NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Pain and bleeding in early pregnancy

Date of Quality Standards Advisory Committee post-consultation meeting:
01 May 2014

2 Introduction

The draft quality standard for pain and bleeding in early pregnancy was made available on the NICE website for a 4-week public consultation period between 10 March and 07 April 2014. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 16 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include overarching outcomes, thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Overall support was received for this quality standard and the good practice it promotes.
- The title of the quality standard is not representative of the quality improvement areas prioritised. In particular pain and bleeding implies symptoms that may not always be present in ectopic pregnancy and miscarriage.
- The needs of training and competencies were endorsed.
- Concern raised regarding generic introductory text in the quality standard regarding the involvement of family members in the decision making progress. A stakeholder felt that while family members can take part in consultation (with the

woman's consent) the decision making should be the woman's only and that autonomy must be preserved.

- Stakeholders made suggestions for amending and improving certain aspects of the content and introduction to the quality standard.

Consultation comments on data collection

- Generally it was felt that if appropriate systems were available it would be possible to collect the data for the proposed quality measures.
- A stakeholder did feel that some of the quality measures were superficial and in themselves will not lead to quality improvement.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Women with suspected ectopic pregnancy or miscarriage are seen in early pregnancy assessment services within 24 hours of referral.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Stakeholders suggested that at this stage of the pathway a referring clinician would not necessarily specify a suspected diagnosis and would most commonly refer a woman with having abdominal pain and/or bleeding in early pregnancy.
- Concerns were raised over the timescale for referral. Stakeholders felt that 24 hours is not always required particularly in the case of suspected miscarriage, and that if all cases met this timescale services would be overwhelmed.
- Conflicting suggestions were made regarding referral of women with gestation under 6 weeks. Some stakeholders felt that women with gestation under 6 weeks do not warrant referral to early pregnancy assessment services and this should be more prominent within the quality standard. There were other stakeholders who felt that 6 weeks gestation should not be the basis for entry into the pathway, as this may not be accurate and women may be missed.

- Women may not always need to be assessed before referral as some may be triaged by a midwife rather than seeing their GP.
- Concerns were raised over 7 day availability of early pregnancy assessment services. Stakeholders felt that only a minority of services currently offer 7 day working and what is available at weekends may not be of the best quality, funding from commissioning would need to be addressed.
- Some women may not know they are pregnant when presenting with symptoms of early pregnancy complications. As a result the statement should include the provision of pregnancy tests to ensure potential diagnoses are not missed.
- Stakeholders queried the measurement of being seen in an early pregnancy assessment service and how this is defined.

5.2 Draft statement 2

Women with suspected ectopic pregnancy or miscarriage are offered a transvaginal ultrasound scan for diagnosis.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Stakeholders highlighted that in some areas the practice is to use transabdominal and transvaginal ultrasound scans which are not necessarily mutually exclusive. Stakeholders also highlighted that some ectopic pregnancies can only be diagnosed with transabdominal ultrasound scans.
- Concerns were raised about the current standards of training for sonographers. Stakeholders felt that there should be a statement or measure relating to the training to improve diagnostic accuracy since the greatest risk of misdiagnosis is poorly trained staff.
- While stakeholders agreed with the principle of offering the option for examination by a female member of staff (Equality and Diversity considerations), they felt that in practice this may delay diagnosis, and possibly lead to diagnosis by a less experienced member of staff. They also felt that there is a difference for a woman who for cultural or religious reasons may only wish to see a female practitioner and those women who a female practitioner is a preference. The term

'accommodating' rather than offering would be preferable. Another stakeholder however commented that the offer should be made to all regardless.

- Concerns were raised about where scans are performed. Stakeholders felt that women with suspect ectopic pregnancy or miscarriage should receive a scan in dedicated early pregnancy assessment services, away from women with healthy pregnancies, having terminations of unwanted pregnancies and women receiving post-natal care.
- Stakeholders felt that communication should be made with a woman's GP after any investigations have taken place.

5.3 Draft statement 3

Women with a suspected miscarriage after an initial transvaginal ultrasound scan are offered a repeat transvaginal ultrasound scan to confirm the diagnosis.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- As with draft statement 2 concerns were raised about the current standards of training for sonographers.
- Stakeholders felt that while a second scan is needed in some cases it is not always necessary, and as a result that statement should have qualification of when this is needed.
- The statement should clarify if the second scan be repeated on the same day (it was noted that waiting 7-14 days for a 2nd scan can cause considerable distress)
- As with draft statement 2, while stakeholders agreed with the principle of offering the option for examination by a female member of staff, they felt that in practice this may delay diagnosis, and possibly lead to diagnosis by a less experienced member of staff. They also felt that there is a difference for a woman who for cultural or religious reasons may only wish to see a female practitioner and those women who a female practitioner is a preference. The term 'accommodating' rather than offering would be preferable. Another stakeholder however commented that the offer should be made to all regardless.
- As with draft statement 2, concerns were raised about where scans are performed. Stakeholders felt that women with suspect ectopic pregnancy or

miscarriage should receive a scan in dedicated early pregnancy assessment services, away from women with healthy pregnancies, having terminations of unwanted pregnancies and women receiving post-natal care.

5.4 Draft statement 4

Women with a suspected ectopic pregnancy or miscarriage are given evidence-based information.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Support was given for a statement on providing information. However stakeholders felt that the current provision of information is of poor quality.
- Stakeholders felt that it should be specified that this information is written in order to avoid confusion.
- Stakeholders highlighted that the information provided should also cover support, counselling, future pregnancies, as well as information of action to take if miscarrying at home.
- Stakeholders felt that a measure in relation to patient experience (positive and negative) would be beneficial to this statement.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Anti-D prophylaxis.
- Quality of aftercare, including primary care follow up and integrated care between hospital staff and community healthcare professionals.
- Weekly multidisciplinary team meetings (MDT) to enable early pregnancy assessment units to review cases and discuss ectopic pregnancies and best practice.
- It was highlighted that none of the statements explicitly address women's psychological and emotional wellbeing and that a separate statement on this would be beneficial.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comments[1]
001	Association for Improvements in the Maternity Services	General	"if appropriate, health professionals should ensure that family members and carers are involved in THE DECISION MAKING PROCESS on investigations, treatment and care." We have already objected to the use of this phrase in our submission to the consultation on Pain and Bleeding in Early Pregnancy in August 2012. and cited supporting evidence. . Whereas family members may take part in consultations with the woman's consent, the DECISION is hers alone. Decisions concerning her body and her unborn child are also hers alone. According to Nice CG 154 1.1.1. all women with early pregnancy complications are to be treated with "dignity and respect". We suggest this begins with respect for the autonomy of the woman. Family can include psychological and physical abusers, who are often charming, plausible and well-educated, and not necessarily male. Domestic violence is known to increase the risk of miscarriage, so there will be a number of unidentified victims in this population. Avoidance of using family members as interpreters for women who do not speak English applies also to this, as to other aspects of maternity care. In emergency care it may be unavoidable, but the risks must be flagged up.
002	Association for Improvements in the Maternity Services	General	We greatly welcome the concern shown here for good practice where suspected ectopic pregnancies area concerned
003	Association for Improvements in the Maternity Services	General	There are two especially vulnerable groups. One is those who have become pregnant after extensive medical intervention, the other is those who have suffered repeat miscarriages. Apart from direct access to specialist units for the latter, no further requirements are mentioned. We would have welcomed recognition that these groups need referral for aftercare.
004	Gloucestershire Hospitals NHS Foundation Trust	General	Rarely it does and it can be removed or treated with methotrexate.
005	Gloucestershire Hospitals NHS Foundation Trust	General	The statement sufficient and appropriate is open to differing interpretations and not measureable against any standard.

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement No	Comments[1]
006	Mumsnet	General	There was a feeling among Mumsnet users who commented that there should be further quality statements relating to the quality of aftercare, which they think is an area that could do with further improvement (greater follow-up from primary healthcare workers, more joined-up communication between hospital staff and community midwives and GPs, greater access to counselling for those who need it).
007	Mumsnet	General	There is some concern that the title 'Pain and bleeding in early pregnancy' implies that these quality standards only apply to miscarriage care where women have self-referred with these symptoms. Of course many miscarriages are missed miscarriages that are only discovered at routine scans, and in these cases there may have been no pain or bleeding. Could it be clarified that these standards apply equally to missed miscarriages?
008	Peterborough City Hospital	General	Oral methotrexate is mentioned – what about IM?
009	Peterborough City Hospital	General	At our unit, women can self refer, even if no previous ectopic or molar pregnancies. I would be interested to hear others comments about whether they feel women should be assessed by primary care prior to attending an EGAU, unless these criteria are satisfied
010	Peterborough City Hospital	General	CRL measurement under 7mm should be rescanned in one week/2nd sonographer to confirm – what about if the CRL is 30mm. Are you suggesting that a second person/2nd scan needs to confirm even if a pregnancy is very large but still no FH is seen?
011	RCGP	General	P2. Maybe add some more about severe complications of miscarriage – it too can lead to maternal death through bleeding or sepsis.
012	RCGP	General	PROVIDING INFORMATION – EPU providing follow up appointments / review clinics – supported by O&G trained nurse; psychological services. Would be able to provide support, counselling, signposting for future pregnancies. Communication with GP should include follow up arrangements; future support available locally for future pregnancies; contact number for GP to give to patient; outcome of psychological interventions/ need for further intervention and if this is to be organised by EPU.
013	Royal College of Nursing	General	Broadly, the draft standard seems comprehensive and practical.
014	Royal College of Nursing	General	The standard mentions sign posting for support and counselling services post pregnancy loss but it does not recommend that there should be support or access to counselling services within the clinics. This is a missed opportunity as there is limited access to counselling within the NHS. We would, therefore like to see a specific statement that makes provision within the service for counsellors. This is a key area for quality improvement.
015	Royal College of Obstetricians and Gynaecologists	General	2nd sentence in ectopic is factually incorrect. The ectopic preg need not always be removed, as spontaneous regression is not uncommon. Expectant and medical methods are accepted approaches to treatment of ectopic.

ID	Stakeholder	Statement No	Comments[1]
016	Royal College of Obstetricians and Gynaecologists	General	The sentence 'rate of ectopic is ... and is associated with maternal death' is misleading. Suggest rephrasing to ' the rate of ectopic is ... with a maternal mortality rate of 0.2....'
017	Royal College of Obstetricians and Gynaecologists	General	Suggest replacing 13 completed weeks of pregnancy in the document with 13^{+0} of pregnancy is better as do all RCOG documents do. Although it states 13 completed weeks in the NICE guidance QS should make it clearer that it refers to 13 +0 weeks.
018	Society and College of Radiographers	General	Some statements appear to be over-simplified versions of what is within the main guidance document CG 154 and lose meaning because of this.
019	Society and College of Radiographers	General	Overall we feel that the Quality Indicators are too superficial and in themselves will not provide worthwhile information. The information arising from any returns as currently worded (especially 2 and 3) could be very mis-leading and open to various different interpretations. For the SCoR important quality indicators that have not been included would be whether scans are being undertaken by competent and appropriately trained professionals, are both TA and TV scans included, has reference been made to CRL/gestation sac size guidelines on diagnosing fetal demise, are there audit and quality assurance procedures (including infection control – MHRA alert) in place, what are the clinical outcomes etc. Was a sonographer involved in the production of these Quality Indicators?

ID	Stakeholder	Statement No	Comments[1]
020	The Ectopic Pregnancy Trust	General	As a patient group, we welcome the opportunity to review and comment on these quality standards. We appreciate the intention to better standards and, with the aim of putting patient's needs at the heart of the consultation, we offer the following additional suggestions and amendments to improve and enhance the guidance and standards: In order to support the objective that people have a positive experience of primary and secondary care, incorporate a measure of patient experiences (both positive and negative) in addition to measuring whether women feel informed about their care in the evaluation protocol. Given non-tubal ectopic pregnancy contributes disproportionately to morbidity and that scar pregnancy contributed to two deaths reported in CMACE, comment specifically in the guidance on the quality standards of these ectopics. To support comments on “data collection”, introducing a standard requiring units to use a suitable reporting database with image archiving for review would be extremely beneficial. For example, Astraia or Viewpoint. Collected data, that could also support the measure of ultrasound quality, should include the maintenance of a rolling audit of the number of Pregnancies of Unknown Location (PUL) in the unit and the number of ectopic pregnancies in the PUL population; the number of missed ectopic pregnancies; and the number of women who undergo surgery for ectopic pregnancy where no pregnancy was found – i.e. the negative laparoscopy rate. We note that the last CMACE report highlights that many cases of ectopic pregnancy are not suspected in primary care, never have a pregnancy test or are misdiagnosed with ultrasound. Clear measurement of the quality of ultrasound can help to highlight where there are problems and support the seeking of a resolution. The recommendation of a weekly Multidisciplinary Team Meeting (MDT) on the unit to review cases and discuss ectopic pregnancies and PUL, as well as risk issues, would go a long way to promote ongoing learning, future earlier diagnosis and the development of good practice.
021	The Ectopic Pregnancy Trust	General	Additional detail would provide helpful guidance in this section. For instance, it would be useful for training to be built into commissioning. As it is not paid for it doesn’t always happen.

ID	Stakeholder	Statement No	Comments[1]
022	The Ectopic Pregnancy Trust	General	The NICE guidance appears to base much of its economic assessment of the management of miscarriage on the MIST trial. We note methodological problems that make drawing conclusions from this trial difficult. Namely, in this randomised trial of 3905 women attending early pregnancy units, 1621 refused trial entry and 1085 were not eligible. This resulted in only 1200/3905 (31%) women being randomised and the trial had to be extended by 33 months to overcome recruitment problems. Accordingly, the subjects ultimately included in this trial represent a highly selected population and basing policy on the outcome of this tranche of 1200 women is risky. This is particularly the case for psychological outcomes, as the women who consented to take part in the trial are likely to be the most motivated and so potentially least likely to show psychological morbidity whichever management option is taken. Consequently, the economic evidence taken from this trial is not as robust as desired. The NICE recommendation that all women with miscarriage should be given a trial of expectant management seems to be based purely on an economic argument and uses the MIST trial to suggest that there is equality between the different management options – and so argues that the economics should be the main driver. This guidance removes patient choice and is a significant concern to patient groups. Furthermore, the assumption that the outcomes of the management options for miscarriage are similar fails to consider the fact that 69% of women who could have entered the MIST trial either chose to exercise their choice to undergo surgery or were not eligible for the trial. That it was so hard to recruit women into this trial, could be an indicator about what patients want and many do not want expectant management for a variety of reasons. We note a gap in the guidance on the use of outpatient surgical treatment of miscarriage. We recognise that data on this is limited but opinion on the utility and selection criteria of this approach would be useful.
023	The Miscarriage Association	General	Re “Why this quality standard is needed”. The second sentence begins accurately “This does not always mean there is a problem”. The second half “and in most cases these symptoms are nothing to worry about” is inappropriate and possibly misleading. It is inappropriate because it is patronising in tone; and possibly misleading because there is no indication of what “nothing to worry about” actually means. There is good evidence that early pregnancy bleeding even in a viable pregnancy is associated with problems later in pregnancy, including a higher rate of pre-term birth. I would also question the evidence behind “in most cases”.
024	The Miscarriage Association	General	Re “Why this quality standard is needed”. The statement at the top of page 2: “When a pregnancy ends before the 24th week of pregnancy, it is called a miscarriage” is not accurate, since that can also be the description of an ectopic or molar pregnancy. It needs revising and possibly the addition of the word “spontaneous(ly)”.
025	The Miscarriage Association	General	Re “Training and competencies”. We thoroughly support this, and equally recognise that is an area requiring considerable investment by commissioners.

ID	Stakeholder	Statement No	Comments[1]
026	The Royal College of Midwives	General	The RCM welcomes this important quality standard and considers that the content in the draft reflects important areas for quality improvement. However, the importance of acknowledging women's views of the experience and emotional and psychological outcomes which is well documented in the guideline is not reflected in any of the statements. A further statement to pick up on emotional well being and how the process of care can improve in that area would be useful and relevant. Moving statement 4 on information giving to statement 1 would reflect more concern with women's experiences.
027	The Royal College of Midwives	General	Use of the word "pain" is rather non-specific. It would be more helpful to describe where the pain would be eg low abdominal pain or abdominal pain
028	The Royal College of Midwives	General	We are pleased to see the recommendation here that "Women provided with information should have access to an interpreter or advocate if needed" here. This recommendation should be present in all the statements.
029	Association for Improvements in the Maternity Services	Question 1	Key areas not covered. 1. Lack of prescribed training for all those scanning pregnant women and unborn children. Although operators in the NHS would invariably have a professional qualification of some kind, there is no standard qualification in use of ultrasound itself. Action on this is long overdue. 2. There is no evidence of safety or otherwise for exposure during the first trimester. Such evidence as we have is not reassuring. A small randomised trial comparing ultrasound with vaginal examinations found shorter gestation in the ultrasound exposed group. (ref. to follow) 3. Whilst tranvaginal ultrasound is most useful for diagnosis of suspected ectopic pregnancy, the embryo/fetus has more intense exposure compared with trans-abdominal scanning. ~Therefore it should be used only when necessary 4. We do not know how many normal babies have been lost after a faulty diagnosis of death was made. Cases continue to be reported in the press and to us of continuation of successful pregnancy after termination was declined. We do not know how many cases there are where the woman declines a second scan or chooses termination, and we can think of no means of monitoring this aspect of quality. We receive many queries from women about safety of exposure, particularly from those who have miscarried shortly after an early pregnancy scan. Unfortunately we cannot supply them with adequate information because it does not exist. They are assured scans are "safe" because there is lack of evidence of harm – but that evidence has never been sought.

ID	Stakeholder	Statement No	Comments[1]
030	RCGP	Question 1	I'm not sure these are the key areas for quality improvement. Would successful anti-D prophylaxis be more significant? There is no attempt to address bereavement/distress/mental health problems after aspects after miscarriage and ectopic pregnancies. Maybe the availability of/access to a counselling service might be more important or at least addressing this issue directly in the information given. In addition the 4 areas chosen are very process and not outcome driven. Maybe it would be better to have something about women's experience of care.
031	RCGP	Question 2	If the systems and structures existed of course it would be possible to measure these things, but I'm not sure that would equate to better care.
032	The Royal College of Midwives	Question 2	If appropriate systems were available, it would be possible to collect the data for the proposed quality measures.
033	Royal College of Obstetricians and Gynaecologists	Question 1 (and 2)	Yes to Q 1and 2 on pg 5
034	Association for Improvements in the Maternity Services	Quality statement 1	We welcome this statement of early referral within 24 hours. The weak point in the system from the user point of view is the out–of-hours GP service, both availability and quality, and over bank holidays they are the only resource for those who are trying to avoid using A & E. And for the most vulnerable groups, transport to access either , or money to pay for transport, may not be available. We suggest that particular attention should be paid to informing out-of-hours GP service, often staffed by overseas locums unfamiliar with NICE guidelines. .

ID	Stakeholder	Statement No	Comments[1]
035	Association of Early Pregnancy Units (AEPU)	Quality statement 1	All suspected miscarriages and ectopic pregnancies should be seen within 24 hours. This needs clarification as it is unlikely to be economically feasible for Trusts to provide a 24/7 specialist Early Pregnancy service. The Unit I lead was the only one in the country offering this and stopped as it was being abused by patients who clinically did not need to be seen “out of hours”. The local commissioners described it as a “luxury they could not afford”. There are real problems staffing units with appropriately qualified personnel. Women bleeding heavily or in pain which is not resolving should always have access to gynaecological care. The focus of their management should be clinical assessment. It is better for those less unwell to wait to be seen by appropriately trained, empathetic staff and scanned by someone with the correct training and experience. All suspected miscarriages and suspected ectopic pregnancies should be seen within 24 hours and all women in a previous point should have an ultrasound scan. The feasibility from a staffing and cost point of view of units being open 7 days a week with access to scanning is questionable on the current tariff. This again does not take into account the smaller units perhaps run by a couple of nurses with a sonographer who could not work 7 days a week. Early Pregnancy Units need to be run by specialised, knowledgeable staff. It will be detrimental if hospitals start to use general or agency staff to ensure they can provide this service. If services are shared with other units there will be travelling involved for patients and this needs to be clear in the standards. In maternity care there are triage and Day Assessment Unit services running 7 days a week but these can be staffed by a wider staff set i.e midwives of whom there are many more to share the 7 day work pattern. There also has to be consideration that this will result in an increased on call operative workload at weekends and will impact on staffing at these times for emergency surgical provision. With adequate funding and increase in staff this will all be possible.
036	Gloucestershire Hospitals NHS Foundation Trust	Quality Statement 1	Statement 1 would read better ‘Women with suspected ectopic pregnancy or miscarriage are contacted within 24 hours of referral and an appropriate plan of investigation and care made for them including attendance at a dedicated Early Pregnancy Assessment Unit’.
037	Gloucestershire Hospitals NHS Foundation Trust	Quality Statement 1	Yes
038	King’s College Hospital, London	Quality statement 1	This data would be difficult for us to collect as the referring clinician does not usually specify the suspected diagnosis. The most common indication is for abdominal pain and/or bleeding in early pregnancy. By implication these women are seen and scanned to check for an ectopic pregnancy. The same goes for suspected miscarriage, but in this case it is bleeding +/- pain. It might be preferable to collect data on women referred due to pain or vaginal bleeding rather than try to break down into suspected ectopic & suspected miscarriage for these standards.

ID	Stakeholder	Statement No	Comments[1]
039	Mumsnet	Quality statement 1	While our members welcome the use of early pregnancy units, they note that many are available only during office hours, Mondays to Fridays. They are concerned about the referral routes and timings for women who start to miscarry outside these hours, particularly over weekends.
040	RCGP	Quality statement 1	Comment about Quality Statement1 Rationale states 'Women with a suspected ectopic pregnancy or miscarriage should be seen within 24 hours of referral to ensure that their clinical situation does not worsen.' What is the evidence that this applies to suspected miscarriage as well as to ectopic? CG 154 recommendation 1.2.4 states 'Ensure that a system is in place to enable women referred to their local early pregnancy assessment service to attend within 24 hours if the clinical situation warrants this.' Of course this applies for a suspected ectopic, but if that is not the case (for example if the patient has had a previous scan confirming intrauterine pregnancy) and the concern is limited to a possible miscarriage I am not aware of any evidence that an assessment needs to be done urgently, and this could potentially generate a large and unmanageable workload. Further, CG 154 recommendation 1.3.9 states 'The urgency of this referral depends on the clinical situation' and 1.3.10 indicates that below 6 weeks' gestation there is no indication for scanning at all if there is bleeding but no pain (which would still be defined as 'suspected miscarriage'). Finally, on Page 8 the Referral section states 'A decision should be taken about whether the woman should be seen immediately or within 24 hours depending on the clinical situation. [NICE clinical guideline 154, recommendations 1.2.3 and 1.3.11]' In fact, 1.2.3 does not specify a timescale (this is actually referred to in 1.2.4, see above) and 1.3.11 applies specifically to suspected ectopic and not to suspected miscarriage. Quality Statement 1 as currently worded is not supported by the Guideline on which it is supposedly based, and if implemented could overload early pregnancy assessment services, potentially reducing access for genuinely urgent cases.
041	RCGP	Quality statement 1	Not sure that all women need to be seen within 24 hours. CG154 says "within 24 hours if the clinical situation **warrants this**". I think the basis of this statement is that services should be available 7 days a week (otherwise there will be a Monday numbers bulge and services may not be able to cope). That would be aspiration enough in the current climate
042	RCGP	Quality statement 1	I think the "6 weeks gestation" needs to be emphasised earlier, maybe in the introduction on p 2 and the justification for this: i.e. the stage at which the FH becomes visible/fetal pole visible, so it is possible to diagnose a viable pregnancy
043	RCGP	Quality statement 1	REFERAL – increased role / responsibility for role of Midwife in referring patients presenting with this problem – rather than directing them to their GP. If a patient is known to the midwifery service and contacts them with bleeding in early pregnancy it would be more appropriate for the MW to refer directly to EPU than to the GP – this would be better care for the patient and provide more continuity.

ID	Stakeholder	Statement No	Comments[1]
044	Royal College of Nursing	Quality statement 1	This is good, however need to add to the definition below as the crucial bit is early diagnosis and scanning at 6 weeks and not seeing a pregnancy scan would give rise to the suspicion of ectopic especially if patient has pain and light bleeding.
045	Royal College of Nursing	Quality statement 1	Need some clarity around definition. Suggest adding: Scan patient at 6 weeks to establish pregnancy is in the right place (i.e. uterus). If a pregnancy is not seen in the uterus and patient has rising Beta Human Chorionic Gonadotropin (BHCG) levels then an ectopic pregnancy would be suspected.
046	Royal College of Obstetricians and Gynaecologists	Quality statement 1	Last sentence- ' ' it is important to ensure that services are accessible **to** women from these groups'
047	Royal College of Obstetricians and Gynaecologists	Quality Statement 1	QS1 implies seven day a week availability of EPAs, unless some rider is added. Though a few units are working towards such provision it is currently rarely available. For example, most departments provide dedicated EPAS sessions during the day, Mon to Fri. EPAS related activity is undertaken by on call gynaecology services over the weekend. So, does referral to the on call gyn service qualify as referral to an EPAS ,when an EPAS referral simply cannot be made within the timeframe?
048	Society and College of Radiographers	Quality Statement 1	Women with suspected miscarriage being seen within 24 hrs in an early pregnancy assessment service. It needs to be made clearer that pregnancies under 6 weeks should not warrant referral unless there is uncertainty of dates or women are experiencing pain
049	The Ectopic Pregnancy Trust	Quality Statement 1	We welcome the quality statement that women with a suspected ectopic pregnancy or miscarriage are seen in early pregnancy assessment services within 24 hours of referral as such units have specific training and experience of caring for this patient group. We note that the diagnosis must be suspected first and not all women know they are pregnant when they present at their GP with ectopic pregnancy symptoms. Including the provision of urinary pregnancy tests in primary care where symptoms exist would assist in the process of ensuring a referral. We note that the CMACE report highlights that many cases of ectopic pregnancy are not suspected in primary care, never have a pregnancy test or are misdiagnosed with ultrasound. Referral within 24 hours suggests that early pregnancy assessment services must be available over the weekend. This has major implications for commissioning and we are concerned about the quality of care that will be provided in such circumstances. For instance, this could encourage the development of single-handed cover at weekends and lack of senior supervision which may lead to errors and possibly misdiagnoses. We would encourage that the route forward might be for each clinical commissioning group/local area team to ensure the availability of at least one early pregnancy assessment unit in its local area that was adequately staffed on a rota basis.

ID	Stakeholder	Statement No	Comments[1]
050	The Ectopic Pregnancy Trust	Quality Statement 1	Page 8, line 8: Suggest this should be specified as "TRANSVAGINAL" ultrasound. Page 8 line 8: "offer...assessment of serum hCG levels" - In our view, offering analysis of hCG levels in itself does not provide sufficient meaningful information or support in these circumstances. As a refinement, we would suggest that this statement should include a time frame within which the results will be required. We would suggest four hours to ensure that the results are reviewed and patients contacted the same day.
051	The Ectopic Pregnancy Trust	Quality Statement 1	Page 8, line 14: "A decision should be taken about whether the woman should be seen immediately or within 24 hours depending on the clinical situation". The use of "immediate" in this context could be ambiguous for some and could lead to confusion in circumstances where, for instance, a woman presents with symptoms overnight.
052	The Ectopic Pregnancy Trust	Quality Statement 1	Page 9, lines 1 – 2: We are unclear as to the implications of this wording for women who fall into the category of being less than six weeks gestation and present with bleeding but no pain i.e. in the current standard wording they **do not** require a scan or assessment. We suggest that this be amended, as such women may also be suffering miscarriage or, more importantly, an ectopic pregnancy given that 30-40% of ectopic pregnancies present with bleeding. Our basis for this comment is that there is no evidence to suggest that women with ectopic pregnancies are not a problem if they only have bleeding but no pain. Additionally, many women do not recall their dates with certainty/accuracy and they may be beyond six weeks gestation without realising it. Furthermore, Bottomley et al have evidenced that if scans are restricted on the basis of gestation, ectopic pregnancies may also be overlooked in the symptomatic group. We query the rationale of having 42 days as the basis for entry into the scanning pathway and debate whether this would in reality constitute safe practice.
053	The Miscarriage Association	Quality statement 1	Referral to assessment services. I think the key information about gestation (i.e. 6 weeks or more) needs to appear much earlier, preferably in the QS. As is, it is several pages in and almost a minor point. This could lead to massive over-referral.
054	The Miscarriage Association	Quality statement 1	There is lack of clarity about the definition of being "seen". The rationale includes "seen in an epas for diagnosis and management", but it is not clear if this will include an ultrasound scan and/or serum hCG testing, though these facilities should be available. Ultrasound scanning is only specified in QS2.
055	The Royal College of Midwives	Quality Statement 1	States that woman should be assessed by a health care professional prior to referral. Women often self refer and telephone triage is undertaken by a midwife prior to attending unit. This option is not documented in the statement.
056	Association of Early Pregnancy Units (AEPU)	Quality statement 2	diagnosis using ultrasound Suggest add diagnosis of miscarriage & ectopic pregnancy using one vaginal ultrasound cannot be guaranteed to be 100% accurate and so repeat transvaginal ultrasound scan should be offered to confirm diagnosis.
057	Gloucestershire Hospitals NHS Foundation Trust	Quality Statement 2	Yes

ID	Stakeholder	Statement No	Comments[1]
058	RCGP	Quality statement 2	In rationale, the 3rd sentence is part of the justification for QS 3 not QS 2
059	RCGP	Quality statement 2	DIAGNOSIS – prompt communication with GP practice of results of any investigations' / scans undertaken by the EPU and details of any review appointments. Patients often attend GP surgery for review / sicknote after seeing EPU. To have information from EPU after they have been seen there would be useful.
060	Society and College of Radiographers	Quality statement 2	Just performing a transvaginal scan is not enough. Many sonographers consider that the 'gold standard' is to undertake a preliminary transabdominal scan. Some ectopic pregnancies can only be seen on a transabdominal scan and can not be identified on a transvaginal scan due to falling outside the field of view. One respondent to this consultation reported having seen inexperienced operators undertaking transvaginal scans miss a more advanced intrauterine pregnancy which was beyond the 'depth' of a TV scan. Many viable intrauterine pregnancies can be easily diagnosed on a transabdominal scan, and women should not be pressurised into having an unnecessary transvaginal scan. Many sonographers believe that you cannot appropriately counsel women about the need for a transvaginal scan without having first scannned transabdominally. To give informed consent, women need to be given accurate information as to the pros/cons and value (or not) of proceeding to a transvaginal scan. A Quality Standard (No. 2) relating to whether TV scanning is offered or not is somewhat arbitrary and does not reflect the complexities of this area of practice. Why is quality not being assessed against outcomes? No information as to the quality of that scan will have been obtained.
061	Society and College of Radiographers	Quality statement 2	Practitioners undertaking transabdominal scans when transvaginal scans declined will also need to be appropriately qualified and competent. By far the greatest risk of ultrasound is misdiagnosis by poorly trained staff.
062	Society and College of Radiographers	Quality Statement 2	Not all women who are offered a transvaginal scan will consent to this and only a transabdominal scan will be performed. Recognition should be made of this in the data requested if accurate figures are to be obtained. Please also see below, TV scanning and TA scanning complement each other, they are not mutually exclusive. If the information can easily be obtained by a transabdominal scan (always a good starting point) a TV scan is not necessary. Your quality indicator would not reflect what is actually good practice.
063	Society and College of Radiographers	Quality statement 2	Healthcare professionals offer women with suspected ectopic pregnancy or miscarriage a transvaginal ultrasound scan that identifies the location of the pregnancy and whether there is a fetal pole and heartbeat to diagnose ectopic pregnancy or miscarriage'' This paragraph is over-simplified. There may be no fetal pole or heartbeat visible with an ectopic pregnancy, only an adnexal mass.

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064	The Ectopic Pregnancy Trust	Quality Statement 2	Page 10, lines 1-2: We understand what is meant by this statement and wholeheartedly agree, however, have concerns that there is room for misinterpretation of the standard. "Women with suspected ectopic pregnancy or miscarriage are offered a transvaginal ultrasound scan for diagnosis." This language could be interpreted that every woman must have a transvaginal scan. At, say, nine weeks gestation, it is perfectly possible to see an embryo and heartbeat through an abdominal scan. With this in mind, it may transpire from an abdominal ultrasound that the woman does not require a transvaginal scan and we would question the ethical stance in insisting on an internal scan in these circumstances. We wish to distinguish that if an abdominal ultrasound scan results in a PUL or PUV (pregnancy of uncertain viability) THEN a transvaginal scan should be offered to consider possible diagnosis of miscarriage or ectopic pregnancy.
065	The Ectopic Pregnancy Trust	Quality Statement 2	Page 12, last paragraph: "all women should be offered the option of being examined by a female member of staff". We wish to note that this would be very difficult in practice at a unit where female staff may not be available. We note that, in many cases, this could lead to a reduced standard of care through a delay for a scan or the patient being examined by a less experienced member of staff. These risks must be clearly explained to the patient particularly to enable women to make an informed choice and give informed consent. We suggest rephrasing this to "Wishes of all women who ask to be examined by female staff should be respected and followed and a female chaperone should be present during all examinations. In the event that this would lead to a delay or being seen by a less experienced member of staff, this should be discussed with the patient so an informed choice can be made".
066	The Miscarriage Association	Quality statement 2	Re "Rationale". The final sentence states that diagnosis of miscarriage using 1 TVUS cannot be guaranteed to be 100% accurate and so repeat TVUS should be offered to confirm diagnosis. I think this needs room for options as there will be cases where a TVUS showing a large sac with no fetal pole or heartbeat provides a very clear diagnosis. Insisting on a repeat scan in 7-14 days can significantly increase patient distress. A second scan to confirm findings at the same appointment might be much more acceptable.
067	Association for Improvements in the Maternity Services	Quality statement 2 (and 3)	We greatly appreciate the section saying that women should be offered the opportunity for transvaginal scans to be carried out by female members of staff. This offer should be made to all. We know that women who have suffered sexual abuse are often reluctant to have examinations by male staff. Nor do they wish to give the reason for their reluctance (which may result in case note records). The offer should be made to all, with no questioning or implications that the women are being awkward or difficult.

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068	Association of Early Pregnancy Units (AEPU)	Quality statement 2 (and 3)	The standards miss the opportunity to collect essential data such as “negative laparoscopy”, “pregnancy of unknown location” and “new to follow up” rates. All of these are essential to ensure high quality ultrasound scanning is being implemented and management decisions are being made by sufficiently senior and/or specialist health professionals for patient safety and to minimise emotional and social disruption for them. I am very disappointed to see that there are no standards with regard to the standard of scanning other than the 2 scans for diagnosis of miscarriage. There should be a standard that states that all sonographers should be appropriately trained for unsupervised practice (there are a lot of junior doctors having a go without direct supervision and not appropriately trained). There also should be a standard relating to diagnostic accuarcy eg number of ectopics diagnosed before theatre, at first scan and inconclusive scan rate. It is all well and good to have a patient with a potential ectopic pregnancy seen in 24 hours by a female doctor who actually cannot scan to an appropriate level and misses the ectopic pregnancy. The unit would be scoring well against NICE standards. The AEPU welcomes standard on access to scanning 24 hours. However, we would wish to see criteria set for standards of scanning equipment and qualifications.
069	Association of Early Pregnancy Units (AEPU)	Quality statement 2 (and 3)	All women should be offered examination by a female if requested. This is clearly optimal however in a small unit actually means that it would be difficult for male doctors/ sonographers to work there. It also does not help units where the senior opinion is male - i.e second opinion. This is clearly an ideal but I do not think it will always be deliverable especially in single scan room units.
070	Mumsnet	Quality statement 2 (and 3)	Our members have reiterated that they feel scans on women suspected of undergoing a miscarriage would be best carried out in dedicated EPUs. Where this isn’t possible, these scans should really be done in settings separate from women with ongoing healthy pregnancies, women having terminations of unwanted pregnancies, and women receiving post-natal care. Miscarrying women are often caused great distress by having scans alongside these other categories of healthcare users.
071	Royal College of Obstetricians and Gynaecologists	Quality Statement 2 (and 3)	Equality and Diversity considerations section, it states that: ‘ALL women should be offered the option to be examined by a female member of staff.’ This may not be possible and as such should not be included as part of this document. Implementing it can be to the detriment of the patient depending upon the clinical situation. It is vital to cater to individual circumstances but the statement seems too rigid. ‘Offering’ is different to ‘accommodating’ when requested; the latter is usual. If the QS sticks to ‘offering’ (rather than ‘accommodating upon request’) then the same offer of a specific gender healthcare professional must apply to any medical encounter, must it not? Not at all confident that would work in practice. Please re-consider.
072	Society and College of Radiographers	Quality statement 2 (and 3)	All practitioners performing early pregnancy ultrasound should be appropriately qualified and their work subject to audit. Equipment used should be within the employer’s quality assurance/governance arrangements for ultrasound equipment and particular attention paid to cleaning and preparing the transvaginal probe and its cover

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			to avoid cross infection (MHRA alert).
073	Society and College of Radiographers	Quality Statement 2 (and 3)	It is appreciated that there are some women, particularly from some ethnic and religious groups, who will decline a TV scan if a female practitioner is not available and this is of course their right. However, this is not the case for the majority of women who while perhaps *preferring* a female will consent to a male performing the examination. They often state that the most important thing for them is that the examination is performed competently by a practitioner who is qualified and experienced in the field. The option of a female practitioner should be available but if the wording were to imply that one *must* be offered without there being any prior feedback from the patient (either verbal or non-verbal) this will become a very difficult working environment for the many male doctors and sonographers involved. There may also be some units who cannot offer a female practitioner straight away and the scan may need to be re-scheduled. A distinction needs to be made between a woman who may *prefer* a female but will consent to an examination undertaken by a male (applies in many other clinical situations, including gynaecology), and when it is not acceptable for that woman to have a male practitioner performing the scan and not having a female practitioner immediately available could compromise care. Some women express the view that they have no particular concerns or preferences with regards to the sex of the practitioner at all. It would be helpful if any related statements were as flexibly worded as possible.
074	Gloucestershire Hospitals NHS Foundation Trust	Quality Statement 3	Yes
075	Mumsnet	Quality statement 3	There was a consensus that the second scan should not be mandatory, as in some circumstances it is not clinically necessary and leads to women having to wait an extra period of time before they can receive active treatment.
076	RCGP	Quality statement 3	In rationale, QS2 p10, the 3rd sentence is part of the justification for QS 3 not QS 2. Are you advocating that every woman has a repeat scan, even if her miscarriage is complete and her bleeding has stopped? This has huge resource implications. Is there a research basis for this? Is this really such an important aspiration? Is it more important to recheck the pregnancy test first (as recommended in the pathway) and only do a repeat scan if the test is positive?
077	Society and College of Radiographers	Quality Statement 3	The wording of the rationale does not reflect the complexities of the situation and does not fully reflect the guidance in CG154
078	Society and College of Radiographers	Quality statement 3	Repeating a scan after minimum 7 or minimum 14 days to confirm a miscarriage. There are many occasions when miscarriage can be diagnosed without waiting 7 – 14 days i.e. fetal pole greater than 7mm without heart activity, an empty sac with mean diameter of 25mm or more. It is usual in these cases to have findings confirmed by a second operator. This is included in NICE CG 154.

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079	The Ectopic Pregnancy Trust	Quality statement 3	Page 13, lines 3-4: “Women with a suspected miscarriage after an initial transvaginal ultrasound scan are offered a repeat transvaginal ultrasound scan to confirm the diagnosis”. We query whether, in some cases, it is important to be encouraged to HAVE one versus, in other cases, to be OFFERED one and this is an option taken according to preference and personal choice by patients to have a repeat ultrasound to confirm a diagnosis of miscarriage. We agree that women need repeat scans at an interval when the mean sac diameter or crown-rump length is near the decision boundary but the statement that all women have to have a repeat scan to confirm miscarriage does not appear to be sufficiently evidence-based. For instance, a patient at nine weeks gestation with a 20mm embryo and no fetal heartbeat checked by two people, presumably, does not require a second scan. This point also stands in relation to women who miscarry at home and bleed at late gestations. We suggest this noting two key factors (1) that specificity of the amended guidance for miscarriage is 99.5% with tight confidence intervals according to the updated Imperial College data and (2) There may be unknown psychological morbidity from making women with certain miscarriages wait for days before any action is taken. In effect, this is making every woman have a trial of expectant management of miscarriage without explicitly informing them of the fact and this is ethically questionable. A further concern is that, while the quality statement states that women need repeat scans, it fails to specify the criteria for diagnosing miscarriage on conducting such repeat scans. It also does not clarify what the repeat scan should analyse. We suggest criteria should consider gestation, initial size of the sac, no growth in the gestation sac, no new embryonic structures etc).
080	The Ectopic Pregnancy Trust	Quality statement 3	Page 14, last paragraph: We suggest two additional sentences stating that: "If the woman wishes to pursue definitive treatment of miscarriage without having a second scan, she should be appropriately counselled and treatment should be offered." "A woman who has a miscarriage that is confirmed by a second experienced sonographer on the same day need not have a second scan in seven days if she does not wish".
081	The Miscarriage Association	Quality statement 3	Re rationale. Comment as above. My understanding is that repeat transvaginal ultrasound is NOT always needed to confirm miscarriage, though EPASs might want to build in a second confirmatory/checking scan at the same appointment.
082	Association for Improvements in the Maternity Services	Quality statement 3 (and 2)	We greatly appreciate the section saying that women should be offered the opportunity for transvaginal scans to be carried out by female members of staff. This offer should be made to all. We know that women who have suffered sexual abuse are often reluctant to have examinations by male staff. Nor do they wish to give the reason for their reluctance (which may result in case note records). The offer should be made to all, with no questioning or implications that the women are being awkward or difficult.

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083	Association of Early Pregnancy Units (AEPU)	Quality statement 3 (and 2)	The standards miss the opportunity to collect essential data such as “negative laparoscopy”, “pregnancy of unknown location” and “new to follow up” rates. All of these are essential to ensure high quality ultrasound scanning is being implemented and management decisions are being made by sufficiently senior and/or specialist health professionals for patient safety and to minimise emotional and social disruption for them. I am very disappointed to see that there are no standards with regard to the standard of scanning other than the 2 scans for diagnosis of miscarriage. There should be a standard that states that all sonographers should be appropriately trained for unsupervised practice (there are a lot of junior doctors having a go without direct supervision and not appropriately trained). There also should be a standard relating to diagnostic accuarcy eg number of ectopics diagnosed before theatre, at first scan and inconclusive scan rate. It is all well and good to have a patient with a potential ectopic pregnancy seen in 24 hours by a female doctor who actually cannot scan to an appropriate level and misses the ectopic pregnancy. The unit would be scoring well against NICE standards. The AEPU welcomes standard on access to scanning 24 hours. However, we would wish to see criteria set for standards of scanning equipment and qualifications.
084	Association of Early Pregnancy Units (AEPU)	Quality statement 3 (and 2)	All women should be offered examination by a female if requested. This is clearly optimal however in a small unit actually means that it would be difficult for male doctors/ sonographers to work there. It also does not help units where the senior opinion is male - i.e second opinion. This is clearly an ideal but I do not think it will always be deliverable especially in single scan room units.
085	Mumsnet	Quality statement 3 (and 2)	Our members have reiterated that they feel scans on women suspected of undergoing a miscarriage would be best carried out in dedicated EPUs. Where this isn’t possible, these scans should really be done in settings separate from women with ongoing healthy pregnancies, women having terminations of unwanted pregnancies, and women receiving post-natal care. Miscarrying women are often caused great distress by having scans alongside these other categories of healthcare users.
086	Royal College of Obstetricians and Gynaecologists	Quality Statement 3 (and 2)	Equality and Diversity considerations section, it states that: ‘ALL women should be offered the option to be examined by a female member of staff.’ This may not be possible and as such should not be included as part of this document. Implementing it can be to the detriment of the patient depending upon the clinical situation. It is vital to cater to individual circumstances but the statement seems too rigid. ‘Offering’ is different to ‘accommodating’ when requested; the latter is usual. If the QS sticks to ‘offering’ (rather than ‘accommodating upon request’) then the same offer of a specific gender healthcare professional must apply to any medical encounter, must it not? Not at all confident that would work in practice. Please re-consider.
087	Society and College of Radiographers	Quality statement 3 (and 2)	All practitioners performing early pregnancy ultrasound should be appropriately qualified and their work subject to audit. Equipment used should be within the employer’s quality assurance/governance arrangements for ultrasound equipment and particular attention paid to cleaning and preparing the transvaginal probe and its cover to avoid cross infection (MHRA alert).

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088	Society and College of Radiographers	Quality Statement 3 (and 2)	It is appreciated that there are some women, particularly from some ethnic and religious groups, who will decline a TV scan if a female practitioner is not available and this is of course their right. However, this is not the case for the majority of women who while perhaps *preferring* a female will consent to a male performing the examination. They often state that the most important thing for them is that the examination is performed competently by a practitioner who is qualified and experienced in the field. The option of a female practitioner should be available but if the wording were to imply that one *must* be offered without there being any prior feedback from the patient (either verbal or non-verbal) this will become a very difficult working environment for the many male doctors and sonographers involved. There may also be some units who cannot offer a female practitioner straight away and the scan may need to be re-scheduled. A distinction needs to be made between a woman who may *prefer* a female but will consent to an examination undertaken by a male (applies in many other clinical situations, including gynaecology), and when it is not acceptable for that woman to have a male practitioner performing the scan and not having a female practitioner immediately available could compromise care. Some women express the view that they have no particular concerns or preferences with regards to the sex of the practitioner at all. It would be helpful if any related statements were as flexibly worded as possible.
089	Gloucestershire Hospitals NHS Foundation Trust	Quality statement 4	Statement 4 – this is controversial when much of the evidence available is of poor quality.
090	Gloucestershire Hospitals NHS Foundation Trust	Quality statement 4	We can give information, but the evidence is generally of a poor standard.
091	RCGP	Quality statement 4	Should this say “written” evidence-based information as it’s a bit vague otherwise?
092	Royal College of Nursing	Quality statement 4	How the data on evidenced based information be captured for audit? Are there systems in place to facilitate this? This could be a challenge if the systems are not readily available to capture this.
093	Royal College of Nursing	Quality statement 4	Consistent clear evidence based information will be welcomed, particularly for colleagues in primary care and areas where women are seen by a range of healthcare professionals, will help reduce variation in the information given to pregnant women about pain and bleeding in pregnancy.
094	The Ectopic Pregnancy Trust	Quality statement 4	We agree that providing information about the likely outcome and what to expect following bleeding in early pregnancy would be helpful for patients. However, the content and timing of distributing the information/leaflets will need to be carefully considered. It would be helpful to incorporate information about the range of psychological and emotional reactions that couples experience after bleeding and pain in early pregnancy along with some ways to cope and information on when to seek further help and details of relevant organisations/helplines etc. Many support organisations are not accessible to women who do not have internet access or who do not have a good grasp of English and this may need to be considered.

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095	The Miscarriage Association	Quality statement 4	In general, we thoroughly approve this QS. Re the items listed in the definition of evidence-based information, we would strongly recommend adding information about disposal of pregnancy remains, whether in hospital or at home.
096	The Royal College of Midwives	Quality Statement 4	The list of evidence based information that should be included is very helpful. Referring to this to under the section 'What the quality statement means for service providers, heath care professionals and commissioners' could facilitate good data collection for the quality measure here.
097	Department of Health	None	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation
098	NHS England	None	Thank you for the opportunity to comment the draft consultation for the above Quality Standard I wish to confirm that NHS England has no substantive comments to make regarding this consultation
099	Royal College of Paediatrics and Child Health	None	Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the NICE QS: Pain and bleeding in early pregnancy (draft standard). We have not received any responses for this consultation

Stakeholders who submitted comments at consultation

- Association for Improvements in the Maternity Services
- Association of Early Pregnancy Units
- Department of Health
- Ectopic Pregnancy Trust
- Gloucestershire Hospitals NHS Foundation Trust
- King’s College Hospital
- Miscarriage Association
- Mumsnet
- NHS England
- Peterborough City Hospital
- Royal College of GPs
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- Royal College of Paediatrics and Child Health
- Society and College of Radiographers