Caesarean birth – Diamorphine for spinal analgesia

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British National Formulary publications	Guideline	002	It would be helpful to include that alternative analgesia options (morphine, fentanyl) are off-label, as this is already stated for diamorphine.	Thank you for your comment. As you have stated, fentanyl is not approved for neuraxial administration and so this has been added to the advice on off-label use. Preservative-free morphine is a licensed product (available from licensed specials manufacturers) and so has not been included in the off-label warning text.
Chelsea and Westminster Hospital NHS Foundation Trust	Guideline	General	Intrathecal diamorphine is used as the opiate of choice for spinal anaesthetics as it offers good intra-operative and post-operative analgesia with a minimal risk of post-operative respiratory depression.	Thank you for your comment, which agrees with our recommendations.
Chelsea and Westminster Hospital NHS Foundation Trust	Guideline	General	Where possible, intrathecal diamorphine should be delivered from pre-filled syringes, prepared in a sterile pharmacy production unit. This improves patient safety by reducing the risk of drug error. It minimises drug wastage compared with the 97% or 92% of drug that is currently wasted when prepared from 10 mg or 5 mg diamorphine ampoules which is important in the face of drug shortages	Thank you for your comment. The committee agreed that pre-filled syringes would reduce wastage of diamorphine, but this level of detail would not be included in NICE guidelines and method of obtaining and preparing the intrathecal injection would be a matter for local implementation.
Chelsea and Westminster Hospital NHS	Guideline	General	If there is no diamorphine available in the form of pre-filled syringes or ampoules, a combination of intrathecal fentanyl and	Thank you for your comment, which agrees with our recommendations.

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Foundation Trust			preservative free-morphine can be used as an alternative. This is associated with a higher level of post-operative nausea and vomiting than diamorphine.	
NHS England	Guideline	General	No *specific* comments to add, however we wish to make these general comments I was going to however ask about general guidelines for post-natal care and mental health in the primary care setting:	Thank you for your comment. As your comment does not relate to the recommendations being consulted on and does not seem to require any action relating to the use of morphine as an alternative to diamorphine, no changes to the recommendations have been made.
NHS England	Guideline	General	At the moment Midwives do the bulk of step-down contact after C sections and then handover to the health visitors.	Thank you for your comment. As your comment does not relate to the recommendations being consulted on and does not seem to require any action relating to the use of morphine as an alternative to diamorphine, no changes to the recommendations have been made.
NHS England	Guideline	General	GPs will do the new baby checks at 6-8 weeks.	Thank you for your comment. As your comment does not relate to the recommendations being consulted on and does not seem to require any action relating to the use of morphine as an alternative to diamorphine, no changes to the recommendations have been made.
NHS England	Guideline	General	Currently we would note whether the women had a vaginal delivery, assisted vaginal delivery or C section (planned or emergency).	Thank you for your comment. As your comment does not relate to the recommendations being consulted on and does not seem to require any action relating to the use of morphine as an

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				alternative to diamorphine, no changes to the recommendations have been made.
NHS England	Guideline	General	We should also be aware that where there has been intervention in delivery-especially if there is an emergency situation, the risk of psychological illness/maternal bonding is greater and have a low threshold for referral into psychological services.	Thank you for your comment. As your comment does not relate to the recommendations being consulted on and does not seem to require any action relating to the use of morphine as an alternative to diamorphine, no changes to the recommendations have been made.
NHS England	Guideline	General	I note that even elective C sections due to maternal choice have a higher risk of psychological ill health (affects bonding etc) and wonder how much awareness there is in primary care to that effect?	Thank you for your comment. As your comment does not relate to the recommendations being consulted on and does not seem to require any action relating to the use of morphine as an alternative to diamorphine, no changes to the recommendations have been made.
NHS England	Guideline	General	I also note that there are aspirations in the LTP (long term plan) to address perinatal mental health but wondered if this includes the risk of even 'normal' planned surgical birth?	Thank you for your comment. As your comment does not relate to the recommendations being consulted on and does not seem to require any action relating to the use of morphine as an alternative to diamorphine, no changes to the recommendations have been made.
NHS England	Guideline	General	Sorry, this might not be your call to answer but as non emergency surgical birth does increase the risk of maternal MH then perhaps there should be a greater awareness and ease of access to psychological therapies.	Thank you for your comment. As your comment does not relate to the recommendations being consulted on and does not seem to require any action relating to the use of morphine as an alternative to diamorphine, no changes to the recommendations have been made.

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NHS England	Guideline	General	We strongly suggest making reference to reasonable adjustments throughout the guideline: This is a legal requirement as stated in the Equality Act 2010 and is important to help you make the right diagnostic and treatment decisions for an individual. You can ask the person and their carer or family member what reasonable adjustments should be made. Adjustments aim to remove barriers, do things in a different way, or to provide something additional to enable a person to receive the assessment and treatment they need.	Thank you for your comment. Making reasonable adjustments as required by the Equality Act is a statutory requirement and so this requirement would not be repeated in each individual NICE guideline.
NHS England	Guideline	General	We strongly reference to the importance of communication. Staff should communicate with and try to understand the person they are caring for. Check with the person themselves, their family member or carer or their hospital or communication passport for the best way to achieve this. Use simple, clear language, avoiding medical terms and 'jargon' wherever possible. Some people may be non-verbal and unable to tell you how they feel. Pictures may be a useful way of communicating with some people, but not all.	Thank you for your comment. We agree that women need to be communicated with in an appropriate way and given information in an appropriate format and this detail is already included in the separate sections of the caesarean birth guideline called 'provision of information' and 'shared decision making'. Further detail on communication and treating people as individuals is covered in the NICE guideline on Patient experience in adult NHS services: improving the experience of care for people using adult NHS services, and so this

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				information is not repeated in all other NICE guidelines.
NHS England	Guideline	General	We strongly suggest reference to the consideration for existing multidisciplinary input into the care of the person. Consideration should also be given to the role of an organisation's learning disability team or liaison nurse on issues of communication, reasonable adjustments, pain assessment etc	Thank you for your comment. We agree that women need to be communicated with in an appropriate way, cared for by the appropriate multidisciplinary team and given information in an appropriate format and this detail is already included in the separate sections of the caesarean birth guideline called 'provision of information' and 'shared decision making'. Further detail on communication and treating people as individuals is covered in the NICE guideline on Patient experience in adult NHS services: improving the experience of care for people using adult NHS services, and so this information is not repeated in all other NICE guidelines.
NHS England	Guideline	004	The impact of change for bullet 4 – existing recommendation 1.6.5 notes that the revised recommendations may increase the number of people being assessed as being at risk of respiratory depression. We strongly suggest it is made clear that some people with a learning disability and autistic people may not report respiratory symptoms as quickly (or at all), therefore extra support and monitoring	Thank you for your comment. This recommendation relates to the regular monitoring of people by assessing their oxygen saturation, respiratory rate and sedation, so it will not require people to report respiratory symptoms. The committee noted that the 2021 LeDeR report relates to deaths in general and so does not reflect this situation after a caesarean birth where there is specific intensive

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			should be considered and made for this group of people. Data from the 2021 LeDeR report evidences this point: - 17% of avoidable deaths were linked to respiratory conditions	monitoring of respiratory status in an acute care setting.
NHS England	Guideline	007	The monitoring frequency is based on recommendations from SOAP, an American organisation. Whilst recognised in the 'Impact of Change' section, I don't think NHS maternity units will have the capacity to perform hourly observations for 12 hours, followed by a set of observations once every 2 hours for the next 12. This would lead to 18 sets of observations over a 24 hour period, which would be disruptive to the new mother and staff workload. The impact change notes that 'the level of monitoring would require the woman or person who has given birth to stay on a high dependency ward'. High dependency postnatal wards are not widely available, and would be unlikely to have capacity for all women with BMI > 40 having a Caesarean section during a period of diamorphine shortage. The expected	Thank you for your comment. The additional monitoring for people receiving neuraxial morphine after caesarean birth has been amended to make it similar to the monitoring already recommended for diamorphine, except in cases where clinical assessment suggests ongoing or additional monitoring of respiratory status is needed. This will greatly reduce the resource impact of these recommendations. The committee agreed that the important point about monitoring was that it was done by an appropriate person who could then intervene or flag deviations from expected parameters, and not the location of the monitoring and so they have removed the reference to a high dependency ward. The resource impact section has therefore been amended to state this.

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			monitoring intervals therefore may need to be revised, if they are unlikely to work in practice?	
NHS England	Guideline	012	The Spinal diamorphine looks fine to me. The only bit that seems strange to me is recommendation 12 (1.6.12) where the first line recommendation is for PCA morphine. I'm not sure what the evidence is for this rather than oral morphine.	Thank you for your comment. Many of the women in whom the guideline suggests that PCA should be 'considered' will not have had neuraxial opioids and may benefit from PCA (and control of their own opioid analgesia) before step-down to oral morphine. Oral morphine is already suggested as a pain relief option for women with less severe pain or if PCA is not acceptable. In addition, oral morphine is advised for post-operative pain relief for all women or people who have given birth in subsequent recommendations (which were not included as part of this update and so are not included in the table).
NHS Fife	Guideline	001	Change 1 - fully agree with	Thank you for your comment.
NHS Fife	Guideline	002	Change 2 - agree in principal and our local audit work suggests that the addition of fentanyl with intrathecal morphine is important at reducing intraoperative discomfort in elective sections, however it should be noted that adding a third agent into the intrathecal bolus may increase the risk of drug/dosing errors and slightly increase	Thank you for your comment. We agree that increasing the number of drugs may increase the risk of errors. However, fentanyl is an important component to ensure the rapid onset of adequate analgesia and drawing up this drug does not significantly increase the preparation time. The committee agreed that the use of fentanyl is particularly important in situations

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			preparation time. During the previous 2 diamorphine shortages we have highlighted this to staff and advised that in 'quick' spinal for an emergency section fentanyl can be omitted without significant impact on surgical anaesthesia.	where a 'quick' spinal is to be used (for example in a category 1 caesarean birth) when it is necessary to start the procedure urgently. Therefore the recommendations have not been amended to advise that the fentanyl could be omitted.
NHS Fife	Guideline	007	Change 7 - I do not think it is necessary to specify the morphine doses again as to the pedant this 'intrathecal morphine (up to 0.1 mg) or epidural morphine (up to 3 mg) for caesarean birth' reads that if (for whatever reason and I appreciate this would be against earlier guidance) a woman was given more than 0.1mg/or 3mg epidurally the advice does not apply. I'm also not convinced about the resource implication of these women having to be on a high dependency ward. Surely they need to be in a location that can facilitate 2 hourly observations and intervene appropriately.	Thank you for your comment. The committee agree that the doses do not need to be repeated here and so have removed them from the recommendations, so they are consistent with the monitoring recommendations for diamorphine. The committee agreed that the important point about monitoring was that it was done by an appropriate person who could then intervene or flag deviations from expected parameters. The resource impact section has therefore been amended to state this.
NHS Fife	Guideline	012	Change 12 - might be worth specifying 'de novo' general anaesthesia as this group are likely to be different to those who are converted to general anaesthesia intraoperatively. I would be firmer in this	Thank you for your comment. The committee discussed that there are many reasons why conversion to a general anaesthetic may be required intra-operatively, and that this represents a very heterogeneous group. Some of the women in this group who started out with

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			recommendation and say 'offer intravenous PCA morphine' to this group.	neuraxial anaesthesia may benefit as much from intravenous PCA post-operatively as those who had 'de-novo' general anaesthesia. For this reason, the committee did not change this part of the recommendation. The committee agreed that 'consider' was a more appropriate word to use than 'offer', as conversely, some women who had a neuraxial block at the outset may not need a PCA.
Obstetric Anaesthetists' Association	Guideline	001	1.6.9a We support not providing a dose range, and the dosages, as currently stated, are too definitive. Please consider softening the language here to allow for professional judgment to be exercised, e.g. 0.3mg is a recommended or suggested dosage for intrathecal diamorphine for analgesia after a caesarean birth. This comment applies everywhere dosages are given, not just to row 1.	Thank you for your comment. The doses were chosen to balance the effectiveness and side-effects for neuraxial opioids and were the doses recommended by the Obstetric Anaesthetists' Association. However, in order to allow clinicians some flexibility we have amended the recommendations to say 'up to 300 micrograms' and 'up to 3 mg'.
Obstetric Anaesthetists' Association	Guideline	002	1.6.9b We support the recommended alternatives to diamorphine (fentanyl and morphine), but please see comment 1 about dosages.	Thank you for your comment. As with the doses of diamorphine, the doses of morphine and fentanyl were chosen to balance the effectiveness and side-effects for neuraxial opioids and were the doses recommended by the Obstetric Anaesthetists' Association.

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				However, in order to allow clinicians some flexibility, we have amended the recommendations to say 'up to' before all the suggested doses.
Obstetric Anaesthetists' Association	Guideline	003	1.6.4 No comments - agree	Thank you for your comment.
Obstetric Anaesthetists' Association	Guideline	004	1.6.5 We support the recommended actions here, but please remove the specific examples (e.g. BMI). It would be sufficient to say 'who have known risk factors for respiratory depression.' The examples may lead to people overlooking risk factors not mentioned, and we are particularly concerned about listing class 3 obesity as this may place an unnecessary burden on maternity units. This comment applies everywhere to examples of known risk factors for respiratory depression are given, not just to row 4.	Thank you for your comment. The committee has removed the list of examples of high risk groups from all the relevant recommendations to encourage healthcare professionals to consider all possible risk factors. However, in order to provide some guidance for those who find examples useful, the risk factors have been described in the rationale sections.
Obstetric Anaesthetists' Association	Guideline	005	1.6.6 We support drawing attention to this limitation of some pulse oximeters.	Thank you for your comment.
Obstetric Anaesthetists' Association	Guideline	006	1.6.7 We do not think the statement about neuraxial morphine in this recommendation is accurate. We would support replacing 'is' and	Thank you for your comment. The committee agreed that this statement is based on pharmacokinetics and data from the Sharawi

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			'will be' with 'may be' in this recommendation but would ask NICE to ensure that the evidence supports the final wording. From the rationale, the committee appears to be arguing from pharmacokinetic properties alone. If so, we would suggest looking at a relevant study (Sharawi 2018), which states: 'The physicochemical and pharmacokinetic properties of morphine suggest that intrathecal morphine may confer a higher risk of delayed respiratory depression secondary to rostral spread within the CSF compared with diamorphine. However, this increased risk has not been confirmed clinically, and the actual risk of respiratory depression of either drug, administered at clinically recommended doses, is extremely small. A systematic review reported that the incidence of clinically significant respiratory depression (defined as the requirement for an intervention, such as airway intervention, oxygen therapy, pharmacological therapy, or more than verbal stimuli to rouse the patient), with contemporary doses of neuraxial morphine or diamorphine, was 1.08–1.63 per 10 000	2018 paper but agreed to soften it to 'may be' as you suggest. The committee noted that the Closed Claims Analysis was not included in the Sharawi 2018 systematic review as it did not meet the inclusion criteria, and was merely mentioned in the paper as a secondary analysis, while the results of the systematic review itself found: '11 patients had definite CSRD, with a rate of 5.96 per 10,000 (95% CI, 2.23–11.28). All instances of CSRD involved the administration of neuraxial morphine; there were no CSRD events involving neuraxial diamorphine. Of these reports, 3 cases (definite and probable/possible CSRD) involved contemporary doses of neuraxial morphine that represents modern anesthesia practice, with a prevalence of 1.63 per 10,000 (95% CI, 0.62–8.77).63,84 There were 2 events of definite CSRD with a prevalence of 1.08 per 10,000 (95% CI, 0.24–7.22).84 There were no reported events of CSRD with contemporary doses of neuraxial diamorphine.'

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			women. The vast majority of studies included in the analysis of this review involved neuraxial morphine administration (63 out of the 78 included studies). Additionally, the ASA Closed Claims Project database found no cases related to intrathecal morphine after Caesarean delivery in the past two decades, despite the majority of practices in the USA using intrathecal morphine for Caesarean delivery, which impacts 1.3 million women per year within the USA.'	Based on this information the committee did not change this recommendation.
Obstetric Anaesthetists' Association	Guideline	007	1.6.8 We think the action recommended here is unnecessarily onerous. The same monitoring actions should apply in women who have had intrathecal or epidural ***morphine*** and have known risk factors as in women who have had intrathecal or epidural ***diamorphine*** and have known risk factors, i.e. hourly monitoring for at least 12 hours and then routine postnatal observations in accordance with local protocols. See row 4.	Thank you for your comments. The additional monitoring for people receiving neuraxial morphine after caesarean birth has been amended to make it similar to the monitoring already recommended for diamorphine, except in cases where clinical assessment suggests ongoing or additional monitoring of respiratory status is needed. This will greatly reduce the resource impact of these recommendations.
Obstetric Anaesthetists' Association	Guideline	008	1.6.9 We support this recommendation.	Thank you for your comment.

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Obstetric Anaesthetists' Association	Guideline	009	1.6.10 As with women with known risk factors, this recommendation is unnecessarily onerous. The same monitoring actions should apply in women who have had intrathecal or epidural ***morphine*** and ***do not have known risk factors*** as in women who have had intrathecal or epidural ***diamorphine and do not have known risk factors***, i.e. carry out routine postnatal observations in accordance with local protocols. See row 8.	Thank you for your comment. The additional monitoring for people receiving neuraxial morphine after caesarean birth has been amended to make it similar to the monitoring already recommended for diamorphine, except in cases where clinical assessment suggests ongoing or additional monitoring of respiratory status is needed. This will greatly reduce the resource impact of these recommendations.
Obstetric Anaesthetists' Association	Guideline	012 & 013	1.6.11, 1.6.12 and deletions to previous recommendations. We support these changes and recommendations.	Thank you for your comment.
Royal College of Anaesthetists	Guideline	General	The recommendations in this draft NICE guideline have very significant staffing implications. For many units hourly or 2 hourly observations could only be carried out on labour ward. Few postnatal units would be able to carry out this frequency of observations for the prolonged periods proposed. The guideline suggests that high risk women receiving diamorphine should have observations hourly for 12 hours. High risk	Thank you for your comment. The additional monitoring for people receiving neuraxial morphine after caesarean birth has been amended to make it similar to the monitoring already recommended for diamorphine, except in cases where clinical assessment suggests ongoing or additional monitoring of respiratory status is needed. This will greatly reduce the resource impact of these recommendations.

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			women receiving morphine should have hourly Obs for 12 hours then 2hourly Obs for 12 hours. Low risk women receiving morphine should have 2 hourly Obs for 12 hours. ALL women having C section should receive neuraxial opiates. The CS rate in the UK is soaring - 40%+ in many units: This represents a huge amount of work and the resource implications are not properly acknowledged in the document.	
Royal College of Anaesthetists	Guideline	General	The safety implications of using morphine especially in units used to diamorphine need more emphasis. When preservative containing and preservative free morphine are stored in the controlled drug cupboard, the risk of using the wrong one is significant. Ideally only one formulation should be kept. Since only preservative free can be used for neuraxial use, this is the formulation that should be used - but it is much more expensive than the preservative containing one that can only be used for systemic use.	Thank you for your comment. The committee agreed that it was important to highlight the fact that only preservative-free morphine should be administered via the neuraxial route and added an additional recommendation to state this.
Royal College of Anaesthetists	Guideline	001	In regards to the dose of diamorphine; 250mcg intrathecally or 2.5mg epidurals is widely used: where is the evidence to suggest 300mcg or 3mg should be used	Thank you for your comment. The doses were chosen to balance the effectiveness and side-effects for neuraxial opioids and were the doses recommended by the Obstetric Anaesthetists'

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			when increased doses are associated with more side effects?	Association. However, in order to allow clinicians some flexibility we have amended the recommendations to say 'up to 300 micrograms' and 'up to 3 mg'.
Royal College of Anaesthetists	Guideline	004	We do not think the consensus group have shown sufficient evidence that hourly monitoring for 12 hours is needed after IT diamorphine even in the high risk group. Those who are well and have had an uncomplicated caesarean section will go back to the ward after 2 hours and this level of monitoring will be impractical. Those who have complications will remain in high dependency areas or on the delivery suite so will have this level of monitoring	Thank you for your comment. This recommendation for monitoring after neuraxial diamorphine has been in place since 2021 so this is not a change in practice. The committee agreed that this level of monitoring (which can be carried out in recovery, high dependency areas, on the delivery suite or a postnatal ward) could be carried out by a healthcare assistant or maternity support worker. This recommendation has not therefore been amended.
Royal College of Anaesthetists	Guideline	007	We do not think there is sufficient evidence to suggest the level of monitoring described by the SOAP consensus group. (same comments as above)	Thank you for your comment. The additional monitoring for people receiving neuraxial morphine after caesarean birth has been amended to make it similar to the monitoring already recommended for diamorphine, except in cases where clinical assessment suggests ongoing or additional monitoring of respiratory status is needed. This will greatly reduce the resource impact of these recommendations.

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Royal College of Anaesthetists	Guideline	012	As above we do not think there is sufficient evidence to increase monitoring to this level for women with no known risk factors- a	Thank you for your comment. Line 12 relates to patient-controlled analgesia but we think this comment may relate instead to line 9. The additional monitoring for people receiving neuraxial morphine after caesarean birth has been amended to make it similar to the monitoring already recommended for diamorphine, except in cases where clinical assessment suggests ongoing or additional monitoring of respiratory status is needed. This will greatly reduce the resource impact of these recommendations.
UK Drugs in Lactation Advisory Service	Guideline	General	One of the challenges may be deciding whether it is ok to breastfeed if diamorphine has been given. Finding this information quickly may be difficult to come by. It would be really helpful to include a signpost to diamorphine use and breastfeeding and the considerations which also need to be given around infant monitoring. The UK Drugs in Lactation Advisory Service has provided such guidance via the SPS website: Using strong opioid analgesics during breastfeeding – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice	Thank you for your comment. The guidance to which you have included a link relates to the use of opioids as pain relief after birth. Advice about breastfeeding and the use of opioids is already covered in the subsequent recommendations in the guideline (which were not included as part of this update and so are not included in the table). The committee discussed whether the use of neuraxial opioids would lead to any concerns about breastfeeding but agreed that as the neuraxial opioids will be given at the time of caesarean birth and not for a prolonged period afterwards there would be no concerns about

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				women starting to breastfeed as soon as they are able to.