Ectopic pregnancy and miscarriage – medical management of miscarriage

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Stakeholder	Document	Line No	Comments	Developer's response
FTWW: Fair Treatment for the Women of Wales	Guideline	General	We note that recommendations 4, 7, 9, and 10 require healthcare professionals to 'advise', 'inform', and 'provide' patients with what can be quite complex instructions and time-frames to carry out tests and or make contact with their healthcare provider. We would suggest that there is clear guidance within the document regarding ensuring that patients have instructions provided to them in easy-read / plain language written format as well as verbal advice. This hasn't been mentioned within the Equality Impact Assessment but would constitute a reasonable adjustment for disabled people, as well as likely improve understanding and compliance for any / all patients seeking support for medical management of miscarriage.	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 section of the ectopic pregnancy and miscarriage guideline called 'support and information giving'. Further detail on communication and treating people as individuals is covered in the NICE guideline on Patient experience in adult NHS services which is hyperlinked from this section, and so this information is not repeated in all other NICE guidelines. 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.
Kings college Hospital Early Pregnancy nit	Guideline	002	We would find it useful to have some practical guidance about when and how to issue and administer the treatment because this was not an issue when we were using misoprostol alone. The termination of pregnancy services offer 'pills by post' sending patients both mifepristone and	Thank you for your comment. The committee discussed the methods different clinics use – these include asking women or people to take the mifepristone in the clinic or giving them the option to take it at home, and then

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			misoprostol, but we are reluctant to prescribe an abortifactant that may not be needed should the miscarriage happen after the mifepristone alone, so we usually ask women to return to EPU for their misoprostol rather than prescribing it and giving them the drug to use at home 48 hours after their mifepristone. This is to prevent the misoprostol being saved or sold should it not be needed, as this would be illegal. However, this necessitates an additional visit back to hospital to then give the misoprostol & it may be that we should be less concerned?	to return to the clinic for the misoprostol, or to take the misoprostol home with them to take after 48 hours. The committee agreed that it was up to individual units to decide on the specifics of treatment administration, as it may also depend on factors such as geographical location, and to use locally agreed protocols. The committee therefore did not amend this recommendation.
Kings college Hospital Early Pregnancy nit	Guideline	008, 010	We are concerned that the recommendation for the NHS to provide women with pregnancy tests for their follow up will have a resource impact when there are cheap pregnancy tests available on the high street. We offer urinary pregnancy tests in our EPU for women who do not have the money or ability to obtain their own urinary pregnancy tests, but this is unusual. GPs & hospital TTA's do not usually include cheap over the counter medications and we would consider urinary pregnancy tests to be in the same category.	Thank you for your comment. The change to the recommendations to provide pregnancy tests was to reduce health inequalities and ensure that all women have access to the pregnancy test to complete their management regardless of ability (financial or otherwise) to obtain a pregnancy test themselves.
Kings college Hospital Early Pregnancy nit	Guideline	009	Rational for change: The recommendation for a follow up pregnancy test was introduced in the original guideline to exclude persistent gestational	Thank you for your comment. The need to rule out a molar or ectopic pregnancy after a positive pregnancy test at 3

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			trophoblastic disease due to an undiagnosed molar pregnancy and to exclude an undiagnosed ectopic pregnancy. This is because with traditional surgical management there is histological examination of the villous tissue to check for a molar pregnancy and to confirm a normally located pregnancy, but histology is not usually performed with medical or expectant management of miscarriage. With respect to the committee, at best 1 in 10 complete moles are missed on ultrasound examination, with some studies reporting that 1 in 4 are missed (PMID: 32877774). We agree that ongoing heterotopic ectopic pregnancies would be unusual three weeks post diagnosis of miscarriage, but occasionally there is a misdiagnosis of a normally located pregnancy due to a pseudosac, intrauterine or interstitial ectopic pregnancy or uterine anomaly.	weeks has been added back into the recommendation as you suggest.
Kings college Hospital Early Pregnancy nit	Guideline	009	Proposed revised recommendation: With medical termination of pregnancy it is important to do a pregnancy test to exclude a failed termination & an ongoing pregnancy, particularly if performed very early on, but the situation is not the same with a miscarriage. If there is retained pregnancy tissue post miscarriage, the pregnancy test may or may not be positive, depending on whether there is any metabolically active villous tissue left and how high	Thank you for your comment. The need to rule out a molar or ectopic pregnancy after a positive pregnancy test at 3 weeks has been added back into the recommendation. The committee also agreed that a negative pregnancy test and ongoing bleeding or other symptoms would need further

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			the hCG was before the pregnancy was expelled. If a woman is asymptomatic, it does not matter whether there is any retained tissue after her miscarriage– it will usually be passed with her first period. If she has persistent or heavy bleeding then she should have a repeat scan to assess for retained tissue and the need for intervention, even if her pregnancy test is negative. Likewise, if she has very little bleeding or it is uncertain whether the sac has been passed, then a scan is indicated sooner than 3 weeks.	investigation and so have added an additional recommendation to state this.
Kings college Hospital Early Pregnancy nit	Guideline	General	We know it's difficult to please everyone regarding gender terminology, but women are also people, so we find it clunky to read 'women and people'. We think it somehow depersonifies women – we're all people whether we're women or trans men or any other gender ID. If you want to keep the guideline gender neutral, we would suggest sticking to 'people' or 'patients' across the board. Personally, we'd be happy with 'women' given that women form the vast majority of people having miscarriages, but we recognise that ignores the people with other gender IDs.	Thank you for your comment. The use of additive language (women and people…) is the language advised in the current version of the NICE style guide. This sets out how NICE approaches language to achieve consistency in our communications and ensure our guidance is safe, clear and inclusive for all our audiences. The style guide is available on the NICE website in the interest of openness and transparency. In developing the advice in NICE's style guide, we have considered academic research, feedback from stakeholders,

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				and advice and publications from organisations including NHS England, NHS Digital, NHS Scotland, the Health Service Executive (Republic of Ireland), the Royal College of Midwives and the Royal College of Obstetricians and Gynaecologists.
NHS England	Guideline	001	No alternative treatment for incomplete miscarriage is included within the revised recommendation. Whilst this is not different from the 2012 guideline, it becomes important when considered in conjunction with the revised recommendation included within pg 3, line 2. See comment 2.	Thank you for your comment. The order of the recommendations has been changed to make it clearer that the management of missed miscarriage and incomplete miscarriage are now different, and the recommendations on incomplete miscarriage have been grouped together for clarity.
NHS England	Guideline	001	There should be no significant impact on primary care from this change since early pregnancy care relating to miscarriage is not generally managed in general practice.	Thank you for your comment and noting the lack of impact on primary care.
NHS England	Guideline	002	Vaginal misoprostol for the medical treatment of incomplete miscarriage is now not included within the revised treatment recommendation. As the revised guideline does not recommend mifepristone within pg 2, line 1, the revised guideline needs to provide guidance on what the	Thank you for your comment. The order of the recommendations has been changed to make it clearer that the management of missed miscarriage and incomplete miscarriage are now different, and the recommendations on

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			treatment options are for incomplete miscarriage – are there any other medical options, or should the treatment recommendation for incomplete miscarriage be surgical management? If surgical management is now the only option for incomplete miscarriage, has an impact assessment been undertaken on the capacity of surgical services (NHS and independent sector) to carry out additional surgical interventions for incomplete miscarriage?	incomplete miscarriage have been grouped together for clarity. This makes it clear that misoprostol is still a treatment option for the medical management of incomplete miscarriage.
NHS England	Guideline	002	There should be no significant impact on primary care from this change since early pregnancy care relating to miscarriage is not generally managed in general practice.	Thank you for your comment and noting the lack of impact on primary care.
NHS England	Guideline	003	There should be no significant impact on primary care from this change since early pregnancy care relating to miscarriage is not generally managed in general practice.	Thank you for your comment and noting the lack of impact on primary care.
NHS England	Guideline	004	How is it proposed that services will identify patients where there are concerns that they may not contact the service if bleeding has not commenced within 48 hours of medical treatment? There needs to be practical guidance to services on how to identify at risk patients, and how to avoid conscious or unconscious bias, in order that equity	Thank you for your comment. The committee agreed that, in the vast majority of cases, women or people whose bleeding has not started after 48 hours get back in touch with the service as advised. However, there may occasionally be people who do not speak English, who do not have access

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			of access is maintained in the way intended by the revised guideline.	to a phone, or where there are other concerns and in these cases the service may identify the need to follow them up. This recommendation was designed to encourage this pro-active approach, but the committee agreed that identification of people who needed this pro-active approach would have to be done on an individualised basis.
NHS England	Guideline	004	This will be helpful to GP services since patients sometimes seek advice when early pregnancy services are closed and are not the best point of contact for the reasons above.	Thank you for your comment and support of this recommendation.
NHS England	Guideline	007	Consideration needs to be given to the form/format of the advice given on when and how to seek help during the miscarriage process to ensure that equity of support is maintained in the way intended by the revised guideline, for example for patients with disabilities or where English is not their first language.	Thank you for your comment. There are already over-arching recommendations in the section of the guideline on 'Support and information-giving' (which were not included in this update) which provide advice on communication and providing information, including a link to the NICE guideline on patient experience in adult NHS services, which includes all the considerations you have outlined.
NHS England	Guideline	007	This is also very helpful as misdirection or uncertainty regarding when and who to contact can	Thank you for your comment and support of this recommendation.

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			be confusing for patients and not a good use of resource when those services that don't hold the answers are contacted first.	
NHS England	Guideline	009	This could reduce contacts from patients concerned that they may have an ectopic or molar pregnancy (since patients may "google" these specific terms), so likely to be beneficial.	Thank you for your comment. Based on feedback from other stakeholders, the need to rule out a molar or ectopic pregnancy after a positive pregnancy test at 3 weeks has been added back into the recommendation, in order to ensure these conditions are not missed.
NHS England	Guideline	010	No impact on primary care	Thank you for your comment and noting the lack of impact on primary care.
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 and given information in an appropriate format and this detail is already included in the section of the ectopic pregnancy and miscarriage guideline called 'support and information giving'. Further detail on communication and treating people as individuals is covered in the NICE guideline on Patient experience in adult NHS services which is hyperlinked from this section, and so this information is

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				not repeated in all other NICE guidelines.
NHS England	Guideline	General	Overall this revision makes some very helpful adjustments to aid clarity for patients and reduce unnecessary calls to GP services (unnecessary calls to general practice are a significant factor in reducing patient access and GP retention)	Thank you for your comment and support for these changes.
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	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 section of the ectopic pregnancy and miscarriage guideline called 'support and information giving'. Further detail

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			non-verbal and unable to tell you how they feel. Pictures may be a useful way of communicating with some people, but not all. It should also be mentioned that staff should be aware of and pay attention to healthcare passports: Some people with a learning disability and some autistic people may have a healthcare passport giving information about the person and their health needs, preferred method of communication and other preferences. Ask the person or their accompanying carer if they have one of these.	on communication and treating people as individuals is covered in the NICE guideline on Patient experience in adult NHS services which is hyperlinked from this section, and so this information is not repeated in all other NICE guidelines.
Royal College of Obstetricians and Gynaecologiests	Guideline	004	While I agree that some people may not be able to contact the early pregnancy services. Lots of resources will be needed to allow staff nurse to contact people after 48 hours and some of them may be able to call but they do not want to. So, I believe, people need to have the options and share the responsibility for their care. I think we need to offer the options either they will prefer to call the early pregnancy services or they prefer to be called by the staff nurse as they are unable to call and provide time frame for that phone call. This will be at the time of initial presentation and be documented in the plan	Thank you for your comment. The committee agreed that, in the vast majority of cases, women or people whose bleeding has not started after 48 hours get back in touch with the service as advised. However, there may occasionally be people who do not speak English, who do not have access to a phone, or where there are other concerns and in these cases the service may identify the need to follow them up. This recommendation was designed to encourage this pro-active approach, but offering to contact all

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				women would not only be unnecessary (as many will have started bleeding) but also have a large resource impact. The committee therefore agreed not to change this recommendation.
Royal College of Obstetricians and Gynaecologists	Guideline	004	1.5.14 I suggest recommend 800mcg instead of 600 to align protocols unless significant financial impact	Thank you for your comment. The dose of 600 micrograms was based on evidence that was assessed by the committee when making the original recommendations for incomplete miscarriage in 2012. As the committee carrying out this update had not reviewed the evidence for incomplete miscarriage they did not amend this dose. However, the recommendation does already contain the option to use 800 micrograms for units who wish to align their protocols.
Royal College of Obstetricians and Gynaecologists	Guideline	009	I agree that ectopic and molar pregnancy should have been ruled out before starting medical management however, molar pregnancy is suspected in case of irregular bleeding or positive pregnancy test after any pregnancy event so we need to keep molar pregnancy as possible differential diagnosis for positive pregnancy test after 3 weeks	Thank you for your comment. The need to rule out a molar or ectopic pregnancy after a positive pregnancy test at 3 weeks has been added back into the recommendation as you suggest.

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Royal College of Obstetricians and Gynaecologists	Guideline	010	Impact of change - this will reduce health inequalities as will ensure all women have access to the pregnancy test to complete their management regardless of ability (financial or otherwise) to obtain a pregnancy test themselves.	Thank you for your comment. This reduction in health inequalities has been added to the impact section.
The Ectopic Pregnancy Trust	Guideline	010	We welcome the provision of pregnancy tests rather than advice to take a pregnancy test that would need to be self-purchased.	Thank you for your comment and support for this recommendation.
The Miscarriage Association	Guideline	004	We welcome the recommendation for follow-up after 48 hours if bleeding has not started and the suggestion that clinicians proactively contact patients whom they think might not get back in touch. Despite the resource implications, might it not be best practice to contact **all** treated patients after 48 hours?	Thank you for your comment. The committee agreed that, in the vast majority of cases, women or people whose bleeding has not started after 48 hours get back in touch with the service as advised. However, there may occasionally be people who do not speak English, who do not have access to a phone, or where there are other concerns and in these cases the service may identify the need to follow them up. This recommendation was designed to encourage this pro-active approach, but contacting all women would not only be unnecessary (as many will have started bleeding) but also have a large resource impact. The

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				committee therefore agreed not to change this recommendation.
The Miscarriage Association	Guideline	010	We welcome the recommendation that women and people having expectant management are provided with a urine pregnancy test, as are those with medical management.	Thank you for your comment and support for this recommendation.
The Miscarriage Association	Guideline	General	We welcome this revised guideline and will amend our patient information to reflect it.	Thank you for your comment.

In September 2023, NICE became aware that, due to an IT issue, 3 comments submitted by a registered stakeholder as part of the consultation on this guideline update had been missed. These are shown below with post-publication responses. NICE apologises for this error.

Stakeholder	Document	Line No	Comments	Developer response
GPCPC	Guideline	8 1.5.17	GPCPC is delighted to see that women will be provided with a urine pregnancy test and not expected to buy one themselves	Thank you for your comment.
GPCPC	Guideline	9 1.5.18	In rec 8 it is clear that the healthcare professional to return to if the test is still positive at 21 days, should be the one providing their medical management, but this is less clear in rec. 9. It would be unhelpful for the woman if she returned to her GP, as she would need further referral and experience delays in treatment. It should be made	Thank you for your comment. In view of your comment, NICE has made a post-publication amendment to the recommendation which aligns its wording with 1.5.17. 1.5.18 now reads: 1.5.18 Advise women and people with a positive urine pregnancy

			clear that she returns to hospital or secondary care provider or early pregnancy unit that provided the treatment	test after 3 weeks to return for a review to the healthcare professional responsible for providing their medical management to rule out a retained pregnancy, molar or ectopic pregnancy, and assess the need for further investigations or treatment. **[2012, amended 2023]**
GPCPC	Guideline	9 1.5.18	We are less happy about the amended recommendations. Amongst our team one doctor has experience of a partial molar pregnancy, diagnosed as a missed miscarriage and NOT detected before treatment, that led to passing the POC at home, with persistently positive pregnancy test. We feel that the former rec was more specific and that the new rec could potentially be unsafe. This may be very rare, but it is clearly possible.	Thank you for your comment. Based on feedback from other stakeholders, the need to rule out a molar or ectopic pregnancy after a positive pregnancy test at 3 weeks was added back into the recommendation, in order to ensure these conditions are not missed. The final recommendation (see above for post-publication amendment which affects this recommendation) reads: 1.5.18 Advise women and people with a positive urine pregnancy test after 3 weeks to return for a review to the healthcare professional responsible for

				providing their medical management to rule out a retained pregnancy, molar or ectopic pregnancy, and assess the need for further investigations or treatment. **[2012, amended 2023]**

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*