National Institute for Health and Care Excellence

Heavy Menstrual Bleeding
Quality Standard Consultation Comments Table
15th April- 14th May 2013

ID	Stakeholder	Statement No	Comment on	Comments Please insert each new comment in a new row.	Response Please respond to each comment
005	Department of Health	General comment		The Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
006	Faculty of Sexual and Reproductive Healthcare	General comment	Measures	There should be reference to the large but unquantified number of women who chose the IUS both to use as their method of contraception and as treatment for their HMB. Milder cases of HMB treated in this way are not reflected in hospital statistics. Nor are they reflected in community contraception clinic or GP statistics.	Thank you for your comment. Please note that the statement about 'Drug treatment' makes reference to the need to take account of individual circumstances, including family planning requirements and sign-posts the reader to 'Long-acting reversible contraception' (NICE clinical guideline 30). Please note that the library of quality standard topics includes 'Contraceptive services (including emergency contraception)'. This topic is awaiting development.
004	NHS Direct	General comment		NHS Direct welcome the quality standard and have no comments as part of the consultation	Thank you for your comment.
002	Primary Care Women's Health Forum	General comment		There is a concern that this document is very focused on fibroids and their management. Although fibroids are a common cause of HMB they are not the most frequent cause and also many fibroids do not cause HMB. This seems to be a significant change in focus and emphasis since the previous guidance CG44. One suggestion is to have a separate pathway for the management of fibroids.	Thank you for your comment, which has been considered by the QSAC. Following consultation the quality standard has been updated to include a great emphasis on women with HMB alone or HMB related to small fibroids.
007	Royal College of Obstetricians and	General comment		Thank you for inviting the RCOG to participate in the NICE Heavy Menstrual Bleeding Quality	Thank you for your comment.

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	Gynaecologists			Standard consultation. We read the draft quality standard with interest and are pleased to offer our responses to the general questions for consultation.	
010	Royal College of Paediatrics and Child Health	General comment		Astonishingly there is no reference to HMB in adolescents in the guidance, apart from footnotes and occasional mentions such as fibroids less likely. It needs to be clear in the Quality standard that the NICE guidance and Quality standard does not apply to under 18s, and if this is the case will under 18s have their own separate guidance?	Thank you for your comment. The NICE quality standard for heavy menstrual bleeding applies to women of reproductive age and the introductory text has been revised to ensure it is clear that this includes women under the age of 18 years.
014	British Society of Interventional Radiology	General Comment		Overall this is an excellent document with some sensible and realistic quality standards for management of patients with HMB. It largely reflects the recommendations in NICE clinical guidance 44 – Heavy Menstrual Bleeding.	Thank you for your comment.
009	Royal College of Nursing	General comment		Although we agree that all women should be offered the same options, we are at risk of some facilities closing if they cannot afford to provide equal services to others so women's access to healthcare facilities could become compromised. We know there is reluctance for a lot of trusts to spend money on women's health. Clinicians will not want to offer treatments that are not provided at their Trust because they would need to refer them elsewhere this could result to lack of continuity of care and a reduction in funds generated.	Thank you for your comment. The quality standard describes high-priority areas for quality improvement. The delivery of high quality care is signalled by good performance across the breadth of all statements and measures. NICE has produced a support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard and patient information to explain to patients and carers what the quality standard means to them, both are available from www.nice.org.uk

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012	Bayer plc (formerly Schering HealthCare Ltd.)	S01		For increased convenience, the 'related symptoms' could be further defined in line with clinical guideline 44 recommendation 1.2.4, which lists "intermenstrual or postcoital bleeding, pelvic pain and/or pressure symptoms."	Thank you for your comment. The definition of 'detailed history' has been reviewed and expanded to include further information about related signs and symptoms.
003	British Medical Association	S01		We are happy with this statement. However, the addition of a ferritin blood test to the full blood count should be also considered as patients can bleed heavily for a long time before it actually shows in their full blood count. Many patients will be young and may be within the normal range for their haemoglobin when tested, but already have dropped considerably from their personal baseline. Such patients will benefit from having this corrected.	Thank you for your comment which was considered by the QSAC. The committee noted that NICE clinical guideline 44 (Heavy menstrual bleeding) includes recommendation 1.2.10 which states: A serum ferritin test should not routinely be carried out on women with HMB Therefore the statement has not been expanded beyond full blood count.
011	Nordic Pharma Ltd	S01		Comment about quality statement 1 (Diagnosis – history) The standard appears to be missing information or a statement about coagulation disorders, the NICE clinical guideline 44, states that testing for coagulation disorders should be considered for women who have had heavy menstrual bleeding (HMB) since menarche and have a personal or family history suggesting a coagulation disorder. The draft quality statement talks about tests for blood count, structural abnormalities but appears to have omitted a reference to those patients where there might be a coagulation disorder as the pathology behind the HMB.	Thank you for your comment. The definition of 'detailed history' has been reviewed and expanded to include coagulation disorders.

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				The NICE clinical guideline 44 reviewed data that suggested approx. 13-15% of patients with HMB may suffer from an inherited blood disorder such as von Willebrand disease (the guidelines discussed two reviews of the prevalence, one review- found a prevalence of 5.3%- 20%, another found a mean of 13% with a range of 5-24%. According to data reviewed in the guidelines, these patients could make up a significant HMB portion of patients so it would be useful for the quality statement to take these into account so that the correct identification of the pathology associated with HMB may be made and the appropriate treatment undertaken.	
002	Primary Care Women's Health Forum	S01 (& S02)		The concern is about how the history can lead to a suspicion of histological abnormality. IMB and PCB would be obvious examples of history points indicating histological or structural abnormalities but these are out with the scope of this. The main risk factors for histological abnormalities – presumably hyperplasia - are obesity, PCOS, Diabetes, tamoxifen use, which are all increasing and these risk factors should be considered when deciding on investigations etc. Doing a pelvic/speculum examination is important to rule out cervical lesions and uterine enlargement etc but may not exclude pelvic pathology in a woman at higher risk It may require clearer advice on who should have US scanning and who should have endometrial sampling.	Thank you for your comment. The definition of 'detailed history' has been reviewed and expanded to include further information to support the history taking, including signs and symptoms suggestive of a structural or histological abnormality. This is within the scope of the quality standard and includes reference to □ intermenstrual bleeding □ postcoital bleeding □ pelvic pain □ pelvic pressure. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented. The underpinning clinical guideline includes recommendations for undertaking endometrial biopsy and ultrasound scanning.

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002	Primary Care Women's Health Forum	S01		There is no mention about 'clotting concerns' and who would benefit from a Von-Willebrands screen.	Thank you for your comment. The definition of 'detailed history' has been reviewed and expanded to include coagulation disorders.
009	Royal College of Nursing	S01		We would agree with the statement but are unsure how this data would be collected and what would constitute a comprehensive history. How would this be defined?	Thank you for your comment. Examples of existing national data collection which may be relevant, in part at least, to the quality measure are referenced where appropriate. It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full. The definition of 'detailed history' has been reviewed and expanded.
010	Royal College of Paediatrics and Child Health	S01		Statement is very concise & appropriate highlighting the need to measure FBC. HMB is largely diagnosed on symptoms and so a detailed, accurate history is paramount.	Thank you for your comment.
003	British Medical Association	S02		We are happy with this statement.	Thank you for your comment.
008	British Society for Gynaecological Endoscopy	S02		Draft quality statement 2. The statement suggests that a physical examination is sufficient when diagnosing uterine fibroids. It would improve the patient journey between primary and secondary care if a pelvic ultrasound scan was undertaken, when indicated by the physical examination, prior to treatment of referral for additional investigations.	Thank you for your comment which has been reviewed by the QSAC. The QSAC prioritised the areas of care they felt were most important for patients, based on the development sources listed. The committee prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improve outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the committee and although ultrasound scan is within the scope of the

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					quality standard the committee chose not to prioritise this for statement development. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented.
009	Royal College of Nursing	S02		We are not sure how one would suspect structural abnormalities without undertaking a pelvic examination. Histological abnormality would only be picked up on scan or hysteroscopy and biopsy. What would be the key questions that would prompt an examination or investigations? An indicator of this may be abnormal bleeding but this would be outside the scope of the quality statements.	Thank you for your comment. Please note that the statements about 'diagnosis – initial assessment' and 'diagnosis – physical examination' are about accurate diagnosis. The definition of 'detailed history' has been reviewed and includes the symptoms which may suggest a structural or histological abnormality. Based on a range of clinical information, including the woman's detailed history, the practitioner makes a clinical judgement about whether a structural or histological abnormality is the underpinning cause of the woman's HMB. Those women in whom a structural or histological abnormality is suspected, would then undergo a physical examination prior to referral (as per the statement headed 'diagnosis – physical examination').
009	Royal College of Nursing	S02	measures	We are unsure how the data would be collected. Also how would one know that one had missed an abnormality without the examination?	Thank you for your comment. Examples of existing national data collection which may be relevant, in part at least, to the quality measure are referenced where appropriate. It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full.

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010	Royal College of Paediatrics and Child Health	S02		A physical examination if a structural abnormality is suspected is appropriate and avoids the need for a vaginal examination in women with more straightforward histories. This is perhaps particularly important for adolescents and young women.	Thank you for your comment. A note has been added to the supporting information in the statement headed 'diagnosis – physical examination'. This states 'A physical examination may be inappropriate for a woman who has never been sexually active. This may be of relevance to all women, but could be particularly important for younger women.'
015	Sheffield Teaching Hospitals NHS Trust	S02		Draft quality statement 2. The statement suggests that a physical examination is sufficient when diagnosing uterine fibroids. It would improve the patient journey between primary and secondary care if a pelvic ultrasound scan was undertaken, when indicated by the physical examination, prior to treatment	Thank you for your comment which has been reviewed by the QSAC. The quality standard includes priority areas for quality improvement and does not cover the entire pathway. The QSAC prioritised the areas of care they felt were most important for patients, based on the development sources listed. The committee prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improve outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the committee and although ultrasound scan is within the scope of the quality standard the committee chose not to prioritise this for statement development. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented.
013	The Royal College of Radiologists	S02		We note that the document does not discuss the diagnostic pathways. However, it does	Thank you for your comment.

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				invoke the use of a full gynaecology physical examination prior to referral for any further diagnostic tests as a quality standard and we strongly agree with this.	
006	Faculty of Sexual and Reproductive Healthcare	S02 (& S01)		There needs to be a pathway for how it is judged that a woman with HMB needs investigation beyond full blood count, including histological (endometrial biopsy) and ultrasound. Those with structural / histological abnormality need to be identified, but not necessarily all women will need all investigations.	Thank you for your comment**.** Please refer to the NICE Pathway for heavy menstrual bleeding which is an interactive tool for health and social care professionals providing fast access to NICE guidance and associated products, including the quality statements. The quality standard does not state or assume that all women will require all investigations and this is also reflected in the underpinning guidance 'Heavy menstrual bleeding' (NICE clinical guideline 44). It remains important that other evidence-based guideline recommendations continue to be implemented. The quality standard includes priority areas for quality improvement and does not cover the entire pathway. Please see the statements about 'diagnosis – initial assessment' and 'diagnosis – physical examination' which specifically focus on the importance of accurate diagnosis, which includes underlying pathology.
002	Primary Care Women's Health Forum	S02 (& S01)		The concern is about how the history can lead to a suspicion of histological abnormality. IMB and PCB would be obvious examples of history points indicating histological or structural abnormalities but these are outwith the scope of this. The main risk factors for histological abnormalities – presumably hyperplasia - are obesity, PCOS, Diabetes, tamoxifen use, which are all increasing and these risk factors should be considered when	Thank you for your comment. Please note that the statements about 'diagnosis – initial assessment' and 'diagnosis – physical examination' are about accurate diagnosis. The definition of 'detailed history' has been reviewed and includes the symptoms which may suggest a structural or histological abnormality. Based on a range of clinical information, including the woman's detailed history, the practitioner makes a clinical

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				deciding on investigations etc. Doing a pelvic/speculum examination is important to rule out cervical lesions and uterine enlargement etc but may not exclude pelvic pathology in a woman at higher risk. It may require clearer advise on who should have US scanning and who should have endometrial sampling.	judgement about whether a structural or histological abnormality is the underpinning cause of the woman's HMB. Those women in whom a structural or histological abnormality is suspected, would then undergo a physical examination prior to referral (as per the statement headed 'diagnosis – physical examination'). The statement about 'diagnosis – physical examination' focuses on the importance of a physical examination for some women as a means of detecting underlying pathology. The quality standard includes priority areas for quality improvement and does not cover the entire pathway. The committee prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improve outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the committee and although ultrasound scan and endometrial sampling are within the scope of the quality standard the committee chose not to prioritise these areas for statement development. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented.
012	Bayer plc (formerly Schering HealthCare Ltd.)	S03	Measures	The 'structure' should include a specific requirement for an appropriate mechanism to be in place for referring women for LNG-IUS	Thank you for your comment. See the statement about 'drug treatments' which now includes a structure measure about referral

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				insertion from providers who do not offer this service themselves. This is in line with recommendation 1.1.6.2 from NICE clinical guideline 30, Long acting reversible contraception (2005), which is also a key priority for implementation: “Contraceptive service providers who do not provide LARC within their own practice or service should have an agreed mechanism in place for referring women for LARC.”1 It is also reflected in a ‘key clinical issue’ outlined in the NICE commissioning guide: Services for the provision of intrauterine devices and the intrauterine system for contraception and the management of heavy menstrual bleeding (2008): “Ensuring that appropriate referral pathways are in place to support access to IUDs and the IUS from service providers who do not offer LARC, for emergency contraception and for the management of HMB.”2 Together with the RCOG standards for gynaecology (June 2008) which state that: 11.2.1 “Local protocols derived from national guidelines should be in place for speedy and evidence-based management of heavy menstrual bleeding in primary care” and 11.3.3 “adequate facilities and trained individuals should be available for the insertion of levonorgestrel-releasing intrauterine system (LNG-IUS) in the outpatient clinics and in primary care settings.”3 This requirement should also be reflected in the ‘description of what the quality statement means’ for service providers and for commissioners.	networks.

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				(1) National Institute of Health and Clinical Excellence. CG 30 Long-acting reversible contraception: full guideline. Oct 2005. Available from: http://www.nice.org.uk/nicemedia/live/10974/29912/29912.pdf. (2) National Institute of Health and Clinical Excellence. Commissioning Guide: Services for the provision of IUDs and the IUS for contraception and the management of heavy menstrual bleeding. Jan 2008. Available from: http://www.nice.org.uk/media/815/A0/ServicesForTheProvisionOfIUDsAndTheIUS.pdf. (3) The Royal College of Obstetricians and Gynaecologists. Standards for Gynaecology. Report of a Working Party. June 2008. Available from: http://www.rcog.org.uk/files/rcog-corp/uploaded-files/WPRGynStandards2008.pdf.	
012	Bayer plc (formerly Schering HealthCare Ltd.)	S03		The current definition erroneously includes tranexamic acid and NSAIDS under the heading of Pharmaceutical treatments (hormonal). We suggest that the definition should incorporate clinical guideline 44 recommendations 1.5.3, and 1.5.4 verbatim without the addition of the bold headings which are misleading e.g. NICE clinical guideline 44 recommendation 1.5.3 recommends that if history and investigations indicate that pharmaceutical treatment is appropriate and either hormonal	Thank you for your comment. The definition has been reviewed and revised.

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				or non-hormonal treatments are acceptable, treatments should be considered in the following order: • levonorgestrel-releasing intrauterine system (LNG-IUS) provided long-term (at least 12 months) use is anticipated • tranexamic acid or non-steroidal anti-inflammatory drugs (NSAIDs) or combined oral contraceptives (COCs) • norethisterone (15 mg) daily from days 5 to 26 of the menstrual cycle, or injected long-acting progestogens. NICE clinical guideline 44 recommendation 1.5.4 recommends that if hormonal treatments are not acceptable to the woman, then either tranexamic acid or NSAIDs can be used.	
003	British Medical Association	S03		We are happy with this statement.	Thank you for your comment.
008	British Society for Gynaecological Endoscopy	S03		Draft quality statement 3. Comment about women presenting with HMB without suspected structural or histological abnormality. It is sometimes difficult to judge this based on history alone therefore a physical examination remains helpful even in these circumstances.	Thank you for your comment. Please note that the statements about 'diagnosis – initial assessment' and 'diagnosis – physical examination' are about accurate diagnosis. The definition of 'detailed history' has been reviewed and includes the symptoms which may suggest a structural or histological abnormality. Based on a range of clinical information, including the woman's detailed history, the practitioner makes a clinical judgement about whether a structural or histological abnormality is the underpinning cause of the woman's HMB. Those women in whom a structural or histological abnormality

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					is suspected, would then undergo a physical examination prior to referral (as per the statement headed 'diagnosis – physical examination'). The statement about 'diagnosis – physical examination' focuses on the importance of a physical examination for some women as a means of detecting underlying pathology.
017	Gedeon Richter Women's Health Division	S03		Gedeon Richter support quality statement 3 as current evidence (FemiSA, 2012) suggests that patients are often not told about pharmaceutical treatments that might be suitable as a first-line therapy ahead of, or as an adjunct to, operative intervention. We note, however, that the scope of the quality measure in relation to this particular statement is limited to those patients with heavy menstrual bleeding (HMB) who do not have structural or histological abnormalities. As described in CG44 (section 3.3.1) patients with additional pathologies such as uterine fibroids or endometriosis represent significant proportions of the overall HMB patient population. Given that quality standard 4 only reflects more formal radiological or surgical interventions for uterine fibroids we feel that the scope of quality standard 3 should be broadened to include those patients whose HMB is due to uterine fibroids.	Thank you for your comment. Following consultation the committee have included an additional statement about 'Interim drug treatment' which focuses on drug treatments for women who are undergoing investigations or awaiting definitive treatment.
017	Gedeon Richter Women's Health Division	S03		As described in CG44 HMB can occur in patients with or without additional pathologies such as uterine fibroids. The pharmaceutical treatments that are available for patients with	Thank you for your comment. Following consultation the committee have included an additional statement about 'Interim drug treatment' which focuses on drug treatments

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				HMB vary according to their different therapeutic indications with some being licensed for use in patients with additional pathologies while others are not. This may lead to the case that the current list of pharmaceutical treatments in the draft quality standard is therefore not applicable to a large number of patients. Given the high proportion of HMB patients who have additional pathologies we would gratefully suggest that the HMB quality standard development team consider dividing the pharmaceutical treatments that are referred to into separate groups depending on the presence or absence of additional gynaecological pathology.	for women who are undergoing investigations or awaiting definitive treatment.
017	Gedeon Richter Women's Health Division	S03		In addition to the pharmaceutical treatments that are currently listed we would like to draw the development group's attention to Esmya (ulipristal acetate), a selective progesterone receptor modulator (and therefore a different therapeutic class to GnRH agonists) which is licensed for the treatment of symptoms, including bleeding, relating to uterine fibroids in patients for whom surgical intervention has been deemed appropriate. Marketing Authorisation for Esmya was granted by the European Medicines Agency on the 23rd of February 2012 and it was first made available in the UK on the 2nd of April 2012. As such it does not appear in CG44. Clinical trial data in the form of the PEARL I (N Engl J Med 366;5 11-22) and PEARL II (N Engl J Med 366;5 23-34) studies show the clinical effectiveness and safety profile of the drug. While NICE has not formally assessed Esmya for cost-effectiveness it has been reviewed by	Thank you for your comment. The quality standard is based on NICE accredited evidence sources ('Heavy menstrual bleeding' (NICE clinical guideline 44). Esmya is not included within an evidence source and therefore has not been considered by the committee. Please see the NICE quality standards process guide for further information about the NICE quality standard development process. Your comment could be re-submitted as part of the clinical guideline review process.

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				the Scottish Medicines Consortium (SMC Drug ID 834/13) who published guidance on the 11th of February 2013 which accepted the use of Esmya within NHS Scotland with no restrictions. We believe that Esmya should therefore be included in the list of pharmaceutical treatments that are referred to in the quality standard for heavy menstrual bleeding.  Esmya SPC 21032013 FINAL.pdf  Pearl II NEJM article.pdf  Pearl I NEMJ article.pdf	
002	Primary Care Women's Health Forum	S03		It is probably more relevant for women to receive information about the pharmaceutical options at her initial consultation if this is happening in primary care. Most primary care practices who insert IUS would be unable to perform the procedure during routine clinic time. There should be an expectation that this is performed as a one-stop procedure if referred to secondary care/community clinics for the procedure if the woman is already informed, to prevent unnecessary appointments and cost.	Thank you for your comment. See the statement about 'drug treatments' which now includes a structure measure about referral networks. It would be expected that local commissioners and providers would develop a locally appropriate mechanism and service-model for this.
002	Primary Care Women's	S03		There is some data assessing the effectiveness of the other combined hormonal	The quality standard is based on evidence-based recommendations from national

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	Health Forum			contraceptives – NuvaRing, so maybe COC should be changed to read CHC (cf FSRH guidance on CHC 2011). There is also concern about the VTE risk of Norethisterone in obese women. This should probably be changed to read – long cycle progestrogens including MPA or NET if recommended.	accredited guidance, i.e. the NICE heavy menstrual bleeding clinical guideline. The quality standards do not seek to reassess or redefine the evidence base. Please refer to the full clinical guideline for detailed summary of the underpinning evidence base for the clinical recommendations on which the quality standard is based.
002	Primary Care Women's Health Forum	S03		With current changes in funding with sexual health funding transferring to LA there are concerns about the future of payments for Primary care for performing procedures including IUS insertion for non-contraceptive reasons. It would be good to add any advise about costing and commissioning of enhanced services for this in this post-April 2013 era. The concern being that if these services are not funded appropriately in primary care then the skills will be lost and women will not be offered this procedure in many areas in primary care which will increase costs.	Thank you for your comment. The quality statement about 'Drug treatment' is about supporting women to access the full range of drug treatment options, including where appropriate the levonorgestrel-releasing intrauterine system. NICE has produced a support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard and patient information to explain to patients and carers what the quality standard means to them, both available from www.nice.org.uk
016	Royal College of General Practitioners	S03		Is it clear what "offered" means? After a 10 minute consultation in primary care, that includes a physical examination +/- a blood test, there will be little time to discuss the options for treatment at the initial consultation and it does not recommend this in CG44. I think "at the initial consultation" should be removed. In reality likely to happen as part of a series of consultations, especially when the woman is returning to get results of blood test/scan, if that has been ordered	Thank you for your comment. Please see statement the about 'Drug treatment' which has been reviewed and revised to refer to 'at the initial assessment' rather than 'initial consultation'. The meaning of 'initial assessment' is detailed in the definition section.

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009	Royal College of Nursing	S03	Measures	We are unsure how the data would be collected. Also unsure of who would be collating HMB satisfaction.	Thank you for your comment. Examples of existing national data collection which may be relevant, in part at least, to the quality measure are referenced where appropriate. It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full.
010	Royal College of Paediatrics and Child Health	S03		The first-line treatment for HMB tends to be tranexamic acid rather than LNG-IUS. In girls wanting contraception, the COC is useful. There are concerns regarding the use of depot progestogens in women younger than 25 in view of effects on accrual of peak bone mass.	Thank you for your comment. Please refer to the statements about 'Drug treatment' and 'Interim drug treatment'. These statements are underpinned by evidence-based recommendations from 'Heavy menstrual bleeding' (NICE clinical guideline 44).
014	British Society of Interventional Radiology	S04		Women with a structural abnormality who desire invasive treatment should have access to both UAE and myomectomy (uterine sparing procedures)	Thank you for your comment which is reflected in the underpinning guidance 'Heavy menstrual bleeding' (NICE clinical guideline 44). Please see the statement about 'Access to further interventions for uterine fibroids' which includes the treatment options uterine artery embolisation, myomectomy and hysterectomy.
002	Primary Care Women's Health Forum	S04		Unfortunately many CCGs do not commission UAE from their local providers so this is not recommended by many primary care clinicians who do not understand the intervention. It will be good for this to be included to improve the number of sites where this is available but will require publicity for women to be able to make a fully informed choice.	Thank you for your comment. The quality statement about 'Access to further interventions for uterine fibroids' is about supporting women who choose further intervention to have access the full range of surgical and interventional treatment options which includes uterine artery embolisation, myomectomy and hysterectomy. There is also

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					a structural measure to support the provision of referral networks, where interventions are not provided locally.
009	Royal College of Nursing	S04		What is the definition of large? The treatments offered will depend on size, location and number of fibroids and the presenting complaints. It is too simplistic to suggest large fibroids?	Thank you for your comment. The definition of fibroid size has been adapted from the full clinical guideline on heavy menstrual bleeding. The statements reflect the evidence-based recommendations in the underpinning guidance 'Heavy menstrual bleeding' (NICE clinical guideline 44).
009	Royal College of Nursing	S04 (& question 1)		Statement 4 does not mention endometrial ablation	Thank you for your comment. Following consultation the committee have included an additional statement about 'Access to endometrial ablation'.
009	Royal College of Nursing	S04	Measures	We are unsure how the data would be collected	Examples of existing national data collection which may be relevant, in part at least, to the quality measure are referenced where appropriate. It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full.
010	Royal College of Paediatrics and Child Health	S04		In women with HMB secondary to large fibroids, ensuring a system is in place to allow access to UAE, myomectomy or hysterectomy is fundamental.	Thank you for your comment. The quality statement about 'Access to further interventions for uterine fibroids' is about supporting women who choose further intervention to have access the full range of surgical and interventional treatment options which includes uterine artery embolisation, myomectomy and hysterectomy. There is also a structural measure to support the provision of referral networks, where interventions are not provided locally.

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001	The Hysterectomy Association	S04	Definitions	"Written information about the different treatment options should be provided for the woman to take away with her". Who will provide the information? Will it be consistent information across the NHS? .	Thank you for this comment. In the absence of a national source, it is anticipated that this information would be developed locally. The NICE quality standard for heavy menstrual bleeding highlights the importance of high quality patient information and it is anticipated that the publication of the quality standard will support the development of this.
013	The Royal College of Radiologists	S04 (& S05)		The Royal College of Radiologists would like to emphasise that uterine artery embolisation is to be available as a patient choice and this point is supported by our lay representative.	Thank you for your comment. The quality statement about 'Access to further interventions for uterine fibroids' is about supporting women who choose further intervention to have access the full range of surgical and interventional treatment options which includes uterine artery embolisation, myomectomy and hysterectomy. There is also a structural measure to support the provision of referral networks, where interventions are not provided locally.
008	British Society for Gynaecological Endoscopy	S04 (& Question 1)		Treatment options discussed are mainly UAE, myomectomy and hysterectomy. There is no mention about endometrial ablation/ resection as these treatments are effective for submucosal fibroids especially if less than 3 cm.	Thank you for your comment. Following consultation the committee have included an additional statement about 'Access to endometrial ablation'.
008	British Society for Gynaecological Endoscopy	S05		Good information should be given to all women with HMB. Unfortunately there are no national leaflets about treatment options and it would be useful to have these so that there is uniformity of information given to patients.	Thank you for this comment. In the absence of a national source, it is anticipated that this information would be developed locally. The NICE quality standard for heavy menstrual bleeding highlights the importance of high quality patient information and it is anticipated that the publication of the quality standard will support the development of this.

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009	Royal College of Nursing	S05		Again the definition of large is needed. If the fibroid is pedunculated then uterine artery embolisation (UAE) is contraindicated so this statement would not be true if the women preferred UAE and the fibroid is not suitable.	Thank you for your comment. The definition of fibroid size has been adapted from the full clinical guideline on heavy menstrual bleeding. The statements reflect the evidence-based recommendations in the underpinning guidance 'Heavy menstrual bleeding' (NICE clinical guideline 44). The statement about 'Access to interventions for uterine fibroids' states that women have a 'documented discussion' about treatment options, which will include details of where specific treatments are contraindicated or unsuitable.
009	Royal College of Nursing	S05	Measures	We are unsure how the data would be collected.	Examples of existing national data collection which may be relevant, in part at least, to the quality measure are referenced where appropriate. It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full.
010	Royal College of Paediatrics and Child Health	S05		Access to UAE. The area commissioners need to ensure that they commission appropriate services to enable women to opt for UAE following full discussion regarding their treatment options.	Thank you for your comment. The quality statement about 'Access to further interventions for uterine fibroids' is about supporting women who choose further intervention to have access the full range of surgical and interventional treatment options which includes uterine artery embolisation, myomectomy and hysterectomy. There is also a structural measure to support the provision of referral networks, where interventions are not provided locally.
013	The Royal College of Radiologists	S05 (& S04)		The Royal College of Radiologists would like to emphasise that uterine artery embolisation is	Thank you for your comment. The quality statement about 'Access to further

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				to be available as a patient choice and this point is supported by our lay representative.	interventions for uterine fibroids' is about supporting women who choose further intervention to have access the full range of surgical and interventional treatment options which includes uterine artery embolisation, myomectomy and hysterectomy. There is also a structural measure to support the provision of referral networks, where interventions are not provided locally.
008	British Society for Gynaecological Endoscopy	Question 1		General question no 1 The 5 standards do not include the use of specific relevant investigations. The patient journey between primary and secondary care would be smoother if patients were referred having already had a pelvic ultrasound scan when indicated from the history or following a poor response to medical treatment.	Thank you for your comment which has been reviewed by the QSAC. The quality standard includes priority areas for quality improvement and does not cover the entire pathway. The QSAC prioritised the areas of care they felt were most important for patients, based on the development sources listed. The committee prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improve outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the committee and although ultrasound scan is within the scope of the quality standard the committee chose not to prioritise this for statement development. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented.
008	British Society for Gynaecological Endoscopy	Question 1		General question no 1 The 5 standards include hysterectomy as treatment, but not endometrial ablation. NICE CG44 advocates these procedures, especially	Thank you for your comment. Following consultation the committee have included an additional statement about 'Access to endometrial ablation'.

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				using second generation devices, for the treatment of HMB when medical treatment has failed, especially if the uterus is normal. Wide variation in the provision of these procedures remains as shown by the RCOG National Audit of HMB. The provision of endometrial ablation services are also a key area for service improvement.	
008	British Society for Gynaecological Endoscopy	Question 1		There is no mention about the role of (outpatient) hysteroscopy, menstrual disorders clinic or One Stop clinic referrals. Many patients with HMB are now seen directly in one of these clinics where diagnostic and treatment services can be undertaken at the same sitting. It would be useful to highlight such services in the patient pathway.	Thank you for your comment. The underpinning clinical guideline does not include recommendations about specific service models. NICE has produced a support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard. This includes signposts to examples of service models.
008	British Society for Gynaecological Endoscopy	Question 1		To have pathways whereby services / treatments that can be managed in primary care should be highlighted and made clear.	Thank you for your comment. Please refer to the NICE Pathway for heavy menstrual bleeding which is an interactive tool for health and social care professionals providing fast access to NICE guidance and associated products, including the quality statements. The quality standard does not preclude statements from being undertaken in all settings where appropriate. However, it is acknowledged that some statements will largely apply to primary care and others to specialist services.

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008	British Society for Gynaecological Endoscopy	Question 1		Have clear pathways of referral from primary to secondary care in women who present with HMB.	Thank you for your comment. Please refer to the NICE Pathway for heavy menstrual bleeding which is an interactive tool for health and social care professionals providing fast access to NICE guidance and associated products, including the quality statements. The quality standard does not preclude statements from being undertaken in all circumstances where appropriate.
014	British Society of Interventional Radiology	Question 1		Women with a history of HMB have a pelvic examination.	The statement about 'diagnosis – physical examination' focuses on the importance of a physical examination for some women as a means of detecting underlying pathology.
014	British Society of Interventional Radiology	Question 1		Women with in whom a structural or histological abnormality is suspected or in whom pharmacological treatment has failed are referred for imaging	The quality standard includes priority areas for quality improvement and does not cover the entire pathway. The committee prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improve outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the committee and although ultrasound scan and endometrial sampling are within the scope of the quality standard the committee chose not to prioritise these areas for statement development. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented.

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014	British Society of Interventional Radiology	Question 1		Women with a structural abnormality who desire invasive treatment should be referred to secondary care	Thank you for your comment. The QSAC recognised that communication between sectors is important, however this is a cross-cutting issue applicable to many services. This is partly addressed in the NICE quality standard for patient experience in adult NHS services.
014	British Society of Interventional Radiology	Question 1		The indications for UAE be broadened to include women with adenomyosis as well as fibroid disease	Thank you for your comment. The management and treatment of adenomyosis is out of the scope of the NICE quality standard for heavy menstrual bleeding.
014	British Society of Interventional Radiology	Question 1		Formal HMB networks be set up so that women have access to accurate advice and counselling, and to the whole spectrum of therapeutic options currently available.	Thank you for your comment. Please see quality statement about 'Access to endometrial ablation' and 'Access to interventions for uterine fibroids' which support women being offered a documented discussion about the full range of surgical and radiological treatments. These statements also include structure measure to support the provision of referral across networks where services are not provided.
006	Faculty of Sexual and Reproductive Healthcare	Question 1		Many IUSs are inserted in general practice or community contraception clinics now. Sometimes investigations are done in hospital, but women are sent to general practice or community contraception clinics for the IUS insertion. Often the results of the investigations are not communicated. There needs to be better collaboration between primary and secondary care in this respect.	Thank you for your comment. See the statement about 'drug treatments' which now includes a structure measure about referral networks. The QSAC recognised that communication between sectors is important, however this is a cross-cutting issue applicable to many services. This is partly addressed in the NICE quality standard for patient experience in adult NHS services.

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002	Primary Care Women's Health Forum	Question 1		There should be a section on endometrial ablation and allowing women the option of having this procedure performed in the out-patient setting or using general anaesthetic. The guideline seems to have too much emphasis on fibroid management and less on the other treatment options for HMB.	Thank you for your comment. Following consultation the committee have included an additional statement about 'Access to endometrial ablation'.
016	Royal College of General Practitioners	Question 1		I think this draft quality standard accurately reflects the key areas for quality improvement	Thank you for your comment.
009	Royal College of Nursing	Question 1 (&S04)		Statement 4 does not mention endometrial ablation	Thank you for your comment. Following consultation the committee have included an additional statement about 'Access to endometrial ablation'.
007	Royal College of Obstetricians and Gynaecologists	Question 1		Question 1: Does this draft quality standard accurately reflect the key areas for quality improvement? Answer 1: We agree that the salient points are covered. However we would like to recommend an additional point; women who have a heavy menstrual bleeding and a normal size uterus should be offered endometrial ablation in preference to hysterectomy as a second line of treatment.	Thank you for your comment. Following consultation the committee have included an additional statement about 'Access to endometrial ablation'.
015	Sheffield Teaching Hospitals NHS Trust	Question 1		General question no 1 The 5 standards do not include the use of specific relevant investigations. The patient journey between primary and secondary care would be smoother if patients were referred having already had a pelvic ultrasound scan when indicated from the history or following a	The quality standard includes priority areas for quality improvement and does not cover the entire pathway. The committee prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improve outcomes, and where there is potential to generate

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				poor response to medical treatment.	measurable indicators. All suggestions for additional statements were discussed by the committee and although ultrasound scan is within the scope of the quality standard the committee chose not to prioritise this area for statement development. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented.
015	Sheffield Teaching Hospitals NHS Trust	Question 1		General question no 1 The 5 standards include hysterectomy as treatment, but not endometrial ablation. NICE CG44 advocates these procedures, especially using second generation devices, for the treatment of HMB when medical treatment has failed, especially if the uterus is normal. Wide variation in the provision of these procedures remains as shown by the RCOG National Audit of HMB. The provision of endometrial ablation services are also a key area for service improvement.	Thank you for your comment. Following consultation the committee have included an additional statement about 'Access to endometrial ablation'.
013	The Royal College of Radiologists	Question 1		There should also be some quality standard for imaging and this is an omission which should be rectified.	The quality standard includes priority areas for quality improvement and does not cover the entire pathway. The committee prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improve outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the committee and although ultrasound scan is within the scope of the quality standard the committee chose not to

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					prioritise this area for statement development. The quality standard contains priority markers for quality improvement and it remains important that other evidence-based guideline recommendations continue to be implemented.
013	The Royal College of Radiologists	Question 1		We note that there is a suggestion in the briefing that dedicated HMB clinics should be set up. If that is the case, the Royal College of Radiologists' supports this as a good concept, providing an IR is included in the clinic and that their Job Plan adequately reflects that time commitment.	Thank you for your comment. The underpinning clinical guideline does not include recommendations about specific service models. NICE has produced a support document to help commissioners and others consider the commissioning implications and potential resource impact of this quality standard.
008	British Society for Gynaecological Endoscopy	Question 1 (& S04)		Treatment options discussed are mainly UAE, myomectomy and hysterectomy. There is no mention about endometrial ablation/ resection as these treatments are effective for submucosal fibroids especially if less than 3 cm.	Thank you for your comment. Following consultation the committee have included an additional statement about 'Access to endometrial ablation'.
008	British Society for Gynaecological Endoscopy	Question 2		General question no 2. Collecting data about whether a history has been taken is likely to be possible, less easy is whether a sufficiently 'comprehensive and detailed history' is obtained with the present systems and structures.	Thank you for your comment. The definition of 'detailed history' has been reviewed and expanded and it is anticipated that this additional detail may be helpful when establishing systems to record and measure the elements of a detailed history.
016	Royal College of General Practitioners	Question 2		QS 1-3 data should easily be collected by GP computer systems	Thank you for your comment.
009	Royal College of Nursing	Question 2		Overall with the continued fragmentation of gynaecology we do not think that this data would be easy to collect. Women may be seen	Thank you for your comment. It is expected that local data sources and audits where appropriate will be considered in order to

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				in primary care, sexual and reproductive health services, community gynaecology and gynaecology with no common standards within each of these and different administration systems that collect different data.	measure the quality statements in full.
007	Royal College of Obstetricians and Gynaecologists	Question 2		Question 2: If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Answer 2: Yes this is possible.	Thank you for your comment.
015	Sheffield Teaching Hospitals NHS Trust	Question 2		General question no 2. Collecting data about whether a history has been taken is likely to be possible, less easy is whether a sufficiently 'comprehensive and detailed history' is obtained with the present systems and structures.	Thank you for your comment. The definition of 'detailed history' has been reviewed and expanded and it is anticipated that this additional detail may be helpful when establishing systems to record and measure the elements of a detailed history.