NICE National Institute for Health and Care Excellence

Quality Standards Advisory Committee 1

Haematological cancers – prioritisation meeting

Menopause - post consultation meeting

Minutes of the meeting held on Thursday 3 November 2016 at the NICE offices in Manchester

Attendees	**Standing Quality Standards Advisory Committee (QSAC) members** Bee Wee (Chair), Ivan Benett, Helen Bromley, Amanda De La Motte, Phyllis Dunn, Steve Hajioff, Gavin Maxwell, Teresa Middleton, Hazel Trender [agenda items 1-6] , Hugo van Woerden, Ian Reekie, Alyson Whitmarsh, Arnold Zermansky **Specialist committee members** **Haematological cancers –** Sam Ahmedzai, Barbara von Barsewisch, Chris Dalley, Morag Day, Peter Hoskin, Lesley Roberts, Bhupinder (Bhuey) Sharma, Elizabeth Soilleux, , **Menopause –** Jane Davis, Linda Parkinson-Hardman, Debra Holloway, Geeta Kumar **NICE staff** Mark Minchin (MM), Alison Tariq (AT) [agenda items 1-6], Sabina Keane (SK) [agenda items 1-6], Jane Lynn (JL) [agenda items 1-6] Stephanie Birtles (SB) [agenda items 7-11], Nicola Greenway (NG) [agenda items 7-11], Helen Vahramian (HV) **NICE Observers** Mark Rasburn
Apologies	**Standing Quality Standards Advisory Committee (QSAC) members** Gita Bhutani, Phillip Dick, Sunil Gupta, Peter Jenks, Ian Manifold, Jane Worsley **Specialist committee members** **Menopause -** Jo Justice, Mary Ann Lumsden

Agenda item	Discussions and decisions	Actions
1. Welcome, introductions and plan for the day (public session)	The Chair welcomed the attendees and the Quality Standards Advisory Committee (QSAC) members introduced themselves. The Chair informed the committee of the apologies and reviewed the agenda for the day.	
2. Committee business (public session)	**Declarations of interest** The Chair asked standing QSAC members to declare any interests that were either in addition to their previously submitted declaration or specific to the topic(s) under consideration at the meeting today. The Chair asked the specialist committee members to declare all interests. The following interests were declared: <u>Specialist committee members</u> <u>Haematological Cancers:</u> <u>Sam Ahmedzai</u> Personal Financial Interest: • NIHR National Specialty lead - Cancer Research Outside the Acute Hospital (current) • Clinical Adviser - NICE guideline development group on service delivery in last year of life (current) • Clinical Lead - Royal College of Physicians National Audit of End of Life Care (finished 30 June 2016) • Chair - NICE guideline development group for Care of the dying adult in last days of life (finished December 2016) • NIHR HTA research grant (effectiveness of early palliative care for advanced non-small cell lung cancer patients – study closed May 2016) • Prostate Cancer UK research grant (development and validation of an online holistic needs assessment and care plan for prostate cancer patients – study closed December 2015) • MRC research grant (clinical trial of saracatinib for bone cancer pain – continuing till August 2017) • Royalty fees - Oxford University Press (Textbook of Supportive Care in Respiratory Disease) • Lecture fees - annual University of Amsterdam Masterclass on Palliative Care • PhD external examiner for University of Odense, Denmark	

Agenda item	Discussions and decisions	Actions
	• Honoraria for lectures on cancer pain management – Grunenthal, Mundipharma • Consultancy and advisory boards for cancer pain management – Grunenthal, Mundipharma • Consultancy and advisory board for management of opioid-induced constipation – AstraZeneca, Mundipharma. Non-personal financial interest: Funding for the following have gone to University department - • Lecture fees - Amgen, AstraZeneca, Grunenthal, Mundipharma • Consultancy fees - AstraZeneca, Grunenthal, Mundipharma Research Funding for the following have gone to NHS Trust R&D department : - Mundipharma (management of opioid-induced constipation) - AstraZeneca (prevalence and impact of opioid-induced constipation) - Grunenthal (management of cancer pain) Personal non-financial interest: • Member - NICE guideline development group on Multiple Myeloma • Member - Royal College of Surgeons National Confidential Audit on Oesophago-gastric Cancer • Chair - National Cancer Research Institute Clinical Studies Group on Supportive and Palliative Care • Member - Resuscitation Council committee on Emergency Care and Treatment Plan • Elected Council Member and Trustee - British Pain Society • Member - Target Ovarian Cancer Scientific Board • Member - Professional Advisory Board and Scientific Committee of Maggie's Centre • Steering group member - British Thoracic Oncology Group • Chair - Respiratory Study Group of Multinational Association for Supportive Care in Cancer <u>Barbara von Barsewisch</u> • 2014/2015 NICE Guideline Committee Member on Updating Haematology Guidelines (£0) • 22/10/2015 Gilead Idelalisib pneumonitis discussion facilitator (£625) • 29/04/2016 AbbVie participate in interview to evaluate Navigate programme for Idelalisib (£300) • 11/05/2016 AbbVie clinical nurse specialist advisory group meeting for venetoclax (£80)	

Agenda item	Discussions and decisions	Actions
	Christopher Dalley • June 2015, non-personal financial interest: Chaired an educational meeting held by Pfizer and the honorarium was paid to department's haematology fund. • September 2015, non-personal financial interest: Chaired an educational meeting held by Celgene and the honorarium was paid to departments haematology fund Peter Hoskin • Grants from Varian, Astellas, Bayer, Millenium for trials in Prostate cancer paid to Department through E&N Herts NHS Trust • Payment to E&N Herts NHS Trust by Gilead for participation in lymphoma research trials (unrelated to subjects considered in NICE GDG). • Member, Medical Advisory panel, Lymphoma Association Bhupinder Sharma • Full time NHS consultant with private work undertaken at Alliance Medical and BUPA • Cromwell in evenings. • 2014 – 2016 NICE Non-Hodgkin's Lymphoma Guideline committee member. • 2015 – 2016 NICE Haematological Cancers, Improving Outcomes Guideline committee member Elizabeth Soilleux • Honoraria in the last 2 years: Novartis (for attending the UK Myeloproliferative Neoplasm Steering Group meeting) Adept Field Solutions (telephone-based research study) Porterhouse (telephone-based research study) • Meeting sponsorship/ hospitality, Roche-Ventana (March 2016). • Ad hoc: Employment as the trial pathologist for the UK CHOP-OR trial funded by GlaxoSmithKline. Consultancy for Oxford Cancer Biomarkers.	

Agenda item	Discussions and decisions	Actions
	Medicolegal work for a range of law firms and occasionally for private individuals. Remunerated teaching for the Oxford FRC Path course, St Hugh's College, Oxford, and other colleges within Oxford University. • Chair - Education Subcommittee of the Pathological Society of Great Britain and Ireland, attracts free registration for meetings and reimbursement of travel and accommodation costs for Pathological Society meetings. • Speaker - British Lymphoma Pathology Group/ British Division of the International Academy of Pathology joint meeting: travel and accommodation costs paid. (May 2014) • Speaker - British Division of the International Academy of Pathology Molecular Pathology: travel costs paid. (March 2015) • Member - NICE Guideline Committee for NG 47 Haematological Cancers: Improving outcomes • With colleagues in Oxford, filed the following patent, which may, in the future (1 – 2 years hence, at least) form the basis of a diagnostic reagent: G. Ogg, E. Soilleux and M. Salimi: T-cell Monotypia and Clonality. UK Patent Application No. 1417498.1 for ISIS Innovation Limited (7261 / BB Ref. JA74505P.GBA) Filed 3.10.2014. • Collaboration - Roche-Ventana, Leica-Novocastra and Zytovision in many areas of diagnostics. Receives a variety of free reagents as well as considerable staff time in terms of providing technical expertise. • Supervision - trainee pathologist, undertaking a collaboration with Biocartis/ Janssen, who are loaning a machine and providing all reagents free of charge for a small study. • Grants: Celgene – (c. £300, 000 final figure tbc) The Pathological Society of Great Britain and Ireland (£10,000) The Medical Research Council (£65,208.12) Oxford Health Sciences Research Committee (£81, 000 – split between 3 grants) Coeliac UK (£26, 500) Julian Starmer-Smith Lymphoma (Fund £10, 500) Lymphoma and Leukaemia Research – funding for 1 day per week's salary Oxford Biomedical Research Centre – funding for 1 day per week's salary Assists by providing pathology support for a number of clinical trials, none of which attract honoraria, although aspires to author publications resulting from these. • Refreshments and occasional venue hire fees for intermittent educational and multidisciplinary team meetings in the Thames Valley region regularly sponsored by: Alexion, Amgen, Astellas, Bayer, the Binding Site, Biotest, Celgene, Chugai, Gilead,	

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	GlaxoSmithKline, Janssen, Napp, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi and Takeda. • Ventana annual symposium in Tucson, Arizona, sponsored (i.e., paid for in entirety) by Roche-Ventana (March 2016) • Roche-Ventana also sponsored an educational day run for histopathology trainees in the Oxford deanery last week. (c£300 for refreshments.)	
3 Topic overview and summary of engagement responses	SK presented the topic overview and a summary of responses received during engagement on the topic.	
3.2 Prioritisation of quality improvement areas	The Chair and SK led a discussion in which areas for quality improvement were prioritised. The QSAC considered the draft areas as outlined in the briefing paper prepared by the NICE team. The outcome of discussions is detailed below.	

Suggested quality improvement area	Prioritised (yes/no)	Rationale for prioritisation decision	If prioritised, which specific areas to be included?
1. NHL-Diagnosis and staging a) Type of biopsy b) Diagnosing B-cell lymphomas: gene testing strategies	 No No	<u>Type of biopsy</u> The committee discussed biopsy types and heard from the SCMs that accurate and timely diagnosis is a key issue to support good outcomes. Whilst recognising that biopsy is an important part of accurate and timely diagnosis the committee was aware that recommendations in NG52 do not	Prioritised - Staging using FDG-PET-CT for specific diagnostic groups. NG52 recommendations (1.2.1) and Burkitt lymphoma (1.2.4)

c) Staging using FDG-PET-CT	Yes	specify the timeliness for the biopsies it was agreed not to prioritise this area. <u>Diagnosing B-cell lymphomas: gene testing strategies</u> The committee discussed the reported wide variation in use of FISH (fluorescence in situ hybridisation) testing. It was noted that blood cancer genetic testing may change rapidly, with newer technologies becoming available and superseding existing techniques. The committee was also aware that the underpinning recommendation for FISH is a consider recommendation. SCMs commented that the accuracy of determining DLBCL or Burkitt lymphoma via microscopy was also important. It was agreed to not prioritise gene testing strategies. <u>Staging using FDG-PET-CT</u> The committee discussed the variation in current practice for confirming staging. The committee heard that FDG-PET-CT imaging offers a more accurate staging compared to standard CT scans. The committee concluded that accurate staging would make a significant difference in terms of treatment and management for some specific lymphoma types as mentioned in NG52 recommendation 1.2.1. It was therefore agreed to be prioritised as an area.	

Suggested quality improvement area	**Prioritised (yes/no)**	**Rationale for prioritisation decision**	**If prioritised, which specific areas to be included?**
2. NHL- Management of follicular lymphoma (FL) and diffuse large B-cell lymphoma (DBCL) a) First-line treatment for stage IIA FL b) Consolidation with stem cell transplantation c) Management of diffuse large B-cell lymphoma (DLBCL)	Yes No Yes	<u>First-line treatment for stage IIA FL</u> The committee was aware of variation in survival rates for people with localised stage IIA follicular lymphoma, it was also noted that access to local radiotherapy treatment is variable. The committee heard that treatment with local radiotherapy for people with stage II follicular lymphoma showed a 10% improvement in survival at 10 years. The committee agreed to prioritise this area using NG52 recommendation 1.3.1. <u>Consolidation with stem cell therapy</u> The committee discussed the need to consider that the preconditioning treatment for autologous stem cell transplants means stem cell therapy is not suitable for all people. The committee recognised there are a number of factors to be considered to assess if someone is fit enough for a transplant, this is the role of the transplant centre. The committee noted that no data was available to demonstrate variation in practice so it was agreed not to prioritise this. <u>Management of DLBCL: Central nervous system</u>	Prioritised- local radiotherapy as first-line treatment for stage IIA FL (NG52 recommendation 1.3.1). Prioritised-management of DBCL-Central nervous system-directed prophylactic therapy (NG52 recommendation 1.6.3 and 1.6.4).

		(CNS) -directed prophylactic therapy The committee discussed the significant variation in practice noted by SCMs. The committee heard that CNS relapse in people with DLBCL occurs infrequently, but is a major complication with very poor outcomes. It was reported that a low number of patients are affected overall but as the impact upon them is significant the area should be prioritised.	
Suggested quality improvement area	**Prioritised (yes/no)**	**Rationale for prioritisation decision**	**If prioritised, which specific areas to be included?**
3. Follow-up, communication, information and support a) DLBCL-follow-up b) NHL-Information and support c) Myeloma-Communication and support	Yes Yes No	DLBCL- follow-up Committee discussed this with the next area on NHL - information and support. NHL - Information and support The committee discussed the importance of end-of-treatment summaries (NG52 recommendation 1.11.1) to aid patient support and reduce the number of unnecessary follow-up appointments. It was therefore agreed to prioritise this area and combine with NG52 recommendation 1.10.1 on follow-up for people not offering routine surveillance imaging for detecting relapse in people who are asymptomatic. It was agreed that this area would be prioritised.	Prioritised end-of-treatment summaries NG52 recommendation 1.11.1 and combine with recommendation 1.10.1 on not offering routine surveillance imaging for detecting relapse in people who are asymptomatic.

		Myeloma – Communication and support The committee discussed access to clinical nurse specialists for people with myeloma and haematological cancer. The committee heard that patients and their carer's value having access to a CNS. It was highlighted that larger hospitals have more resources for clinical nurse specialists. Also travel time was discussed to get to larger hospitals where specialist nurses are more likely to be based. Ensuring that carers receive sufficient information and support was discussed, the committee was aware that QS15 on patient experience includes a statement on carers (statement 13). The committee concluded that no specific aspect of patient information and experience for this condition exceeds that covered in QS15, so it was agreed not to prioritise.	
Suggested quality improvement area	**Prioritised (yes/no)**	**Rationale for prioritisation decision**	**If prioritised, which specific areas to be included?**
4. Myeloma- Imaging investigations	No	Access to diagnostic testing The committee noted that there are a number of consider recommendations within the guideline for this area. It was felt this was an area of research with new techniques being developed and made available. The committee heard that whole-body MRI imaging is an area where clinical practice is	N/A

		rapidly changing, it was noted that currently there is limited access to whole-body MRI imaging in England. It was therefore agreed that diagnostic testing techniques would be an area for future development but this should not be prioritised at this time.	
Suggested quality improvement area	**Prioritised (yes/no)**	**Rationale for prioritisation decision**	**If prioritised, which specific areas to be included?**
5. Myeloma: preventing and managing complications **a) Preventing infection** **b) Managing peripheral neuropathy**	No No	Preventing infection Testing for hepatitis B, hepatitis C and HIV before starting myeloma treatment was discussed. Overlaps with other quality standards within the published library were discussed. It was therefore agreed not to progress this area. Managing peripheral neuropathy The SCMs reported that side effects of the drugs used to treat myeloma can be very disabling and people can be left with significant long-term high levels of pain. The committee heard that some of the newer treatments have reduced side effects. Whilst noting that this is an important area of care the committee agreed not to prioritise this area.	N/A
Suggested quality improvement area	**Prioritised (yes/no)**	**Rationale for prioritisation decision**	**If prioritised, which specific areas to be included?**

6. Myeloma- Service organisation a) Service organisation b) Other facilities	 No No	<u>Service organisation: therapeutic services</u> Local access to 24-hour therapeutic apheresis services was discussed. It was agreed not to progress this area. <u>Other facilities: availability of blood counts and components</u> It was agreed that other facilities needed to be considered with staffing and structures so it was agreed this area would be discussed with the next suggested quality improvement area on specialist integrated haematological malignancy diagnostic services (SIHMDS).	N/A
Suggested quality improvement area	**Prioritised (yes/no)**	**Rationale for prioritisation decision**	**If prioritised, which specific areas to be included?**
7. Specialist integrated haematological malignancy diagnostic services (SIHMDS) a) Integrated reporting b) Haematopathologist c) Clinical nurse specialist	 Yes No No	<u>Integrated reporting by SIHMDS</u> The committee discussed how SIHMDS coverage is variable with no national implementation. It was agreed to focus on the need for integrated reporting NG47 recommendation 1.1.2 (penultimate bullet point) this reporting will be shared with the MDT which was highlighted as especially important to aid myeloma diagnosis as the composition of myeloma MDTs differ from lymphoma MDTS as mentioned in NG35 recommendation 1.4.3.	Prioritised- integrated reporting (NG47 recommendation 1.1.2- penultimate bullet point) to be shared with MDT. MDT composition defined in NG47 1.3.9 and should also include psychological support roles as mentioned in NG52 recommendation 1.9.1 Prioritised- Clinical nurse specialist- add within the area of end of treatment summaries and their role within the MDT composition for the SIHMDS.

		Psychological needs and the inclusion of psychological support roles within the MDT composition was also highlighted as important with unequal access discussed. NG47 recommendation 1.1.3 on report validation was also discussed, and double reporting was agreed to be prioritised as it was highlighted that it was important that 2 experts should look at investigations to ensure correct and timely diagnosis. Integrated reports can be delayed by genetic testing results therefore timeliness of their dissemination was highlighted as important. NG47 subsequent recommendations 1.1.6-1.1.8 include caveats on appropriateness to produce reports locally and non-integrated reports based on clinical urgency for example which needs to be considered. <u>Haematopathologist</u> The committee discussed this role within the MDT. It was reported that currently there was a national shortage therefore it was unlikely to make a significant difference so it was agreed not to prioritise this as an area. <u>Clinical nurse specialist</u> The SCMs agreed that this role should not be prioritised as a standalone statement as generally staffing levels are not considered in quality	

		standards. It was however recognised as important which could be highlighted within the MDT composition for the SIHMDS and added within the end-of-treatment summaries. Their role is covered in NG47 recommendations 1.3.15.	

Additional areas suggested	Committee rationale	Area progressed (Y/N)
Cancer Recovery Package	Stakeholder highlighted that The Cancer Strategy recommends by 2020 all patients should have access to the different elements of the Recovery Package including carer support. There are no guideline recommendations on the use of the Cancer recovery package.	**No**
2014 Care Act	A stakeholder highlighted the 2014 Care Act which supports carers and deliver needs assessments. Quality standard statements do not cover areas already covered by legislation.	**No**
Myeloma education for GPs	A stakeholder raised that as myeloma is a more rare cancer GP education on symptoms is essential. Quality standard statements do not cover the training and education of healthcare professionals.	**No**
NICE Cancer Service Guideline (CSG7, 2005) Improving outcomes in children and young people with cancer	Stakeholders highlighted that the interdependency and integration of services for all children with cancer must be recognised. They referred to NICE cancer service guidance for general guidance on staffing and service organisation for children with cancer. No specific suggestions were made and there is a published quality standard in the library for QS55 on cancer services for children and young people.	**No**
Treating advanced-stage asymptomatic follicular lymphoma	NICE TA243 recommends rituximab as an option for the treatment of symptomatic stage III and IV follicular lymphoma in previously untreated people NG52 (1.3.4) Offer rituximab induction therapy to people with advanced-stage (stages III and IV) follicular lymphoma who are asymptomatic The committee agreed that an improvement area is recommendation 1.3.4 from NG52 – the guideline (NG52) covers a group that is not covered by TA243 or the marketing authorisation given to rituximab.This was discussed as a cost effective, low toxicity intervention which was major change in management. It was therefore agreed to progress as an area.	**Yes**
Vial sharing	A stakeholder highlighted that vial sharing would improve cost efficiency for pharmacy. There are no guideline recommendations identified on this area for quality improvement.	**No**

3.3. Resource impact	JL presented resource impact considerations to the committee on first-line imaging investigations in NG35 recommendation 1.3.2 on whole-body MRI and if this is unsuitable or declined recommendation 1.3.3 on whole-body low-dose CT. It was recommended that organisations should consider impact within demand and capacity planning for MRI and CT services. Instead of skeletal surveys, there were reported cost increases of £94.24 for each person having MRI and £38.35 for each person having whole-body CT. JL also presented the resource impact of NG47 recommendation 1.1.2 on a formal Specialist Integrated Haematological Malignancy Diagnostic Services (SIHMDS) director role with additional PAs in clinical job plans required and expansion or reduction changes to other staff roles. It was recommended that organisations assess staffing levels locally.	
3.4 Overarching outcomes	The NICE team explained that the quality standard would describe overarching outcomes that could be improved by implementing a quality standard on haematological cancers. It was agreed that the committee would contribute suggestions as the quality standard was developed.	
3.5 Equality and diversity	The NICE team explained that equality and diversity considerations should inform the development of the quality standard, and asked the committee to consider any relevant issues. It was agreed that the committee would contribute suggestions as the quality standard was developed.	
4. QSAC specialist committee members (part 1 – open session)	**Specialist members**: It was agreed that the composition of SCMs was correct	
5. Next steps and timescales (part 1 – open session)	The NICE team outlined what will happen following the meeting and key dates for the haematological cancers quality standard.	
6. Any other business (part 1 – open session)	The following items of AOB were raised: • None raised **Date of next meeting for haematological cancers: Thursday 2 March 2017**	
7. Welcome and code of conduct for members of the public attending the meeting	The Chair welcomed the public observers and reminded them of the code of conduct that they were required to follow. It was stressed that they were not able to contribute to the meeting but were there to observe only. They were also reminded that the committee is independent and	

(public session)	advisory therefore the discussions and decisions made today may change following final validation by NICE's guidance executive.	
8. Committee business (public session)	The Chair welcomed Geeta Kumar, a consultant in obstetrics and gynaecology to the committee. Geeta joined the committee as an SCM, it was noted that Geeta is a standing member of QSAC3. A specialist committee member who could not present submitted comments prior to the meeting. SB presented these comments following the presentation of the consultation comments for each of the statements for the committee to consider. **Declarations of interest** The Chair asked standing QSAC members to declare any interests that were either in addition to their previously submitted declaration or specific to the topic(s) under consideration at the meeting today. The Chair asked the specialist committee members to declare all interests. The following interests were declared: <u>Specialist committee members</u> – <u>Geeta Kumar</u> o Chair-patient info committee-RCOG and author of text book on "Early pregnancy issues" o Author of a chapter in text book published April 2016—"Fetal medicine" o Invited speaker at British Menopause Society meeting (May 2015) o Member of British Menopause Society o Contributed to the submission of consultation comments from Wrexham Maelor Hospital - <u>Debra Holloway</u> • Chair - RCN women's health Forum - ongoing • Consultant - guide line for nurses - paid position Jan 16 • Session - menopause for Lambeth practice nurses Dec 15 not paid and via Trust. • Chair - RCN women's health conference November 15- not paid. • Chair - RCN endometriosis nurse conference November 15 not paid • 2015 - Menopause session at de Montfort University • 2015 - BM S-hysteroscopy and perimenopause bleeding and menopause café	

	on primary care consultations • Yearly gynaecology nursing course for KCl level 6, 2015 - session on menopause and module co lead. • RCN congress -Chair fringe event endometriosis and fertility- June 2015 • BSGE- invited speaker for satellite nurses meeting- RCN endometriosis project and co-chair of nurse hysteroscopy session- May 2015 • RCN launch of CNS endometriosis document - chair and speaker March 2015 • Publications: 2015 - Oxford Handbook of Women's Health Nursing. Gupta, **Holloway**, Kubba (translated into Greek) 2015 - The Role of the CNS in endometriosis- RCN publication (chair of group and author 2015 - Endometriosis fact sheet- RCN publication (chair of group and author) 2015 - Iron deficiency and anaemia in adults- RCN guidance for nurse. RCN (working party) 2015 - Managing the Menopause at Work- Carmel Bagness and Debby Holloway. Practice Nursing 26.11 <u>Mary Ann Lumsden</u> • Chair - Guidelines Development Group for Menopause: Diagnosis and Treatment • Chair - Consortium Board for the National Collaborating Centre in Women's and Children's Health • Vice Chair - Women's Health Expert Advisory Group to the MHRA. • Advisor - NeRRe Biotechnologies, on potential new molecules for treating menopausal symptoms (non-personal). • President Elect - International Menopause Society • Member - Council of the British Menopause Society.	
9. Recap of prioritisation exercise	NG presented a recap of the areas for quality improvement discussed at the first QSAC meeting for menopause: **At the first QSAC meeting on 2 June 2016 the QSAC agreed that the following areas for**	**5. Recap of prioritisation exercise**

	quality improvement should be progressed for further consideration by the NICE team for potential inclusion in the draft quality standard: • Diagnosis – prioritised • Information – prioritised • Review – prioritised • Premature ovarian insufficiency – prioritised 2 statements • Managing short term menopausal symptoms – not prioritised • Referral – not prioritised The full rationale for these decisions is available in the prioritisation meeting minutes which can be found here.	
9.1 and 9.2 Presentation and discussion of stakeholder feedback and key themes/issues raised	NG presented the committee with a report summarising the consultation comments received on menopause. The committee was reminded that this document provided a high level summary of the consultation comments, prepared by the NICE quality standards team, and was intended to provide an initial basis for discussion. The committee was therefore reminded to also refer to the full list of consultation comments provided throughout the meeting. The committee was informed that comments which may result in changes to the quality standard had been highlighted in the summary report. Those comments which suggested changes which were outside of the process, were not included in the summary but had been included within the full list of comments, which was within the appendix. These included the following types of comment: • Relating to source guidance recommendations • Suggestions for non-accredited source guidance • Request to broaden statements out of scope • Inclusion of overarching thresholds or targets • Requests to include large volumes of supporting information, provision of detailed implementation advice • General comments on role and purpose of quality standards • Requests to change NICE templates The committee discussed the general themes identified from the consultation comments. • Statements supported and all key areas for quality improvement • Suggested changes to the introduction	**5.2 and 5.3 Presentation and discussion of stakeholder feedback and key themes/issues raised**

	• Suggested additional measures
	• Information not routinely collected in primary and secondary care.
	• 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.
	
	NG highlighted that the additional measures would be considered when drafting the quality standard but stated that they must directly measure the statement. The committee agreed to consider data collection and the potential resource impact for each statement as they are discussed to ensure they are achievable.	

9.3 Discussion and agreement of final statements	The committee discussed each statement in turn and agreed upon a revised set. **These statements are not final and may change as a result of the editorial and validation processes.**	**5.4 Discussion and agreement of final statements**

Draft statement 1	Themes raised by stakeholders	Committee rationale	Statement revised (Y/N)
Diagnosis Women over 45 years presenting to primary care with menopausal symptoms are diagnosed based on their symptoms, without laboratory tests	• 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	**Supported subject to clarification of wording to read:** Women over 45 years presenting with menopausal symptoms are diagnosed based on their symptoms, without laboratory test confirmation. FSH testing is not specified in the statement but reference should be made in the supporting rationale that FSH is included among the laboratory tests that are not recommended. Noted that FSH testing had limited efficacy as a diagnostic tool in women over 45 years, as hormone levels can be suppressed by hormonal contraception.	**Yes, subject to amendments**

	measurable. • The statement should also include secondary care.	GPs need to have a clear signal that women over 45 years of age can be given a diagnosis of menopause without the need for blood tests. Agreed that the statement should be applicable for women presenting to any service and not just primary care.	
Draft statement 2	**Themes raised by stakeholders**	**Committee rationale**	**Statement revised (Y/N)**
Diagnosing premature ovarian insufficiency 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	• 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,	**Supported subject to amended wording to read:** Women under 40 years presenting with menopausal symptoms, who are not pregnant, are offered FSH tests. The consultation wording leads straight to a diagnosis of premature ovarian insufficiency, does not make clear that 2 tests should be performed and is difficult to measure. The committee agreed with consultation comments that symptoms could have other causes. FSH testing is unhelpful for pregnant women and they are a population that can be easily excluded. NG highlighted that the technical team would need to review the guideline when drafting the statement before agreeing to include this group. Subject to these caveats, women under 40 should be offered FSH testing, and this will be easy to measure. It would remind healthcare professionals to consider a diagnosis of POI for these women which would drive an increase in the accurate diagnosis of POI, and offer potential health benefits in the prevention/early treatment of cardiovascular disease and bone health. The committee agreed the statement should focus on diagnosis but would consider management of POI as a separate statement.	**Yes, subject to amendment**

	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.	It was felt the inclusion of a watch and wait period would make the statement too complicated, is not supported by the guideline recommendations and may lead to some women waiting too long to receive a diagnosis and the following treatment.	
Draft statement 3	**Themes raised by stakeholders**	**Committee rationale**	**Statement revised (Y/N)**
Hormone replacement therapy (HRT) 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	• 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.	**Not supported** The issue the statement was aiming to address was about ensuring women are appropriately informed about the risks and benefits of all treatment options and not just the provision of HRT. This area is covered by QS15 patient experience quality standard. The committee considered that the inclusion of the statement as worded could be misinterpreted as the promotion HRT over other treatments. The committee felt that there is still variation in the perceived risks of HRT but once a correct diagnosis has been made, the appropriate therapy will follow and there is no evidence that this is not happening. The committee concluded that the statement on HRT should not be progressed.	**Not progressed**
Draft statement 4	**Themes raised by stakeholders**	**Committee rationale**	**Statement revised (Y/N)**
Review of treatments for			

short-term menopausal symptoms Women having treatment for short-term menopausal symptoms have a review 3 months after starting each treatment and then at least annually	• Confusing using the term 'short term' symptoms with an annual review. • Clarity needed over the population covered by this quality statement and if it include women with POI. • 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?	**Supported subject to amended wording to read:** Women having treatment for menopausal symptoms have a review 3 months after starting each treatment and then at least annually. Agreed inclusion of short term was confusing and not required in the statement. Committee agreed both the 3 month and 12 month reviews were important especially as they start again with every new treatment and therefore agreed both reviews should remain in the statement. Agreed the statement should be for all women receiving treatment. The technical team to review the evidence in the guideline. Discussed the method of review and agreed that although some reviews for conditions can happen remotely, these reviews include health check measurements which would require a face-to-face meeting.	**Yes, subject to amendment**

	• 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.		
Draft statement 5	**Themes raised by stakeholders**	**Committee rationale**	**Statement revised (Y/N)**
Information for women having treatment that is likely to cause menopause Women who are likely to go through menopause as a result of medical or surgical treatment are given information about menopause and fertility before	• 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	**Supported as worded** This is an important statement as women are not receiving appropriate information to make informed choices. Statement progressed as worded and not expanded as this would introduce additional concepts, quality statements should focus on one concept only.	**No**

they have their treatment.	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? Additional suggestions for the definition were made and included: • other treatments • radiotherapy • breast cancer treatments	Agreed to use the definition of medical or surgical treatment as defined in the guideline which includes radiotherapy.	

	• hysterectomy without oophorectomy, uterine artery embolisation (UAE) and GnRH analogues • family history of early menopause.		

Additional statements suggested	Committee rationale	Statement progressed (Y/N)
Availability of expertise for clinical advice and training	Agreed the lack of availability of clinical expertise was an important issue but not appropriate for the quality standard. The committee felt this was an implementation issue for the guideline. The committee also felt that any statement in this area would have significant resource impact.	**No**
Clinicians raising the issue of screening for sexual problems	Not an area for quality improvement.	**No**
Self-management such as weight loss, alcohol reduction and exercise	Important area for women's health generally but not a priority area for women with menopause and there are no recommendations in the guideline to support a statement.	**No**
Suitable HRT regimes	HRT regimes discussed at the prioritisation meeting and not progressed as it was not felt to be a key area for quality improvement. As with statement 3 the committee did not want to prioritise HRT over other treatment options.	**No**
Discussion of the risks of HRT in younger women	Management of POI discussed at the prioritisation meeting and not progressed however in response to the consultation comments especially relating to statement 2 to expand the statement to include management the committee agreed to discuss this area again. The committee agreed to progress a	**Yes**

	statement based on recommendation 1.6.6 to offer sex steroid replacement with a choice of HRT or a combined hormonal contraceptive to women with POI. Treatment for this group of women is important to prevent cardiovascular problems and improve bone health.	
Discussion and provision of contraceptives for women in perimenopause or menopause	Contraceptives discussed at the prioritisation meeting and not progressed as it was not felt to be a key area for quality improvement.	**No**
Compliance with the use of vaginal oestrogen.	Urogenital atrophy was discussed at the prioritisation meeting and not progressed as it was not felt to be a key area for quality improvement.	**No**

9.4. Resource impact	The committee agreed the 5 statements prioritised would not have a significant resource impact.	
9.5. Overarching outcomes	The NICE team explained that the quality standard would describe overarching outcomes that could be improved by implementing a quality standard on menopause. The committee queried how the outcome on women taking control of their health and wellbeing would be addressed by the statements. It was confirmed this would be influenced by the statement on management of POI. The committee also agreed to expand the outcome on long term health effects to specifically mention cardiovascular disease and bone health. It was agreed that the committee would contribute additional suggestions as the quality standard was developed.	**Amend the overarching outcome measures as stated**
9.6. Equality and diversity	The NICE team explained that equality and diversity considerations should inform the development of the quality standard, and asked the committee to consider any relevant issues. The committee queried if women with disabilities included learning disabilities. The NICE team to amend the group to include learning disabilities. It was agreed that the committee would contribute other suggestions as the quality standard was developed.	**Include learning disabilities in the EQIA**
10. Next steps and timescales (part 1 – open session)	NG outlined what will happen following the meeting and key dates for the menopause quality standard.	
11. Any other	The following items of AOB were raised:	

business (part 1 – open session)	• None raised **Date of next QSAC1 meeting: Thursday 5 January 2017** • **Sepsis (Morning session: Topic prioritisation)** • **Transition between inpatient mental health settings and community and care homes (Afternoon session: Topic prioritisation)**	