncertainty around the effect of tranexamic acid on maternal mortality, severe morbidity and thromboembolic events, it is unlikely that any changes will be made to the guideline at this point. However, the ongoing WOMAN2 trial in this area is being monitored and this area will be reviewed again once the results are available.

New evidence is unlikely to impact on the guideline.

Research recommendations

What are the clinical and cost effectiveness of midwifery-led continuity of care compared with standard care in the UK for healthy pregnant women, their babies and healthcare professionals throughout the antenatal, intrapartum and postnatal periods?

Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified. However, continuity of care in maternity services is now a national policy in the UK following on from the <u>National Maternity Review</u> report <u>Better Births</u> and the subsequent Maternity Transformation Programme. It is no longer necessary to have a research recommendation in this area.

Surveillance decision

This research recommendation should be stood down.

How does the provision of accurate, evidence-based information affect women's decision-making processes and choice of place of birth?

Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

What are the long-term consequences for women and babies of planning birth in different settings?

Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

Does enhanced education specifically about the latent first stage of labour increase the number of nulliparous women who wait until they are in established labour before attending the obstetric or midwifery unit (or calling the midwife to a home birth), compared with women who do not receive this education?

Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

What is the most effective treatment for primary postpartum haemorrhage?

Summary of findings

<u>New evidence</u> was found to be related to this research recommendation however none of the studies fully address the question.

Results from a Cochrane review (91) indicated that there was no difference in outcomes when comparing misoprostol with oxytocin for treating postpartum haemorrhage. The authors point out that all of the included studies were underpowered to detect differences, so it is unlikely that there will be an impact on guideline recommendations.

Evidence was identified to suggest that carbetocin may be more effective than oxytocin in the management of atonic postpartum haemorrhage, with results showing significantly less blood loss and the need for further uterotonic drugs (93). There were no significant differences between groups for adverse events. The guideline does not currently have any recommendations on the use of carbetocin for the management of postpartum haemorrhage. Further studies are required to confirm these results before impact on the guideline can be assessed.

Another Cochrane review (92) found that tranexamic acid given 1-3 hours after birth may be effective at reducing risk of maternal death from bleeding, maternal deaths from all causes and blood loss of more than 500ml. Currently the guideline only recommends tranexamic acid as treatment for significant continuing postpartum haemorrhage (recommendation 1.14.34) rather than as first line treatment. The new evidence suggests that tranexamic acid is more effective when given as early as possible in the event of postpartum haemorrhage, which may need to be reflected in a change to the guideline recommendations.

Surgical or mechanical management

Evidence was identified comparing the effect of different mechanical techniques to manage postpartum haemorrhage (95). Both a condom-loaded Foley's catheter and Bakri Balloon were effective at stopping bleeding, with the balloon being significantly quicker. This is in line with the guideline and other international guidelines that recommend the balloon as one of the primary support tools in treating postpartum haemorrhage.

Breastfeeding

Findings from a Cochrane review (96) suggest that there is insufficient evidence to test the effect of breastfeeding or nipple stimulation to treat postpartum haemorrhage. Results indicated that there were no significant differences between nipple stimulation and no treatment in relation to maternal and neonatal outcomes. The guideline does not make any recommendations in this area and is therefore unlikely to be affected by the new evidence.

Surveillance decision

This research recommendation will be considered again at the next surveillance point unless a new research recommendation is made as part of the update process.

What is the clinical and cost effectiveness of intermittent auscultation versus continuous cardiotocography in otherwise low risk pregnancies complicated by meconium stained liquor?

Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

What is the clinical and cost effectiveness of fetal blood sampling during labour using pH testing or lactate testing or both?

Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

Surveillance decision

This research recommendation will be considered again at the next surveillance point.

Editorial amendments

During surveillance of the guideline we identified the following points in the guideline that should be amended.

- The final bullet point in recommendation 1.10.15 which reads "above 180 beats/minute" needs to be aligned with the previous bullet point as it is currently out of sync.
- Research recommendation 1 on <u>models of midwifery-led care</u> should be stood down. Continuity of care in maternity services is now a national policy in the UK following on

from the <u>National Maternity Review</u> report <u>Better Births</u> and the subsequent <u>Maternity Transformation Programme</u>. It is no longer necessary to have a research recommendation in this area.

 An amendment to tables 10 and 11 in the section on monitoring during labour is required. Feedback from topic experts and stakeholders indicated that the table contents are difficult to interpret and may be causing errors in practice. They advised that the tables provided in other national guidance are more user-friendly. In light of these concerns and to reduce the risk of CTG misinterpretation, we will amend the tables accordingly.

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