Ectopic pregnancy and miscarriage: diagnosis and management

Consultation on draft guideline - Stakeholder comments table
20/07/2021 – 17/08/2021

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Stakeholder	Document	Page No	Line No	Comments	Developer's response
British HIV Association	Guideline	All	All	The document refers only to management of the ectopic pregnancy but I cannot see any recommendation that women with an ectopic pregnancy should be screened for sexually transmitted infection (STI) with a vulvovaginal NAAT test for gonorrhoea and chlamydia as part of their care. This is a test which can be easily done by the patient themselves or by a healthcare provider. It would be important to rule out an STI as a cause for ectopic pregnancy therefore I would suggest it be added to the introduction.	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.
British Pregnancy Advisory Service (BPAS)	Guideline	General	General	We are unclear as to why the scope of this evidence update was limited only to the use of progesterone and not to the use of mifepristone as a preparatory agent for medical management of missed or incomplete miscarriage. A recent NIHR-funded study which we believe has been shared with the guideline committee made clear findings as to the improved efficacy of medical management with the use of mifepristone – bringing it into line with well-established Early Medical Abortion practice. We strongly recommend that this evidence should be considered by the	Thank you for your comment. The scope for this update only included the use of progesterone for threatened miscarriage and did not include the management of missed or incomplete miscarriage. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.

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				committee – or another committee established to update the guideline further. https://evidence.nihr.ac.uk/alert/missed-miscarriage-should-be-treated-with-mifepristone-plus-misoprostol-rather-than-misoprostol-alone/ We also have similar suggestions regarding the administration of misoprostol to bring it into line with more recent evidence reviews undertaken by the NICE Guideline on Abortion Care – for example the use of sublingual rather than oral misoprostol (recommendation 1.5.10) and the use of anti-D prophylaxis (recommendation 1.7.x)	
British Pregnancy Advisory Service (BPAS)	Guideline	015	016	New recommendation 1.5.2 focuses on the use of micronised progesterone for the treatment of women with a history of miscarriage and presenting with vaginal bleeding. As an abortion provider, we are more familiar with this treatment being proposed by anti-abortion organisations and clinicians seeking to 'reverse' a medical abortion after a patient has taken the first medication (mifepristone) of an Early Medical Abortion. There is no evidence supporting its use, and the GMC is currently investigating two doctors who have been providing this 'treatment' in the UK. Regardless, anti-abortion organisations have a	Thank you for your comment and for highlighting this issue. The recommendations on the use of progesterone relate only to women who have a history of miscarriage and early pregnancy bleeding. Progesterone is not recommended for women who have taken mifepristone and we have clarified this in the rationale section of the guideline.

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				long history of using half truths from clinical studies and guidelines to demonstrate why they are providing 'evidence-based treatment'. This is dangerous for our patients, as claims regarding this 'treatment' are already being printed on leaflets and handed out by anti-abortion groups outside our clinics. As such, we strongly recommend that an additional statement is included in this recommendation to make clear that this proposal is not linked to abortion. We would recommend a clear statement that this recommendation refers only to spontaneous miscarriage and that information about care related to induced abortion is contained in NICE Guideline 140 (Abortion Care).	
British Society for Abortion Care Providers (BSACP)	Evidence review C	021	013 – 018	Whilst it is true that there is no evidence of harm or teratogenicity reported in humans, a recent paper* does raise the possibility of an effect in rats and concludes, "prenatal administration of exogenous progesterone … has adverse effects on morphology, skeletal construction of fetuses, and sex organs of male and female fetuses. These adverse alterations seemed to be dose-dependent. The finding of this study could be generalized to other animal species and human to clarify the	Thank you for your comment. Animal studies were not included in the protocol for this review so the committee did not search for or review animal studies. However, the committee discussed the animal evidence you have highlighted, and agreed that they could not extrapolate from this evidence to the human population, and this study used an injectable form of progesterone administered from day 1 of gestation. Furthermore, the human evidence for the particular preparation recommended

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				effect of prenatal exposure of exogenous progesterone." Suggest adding to the last sentence of this paragraph (line 16-18), "…, and with recent reports of teratogenicity in rat fetuses arising from exogenous progesterone, its use in humans should be limited to where benefits are demonstrated." * = Tag, H. M., Elgawish, R. A., Ebaid, H. M., Abdel-Rahman, M., & Abdelrazek, H. M. A. (2021). Prenatal exposure to exogenous progesterone adversely affects fetal development in Albino rats. *The Journal of Basic and Applied Zoology*, *82*(1), 16. https://doi.org/10.1186/s41936-021-00212-3	(micronised vaginal progesterone) showed no evidence of teratogenicity. The committee therefore agreed not to make the addition to the recommendations that you suggested.
British Society for Abortion Care Providers (BSACP)	Guideline	023	001 - 012	**Section 1.7 - anti-D prophylaxis** Although not in scope for this update, you may like to consider including this section on anti-D prophylaxis for review in future revisions. These recommendations from 2012 are not aligned with those of the more recent NICE abortion care guideline 2019 (NG140) or the RCOG/RCM/FSRH/BSACP guidelines on abortion care during COVID, and this difference does create confusion for staff. Simply replacing "offer" with "consider" for	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.

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				1.7.1, and ideally including the context that providers should discuss the absence of evidence with women and come to a shared decision, would align all these guidelines.	
British Society for Abortion Care Providers (BSACP)	Guideline	029	009 – 015	Please could you be explicit in the rationale that the recommendation applies only to this group of women with threatened miscarriage, and that the scope did not extend to examining evidence for the use of progesterone in other groups such as women concerned about a miscarriage after taking mifepristone as part of an early medical abortion. The reason for this is that in our sector we have had significant difficulties with anti-abortion groups targeting women and prescribing progesterone to “reverse” an abortion, despite there being no evidence of benefit (and some evidence of potential harm in this group*). Our primary concern is that the anti-abortion groups promote their practice by stating that they follow guidelines that support the use of progesterone, and they are highly likely to cite these NICE guidelines as an example. If you can make it clear that this patient population (who have taken mifepristone) is not included in the recommendation, it would ensure our patients	Thank you for your comment and for highlighting this issue. The recommendations on the use of progesterone relate only to women who have a history of miscarriage and early pregnancy bleeding. Progesterone is not recommended for women who have taken mifepristone and we have clarified this in the rationale section of the guideline.

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				are not misled by those who seek to impose their views on patients, and help to ensure this small but vulnerable group can access care and support from NHS providers who offer a full range of options following non-directive counselling. * = Creinin, M. D., Hou, M. Y., Dalton, L., Steward, R., & Chen, M. J. (2020). Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. *Obstetrics & Gynecology*, *135*(1), 158-165. https://doi.org/10.1097/aog.0000000000003620	
British Society for Haematology - Transfusion Task Force	Comments form	Questions	Questions	In answer to your questions 1) Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. The changes are small we believe comment 6 summarises the biggest issue from our perspective and practice 2) Would implementation of any of the draft recommendations have significant cost implications? A modest decrease in anti-D Ig use if universally implemented (saving)	Thank you for your comments and answers to questions 1 to 3, which relate to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date. Thank you also for your response to question 4 which we interpret to mean that no changes to the guideline are required due to the Covid-19 pandemic.

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				3) What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) Consistent guidelines – consistency to change back to previous practice as suggested in comment 6 would lead to a little more anti-D use but less variability / “error”. 4) The recommendations in this guideline were largely developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication. Other than obvious issues with attendances at a health care setting the only other issue may be consumables for tests (sample bottles, pipette tips etc) we cannot see any other specific issues	
British Society for Haematology - Transfusion Task Force	Guideline	002 and 023	See below	The term Rhesus, shortened to Rh refers to a whole system of antigens including not only D/ RhD but also c / Rhc, E / RhE etc (there are many). It is now international practice to refer to antigens as D or c etc. Similarly the term anti-D immunoglobulin is now used in formulary such as the British National Formulary from NICE.	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.

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				We have pointed out suitable substitutions below	
British Society for Haematology - Transfusion Task Force	Guideline	002	010	"1.7 Anti-D rhesus prophylaxis" should be "1.7 Anti-D immunoglobulin prophylaxis"	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.
British Society for Haematology - Transfusion Task Force	Guideline	023	001	"1.7 Anti-D rhesus prophylaxis" should be "1.7 Anti-D immunoglobulin (Ig) prophylaxis"	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.
British Society for Haematology - Transfusion Task Force	Guideline	023	002 - 007	We have received several contacts from midwives and scientists since the original guidance in 2012 specifically relating to the decision point between surgical and medical management for an ectopic pregnancy or miscarriage. Anti-D is advised in this guidance from NICE for the former but not the latter. This has caused some confusion as the practice in preceding decades originally stated in both Royal College of Obstetrics and Gynaecologists (RCOG) Green Top Guidelines and British Society for Haematology (BSH)	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.

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				Guidelines on the use of anti-D based on the same evidence as originally reviewed by NICE in 2012 had not differentiated between the two and had advised anti-D for both. As the level of evidence is weak for giving anti-D for one scenario but not the other (or indeed giving it for both or neither). Longstanding guidance had erred on the side of giving anti-D for both would it be simpler to revert to this practice less risk of an "error" on the part of practitioners? The RCOG green top guidance was merged into the BSH guidance in 2016 and we plan to update it imminently	
British Society for Haematology - Transfusion Task Force	Guideline	023	002 - 003	This should be as follows with amendments in red "Offer anti-D ~~rhesus~~ Ig prophylaxis at a dose of at least 250 IU (50 micrograms) to all ~~rhesus~~D-negative women who have a surgical procedure to manage an ectopic pregnancy or a miscarriage. **[2012]"** Comment: Manufacturers and guidelines tend to add "at least" to doses. The vials produced by manufacturers are standardised to contain "at least" the dose stated on them. Since previous iterations of the guidance, the one manufacturer who was producing vials of at least 250IU has stopped doing so and only produces vials containing 500IU or 1500IU	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.

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British Society for Haematology - Transfusion Task Force	Guideline	023	005	This should be as follows amended in red "1.7.2 Do not offer anti-D ~~rhesus~~ Ig prophylaxis to women who…."	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.
Fair Treatment for the Women of Wales	Guideline	General	General	We appreciate that there may not be evidence to support prescribing progesterone to women with early bleeding and no previous losses. However, we believe that the definition of 'improved outcomes' does not sufficiently take into account the psychological and emotional impact of being denied a medication that the patient believes may help to save their baby. The cost is low and there is no risk associated with prescribing these women progesterone but the potentially positive impact of being allowed to try something that could save their baby is significant, even if those women subsequently go on to lose the pregnancy. There is a very real risk of long-term emotional trauma for women who are denied medication and then lose their pregnancy, including stress and anxiety which can impact on the woman now and on any future pregnancies. We believe that more attention needs to be given	Thank you for your comment. The committee discussed that threatened miscarriage is distressing but agreed that it would be misleading to women to provide them with progesterone if they present with early pregnancy bleeding and no previous losses, or in women with previous losses but no bleeding in this pregnancy, as there is no evidence that this will improve their chance of a live birth. However, the committee had recognised that more research is needed and so had made a research recommendation.

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				to the emotional and psychological impact of this decision, giving mental wellbeing equal weighting to physical outcomes of pregnancy. It may be that more research is needed on this topic to provide clear recommendations. Similarly, with regards to women who have had two or more previous pregnancy losses, whilst there may not be evidence of improved outcomes associated with the prescribing of progesterone, the emotional and psychological impact of being empowered and actively trying something to have a successful pregnancy is considerable and worthy of consideration, not least with regards to future research.	
MSI Reproductive Choices UK	Equality Impact Assessment			The guidance on progesterone, unless amended as above, is a disproportionate risk to people marginalised on account of one or more protected characteristic. In particular the protected characteristics of sex, disability, and religion can make individuals disproportionately susceptible to reproductive coercion - and therefore disproportionately impacted by unsafe progesterone use after having taken mifepristone. This disproportionate impact as an indirect result of equalities characteristics should be	Thank you for your comment. The recommendations on the use of progesterone relate only to women who have a history of miscarriage and early pregnancy bleeding. Progesterone is not recommended for women who have taken mifepristone and we have clarified this in the rationale section of the guideline.

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				acknowledged and considered in your equalities impact assessment.	
MSI Reproductive Choices UK	Guideline	029	009 - 015	As currently drafted, the amended guidelines could facilitate inappropriate, even unsafe usage of progesterone. It is highly advisable that the guidelines be amended to stipulate that the recommendation to offer vaginal micronised progesterone at 400mgs twice daily is not applicable to patients who have taken mifepristone in order to end a pregnancy. As an abortion provider we are aware of anti-abortion groups exploiting vulnerabilities among people who experience complicated feelings in the aftermath of their choice to have an abortion. Prescribing progesterone in such circumstances would be at best ineffective and at worse actively harmful. We have received calls to our post-operation support telephone line from women who have been prescribed progesterone under these circumstances and have had a poor experience. Unless the language is amended, we foresee a real likelihood that those with an anti-abortion agenda would exploit this as a loophole in the guidance which they could use to justify inappropriate or unsafe of	Thank you for your comment and for highlighting this issue. The recommendations on the use of progesterone relate only to women who have a history of miscarriage and early pregnancy bleeding. Progesterone is not recommended for women who have taken mifepristone and we have clarified this in the rationale section of the guideline.

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				progesterone for those experiencing emotional conflict, or indeed those experiencing reproductive coercion, having taken mifepristone. These individuals, many of whom are the most marginalised women and girls, should be protected. The guidance as currently drafted exposes them to exploitation and unsafe medical treatment.	
NHS England/NHS Improvement	Guideline	General	General	If there is an expectation that prescribing of progesterone should be done in primary care, there should be a mention of this and a recommendation around education of GPs on this change.	Thank you for your comment. The committee discussed that progesterone would be initiated in secondary care, usually by the early pregnancy unit that has conducted the scan and confirmed the intrauterine pregnancy, but the prescription can be continued by the woman's GP. However, the committee were aware that shared care prescribing arrangements are usually agreed locally (as they may require additional education of GPs as you state) and so although they included this information in the rationale and committee's discussion of the evidence, they did not include this detail in their recommendations.
NHS England/NHS Improvement	Guideline	006	030	(remove)	Thank you for your comment. Your comment relates to a section of the guideline that was not updated, and we are

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					not sure what the instruction 'remove' refers to.
NHS England/NHS Improvement	Guideline	015	013	1.5.2 - The Lancet series on Miscarriage supports this recommendation. Coomarasamy A, Dhillon-Smith RK, Papadopoulou A, Al-Memar M, Brewin J, Abrahams VM, Maheshwari A, Christiansen OB, Stephenson MD, Goddijn M, Oladapo OT. Recurrent miscarriage: evidence to accelerate action. The Lancet. 2021 Apr 27	Thank you for your comment and for informing us of this publication that supports the updated recommendation.
Royal College of Nursing	General	General	General	Thank you for the opportunity to contribute to this consultation. We do not have any comments from the RCN.	Thank you for your comment and support of this guideline.
Society and College of Radiographers	Guideline	General	General	It would be useful to define what a "confirmed intrauterine pregnancy" is before women start on progesterone.	Thank you for your comment. The committee agreed that the intrauterine pregnancy should be confirmed by a scan, and so we have added this detail to the recommendation.
Society and College of Radiographers	Guideline	029	018	In relation to the statement about starting progesterone prior to a fetal heartbeat being seen, this could lead to women with a failed pregnancy receiving progesterone. eg. Someone who is 7 weeks by dates but CRL is only 3mm with no fetal heartbeat would need a repeat scan to confirm if this is an on-going pregnancy or not. By giving progesterone it will be giving mixed messages and could be more difficult emotionally for families.	Thank you for your comment. The recommendation advises that progesterone can be started as soon as an intrauterine pregnancy is seen on a scan but that it should only be continued if a fetal heart is seen and we agree that this would need a repeat scan. However, the committee agreed that it was important to start the progesterone as early as possible, and even if no fetal heartbeat is seen or the

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				There is concern that the wording could be interpreted as being able to start progesterone as soon as there is an early gestation sac. It might be helpful to define as intrauterine pregnancy as one with yolk sac and embryonic pole with heart beat. Query caution in performing lots of extra early pregnancy scans in order to confirm a pregnancy is intrauterine for progesterone to start. There is a danger if these scan are performed too early they will be inconclusive perhaps scans should be performed 6 weeks from LMP?	pregnancy is subsequently lost, at least the woman could be reassured that she had done everything possible to try and prevent a miscarriage. The committee agreed it was not necessary to specify in the recommendation that a yolk sac, fetal pole and heartbeat were required for an intrauterine pregnancy, or that scans should be only performed after 6 weeks, as early pregnancy units already scan women who present with early pregnancy bleeding earlier than this.
The Breastfeeding Network	Guideline	General	General	Some women may still be breastfeeding an older child during pregnancy. We suggest that the guideline regarding methotrexate state that if it is used by a breastfeeding mother, she should discard her milk for 24 hours but can then continue to feed as normal. “In addition, methotrexate is believed to be retained in human tissues (particularly gastrointestinal cells and ovarian cells) for long periods (months). It is apparent that the concentration of methotrexate in human milk is minimal, although due to the toxicity of this agent and the unknown effects on rapidly	Thank you for your comment. Your comment relates to a section of the guideline that was not updated. However, we will pass on your comments to the NICE surveillance team who monitor guidelines to ensure they are up to date.

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				developing neonatal gastrointestinal cells, it is probably wise to pump and discard the mother's milk for a minimum of 24 hours post dose if given as a single dose (e.g. 50 mg/m2 IM for ectopic pregnancy) or administered once weekly (e.g. for RA). The period in which the mother discards her milk may require extending (consider 4 days of interruption) if the dose used is quite high (>75mg)" (Hale's Medications and Mothers Millk, 2021, Springer publishing)	
The Breastfeeding Network	Guideline	015	013 - 016	Some women may still be breastfeeding an older child during pregnancy. We suggest that the guideline state that that progesterone is compatible with ongoing breastfeeding if that is what the mother chooses. Hale's Medications and Mothers Milk (2021, Springer publishing) states "The direct effect of progesterone therapy on the nursing infant is generally unknown, but it is believed minimal to none as natural progesterone is poorly bioavailable to the infant via milk. Several cases of gynecomastia in infants have been reported but are extremely rare"	Thank you for your comment. The committee were aware that progesterone is not contraindicated during breastfeeding but agreed that decisions on prescribing progesterone to breastfeeding women would be made on an individual basis (as for all other medications) and it was not necessary to add a separate recommendation to state that.
The Miscarriage Association	Evidence review C	022	004	Beginning at line 4, the committee recommends starting treatment once there is confirmation of an intrauterine pregnancy "to avoid any potential delays". While such	Thank you for your comment. The committee agreed that women presenting with early pregnancy bleeding would currently be scanned when they present,

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				confirmation may be possible before 5 weeks gestation, current common practice is to scan only after 6+ weeks except in rare circumstances (e.g. suspected ectopic pregnancy). Recommending an earlier timeline would require far more capacity in terms of ultrasound appointments and skilled sonographers, and would be challenging for most providers.	and would not be asked to wait until after 6 weeks, so that this recommendation is unlikely to change the current workload of early pregnancy units.
The Miscarriage Association	Guideline	General	General	Implementation of the recommendation for early ultrasound assessment of women with early pregnancy bleeding is likely to be particularly challenging given the reduction in scan appointments due to Covid-19 and the increase in telephone triage. Perhaps this will have reversed by the time the guidance is published but it may still be an issue and should be taken into account.	Thank you for your comment. We appreciate that at the moment Covid-19 may be impacting on the number of appointments, and creating difficulties in seeing the number of women who turn up for scans, but as you point out this will hopefully only be a short-term issue. The committee agreed that women presenting with early pregnancy bleeding would currently be scanned when they present, and that telephone triage would only be appropriate for follow-up after the scan, so that this recommendation is unlikely to change the baseline workload of early pregnancy units.
The Miscarriage Association	Guideline	015	013	We fully support this recommendation	Thank you for your comment and support of this recommendation.
The Miscarriage Association	Guideline	015	015	There is no mention of a top gestational limit for beginning progesterone treatment. We	Thank you for your comment. There is no upper limit for starting progesterone and it

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				wonder if this should be taken to mean that it is any time after evidence of an intrauterine pregnancy up to 13 completed weeks, and whether this, or any different limit, needs to be made clear to clinicians and patients.	can be started any time up to 16 weeks, so we have not added a time limit into the recommendation.
The Miscarriage Association	Guideline	026	007	We fully support this research recommendation.	Thank you for your comment and support of this research recommendation.
The Miscarriage Association	Guideline	026	007	We understand the requirement for this to be a larger randomised controlled trial (larger than the PROMISE trial) and will fully support recruitment by informing our stakeholders. However, we are also conscious that promoting any such trial will also increase the likelihood of potential participants seeing it as an indication that progesterone is likely to be effective. This in turn will increase the chance that they will choose to source treatment privately rather than take part in a trial in which they risk being randomised to the placebo group.	Thank you for your comment and support for this research recommendation. We agree that some women with recurrent miscarriages may seek private treatment with progesterone rather than being randomised in a trial but hope that good communication between healthcare professionals and women may help recruitment.
The Miscarriage Association	Guideline	026	022	We fully support this research recommendation.	Thank you for your comment and support of this research recommendation.