NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Menopause

Date of Quality Standards Advisory Committee post-consultation meeting:
3 November 2016

2 Introduction

The draft quality standard for menopause was made available on the NICE website for a 4-week public consultation period between 5 August and 2 September 2016. 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 12 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 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. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

4. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

5. For draft quality statement 4: What is the specific quality improvement area for this statement? Is it the 3 month review, the annual review or both? Please detail your answer.

6. For draft quality statement 5: Does the definition of medical or surgical treatment capture all women who should be receiving information about the menopause before treatment? If not, what else should be included?

4 General comments

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

- Statements supported and all key areas for quality improvement.
- Stakeholders suggested the introduction needs greater emphasis on premature ovarian insufficiency and to recognise that women with HIV or who receive breast cancer treatment go through menopause earlier.
- Suggested additional measures e.g. incidence of VTE, number of referrals.

Consultation comments on data collection

- For all statements the information would be difficult to capture in primary and secondary care as it is not routinely collected.

Consultation comments on resource impact

- Some stakeholders felt the statements could be achieved by local services, for example statements 1-4 are educational rather than resource based.
- Other stakeholders felt there were not enough resources, in primary and specialist menopause services for example the number of practitioners trained in menopause care.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Women over 45 years presenting to primary care with menopausal symptoms are diagnosed based on their symptoms, without laboratory tests.

Consultation comments

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

- FSH testing is used for some women over 45 to diagnose menopause for example when using certain types of hormonal contraception.
- Some of the laboratory tests listed need to be performed for women presenting with vasomotor symptoms to help assess possible other conditions which cause the same symptoms.
- The statement would be measurable.
- The statement should also include secondary care.

5.2 Draft statement 2

Women under 40 years presenting with menopausal symptoms are diagnosed with premature ovarian insufficiency based on their symptoms and elevated follicle-stimulating hormone (FSH) levels.

Consultation comments

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

- The statement should include ‘persistently’ elevated FSH levels to ensure that there are at least 2 measurements.
- The statement could include a ‘watch and wait’ approach of 6 months as women miss periods for reasons other than ovarian failure.
- The statement should be broadened to include the management of premature ovarian insufficiency.

- Queried including Parkinson’s disease in the rationale and the evidence behind this.
- Queried the appropriateness of the denominator and if this would capture the correct group of women given the vague symptoms of menopause.
- Outcome difficult to measure, suggested time to diagnosis instead.
- Easy to audit but not a useful standard for premature ovarian insufficiency
- It is not clear if women with premature ovarian insufficiency need to attend specialist services or are managed in primary care.

5.3 Draft statement 3

Women over 40 years in menopause presenting to primary care with vasomotor symptoms are offered hormone replacement therapy (HRT) after a discussion of the short-term and longer-term benefits and risks.

Consultation comments

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

- Concern that ‘vasomotor symptoms’ is not an appropriate indication for the 40-45 year old group.
- Statement not easily measurable because ‘discussion’ can be interpreted differently.
- Suggested training may be needed for GPs and nurses to deliver the standard and the use of resources such as patient decision aids.

5.4 Draft statement 4

Women having treatment for short-term menopausal symptoms have a review 3 months after starting each treatment and then at least annually.

Consultation comments

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

- Felt it was confusing using the term ‘short-term’ symptoms with annual review.
- Clarity needed over the population as there were various comments relating to women with premature ovarian insufficiency.

- Further information needed on where the reviews should take place. It was suggested it should be in primary care with appointments in secondary care only for those women with a complex medical history.
- Suggested the method of review does not need to be face-to-face but could include phone or other remote access.
- Additional resources needed because of a lack of knowledge in primary care to undertake the reviews and a lack of funding to expand clinics in secondary care to meet the growing population.

Consultation question 5

What is the specific quality improvement area for this statement? Is it the 3 month review, the annual review or both? Please detail your answer.

Stakeholders made the following comments in relation to consultation question 5:

- Agreed both the 3 month and 12 month reviews were important.
- Questioned if the 3 month review is needed if patients are informed adequately at the start of treatment, suggested review when necessary.
- The purpose of the 3 month review is for identifying and maintaining the right treatment at the outset by assessing its efficacy and side effects.
- The purpose of the 12 month review is to determine the woman's ongoing need for treatment by reviewing the benefits and risks and ensuring compliance with the drug and other health screening programmes.

5.5 Draft statement 5

Women who are likely to go through menopause as a result of medical or surgical treatment are given information about menopause and fertility before they have their treatment.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Important statement as it was reported some women presenting at menopause clinics say they may have made a different decision had the understood the consequences.
- Suggestion to expand the statement to include referral to a healthcare professional as stakeholders reported there is a lot of variation in access.
- Suggestion to expand the wording to include ‘support’.
- Concern over the feasibility of measuring the denominator as it relates to a wide range of situations.
- Further definition needed on ‘giving information’ to include appropriate language and an explanation of where to obtain further advice and help.

Consultation question 6

Does the definition of medical or surgical treatment capture all women who should be receiving information about the menopause before treatment? If not, what else should be included?

Stakeholders made the following comments in relation to consultation question 6:

- Additional suggestions for the definition were made and included
  - other treatments
  - radiotherapy
  - breast cancer treatments
  - hysterectomy without oophorectomy, uterine artery embolisation (UAE) and GnRH analogues
  - family history of early menopause.

6 Suggestions for additional statements

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

- availability of expertise for clinical advice and training
- clinicians raising the issue of screening for sexual problems
- self-management such as weight loss, alcohol reduction and exercise
- suitable HRT regimes
- discussion of the risks of HRT in younger women
- discussion and provision of contraceptives for women in perimenopause or menopause
- compliance with the use of vaginal oestrogen.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	Department of Health	General	The Department of Health has no substantive comments to make, regarding this consultation.
2	King's College Hospital	General	Could HIV and breast cancer in menopausal women be included under 'Coordinated services' / NICE quality standard of safety of care or access to services.
3	NHS England	General	NHS England has no substantive comments to make regarding this consultation.
4	Royal College of Obstetricians and Gynaecologists	General	This is a clear and well-written document
5	Royal College of Obstetricians and Gynaecologists	General	Suggest rewording as: "women's understanding of what menopause is and what to expect, so that…"
6	The Eve Appeal	General	The Eve Appeal celebrate and welcome this document. We believe it brings a significant advance in raising awareness of menopause and enables women to feel validated in going to their GP to seek therapeutic support for symptom relief. Our particular area of expertise is gynaecological cancer and we believe the definition of terms and information provision suggestions are appropriate.
7	Wrexham Maelor Hospital	General	The QS document currently states: Menopause is when a woman stops having periods……… However, it is important to maintain clear definitions in line with NICE guidelines and should clearly state: not having periods for at least 12 months and not using hormonal contraception.
8	Wrexham Maelor Hospital	General	QS document states: average age at which menopause starts in women in the UK is 51. Again this can be confusing for women and HCP as the average age of attaining menopause in the UK is 51—not when it starts
9	Breast Cancer Now	Question 1	We have suggested amendments to draft quality statement 5 below.
10	British Menopause Society	Question 1	Yes, these are the main areas but suggest the following be considered: a. Number of referrals to secondary care/menopause specialists. This is important and could be audited – it will determine the ability of primary care to deal with menopause issues and the demand placed on secondary

[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 number	Comments[1]
			services. Would be helpful to identify source of referral e.g. Primary care, oncology service, another colleague or tertiary referral b. To add to statement 3--are the recommendations of the guideline to consider transdermal in higher risk patients being implemented? Could include capture of relevant risk factors at assessment and then appropriate prescription of transdermal, e.g. women with BMI over 30 Further, the statement for women over 40 years old appears to be limited to 'vasomotor symptoms' as an indication. The 40-45 year old group do not fall in a separate category in the guideline recommendations, but maybe can include 'indications for treatment in women over 40'? (e.g. medical – bone, cardiovascular / symptom control) c. Incidence of VTE in HRT users – possibly captured through HES data collection. This would perhaps demonstrate validity of the bias to transdermal HRT in the guideline. d. For women diagnosed with POI recommend referral to menopause specialist for confirmation of diagnosis and entry onto a national registry such as https://poiregistry.net to facilitate with audit of diagnosis and management of POI as per NICE and BMS guidelines. e. Why is statement 2 only concerned with the diagnosis and not the management of POI? [e.g. ensuring adequate hormone therapy is used at least until the average age of menopause (unless contraindications exist)] f. With widespread use of vaginal estrogen as described in the guideline, compliance with this section could be considered as a statement, or this could be included as part of Statement 3.
11	Cornwall Menopause Service	Question 1	These areas are all relevant and would help to raise care standards generally but miss a key issue of there being availability of expertise for clinical advice and training
12	Faculty of Sexual and Reproductive Healthcare (FSRH)	Question 1	These quality statements are all reasonable and are practical, simple statements about issues which strongly affect management of women's health around the time of menopause.
13	Faculty of Sexual and Reproductive Healthcare (FSRH)	Question 1	It's a shame there wasn't a statement about the clinician raising the issue/ screening for sexual problems as patients can be reluctant to raise this themselves
14	Royal College of General Practitioners	Question 1	Whilst these quality statements partially reflect some key areas for improvement, other standards that should be considered to promote best practice include: • Self-management - it appears to be focused on the discussion of HRT as a treatment for menopause rather than self-management, such as weight loss, alcohol reduction and exercise, which is not only beneficial to menopausal symptoms but general health. • Suitable of the HRT regimes – although the standards evaluate the number of women on HRT or HRT has been discussed with, it does not advocate the assessment whether they are on appropriate regimes such as cyclical or non-cyclical and oestrogen or oestrogen and progesterone. Ensuring women are on the most

ID	Stakeholder	Statement number	Comments[1]
			suitable treatment would most likely have a wider impact. • Contraceptive - another key area for improvement is the discussion and provision of contraceptive for women in perimenopause or menopause as they are still at risk of pregnancy and HRT does not provide contraception.
15	Royal College of Nursing	Question 1	Generally, yes but we consider that POI needs a higher emphasis.
16	Royal College of Obstetricians and Gynaecologists	Question 1	Yes – we believe that this draft quality standard does accurately reflect the key areas for quality improvement
17	The Eve Appeal	Question 1	One area that perhaps needs further attention for the younger woman with treatment induced menopause is the explanation that potential risks of taking HRT are described in research of the older population and therefore do not accurately describe the risks for the younger woman.
18	Wrexham Maelor Hospital	Question 1	No, as stated above women with POI requiring HRT should be included
19	British Menopause Society	Question 2	Capturing the information automatically is not provided for in either primary or secondary care. Statement 3 in particular would be very difficult to measure – 'discussion; can mean so many things from a 2 minute chat to a 40 minute individualised discussion to pointing to a website. Information capture is currently ad hoc and dependent of local implementation of audit. The ideal situation would be if the DoH implemented a national database with linkage to prescription and cancer / cardiovascular registries – an excellent example of this is Finland which is allowing analysis and publication of excellent data in huge populations on morbidity and mortality in women using HRT and alternatives. However some information can be easily captured locally, e.g. inappropriate requests for FSH to diagnose menopause—by local lab data. This is applicable to Statement 1. Re Statement 2—lab data could be collected locally, but essentially important is data around appropriate management, i.e. offering hormone therapy and ensuring continuation at least until average age of menopause (as noted in point e above).
20	Cornwall Menopause Service	Question 2	At present it would be not too difficult to monitor statements 3 and 4 through primary care based software but if the presentation is missed we will not know what is not done in 1 and 2 only what is. My understanding is that secondary care records are unlikely to capture 5
21	Faculty of Sexual and Reproductive Healthcare (FSRH)	Question 2	Statements 1-4 could be measured by local audit projects using electronic primary care records. Statement 5 on treatments which render women prematurely menopausal relates to a wide range of medical and surgical specialities and it would be very difficult to measure how information is given accurately and reliably in these situations.
22	Royal College of Obstetricians and	Question 2	Yes – local systems and structures should be in place already to collect these data.

ID	Stakeholder	Statement number	Comments[1]
	Gynaecologists		
23	Wrexham Maelor Hospital	Question 2	No. Cost-savings definitely expected in the long-term which health organisations would need convincing about
24	British Menopause Society	Question 3	The British Menopause Society has developed criteria and application process to be a BMS recognized Menopause Specialist, relevant to Statement 5. To increase provision of patient information, (relevant to statement 3) there have been updates on www.thebms.org.uk, www.womens-health-concern.org, www.menopausematters.co.uk and to provide individualized advice, www.managemymenopause.co.uk has been launched. Information has been submitted to NICE about a multidisciplinary multiprofessonal Young Women's Breast Cancer Pathway at Imperial College Healthcare NHS Trust which underpins the principles of Statement 5. The POI registry underpins the principles of Statements 2 & 5 – the registry could be used for audit as well as research purposes. Local example of reducing inappropriate requests for FSH to diagnose perimenopause or menopause in women aged over 45 relevant to statement 1. Reducing inappropriate FSH testing. Williams J et al. Post Reproductive Health. Published online 7th March 2016
25	Cornwall Menopause Service	Question 3	Quite the reverse – despite all of this good work my specialist NHS service is about to be closed due to financial deficiency and short sightedness at NHS Kernow
26	Royal College of Obstetricians and Gynaecologists	Question 3	No, sorry we do not
27	Wrexham Maelor Hospital	Question 3	Example in our own region: Have introduced a banner displaying " FSH testing not required routinely for diagnosing menopause in women over 45 years of age" on our IT requesting system used by primary care. Audit to be undertaken to see results of this.
28	British Menopause Society	Question 4	We do not think that there are adequate resources to achieve all facets of this quality standard. In the first instance, there needs to be an initial audit to see whether there is at least one partner in each practice who has an interest in menopause and whether they are familiar with the NICE guideline. If not, further education, training and recruitment should be adequately funded by the DoH to facilitate this. The apparent lack of interest and expertise in managing menopause in many practices is placing an additional burden on limited secondary care services. It is believed that there are inadequate menopause specialist services (which could be in secondary care or community led) and this is preventing implementation of statement 5 and comments d and e in section 1. The BMS

ID	Stakeholder	Statement number	Comments[1]
			could help the DoH identify where the gaps are.
29	Cornwall Menopause Service	Question 4	1-4 potentially yes as that is educational rather than resource based. 5 needs resource and I do not know where that will come from
30	Royal College of Nursing	Question 4	Not at present, as there is no clear identification of those healthcare professional (HCP) specialists who may work outside of secondary care – these need to be identified through audit of primary care. British Menopause Society Register of specialists will help to identify where there are few HCP specialists. Anecdotally, primary care practitioners report that statement 3 (information giving) would be hard to implement realistically within a non-specialist consultation
31	Royal College of Obstetricians and Gynaecologists	Question 4	Yes – I think that each of the statements would be achievable by local services
32	Wrexham Maelor Hospital	Question 4	No
33	British Menopause Society	Question 5	This statement assumes HRT is being given for symptoms only, whereas patients with Premature Ovarian Insufficiency who may not have symptoms, also require review and their management should be measured. Both the 3 month and annual reviews are required – 3 months for identifying and maintaining the right treatment at the outset and 12 months ensuring compliance with drug and other health screening programmes (cervical smears, mammography etc) and to assess the benefit: risk balance of ongoing therapy. This statement perhaps has the biggest resource implications. Data collection though should be relatively straightforward. What could be confusing is the statement about short term symptoms and then annual review. When does short term become long term and therefore could carers use this as an excuse not to review long term patients? Much of the recommended review appointments should take place in primary care but for some patients, eg with complex medical history, secondary care review may be required. However, following on from 4, it is currently impossible for many clinics to provide a routine 3 month review unless the clinics are overbooked. This is due to an expanding specialist clinic population because of lack of resources and knowledge in primary care and due to lack of funding to expand clinics in secondary care. Telephone follow up clinics can help but these still need to be resourced. In summary, increased resourcing is required to ensure that there is flexibility in providing 3 month or earlier appointments where required to monitor response and mitigate side effects as well as annual reviews. We therefore hope that the NICE Menopause Quality Standard drives commissioning of expanded / better resourced menopause services and shared pathways.

ID	Stakeholder	Statement number	Comments[1]
34	Royal College of Obstetricians and Gynaecologists	Question 5	We believe that both the 3 month and the annual reviews are important • The purpose of the 3 month review is to assess for efficacy and for side effects following the initiation of treatment • The purpose of the annual review is to determine the woman's on-going need for HRT
35	Wrexham Maelor Hospital	Question 5	If patient is adequately informed at commencement –What is the advantage of regular review at 3 months? It only increases pressure on primary care. Review as and when necessary should be adequate. Concept of annual review is also questionable but perhaps reassuring and acceptable
36	Breast Cancer Now	Question 6	As far as we are aware, the definition as proposed is adequate. However, in order to future-proof the statement, in the event of any new interventions or techniques which might not be classed as medicines or surgical techniques, you could consider adding 'or any other treatment'.
37	British Menopause Society	Question 6	Generally yes, but one area that is not covered well as it crosses 2 NICE guidelines is the induction of 'menopause' with breast cancer treatments which are increasingly common and can lead to severe consequences. This could be clearer. Please see previous information provided on multidisciplinary / multiprofessional breast cancer pathways. These are essential in the efficient comprehensive physical and psychological management of these patients and should involve breast surgeons, oncologists, geneticists, fertility specialists, menopause specialists and adequate clinical nurse specialist and counselling support. A small number of HIV menopause services are offered– it is recognized that women with HIV go through menopause earlier and have an increased risk of osteoporosis. This important issue is not covered in the NICE guideline or the Quality Standard and should be included in future guidance. HIV and breast cancer could be included under 'Coordinated services' and NICE quality standard of safety of care and also under access to services. In addition, the guideline specifically suggests referral to Healthcare Care Professional with expertise in menopause for information about menopause before treatment and this recommendation should be reflected in the statement.
38	Royal College of Obstetricians and Gynaecologists	Question 6	The full guideline discusses medical treatment, surgical treatment and following radiotherapy – we believe this should be included in the quality standard.
39	Wrexham Maelor Hospital	Question 6	Should include: those with family history of early/premature menopause: However, the denominator of this QS is extremely difficult if not impossible to measure
40	Faculty of Sexual and Reproductive Healthcare (FSRH)	Statement 1	This statement should be fairly easy to measure with reference to menopausal symptoms but FSH levels ***are*** used in women over 45 to diagnose the post menopause, when using certain types of hormonal contraception, in order that advice can be given about when it is appropriate to discontinue contraception.

ID	Stakeholder	Statement number	Comments[1]
41	Royal College of General Practitioners	Statement 1	The statement means without laboratory tests for menopause (FSH or LH). Someone presenting with vasomotor symptoms in primary care would however have a TSH, urea and electrolytes, fbc, lfts, lipids and fbc done to help assess possible other conditions such as thyrotoxicosis, hypertension or other problems causing the same symptoms.
42	Royal College of Nursing	Statement 1	It would be easy to collect data from the laboratories.
43	Wrexham Maelor Hospital	Statement 1	Women over 45 presenting to HCP is better than specifying primary care: these unnecessary tests are often undertaken in secondary care as well and this would be an ideal opportunity to apply similar standards across health care—both primary and secondary No identified concerns about this measure as such
44	Cornwall Menopause Service	Statement 2	Please state persistently elevated FSH so that there are at least two measurements
45	Faculty of Sexual and Reproductive Healthcare (FSRH)	Statement 2	Statement 2 is a little ambiguous and does not make it clear if women with menopause under 40 years need to attend a specialist service or should be managed in primary care.
46	Faculty of Sexual and Reproductive Healthcare (FSRH)	Statement 2	I do not think there is a strong evidence base to link early menopause with Parkinson's disease.
47	King's College Hospital	Statement 2	The quality standards related to POI appear to be limited to diagnosis of POI. Would it be possible to include 'management' of POI as well as 'diagnosis'? This ideally should also include access to required investigations as DEXA.
48	Royal College of General Practitioners	Statement 2	Laboratories are obliging about doing FSH under the age of 40 if ovarian failure is suspected. In practice it is common that women miss periods for reasons other than ovarian failure and the policy of "watch and wait" for 6 months or more would do no harm?
49	Royal College of General Practitioners	Statement 2	The denominator for standard 2 is "the number of women under 40 years presenting with menopausal symptoms" however most menopausal symptoms are very vague and variable and likely to be present in most patients presenting to the GP. Therefore it would be an inappropriate and onerous to measure and it would appear to advocate undertaking FSH testing in women presenting with any of these non-specific symptoms.
50	Royal College of General Practitioners	Statement 2	It would be difficult to reliably and accurately 1a "women's experience of the diagnostic process" across primary care and this cannot be performed within current resources. A national validated survey would need to be developed and implemented. A suitable alternative may be the time of first presentation to diagnosis however it should be acknowledged that it is recommended that women with secondary amenorrhoea should not be investigated for six months.
51	Royal College of Nursing	Statement 2	Easy to audit but not a useful standard for premature ovarian insufficiency (POI)
52	Royal College of	Statement 2	In the section 'Rationale', the sentence "… than women over 45 years in menopause" sounds a bit strange.

ID	Stakeholder	Statement number	Comments[1]
	Obstetricians and Gynaecologists		
53	Breast Cancer Now	Statement 3	We welcome the inclusion of this draft quality statement. However, given the very recent publication of new evidence on HRT and breast cancer risk, which shows that the extent of risk may have been underestimated, we wish to bring this to your attention. NICE may want to consider whether these research findings warrant a discreet update to the Menopause clinical guideline. **The risk of developing breast cancer from taking combined hormone replacement therapy (HRT) is likely to have been underestimated by previous studies** Research published in August 2016 in the *British Journal of Cancer* utilised data gathered by the longitudinal research study - The Breast Cancer Now Generations Study - to show that women taking combined HRT are 2.7 times more likely to develop breast cancer than non-users, during the period that combined HRT is in use, with risk increasing with longer HRT use. The researchers estimate that previous studies may have underestimated the increased risk of breast cancer from combined HRT by around 60%. Jones ME, Schoemaker MJ, Wright L, et al. Menopausal hormone therapy and breast cancer: what is the true size of the increased risk? *British Journal of Cancer*. Published online July 28 2016. For more information please see: http://breastcancernow.org/news-and-blogs/news/effect-of-combined-hrt-on-breast-cancer-risk-likely-to-have-been-underestimated and feel free to get in touch.
54	Faculty of Sexual and Reproductive Healthcare (FSRH)	Statement 3	This should probably read…. Women over 40 years in menopause presenting to primary care with vasomotor symptoms are offered hormone replacement therapy (HRT), ***if appropriate***, after a discussion of the short-term and longer term benefits and risks. In addition, the word 'offered' HRT is used in this statement – this does not reflect the fact that healthcare professionals often have their own views on HRT which are very varied and this may strongly affect a woman's ability to choose HRT or not.
55	King's College Hospital	Statement 3	The statement for women over 40 years old appears to be limited to 'vasomotor symptoms' as an indication. I appreciate the 40-45 year old group do not fall in a separate category in the guideline recommendations, but would it be possible to include 'indications for treatment in women over 40'? (e.g. medical – bone, cardiovascular / symptom control)
56	Royal College of General Practitioners	Statement 3	There are still many patients with a uterus who receive unopposed oestrogen HRT as a first treatment despite BNF advice. There needs to be another quality statement to cover this as the complications of unopposed oestrogen in these people are serious. There are patients requesting tibolone as a straight swap from the pill even though BNF guidance advises a year period free.
57	Royal College of General Practitioners	Statement 3	As with the outcome above, this outcome is subjective and would require national input for the development and data collection.

ID	Stakeholder	Statement number	Comments[1]
58	Royal College of General Practitioners	Statement 3	It would be beneficial, for this standard to be achieved, that resources such as a national patient decision aid for HRT were developed and to aid clinicians and patients to make an informed choice. Furthermore training may be required for GPs and nurses to deliver this standard as not all primary care clinicians feel confident in discussing and initiating HRT.
59	Royal College of Nursing	Statement 3	There is real concern expressed around how easy it will be to measure this standard - What is a valid 'discussion'? To some this may be 5 minutes, others 40 minutes, for others this may equate to giving out a leaflet, which is not individualised.
60	Royal College of Obstetricians and Gynaecologists	Statement 3	This quality statement says that women who are in the menopause and who have vasomotor symptoms are offered HRT after a discussion of the short and long term benefits and risks. However, in the section 'Quality measures', 'process c)' talks about *receiving* HRT. This QS is about discussing and offering but not *receiving*. I'd keep a) and b) but remove c). (i.e. receiving should be removed since it's not in the QS)
61	Wrexham Maelor Hospital	Statement 3	This excludes women under 40 (POI) who form a crucial group requiring HRT! HRT for POI has not been covered and should be included
62	Faculty of Sexual and Reproductive Healthcare (FSRH)	Statement 4	This statement should be fairly easy to measure, using prescription data. Both the 3 month review and the subsequent annual review are quality measures to review response to treatment, changes in medical history and side effects.
63	King's College Hospital	Statement 4	Could this be expanded to include ongoing follow up in secondary care? This will allow patients with complicated medical history or those who have no local menopause expertise in their primary care setting, to have the option to continue their ongoing follow up reviews (3 months and annual thereafter) in secondary care. This may come under NICE quality standard: 'safety of care' and can be audited by secondary care local data collection.
64	Royal College of General Practitioners	Statement 4	The adjective "short term" before menopausal symptoms is confusing and unnecessary. The recalls are needed but there could be patient partnership if measuring their own blood pressure, weight, breasts and satisfaction with treatment, so it could be done on the phone or by other remote access.
65	Royal College of General Practitioners	Statement 4	Three months then minimal annual reviews seem appropriate for monitoring HRT however the review may not need to be face to face considering the changing dynamics of consultations and increasing self management.
66	Breast Cancer Now	Statement 5	Draft quality statement 5 is drawn from the Menopause clinical guideline, where it has extended wording as follows: '*1.3.6 Offer women who are likely to go through menopause as a result of medical or surgical treatment (including women with cancer, at high risk of hormone sensitive cancer or having gynaecological surgery) support and:* · *information about menopause and fertility before they have their treatment* · *referral to a healthcare professional with expertise in menopause.*' The second bullet point has not been included in the draft quality statement. We believe that there is a strong rationale for it to be included, as outlined below. There is a lot of variation in access to menopause specialists, as acknowledged in the NICE Menopause guideline.

ID	Stakeholder	Statement number	Comments[1]
			Therefore, it would be highly desirable to see the referral element of 1.3.6 from the Menopause guideline also included in quality statement 5, along with a quality measure to monitor variation and to indicate to commissioners that it is important to commission local menopause services. In addition, the draft quality statement does not include ‘support’ for patients, as included in 1.3.6 in the Menopause guideline. We feel that this would be a small but important addition to the existing wording of quality statement 5, in light of the qualitative difference between merely giving someone information, and supporting them through a difficult decision-making process. **Rationale for amending draft statement 5 to include referral to a menopause specialist** Supporting patients to cope with side effects and adhere to their adjuvant treatment regime The menopausal side effects of breast cancer treatment can be severe and can have a significant impact upon quality of life. In some cases, they can be severe enough to cause people to discontinue or disrupt their treatment for breast cancer, thus compromising their survival. Treatment options are available to help people to manage the menopausal side effects of breast cancer treatment but more often than not, people are not made aware of these and/or are not referred to the appropriate specialist. It has become clear that patients with early invasive breast cancer need support and information to help them to continue to adhere to their adjuvant treatment plan, and therefore have better survival outcomes. Support with managing side effects could play an important role in encouraging adherence Makubate et al (2013) showed that many women do not take the medication as directed and they stop treatment before completing the standard 5-year duration. The researchers commented that they were unable to examine reasons for non-adherence, but a case note review of the women with an incidence of breast cancer between 1998 and 2007 had 382 women who discontinued medication, reporting they did so owing to side effects (the study comprised 3361 women in total). Over half of the women whose notes were reviewed, reported side effects due to endocrine therapy. The value of increasing adherence McCowan et al (2013) showed that patients with low adherence to their adjuvant medication have shorter time to recurrence, increased medical costs and worse quality of life. They concluded that interventions that encourage patients to continue taking their treatment on a daily basis for the recommended 5-year period may be highly cost-effective. Indeed, they estimated the expected value of changing a patient from low to high adherence as £33,897 (95% CI: £28,322–£39,652).
67	Faculty of Sexual and Reproductive Healthcare (FSRH)	Statement 5	This is a very useful statement, as some women presenting at menopause clinics often say they may have made a different decision, had they completely understood the consequences
68	Royal College of General Practitioners	Statement 5	“Given information” needs unpacking to explain appropriate language, and appropriate means, with explanation of where and how to obtain further advice and help.

ID	Stakeholder	Statement number	Comments[1]
69	Royal College of General Practitioners	Statement 5	The definition of medical or surgical treatment is limited and should be expanded to included women undergoing hysterectomies without oophorectomy, uterine artery emobilsation (UAE) and GnRH analgoues.
70	Royal College of Nursing	Statement 5	The guideline specifically suggests referral to HCP specialist. This should, therefore, be included in the quality standard and can be measured by audit. Many women report difficulty in accessing a HCP specialist prior to risk-reducing bilateral salpingo-oophorectomy (RRBSO) although they may be referred afterwards. The guidance is clear that information should be given before and a standard should reflect this.

Registered stakeholders who submitted comments at consultation

- Breast Cancer Now
- British Menopause Society
- Cornwall Menopause Service
- Department of Health
- Faculty of Sexual and Reproductive Healthcare (FSRH)
- Kings College Hospital
- NHS England
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- The Eve Appeal
- Wrexham Maelor Hospital