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BNF Publications	Guideline	006	003	In the footnote to table 12 it is not clear if the repeat dose of ergometrine or oxytocin plus ergometrine refers just to a second dose for treatment of PPH, (ie. instead of the drug recommended in column 3 of table 12), or if a repeat dose may be given when oxytocin plus ergometrine was given in the third stage of labour as prophylaxis? Can you confirm that there is a maximum of 2 doses of ergometrine or ergometrine with oxytocin (e.g. maximum total of 1 mg ergometrine) across the 2 indications: active management of 3rd stage and PPH? For women who received oxytocin plus ergometrine in the third stage of labour for prophylaxis, what would be used first line for treatment of PPH if carboprost is not available? And what would then be given as second line?	Thank you for your comment. The wording in the footnote ('a repeat dose of ergometrine or the combination of oxytocin and ergometrine may be given if other medicines are not available…') to table 12 is in line with the wording used in the SPCs. This indicates the administration of a 2nd dose of ergometrine or syntometrine. There is no situation in the table where 3 doses of syntometrine or ergometrine would be administered; where no uterotonic is used as prophylaxis there could be 2 doses of syntometrine used as first-line treatment; where oxytocin alone is used as prophylaxis there could be 2 doses of ergometrine used as first-line treatment; where syntometrine is used as prophylaxis there is no option to use this as treatment (so a repeat dose could be used as prophylaxis); and where carbetocin is used as prophylaxis there is the option to have up to 2 doses of ergometrine as 1st line treatment.

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					With respect to your point about people who have had Syntometrine in the 3rd stage of labour, if carboprost is not available, then oxytocin infusion could be given; if administration of oxytocin is not possible, then a repeat dose of Syntometrine could be given and urgent transfer arranged to a place where IM carboprost, oxytocin or misoprostol are available.
British Intrapartum Care Society	Evidence Review Update to NG235 recommendations	018 5 & 6	015-021 Table 12	The committee reviewed the evidence for the use of misoprostol for PPH treatment, but we disagree with their conclusions. The committee notes that there is a high-quality placebo-controlled RCT of 1422 women (Widmer 2010) who all received oxytocin prophylaxis and treatment, and then were randomised to additional sublingual misoprostol 600mcg or placebo. This found no effect on blood loss, but 65% had shivering and 43% a pyrexia over 38ºC. This would be the situation for most women suffering from a PPH in the UK setting. When directly compared to oxytocin for primary PPH treatment in two placebo-controlled RCTs (Blum 2010, Winikoff 2010), misoprostol was found to be less effective than oxytocin in women with a physiological third stage (Winikoff 2010). This mirrors the evidence on misoprostol versus oxytocin for	Thank you for your comment. The recommendation to offer misoprostol as an option for treatment of PPH is unchanged from the previous guideline. The committee were aware of the limitations of the evidence, but agreed it should remain as an option for treatment of PPH, given that it showed some evidence of benefit and given its route of administration was sublingual or rectally it may be of particular use in home-birth or midwife-led settings. The committee noted that there are side effects with using misoprostol, but considered, in their knowledge and experience, when treating PPH, these would be outweighed by the potential benefits.

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				PPH prophylaxis (Gallos et al. Cochrane Data Syst Rev 2018;12:CD011689). In those already given oxytocin as prophylaxis (Blum 2010), misoprostol was equivalent to oxytocin. Note that there is little evidence that a second oxytocin dose has any effect if oxytocin has already been given prophylactically – and for this reason the updated NICE guideline recommends using ergometrine or oxytocin infusion then carboprost instead of an oxytocin bolus. It is therefore likely that in the Blum study, misoprostol treatment, like oxytocin, was largely ineffective. This is supported by a secondary analysis of the Blum study that showed only around 8% of women with PPH responding to the misoprostol or oxytocin (Weeks unpublished, available on request). The only study that suggests any benefit of misoprostol treatment had only 64 participants, was not blinded and, as the NICE evidence review suggests, was "very low to low quality evidence" and at high risk of bias (Lokugamage et al, Acta O&G Scand 2001;80:835). It ended prematurely at the end of the planned 2-year recruitment period when it had recruited only half the planned numbers but when the power had reached 80%. Note that the rectal route used for the misoprostol in this study has largely been abandoned	There is a footnote to table 12 outlining that misoprostol use is off label and states that 'In September 2023, this was an off-label use of misoprostol, so the dosage is included in table 12. Consult the BNF for dosages of other drugs listed. See NICE's information on prescribing medicines.

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				internationally due to the poor bioavailability and slow onset of action (Tang et al. Int J Gynecol Obstet 2007;99:S160). As a result, the later large WHO studies all used the sublingual route instead, but even with that the peak serum concentration is not achieved until 26 minutes after administration (Tang et al, Hum Rep 2002;17:332-6). In the light of the above evidence is it puzzling why the guideline committee would continue to recommend a drug that has high quality evidence of no benefit yet significant side effects and only a single small, flawed study suggesting any benefit. Furthermore, misoprostol (like carbetocin) is not labelled for the treatment of PPH. We consider that the NICE committee therefore needs to take great care before recommending the off-label use of this demonstrably ineffective but harmful treatment. Harm can come both from the side-effects of shivering and high temperature causing clinical concerns about sepsis and an overuse of antibiotics, and the assumed efficacy causing delays in effective treatment and transfer. The only situation in which misoprostol is appropriate for use is where no oxytocin is available for prophylaxis or treatment – which is never the case in the UK. We therefore	

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				believe that it is not appropriate to keep the use of misoprostol in the guideline as a suggested treatment for PPH.	
British Maternal Fetal Medicine Society	Guideline	General	General	The rationale for the change to this guideline is clear as is the review of the evidence and the considered discussion of the committee. It would seem that there is an absence of evidence rather than no evidence for the efficacy for the second dose of oxytocin + ergometrine. With this in mind we would suggest that the wording could be (p6 line 3) "A repeat dose of ergometrine or the combination of oxytocin and ergometrine may be given if other medicines are not available, for example in a home birth setting or if senior clinicians believe it is necessary." Sometimes in extreme situations it is necessary to have this drug available, so we believe it would be useful to include this as an option for senior obstetricians in the guideline. Removing this option which is in many units a standard approach due to an absence of	Thank you for your comment. There was no evidence available for second dose of oxytocin + ergometrine; we have used standard NICE wording as set out in our methods manual to reflect this. We have not amended the wording as you suggested because the committee agreed that this drug has significant unpleasant side effects and should only be used if other medicines are not available. We also outline in a footnote to the table that 'Not all medicines in table 12 will be available in all settings, and this may impact on choice and order of use.' When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the

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				evidence rather than evidence of no effect would seem like a backwards step. In addition, it is important for the Committee to consider that syntometrine is half the dose of ergometrine compared to ergometrine alone. So, it is important to highlight that these preparations are not the same and hence should be taken into account when providing a second dose. Overall, however, this change is relatively minor but will represent a practice change in units in which oxytocin+ergometrine is used routinely (syntometrine) and this will therefore require robust communication and guidelines to be updated.	guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual. In line with our methods and processes, we only include dosage information in our guideline recommendations if they are off-label or if the recommendation would not make sense without the dose.
La Leche League GB	Guideline	General	General	Whilst I appreciate this guideline is on uterotonics, there is no mention of facilitating initiation of breastfeeding and skin to skin where possible. Breastfeeding increases oxytocin release to help the uterus contract. https://laleche.org.uk/birth-breastfeeding/	Thank you for your comment. This is not in the scope of this update so no recommendation was made on initiation of breast feeding and skin to skin contact.
Medicines and Healthcare Products Regulatory	Guideline	General	General	For the proposed change to Table 12 to remove carbetocin, a recently published NHSE National Patient Safety Alert 'Risk of oxytocin overdose during labour and childbirth' includes information on the use of carbetocin in prophylaxis of post-partum haemorrhage.	Thank you for your comment. The updated recommendations where carbetocin has been removed are as an option for the treatment of PPH, not

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Agency (MHRA)					prophylaxis of PPH; so there is no conflict with the NPSA. We have added a link to the NPSA to the document to highlight the issues that healthcare professionals need to be aware of.
NHSE Patient Safety Team	Guideline	000	000	In line with the aim of the guidelines to 'reduce variation in aspects of care' (p1 / line 3) it would be beneficial is the dosage/regime for oxytocin bolus, oxytocin plus ergometrine, oxytocin infusion and carboprost could be added to the guideline for consistency and to assist with the standardisation of national practice. If this is not within the remit of the NICE guideline, would we suggest adding in that ICBs/networks should ensure standardisation of dosage/regimens of uterotonics.	Thank you for your comment. In line with our methods and processes, we only put doses in our guideline recommendations if they are off-label or if the recommendation would not make sense without the dose.
NHSE Patient Safety Team	Guideline	000	000	NHS England have recently issued a National Patient Safety Alert in relation to 'Risk of oxytocin overdose during labour and childbirth' - https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103256	Thank you for your comment. We have added a link to the National Patient Safety Alert that you refer to in the guideline. The actions outlined in the NPSA are related to the review and updating of local

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				It would be beneficial to see some of the actions within the alert added to the NICE guideline, including: • Post-partum haemorrhage (PPH) kits/trolleys are immediately available in all clinical areas/ theatres where it may be required. • A second midwife should be available to support the administration of the postpartum oxytocin infusion. • Roles and responsibilities of staff groups in the labour setting, including theatres, are clearly defined in terms of prescribing, preparation, administration and disposal of oxytocin infusions. Including: ▪ intrapartum oxytocin infusions ▪ postpartum oxytocin infusions unused, pre-prepared oxytocin infusions.	clinical procedures, and are not within the scope of this guideline update.
Royal College of Anaesthetists	Guideline	000	000	The increased emphasis on giving TXA is welcomed	Thank you for your comment.
Royal College of Anaesthetists	Guideline	000	000	There is no consideration given to safe handling of drugs. The use of carbetocin obviates the need to make up an infusion to prolong the effect of oxytocin. After approximately 5 years in development a NPSA concerning oxytocin has recently been distributed regarding this	Thank you for your comment. The committee take into account a range of factors when reaching a decision on what to

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					recommend, including factors such as birth setting, storage and safe handling of drugs. The committee agreed that overall, given that carbetocin is not licensed for treatment of PPH, and the small sample sizes of the studies along with the low quality of some of the evidence, that the evidence was insufficient to recommend it for the treatment of PPH We have added a link to the NPSA concerning risk of oxytocin overdose during labour and childbirth that you refer to.
Royal College of Anaesthetists	Guideline	000	000	The cost comparison of carbetocin and oxytocin does not take into account disposables or staff time	Thank you for your comment. This table has not been amended in this updated version of the guideline, however we would like to respond to your comment. You are correct that the cost comparison does not take into account disposables or staff time. However, in the committee discussion of the evidence in Evidence Review O, it is noted that:

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					'*… the acquisition costs of all the medicines being recommended for the management of PPH were low and were likely to be far outweighed by the cost of a PPH, which if not treated promptly could lead to serious maternal consequences including ITU admission.'* Given the minor costs in comparison to the adverse outcomes of PPH, treatment costs were not a major consideration in the committee decision making.
Royal College of Anaesthetists	Guideline	000	000	Ergometrine - the BNF clearly states that the maximum dose is 500mcg. Where is the evidence that a second dose is either safe or more effective than a different uterotonic? If a second dose is given, there should be a delay of at least 3 hours to avoid severe hypertension.	Thank you for your comment. As outlined in the SPC, a further injection of ergometrine can be given for postpartum haemorrhage, as long as the possibility of retained placental fragments, soft tissue injury or a clotting defect has been excluded. No evidence was identified for a second dose of ergometrine; however the committee agreed, based on their experience, that a second dose could be given in the absence of other uterotonic options for the treatment of PPH. Carboprost may well be unavailable in a home birth setting, and, in addition to not

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					being recommended generally by the committee, carbetocin could not be administered in a home birth setting or a midwife-led unit.. This is detailed in the committee's discussion and interpretation of Evidence Review O.
Royal College of Anaesthetists	Guideline	000	000	Patient experience: Ergometrine has the most distressing side effect profile. This should be taken into consideration, given that the evidence for ergometrine is mainly opinion: '*There was no evidence for the benefits of oxytocin and ergometrine for the management of postpartum haemorrhage but based on their knowledge and experience, the committee knew these were effective so retained them in the guideline as treatment options*'	Thank you for your comment. The committee considered the side effect profile in the context of the situation of a continuing post-partum haemorrhage, and in their experience the benefits of using ergometrine outweighed the side effects.
Royal College of Midwives	General	000	000	The Royal College of Midwives have reviewed the amendments proposed for NG235 and have no further comments. We wish to formerly confirm that we welcome the updates, particularly regarding the clarification that in some midwife-led settings not all drugs are available and the subsequent concessions relating to this.	Thank you for your comment.

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Royal College of Nursing	General			Thank you for the opportunity to comment on this consultation. We don't have any comments to add at this stage.	Thank you for your comment.
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline		003-005	No mention of repeat a dose of oxytocin (only mentions oxy/ergot or ergometrine). If oxytocin had been used initially for prevention of PPH/active management third stage (as in section 1.10.11) would you acknowledge this could also be repeated. This would only be relevant if you agree with my comments on first line treatment of PPH suggesting repeat oxytocin may be more beneficial than an infusion alone.	Thank you for your comment. As noted elsewhere, Oxytocin IM is an off-label use and so the committee considered that it was appropriate to recommend it in its licensed form of IV. The committee also discussed that 'for the management of PPH it was preferable to set up an intravenous infusion of oxytocin to provide a more sustained effect..' This is outlined in the section on 'The committee's discussion and interpretation of the evidence' in Evidence review O. The committee have recommended first-line, second-line and additional options for treatment of PPH; and a footnote to table 12 highlights that 'Not all medicines in table 12 will be available in all settings, and this may impact on choice and order of use.'

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University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Table 12 No uterotonic used	General	Is it correct that the choice for no uterotonic used first line is oxytocin plus ergometrine or an oxytocin infusion? Standard practice would be to give a bolus or IM dose before initiating an oxytocin infusion – initial bolus/IM dose of oxytocin to contract the uterus and oxytocin infusion to maintain contraction. Is there genuinely evidence to support starting an infusion if no previous uterotonics used with the intention of being sufficient dosage to initiate a contraction?	Thank you for your comment. By 'oxytocin infusion' we mean that oxytocin should be administered in line with the BNF and SPC; that is 5 units by slow IV injection, followed by 20 or 40 units in 500 ml given at a rate sufficient to control uterine atony. Oxytocin IM is an off-label use and so the committee considered that it was appropriate to recommend it in its licensed form of IV. The committee also discussed that 'for the management of PPH it was preferable to set up an intravenous infusion of oxytocin to provide a more sustained effect..' This is outlined in the section on 'The committee's discussion and interpretation of the evidence' in Evidence review O. The evidence for oxytocin was IV administration for all studies except 1, where the route of administration was unclear. It is also noted in a footnote to table 12 that 'Not all medicines in table 12 will be available in all settings, and this may impact on choice and order of use.'

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					NICE guidelines should not replace clinical judgement and we state that 'When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual.'
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Table 12 No uterotonic used	General	Why is carboprost the alternative to sytometrine, if contraindicated, when no previous uterotonics have been used. Carboprost also has a significant side effect profile. In this group who have not received uterotonics why would oxytocin IM or iv not be the alternative first line.	Thank you for your comment. The committee considered the side effect profile of carboprost in the context of treating post-partum haemorrhage, and agreed that it was a useful option for the pharmacological treatment of PPH despite its side effects. There was some evidence that carboprost reduced blood loss compared with oxytocin, so therefore carboprost is the alternative if oxytocin plus ergometrine (Syntometrine) is contraindicated. However, we acknowledge in the footnotes to table 12 that not all

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					medicines will be available in all settings and this may impact on choice and order of use.
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Table 12 No uterotonic used	General	Carboprost – there is no suggestion that carboprost might be contraindicated. It has several significant side effects including causing hypertension and precipitating asthma. Would oxytocin IM or IV not be a better first line option for all if ergometrine contraindicated?	Thank you for your comment. The committee considered the benefits and side effects of the possible treatment options, and noted that the benefits of the recommended options outweighed the side effects given the potential consequences of PPH. The committee did not recommend IM oxytocin because this is an off-label use of oxytocin. The committee do recommend IV oxytocin as an alternative to syntometrine or carboprost (if contraindicated) for treatment for PPH. A footnote to the table highlights that not all medicines will be available in all settings, and this may impact on choice and order of use. These guidelines cannot cover all clinical scenarios, and clinicians are expected to use them alongside their clinical knowledge

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					when making decisions about care for individuals.
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Table 12 Suggested first line treatment column	General	Why is oxytocin infusion alone the alternative to IM ergometrine or carboprost. A low dose infusion is unlikely to stimulate a contraction but could maintain one once initiated. The logic of starting an infusion as soon as iv access available suggests this is the drug of choice. If iv access already established is oxytocin infusion then the preferred first line management? This is my interpretation of the current wording, which I find unclear. Drawing up the oxytocin infusion likely to be rate limiting step note recent National patient safety alert on risk of oxytocin overdose	Thank you for your comment. By 'oxytocin infusion' we mean that oxytocin should be administered in line with the BNF and SPC; that is 5 units by slow IV injection, followed by 20 or 40 units in 500 ml given at a rate sufficient to control uterine atony. The committee considered that 'for the management of PPH it was preferable to set up an intravenous infusion of oxytocin to provide a more sustained effect.' Furthermore, Oxytocin IV is licensed for treatment of PPH, whereas IM oxytocin is off-label for treatment of PPH. All the evidence (apart from 1 study) for oxytocin that was considered administered IV (and in the one study, the route of administration was not clear). With regards to your question of 'If iv access already established is oxytocin infusion then the preferred first line management?' This

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					would be down to clinical judgement of that specific situation.
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Table 12 Suggested second line	General	The suggested second line for all situations is carboprost yet in the additional treatment section it gives a choice – either carboprost or misoprotol. I find this confusing. Are you suggesting that you always give a dose of carboprost and then choose to either continue with carboprost or change to misoprostol. Or is the intention that you can choose which prostaglandin you start with? If choice is starting with either then they should both be in the suggested second line column.	Thank you for your comment. As set out in the table, the second-line option for all situations is carboprost (or repeat carboprost for people who had oxytocin + ergometrine as prophylaxis). If the person continues to need treatment then they can have either carboprost or misoprostol (as outlined in the 'additional treatments' column). There was no evidence on the ideal sequencing of pharmacological treatments for PPH. With respect to your question 'Or is the intention that you can choose which prostaglandin you start with?' this is not the intention of the recommendation. The choice is not starting with either, so no changes will be made to the table.
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Below Table 12	General	Would you support giving a different prostaglandin if initial choice inadequate? This is not currently mentioned or is the suggestion to progress to surgical?	Thank you for your comment. The table outlines first-line, second-line and additional pharmacological treatment options for the management of post-partum haemorrhage. We do acknowledge in a

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					footnote to the table that 'Not all medicines in table 12 will be available in all settings, and this may impact on choice and order of use.' Surgical management was not in the scope of this update. Other recommendations on post-partum haemorrhage in this guideline remain unchanged.
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Below table 12	General	We often write a comment that in the face of major ongoing bleeding ergometrine may be appropriate eg avoid ergometrine except if ongoing massive obstetric haemorrhage. Should this be included in the post table 12 comments?	Thank you for your comment. These recommendations cannot cover all clinical scenarios. This guideline should be used in combination with clinical judgement and according to the individual situation. Therefore, no change will be made to the table
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Below table 12	General	Could the rationale for oxytocin infusion de novo (no previous uterotonic) or as an alternative to other injectable medications (oxytocin alone or oxytoin plus ergot for third stage) be explained below the table in "please note that" section.	Thank you for your comment. A brief rationale for the recommendations is included in the guideline below the table, in the section 'why the committee made the recommendations.' No change will be made to the footnotes to the table to include this text.
University Hospitals Bristol and	Guideline	Below table 12	003-005	It is of value that the guidance acknowledges using a repeat dose of ergot or oxy/ergot as we have used this in our unit for many years. I	Thank you for your comment.

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Weston NHS Foundation Trust				realise that this does not support it's use but it acknowledges it may be useful in some circumstances. Do I correctly assume the timings are to reinforce due to anticipated duration of action repeat doses are likely to be unnecessary – this is not clear.	We think that you are referring to the timings outlined in the footnote to table 12. These are to make people aware of the onset of action and duration of action of the different medicines, which will impact on when a repeat dose could be given (if needed).
University Hospitals Bristol and Weston NHS Foundation Trust	Guideline	Below table 12	001	Should this single sentence be built upon to include a second line to cover patients with underlying medical condition which may impact choice and order of medication eg asthma avoiding carboprost and favouring misoprostol.	Thank you for your comment. This guidance cannot cover all clinical scenarios. Clinicians are expected to use their clinical judgement and knowledge, taking into account the individual needs of the person. Therefore no changes will be made to this text.