**National Institute for Health and Clinical Excellence**

**Ovarian cancer quality standard**
**Quality Standard Consultation Comments Table**
25 November – 23 December 2011

PLEASE NOTE: Consultation comments have been grouped for analysis purposes, potentially resulting in some reordering and duplication of comments. Responses are provided in relation to the statement number allocated in the table.

| ID | Stakeholder | Statement No | Comments | Responses |
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| 1 | Airedale NHS Foundation Trust | General | There are only 12 statements in the draft, 10 of them are entirely reasonable.<br>Statement 1 seems impossible to measure<br>Statement 12 is already addressed by the cancer peer review process. | Thank you for your comments. It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full. Draft quality statement 12 has now been removed from the final quality standard. |
| 2 | British Pain Society | General | *Early involvement of pain and palliative care services are to be facilitated to ensure that the patient is benefitted from specialist input throughout the course of their treatment and beyond, so that continuity of care can be maintained in the hospital, hospice and home setting.*<br>I would recommend that the above statement or something of a similar vein should be included among the 15 quality statement in the guidance. | The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed.<br>The topic expert group discussed the suggested statement and decided it was outside the scope of this quality standard. |
| 3 | Department of Health | General | I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation. | Thank you for your response. |
| 4 | International Ovarian Tumour Analysis (IOTA) Group | General | The recommendations from NICE appear to be based on a single meta-analysis [1] and a small study of RMI [2]. The latter study's results are inconsistent with previous validations of the RMI as adjusted by Tingulstad and colleagues, reporting nearly perfect sensitivity and specificity values whereas the meta-analysis reports clearly lower figures. It is unfortunate that they have not taken the opportunity to incorporate some of the largest studies in the literature into their guidance. | The topic expert group identified the development sources they felt were most relevant to developing this quality standard. Statements are based on recommendations, which in turn are based on the best available evidence. The topic expert group do not therefore revisit the evidence base as part of this development process. |
| 5 | Macmillan Cancer Support | General | We are disappointed by the scope of this Quality Standard in that it only focuses on a small part of the ovarian cancer care pathway. We think that all Quality Standards should cover the whole patient journey from diagnosis to | The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 and the lack of other NHS |

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| | | | follow up or end of life care, and are pleased that this is the case in the cancer-specific Standards already published (breast and lung). We think it is important that, in order to make the Quality Standard process more transparent, stakeholders have an opportunity to comment on the scope - something which happens as standard with clinical guidelines and technology appraisals.<br>We know that follow up care is already an issue for cancer patients. Our research shows that over a quarter of people living with cancer (26%) say they feel abandoned by the system when they are not in hospital, while more than 25% of patients have unmet needs a year after treatment has ended<br>This is why it is so important that Quality Standards incentivise quality care for patients throughout the whole pathway and not just during diagnosis and primary treatment. | evidence accredited sources to complete the pathway. The Ovarian Cancer quality standard scoping document is heavily based on the Ovarian Cancer guideline. As the guideline has already been extensively consulted upon, and only sets out what won't be covered rather than what will, NICE's policy is that a consultation at this stage is not required as the scope doesn't give much additional information over and above the guideline consultation. |
| 6 | Macmillan Cancer Support | General | Macmillan Cancer Support improves the lives of people affected by cancer. We provide practical, medical, emotional and financial support and push for better cancer care and think it is vitally important that Quality Standards don't just incentivise high quality clinical care, but also ensure that providers are incentivised to deliver holistic care. | Thank you for your comments. |
| 7 | NHS Direct | General | NHS Direct welcome the QS and have no comments on it content following consultation | Thank you for your response. |
| 8 | Ovarian Cancer Action | General | Ovarian Cancer Action would like the outcomes of the NICE quality standard for ovarian cancer to be peer reviewed, measured and benchmarked. It would be helpful when considering the range of analysis for NICE and other organisations to work with the Third Sector. | It is not anticipated that these quality statements and measures be used as targets. The expectation is that quality statements and measures will be used and adapted locally. |
| 9 | Roche Products Ltd | General | The role of the clinical nurse specialist (CNS) has been established as integral to the delivery of quality care and support for cancer patients. Indeed both the published breast cancer quality standard (QS 12) and the draft lung cancer quality standard (QS 5) make reference to the importance of the CNS role. We request that a similar statement is included within this quality standard to reflect the importance of this role and ensure equity of care across all cancers.<br>A suggested statement could be:<br>'Women with suspected or diagnosed ovarian cancer have access to a named ovarian cancer clinical nurse specialist whose role is to provide continuity of care and support, offer referral to psychological services if required and liaise with other healthcare professionals, including the GP and specialist palliative care services.' | The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed. |

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| | | | Outcome: Patient satisfaction with access to, and support and signposting provided by an ovarian cancer clinical nurse specialist. | |
| 10 | Roche Products Ltd | General | The management of ascites should be covered within the QS for ovarian cancer. Ascites is not a 'complication' of ovarian cancer; rather it is an integral part of the disease process and may, for example, be responsible for some of the symptoms reported by presenting patients. Ascites is also a cause of very considerable morbidity and reduced patient quality of life in the ovarian cancer disease process. Adequate management of ascites should be an integral part of the management of ovarian cancer, akin to surgery and chemotherapy.<br>A suggested statement could be:<br>'Women with stage II-III ovarian cancer should be assessed for ascites and treated accordingly.' | The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed.<br>The topic expert group discussed the management of ascites and decided it was outside the scope of the quality standard. |
| 11 | Royal College of Nursing | General | The RCN welcomes proposals to set this Quality Standard. It is timely. | Thank you for your comments. |
| 12 | Royal College of Obstetricians and Gynaecologists | General | These standards are derived from the recent NICE recommendations in ovarian carcinoma. All seem reasonable. | Thank you for your comments. |
| 13 | Royal College of Radiologists | General | The appendix refers to the RCR MBUR guidance for referrals to the imaging department. There is no link to the Risk of Malignancy Index, which is extremely important and gives a clear description of the ultrasound findings that suggest the diagnosis of ovarian cancer. Also, there is no link to the RCR Cancer Staging guidance. | The topic expert group identified all references they felt were important. The final quality standard now contains the risk of malignancy index calculation. |
| 14 | Royal College of Radiologists | General | It is very difficult to give a ranking as many statements are equally important. It stands to reason that the diagnosis is confirmed by histology or cytology before chemotherapy (statement 10).<br>The RCR did not identify any low priority quality statements.<br>The RCR found some of the statements very open and vague (e.g. QS3) which could potentially result in patients falling through referral channels. However, perhaps this has been left intentionally open to allow for various patterns in different centres.<br>One item which the RCR feels has been left out of the imaging section altogether is the role of percutaneous biopsy for obtaining histopathological evidence of ovarian cancer in those patients in whom cytoreductive surgery is not considered appropriate. We do not know why this is, as this is a widely-used technique to establish the diagnosis of ovarian cancer in patients with advanced disease. Perhaps this should go under the 'other imaging' quality statement? | Thank you for your comments. Draft quality statements 3 and 10 have been removed from the final quality standard.<br>The topic expert group decided the statements were not aspirational as they were either already covered by the National cancer waiting time targets or there was little variation in practice respectively. |

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| 15 | Sussex Cancer Network | General | The emphasis on getting patients diagnosed more quickly is crucial to improving outcomes, so we welcome standards 1-4 & 6; however that means 5 of the 12 standards are about diagnosis. A further two cover staging, leaving only 2 about surgery and three covering chemotherapy. This balance is odd. | The topic expert group are aware the balance of statements is not uniform across the pathway but feel they reflect the areas that are important and where there is variation in practice. |
| 16 | Sussex Cancer Network | General | There is no standard to cover the survivorship agenda, or follow-up.<br>Page 1 refers to QS covering: Enhancing quality of life for people with long-term conditions, And Helping people to recover from episodes of ill health or following injury. Draft does not go as far as long term - consider continence, mobility and general issues of daily living. | The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed.<br>The topic expert group discussed the follow-up of patients and decided it was outside the scope of the quality standard which covers the recognition and initial management ovarian cancer only. The outcomes from the NHS outcomes framework have been updated to reflect this. |
| 17 | Target Ovarian Cancer | General | Target Ovarian Cancer is pleased that ovarian cancer has been selected as one of the first Quality Standards to be developed. However we are disappointed that the Standard does not cover the complete patient pathway. We understand that only certain evidence bases can be used, but we would urge NICE to urgently consider how it can set about the necessary work to ensure that in future commissioners have quality standards that cover extremely important issues such as recurrent ovarian cancer and its management. | Thank you for your comments. The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 and the lack of other NHS evidence accredited sources to complete the pathway. |
| 18 | Target Ovarian Cancer | General | Target Ovarian Cancer welcomes the inclusion of quality measures however the impact of such measures will only reach as far as they are used. This is particularly important in terms of access to diagnostics. We are currently aware that some areas are placing restrictions on access to CA125, and that the majority of GPs have not had direct access to urgent TVU. Therefore there needs to be a fundamental change in commissioning of access to diagnostic tests in order to facilitate earlier investigation and diagnosis. We are concerned that unless these are adopted and measured widely, pressures on PCT/Commissioning budgets will continue to hamper these important investigations. | NICE quality standards are intended to demonstrate what high quality care looks like for a particular topic based on the best available evidence. Cost effectiveness is considered by the topic expert group during development of quality standards and a supporting document has been published alongside the standard reviewing the potential cost impact and implications for commissioners and service providers, however, the configuration of services will be determined locally. Supporting |

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| | | | | documents are available from www.nice.org.uk. |
| 19 | Teenagers and Young Adults with Cancer | General | TYAC is an organisation that is concerned with cancer in Teenagers and Young Adults. Ovarian cancer is rare in this age group but does still occur and therefore it is important to recognise the specialist concerns of this age group and to involve the appropriate specialists. All young people (16-24) that are diagnosed with cancer should be discussed at the Teenage and Young Adult MDT as well as the site specialist MDT. It would be good to see this reflected in the Ovarian Standards. Discussion at the TYA MDT ensures that a young person can access the specialist TYA services that exist across the country. | The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed.<br>The topic expert group discussed the suggested statement and decided it was established practice. The scope of the quality standard includes all adults (18 years and over). |
| 20 | The Society and College of Radiographers | General | It is good that the RCR guidelines feature so prominently. Obviously there may be implications for US and CT services in the light of current staff shortages and difficulty in service provision. | Thank you for your comments. |
| 21 | The Society and College of Radiographers | General | It would reduce referrals if the GP does a CA 125 | Thank you for your comment. |
| 22 | Airedale NHS Foundation Trust | QS1 | It is not clear how the denominator can be estimated.<br>How can women who have these symptoms who do not have CA125 measured be counted? Will electronic records in primary care be interrogated? | It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full. |
| 23 | International Ovarian Tumour Analysis (IOTA) Group | QS1 | These recommendations will result in many women undergoing unnecessary investigation. A large number of premenopausal women with either symptoms of possible ovarian cancer or an ovarian cyst will have a serum CA125 above the suggested threshold of 35 IU/ml due to the lack of specificity of this marker in younger women. Unfortunately, a CA125 of less than 35 IU/ml is not necessarily reassuring; the sensitivity of this test for early stage disease is such that approximately 40% of early stage cancers will be missed if this protocol is followed. For example, data from the International Ovarian Tumour Analysis (IOTA) group show that 63/159 patients with stage I invasive cancer had a CA125 <35 (95% CI 32%-47%). | The statement has been updated to include an age range of 50 years and over because the risk of developing the disease is higher in this group. However the supporting information clearly states women under 50 years should still receive the CA125 test if clinically appropriate.<br>NICE clinical guideline 122, the key development source for this quality standard recommended the use of CA125. Quality statement 3 has been included in the final quality standard to ensure women with a normal serum CA125 and continued symptoms are reassessed. |
| 24 | King's College Hospital | QS1 | *Women reporting one or more of the following symptoms on a persistent or frequent basis are offered a serum CA125 test: persistent abdominal* | NICE clinical guideline 122, a key development source for this quality |

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| | | | *distension, feeling full and/or loss of appetite, pelvic or abdominal pain, increased urinary urgency and/or frequency, unexplained weight loss, fatigue or changes in bowel habit (or symptoms that suggest irritable bowel syndrome if they are over 50).*<br>We have no evidence to support symptom triggered screening for ovarian cancer using CA-125 which is what you are advocating as a measure of quality. To my knowledge, the sensitivity and specificity of CA 125 in this population are unknown. | standard recommends the use of CA125. Quality statement 3 has been included in the final quality standard to ensure women with a normal serum CA125 and continuing symptoms are reassessed. |
| 25 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS1 | Our experts are highly concerned that this Quality Standard makes no mention of *post-menopausal* women. Biochemistry departments have already seen an increase in the number of CA125 tests requested. This was to be expected following the publication of the guidelines which made it clear that the menopausal status of patients is important. Our major concern is that if the Quality framework does *not* uphold the guidance properly then there will be a significant population of younger women with slightly elevated CA125s (for benign or menstrual reasons) that will now be referred, and worried, unnecessarily. | The statement has been updated to include an age range of 50 years and over because the risk of developing the disease is higher in this group. However the supporting information clearly states women under 50 years should still receive the CA125 test if clinically appropriate. |
| 26 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS1 | It is vitally important to apply an age discriminator whilst recommending CA125 testing for symptoms. The majority of epithelial ovarian cancer is diagnosed over 50. By not specifying an age limit it risks unnecessary testing and subsequent anxiety for patients as well as referrals to secondary care. | The statement has been updated to include an age range of 50 years and over because the risk of developing the disease is higher in this group. However the supporting information clearly states women under 50 years should still receive the CA125 test if clinically appropriate. |
| 27 | Ovarian Cancer Action | QS1 | The guidelines omit the symptom of backpain which was recognised in the NAEDI guideline 2008. Evidence of backpain can also be found in Goff B; Mandel L et al JAMA 2004 Freq of symptoms of ovarian cancer in women presenting to Primary care clinics. | The symptom list has been taken directly from the NICE clinical guideline 122. |
| 28 | Roche Products Ltd | QS1 | To measure this QS it will be necessary to define what is a “persistent or frequent basis” for patient reports of symptoms. According the current NICE guideline (CG 122), persistent or frequent is of particular concern if the symptom(s) occur 12 times per month. We suggest this is made explicit in the measure.<br>In addition, this should refer to reports of any of the cluster of symptoms shown in the statement, not just to reports of a single symptom. We suggest the following measures are included in the QS | a) The definition of persistent and frequent are included within the definitions section which accompanies each statement and should be read alongside the statement.<br>b) The topic expert group decided a woman with only one of the symptoms can be offered a CA125 test to reflect the |

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| | | | • Number of patient reports of symptoms in the cluster before serum CA 125 test offered<br>• Time from first report of a possible symptom of ovarian cancer to offering of a CA 125 test | recommendations in NICE clinical guideline 122. |
| 29 | Royal College of Radiologists | QS1 | No comments. | Thank you for your response. |
| 30 | Royal College of Radiologists | QS1 | The statement does not specify that the pelvic US is undertaken by a sonographer that is experienced in transvaginal ultrasound for evaluation of the pelvis. Transvaginal ultrasound is the current standard practice for patients being investigated for suspected ovarian disease, including cancer. It is critical to ensure that this is clearly indicated in the quality standard as this will ensure that commissioners recognize that this is an essential element to the early detection of ovarian cancer. If scans are done as part of a routine general abdominal list, an early stage cancer could easily be missed and the patient is likely to have a worse outcome. The quality statement should state: '..... direct access from primary care to an ultrasound of their abdomen and pelvis, including transvaginal ultrasound by a sonographer experienced in transvaginal ultrasound within 2 weeks……' | The topic expert group considered the additional wording and decided experience is a core requirement for sonographers so this was not added. |
| 31 | Sussex Cancer Network | QS1 | Great but how do you audit this in primary care? | It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full. |
| 32 | Target Ovarian Cancer | QS1 | • The draft quality statement should begin 'All women…'<br>• Frequency and persistency are described in the definition, but we think that '12x per month or more' should be put up front with the symptoms as well<br>• Time frames for how quickly scans are completed/referral to secondary care are included but not for the results of CA125 coming back. Surely this needs to be included to ensure an efficient diagnostic service.<br>• We would like to see the inclusion of the words in connection with persistent abdominal distension -women sometimes refer to this as bloating. This would ensure consistency with CG122. The evidence shows this is often the case, and GPs need to be reminded that if women report bloating they need to ascertain if it is persistent abdominal distension. | a) A standard format is used to write all quality statements.<br>b) The definition of persistent and frequent are included within the definitions section which accompanies each statement and should be read alongside the statement.<br>c) The intention of the statement is to ensure women are offered the CA125 test. It will be down to local services to decide how quickly the results should be made available.<br>d) The list of symptoms has been updated to include bloating. |
| 33 | Airedale NHS Foundation Trust | QS2 | The 2-week time will be problematic here. Within this time the patient has to discuss the CA125 result with the GP (it would be poor practice for her to | Thank you for your comment. The two-week time frame has been retained as the |

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| | | | receive an appointment without the result being explained to her), have the U/S requested and the secondary provider has to arrange, perform and report this test.<br>Commissioners may therefore wish to explore ways of integrating the tests in a single assessment service. | topic expert group wanted to ensure women were receiving a prompt diagnosis. |
| 34 | King's College Hospital | QS2 | *Women with symptoms suggestive of ovarian cancer and serum CA125 of 35 IU/ml or greater are offered direct access from primary care to an ultrasound of their abdomen and pelvis within 2 weeks of receipt of results.*<br>As above – there is no evidence to support this policy. We risk causing anxiety /morbidity / mortality due to intervention for what is ultimately found to be benign disease. What is the PPV of a raised CA-125 in this population? | NICE clinical guideline 122, a key development source for this quality standard recommends the use of CA125. |
| 35 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS2 | It is vitally important to apply an age discriminator whilst recommending CA125 testing for symptoms. The majority of epithelial ovarian cancer is diagnosed over 50. By not specifying an age limit it risks unnecessary testing and subsequent anxiety for patients as well as referrals to secondary care. | Quality statement 1 has been updated to include an age range of 50 years and over because the risk of developing the disease is higher in this group. However the supporting information clearly states women under 50 years should still receive the CA125 test if clinically appropriate. |
| 36 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS2 | It might be sensible to include this standard as QS1 and not wait for CA125 to be available as US is non-invasive, will detect ascites readily and identify ovarian masses as well as begin to characterise them properly. This would help prevent worrying patients unnecessarily with slightly raised CA125. Guidance initially suggested that both US and CA125 should be considered together not one then the other. Normal CA125 does not exclude ovarian cancer. Normal US does not exclude ovarian cancer | The topic expert group decided CA125 and ultrasound should be two separate steps in the ovarian cancer pathway as stated within the recommendations in NICE clinical guideline 122. Quality statement 3 has been included in the final quality standard to ensure women with a normal serum CA125 or normal ultrasound and continuing symptoms are reassessed. |
| 37 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate | QS2 | We have reviewed the imaging aspects of this. It is relatively sensible with a pathway of CA125 then US then if US is positive and CA125 raised, CT. A concern might be that in young women with endometriosis, those parameters may well be positive, and doing CT scans in all these patients would pose an unnecessary radiation burden, particularly on a population basis. One may think that in those under the age of 35yrs, an MRI should be considered first. In any case, these women eventually come to MRI for lesion characterisation. | Thank you for your comments. The statement is based on both guideline recommendations and the consensus of the topic expert group who decided CT should be the initial staging investigation for all women. |

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| | Council for Oncology | | | |
| 38 | Ovarian Cancer Action | QS2 | Ultrasound. Improvements are required in imaging techniques as identified by HHMT Ovarian Cancer Action. Evidence NRC 11,719-725 (Oct 11) Rethinking ovarian cancer :recommendations for improving outcomes | Thank you for your comment. |
| 39 | Royal College of Radiologists | QS2 | Service providers should ensure that women sonographers that undertake such work are experienced in abdominal ultrasound as well as in transvaginal ultrasound. | Thank you for your comment. The topic expert group considered the additional information and decided experience is a core requirement for sonographers so this was not added. |
| 40 | Royal College of Radiologists | QS2 | As above. The pelvis ultrasound should be undertaken by a sonographer that is experienced in transvaginal ultrasound. | Thank you for your comment. The topic expert group considered the additional information and decided experience is a core requirement for sonographers so this was not added. |
| 41 | Sussex Cancer Network | QS2 | QS 2 is desirable but will be difficult to audit. By definition these women do not come under 2WW rules. Cf QS3 where those with suspicious US should have consultant upgrade to 2WW by radiologist. | It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full. |
| 42 | Target Ovarian Cancer | QS2 | We fully support the inclusion of a two week timescale in this quality statement. It is imperative that women are assessed promptly to exclude/include ovarian cancer as a possibility. Until this happens a proportion of women will continue to experience considerable delays in their diagnosis. | Thank you for your comment. The two-week timescale has been retained. |
| 43 | International Ovarian Tumour Analysis (IOTA) Group | QS2 (&QS3) | A large number of ultrasound scans will be scheduled as a second stage test if these recommendations are followed, and it is highly likely that this will lead to unnecessary intervention in some women, especially as the guidelines do not make clear the ultrasound criteria they recommend to characterise an adnexal mass once one has been found. This is a serious omission as clear guidance must be given in order to select patients for expectant management (follow up in primary care), surgery by a general gynaecologist or referral to a gynaecological oncologist. The evidence suggests that ultrasonography would be a better first line investigation in women with symptoms suggestive of ovarian cancer. External validation of ultrasound-based simple rules and risk prediction models have confirmed the excellent performance of ultrasound to distinguish between benign and malignant ovarian masses [3, 4]. If ultrasonography is appropriately used, this could lead to a reduction of costs for the National Health Service (NHS) and reduced anxiety in patients confronted with an abnormal test that they may believe indicates the likely | The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 which recommends the use of ultrasound as the second stage test. Statements are based on recommendations, which in turn are based on the best available evidence. The topic expert group do not therefore revisit the evidence base as part of this development process. |

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| | | | presence of ovarian cancer. | |
| 44 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS3 | Quality of ultrasound in primary care needs validating. The RCR guidance link on the document does not work. This guidance is now part of a paid subscription service iREFER. Can scanners in primary care easily access quality standards of scanning as prescribed by the RCR? | Draft quality statement 3 did not progress to the final quality standard as it was covered by the national cancer waiting time targets and therefore not seen as aspirational.<br>It will be for the commissioner to set the specification for the service provider and in so doing ensure that the ultrasound is carried out by an appropriately trained individual. |
| 45 | Ovarian Cancer Action | QS3 | Specialist referral. Increased awareness for GP's that the best outcomes for surgery in women with ovarian cancer is referral to a specialist Gynaecological surgeon. | Thank you for your comment. Draft quality statement 3 did not progress to the final quality standard as it was covered by the national cancer waiting time targets and therefore not seen as aspirational. |
| 46 | Royal College of Radiologists | QS3 | The RCR agrees that specialist referral is appropriate at this stage. However, there are two important problems with this statement:<br>1. The RCR guidelines that are listed do not give any diagnostic information about the ultrasound signs that suggest ovarian cancer, as far as we can see. We have looked at these once again and could not find anything. The MBUR guidelines (now called iRefer) are not about diagnosis but about which patients should be referred for which tests. We would suggest that this link should be removed, unless we are mistaken here. Perhaps a better listing of the ultrasound findings that suggest a diagnosis of ovarian cancer should be those listed in the Risk of Malignancy index (which are very widely used).<br>2. The title of this section states 'Specialist referral'. However, the statement itself only states 'urgent referral' and does not specify who should make this urgent referral nor does it state to whom the urgent referral should be made. Although this very open statement probably suits the wide variety of practices across the country, it would be difficult to see how commissioners and health care providers would be able to measure/audit this. The title of 'specialist referral' seems correct. At this point in the patients' pathway, if there is suspicion of ovarian cancer based on an ultrasound appearance or CA 125 level, then a specialist referral to a gynaecologist that is experienced in the diagnosis of ovarian cancer should be made. This may be to the loco-regional MDT (as indicated in high risk cases under QS6) or to a specialist gynaecologist. However, those with intermediate risk of malignancy or those | Draft quality statement 3 did not progress to the final quality standard as it was covered by the national cancer waiting time targets and therefore not seen as aspirational. |

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| | | | with a suspicious US need an urgent specialist referral at this stage if early stage ovarian cancer is to be detected efficiently. | |
| 47 | Royal College of Radiologists | QS3 | STRUCTURE: The structure here seems to suggest that 'specialist referral' for further investigation means that the radiology department make the onward urgent referral to a rapid access clinic. The RCR agrees that this seems an excellent approach. However, we do not know of any imaging department that is currently set up to do this routinely (there may well be but we are not aware of any). Radiology departments are not usually listed as referrers and sonographers would normally alert the GP from whom the US was requested for the onward specialist referral. If there is now a need for the radiology department to make these referrals, or indeed to go ahead and request the next most appropriate imaging investigation, then this will require a significant change in current practice that will have major implications and will need discussion with the appropriate professional groups.<br>It would seem appropriate that at this point in the patient pathway referral is made to the local gynaecologic oncology MDT where an appropriate selection of next test can be made (either MRI or CT) and which will ensure review by the appropriate core radiologist. | Draft quality statement 3 did not progress to the final quality standard as it was covered by the national cancer waiting time targets and therefore not seen as aspirational. |
| 48 | Target Ovarian Cancer | QS3 | We fully support the inclusion of a two week timescale in this quality statement. It is imperative that women are assessed promptly to exclude/include ovarian cancer as a possibility. Until this happens a proportion of women will continue to experience considerable delays in their diagnosis. | Thank you for your comment. Draft quality statement 3 did not progress to the final quality standard as it was covered by the national cancer waiting time targets and therefore not seen as aspirational. |
| 49 | International Ovarian Tumour Analysis (IOTA) Group | QS3 (&QS2) | A large number of ultrasound scans will be scheduled as a second stage test if these recommendations are followed, and it is highly likely that this will lead to unnecessary intervention in some women, especially as the guidelines do not make clear the ultrasound criteria they recommend to characterise an adnexal mass once one has been found. This is a serious omission as clear guidance must be given in order to select patients for expectant management (follow up in primary care), surgery by a general gynaecologist or referral to a gynaecological oncologist. The evidence suggests that ultrasonography would be a better first line investigation in women with symptoms suggestive of ovarian cancer. External validation of ultrasound-based simple rules and risk prediction models have confirmed the excellent performance of ultrasound to distinguish between benign and malignant ovarian masses [3, 4]. If ultrasonography is appropriately used, this could lead to a reduction of costs for the National Health Service (NHS) and reduced anxiety in patients confronted with an abnormal test that they may believe indicates the likely | The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 which recommends the use of ultrasound as the second stage test. Statements are based on recommendations, which in turn are based on the best available evidence. The topic expert group do not therefore revisit the evidence base as part of this development process. |

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| | | | presence of ovarian cancer. | |
| 50 | Airedale NHS Foundation Trust | QS4 | How will the fact of this advice being given be recorded? Again, will electronic records in primary care be interrogated?<br>A service that integrates the CA125 and U/S tests would naturally be in a position to give this advice and arrange for it to be followed up. | It is expected that local data sources and audits where appropriate will be considered in order to measure the quality statements in full. |
| 51 | International Ovarian Tumour Analysis (IOTA) Group | QS4 | Unfortunately, a CA125 of less than 35 IU/ml is not necessarily reassuring; the sensitivity of this test for early stage disease is such that approximately 40% of early stage cancers will be missed if this protocol is followed. For example, data from the International Ovarian Tumour Analysis (IOTA) group show that 63/159 patients with stage I invasive cancer had a CA125 <35 (95% CI 32%-47%). In a large study from the IOTA group, we have demonstrated that CA125 offers no benefit when an ultrasound scan can be performed by an appropriately trained operator [5, 6]. Furthermore, we also know that this marker does not improve the performance of the mathematical models and simple rules that can be used to characterise ovarian pathology [3, 7]. Against this evidence base, the recommendation to measure CA125 seems unjustified. The IOTA group has also published on the morphological features of germ cell tumours and it should be possible to be more selective regarding when or if to measure tumour markers to help establish such a diagnosis. In secondary care, we believe ultrasound examination by an experienced operator should be the first line investigation, because this is the best available test to distinguish between most benign and malignant adnexal masses. | The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 which recommends the use of ultrasound as the second stage test. Statements are based on recommendations, which in turn are based on the best available evidence. The topic expert group do not therefore revisit the evidence base as part of this development process. |
| 52 | King's College Hospital | QS4 | *Women with normal serum CA125 (less than 35 IU/ml), or serum CA125 of 35 IU/ml or greater but normal ultrasound, with no other apparent clinical cause for their symptoms, are advised to return to their GP for assessment within 1 month if the symptoms persist*<br>For what reason? The logic behind this statement should be more explicit to. Are you suggesting the GP should repeat the investigations or is it to consider alternative diagnoses? | Quality statement 3 in the final quality standard now includes a reassessment by the GP to diagnose the reason for the persistent symptoms. |
| 53 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate | QS4 | It would be extremely useful to provide more direction to GPs in this regard. The differential diagnosis of raised CA125 includes menstruation, endometriosis and peritoneal irritation from any cause, apart from liver disease and other medical conditions. The poor specificity of CA125 needs to be flagged up here. A survey conducted by the Pan Birmingham gynae cancer centre, (submitted, waiting publication) found that most GPs would in fact refer these patients anyway. | A list of non-ovarian cancer reasons for a raised CA125 have been included in the definitions of the quality statement to assist GPs. |

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| | Council for Oncology | | | |
| 54 | Ovarian Cancer Action | QS4 | Advice. Ovarian Cancer Action recommends that women who have a normal CA125, presenting with symptoms and are over the age of 50, that they keep a Symptoms Diary to provide the GP with improved evidence and monitoring for their next visit. This is also supported by Goff B; Mandel L; Drescher CW et al Development of an Ovarian Cancer symptom index: Possibilites for Earlier Detection CANCER 2007 | The use of symptom diaries is not recommended in the guidance therefore the topic expert group decided it was outside of the remit of the quality standard. |
| 55 | Royal College of Radiologists | QS4 | Agree. The RCR would like this quality statement to specify that the normal ultrasound was undertaken by a sonographer experienced in transvaginal ultrasound. | The purpose of the statement is to ensure women are reassessed. The undertaking of the ultrasound is part of draft quality statement 2. |
| 56 | Royal Cornwall Hospital NHS Trust | QS4 | '…serum CA125 of 35 IU/ml or greater but normal ultrasound, with no other apparent clinical cause for their symptoms…'<br>The document should list the clinical causes that may cause an elevated serum CA125. As an illustration we have had three women referred through the 2 week cancer pathway for elevated CA125 (following NICE guideline 122), two were known to have primary liver disease and the third had acute aggressive rheumatoid arthritis.<br>The UKFOCSS study lists potential clinical causes for raised CA125 in a letter they send GPs who are continuing CA125 monitoring in women with familial risk of ovarian cancer. This list or a similar list should be included in the Quality Standards document rather than just stating 'other apparent causes. | A list of non-ovarian cancer reasons for a raised CA125 have been included in the definitions of the quality statement to assist GPs. |
| 57 | Sussex Cancer Network | QS4 | QS 4 reads like a good standard, but is unmeasurable, as we are talking about tiny numbers per GP. A GP is only likely to see one cases of ovarian cancer every 5 years! | It will be for local providers to decide how best to collect and analyse the data for the measures. |
| 58 | Target Ovarian Cancer | QS4 | Whilst we welcome the fact that women should be reassessed if their symptoms persist, we would like to see the onus on the GP to ensure a woman is reassessed within a month so they can be certain whether or not her symptoms are persisting. We would like to see the GP book a follow up appointment, which the woman if necessary can cancel. Women can often feel uncomfortable about 'bothering' their doctor, and this may be exacerbated if tests at that point have been negative. | The statement has been updated to place the onus of the follow up appointment on the GP. |
| 59 | Airedale NHS Foundation Trust | QS5 | MDTs that discuss patients without a participant in the meeting having met the patient operate at a great disadvantage. The best way to achieve this will be for the patient to be referred to a gynaecologist (or other relevant clinician) in the MDT on a fast-track basis. The pathway to which the MDT works may include a CT before the consultation; this is increasingly how lung cancer | Thank you for your comment. It is expected quality standards will be considered in the context of local circumstances and it will be for local services to decide the best way for MDTs |

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| | | | MDTs are working.<br>Assessment against this standard should therefore be by audit of the MDT's function. | to work. |
| 60 | International Ovarian Tumour Analysis (IOTA) Group | QS5 | An ultrasound scan of the pelvis should be the first line test for any woman with possible ovarian cancer. This should be performed transvaginally. In the event that this scan is suggestive of malignancy, then an abdominal scan should be performed in order to assess the extent of metastatic disease. It is disappointing that NICE has not commented on the ultrasound markers that are important when discriminating between benign and malignant pathology [3, 8, 9]. There are straightforward simple rules that can be applied on the majority of ovarian masses which characterise ovarian pathology with a high level of test performance [3]. The best test for any mass where simple rules do not apply is an ultrasound scan by an experienced operator. In addition, mathematical models have been developed that distinguish between benign and malignant masses. These have undergone temporal and external validation that confirm their robust performance [4, 10]. If a clear guidance is not given on the characterisation of ovarian pathology with ultrasound a high proportion of women will be considered at high risk of cancer and undergo a CT scan for no reason. Whilst CT scanning is very useful for assessing the extent of metastases and for assessment of lymph nodes, it has a limited role for classifying ovarian tumours. | The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 which recommends the use of ultrasound as the second stage test. Statements are based on recommendations, which in turn are based on the best available evidence. The topic expert group do not therefore revisit the evidence base as part of this development process. |
| 61 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS5 | Currently all referral pathways between units and centres in the hub and spoke model of gynae cancer care centres on the Risk of Malignancy Index (RMI). It is important therefore not to bypass ultrasound and move directly to CT as this will only mean more layers of investigations.<br>More research is needed to identify optimal diagnostic pathways in women referred with a raised CA125/ abnormal ultrasound, particularly in the premenopausal group.<br>We are aware that the RCR suggests that it would be worthwhile to include how the risk of malignancy index (RMI) is assessed and that this could be inserted on page 17. | Thank you for your comments. The risk of malignancy index calculation has been added to the definitions. |
| 62 | Royal College of Radiologists | QS5 | The RCR agrees that patients with a strong suspicion of ovarian cancer should be evaluated with CT of the abdomen or pelvis. However:<br>1. We think it will be impossible to ensure that all such CT's are reported by a core member of the MDT, as many of these initial scans will be undertaken at peripheral hospitals – and indeed even those undertaken at the centre are likely to be reported by a variety of radiologists. It may be better to use the word 'reviewed' rather than 'reported' as this will be achievable. | 1) The topic expert group decided to use to word 'reported' as the statement should be aspirational.<br>2) Reference to the RCR guidance has been removed because the original statement has been made into 3 more specific statements. |

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| | | | 2. We believe that it would be best to state what the RCR guidance here is – rather than give the link. In cases of suspicious ovarian ultrasound but a normal or only moderately elevated CA 125, then MRI is needed for characterisation of the indeterminate adnexal mass. This is clearly supported in the literature and should be very clear to commissioners.<br>3. The CT should be scrutinised for other primary sources of peritoneal disease such as colonic or gastric cancer.<br>We suggest:<br>Women with suspected ovarian cancer are offered CT of the abdomen and pelvis, reported by a radiologist experienced in body CT and reviewed by a radiologist who is a core member of the MDT, as the initial staging investigation. Other potential primary sources of peritoneal disease should be specifically sought, including colonic and gastric primaries. In those cases with a suspicious ultrasound but a lower risk of ovarian cancer based on age and/or CA 125 level, then an MRI should be offered for characterisation of the indeterminate adnexal mass. | 3) Other primary sources of peritoneal disease are outside the scope of this quality standard. |
| 63 | Royal College of Radiologists | QS5 | Structure: please see above. | Please see response to comment 25. |
| 64 | Target Ovarian Cancer | QS5 | Reference to MDT should be more specific i.e. ‘specialist MDT’ as in statement 6 or gynaeoncology MDT. | The statement now refers to a 'specialist gynaecological cancer multidisciplinary team'. |
| 65 | Target Ovarian Cancer | QS5 (&QS6) | It would be more logical if section 6 (Malignancy indices) came before section 5 (other imaging) since RMI I is calculated using CA125 and TVU data alone without the requirement for other screening modalities. Further imaging is used once risk of malignancy has been established to give more definitive information about the extent of disease spread prior to treatment commencing. | The order of the statements has been revised; the quality statement on malignancy indices now precedes other imaging. |
| 66 | International Ovarian Tumour Analysis (IOTA) Group | QS6 | The RMI [11] is a reasonable model, however it has been shown in a multicentre external validation study that RMI performs significantly less well than an ultrasound scan by an experienced operator and so should not be the test of choice in the secondary care setting [10]. The selection of an appropriate cut-off value for RMI is challenging and currently the RMI is not calibrated to give clinicians an absolute risk of malignancy. Determining the optimal RMI threshold will not influence overall test performance but merely reflects the balance between false positives and false negatives. Whilst the RMI appears to have acceptable test performance for many masses, when applied to masses in young women and pathology that is difficult to characterise with ultrasound, the performance is poor [3, 6, 7]. In addition, the | The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 which recommends the use of the risk of malignancy index. Statements are based on recommendations, which in turn are based on the best available evidence. The topic expert group do not therefore revisit the evidence base as part of this development process. The topic expert group are aware the RMI I is a |

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| | | | RMI has a relatively low sensitivity for early stage disease. On the other hand, the ultrasound-based simple rules and other prediction models have been shown to have significantly better overall test performance [3, 7, 12].<br>A further concern relates to the confusion in the guidelines in relation to second stage tests. They refer to tests used in the context of an ovarian cancer screening trial and extrapolate this to masses found in women presenting to primary or secondary care with symptoms. Test performance may be completely different in these two populations and such an approach is not appropriate.<br>The management of ovarian pathology is a common problem in gynaecology. Only a very small number of ovarian cysts are malignant and inappropriate referral to secondary care, unnecessary surgery or overly invasive surgical intervention are all significant risks to patients with a cyst that is inappropriately characterised [13]. Most either require no intervention at all, or can be managed laparoscopically with relatively little inconvenience to the patient. The NICE guidance as presented will lead to many women either being unnecessarily referred to a hospital or undergoing procedures they do not require. | mechanism for triage but decided it was an important area of care. As with all statements clinical judgement should also be used. |
| 67 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS6 | Currently all referral pathways between units and centres in the hub and spoke model of gynae cancer care centres on the Risk of Malignancy Index (RMI). It is important therefore not to bypass ultrasound and move directly to CT as this will only mean more layers of investigations.<br>More research is needed to identify optimal diagnostic pathways in women referred with a raised CA125/ abnormal ultrasound, particularly in the premenopausal group.<br>We are aware that the RCR suggests that it would be worthwhile to include how the risk of malignancy index (RMI) is assessed and that this could be inserted on page 17. | Thank you for your comment. The risk of malignancy calculation has been added to the definitions. |
| 68 | Royal College of Radiologists | QS6 | Agree. | Thank you for your comment. |
| 69 | Royal College of Radiologists | QS6 | Structure:<br>1. It is not clear why this statement does not appear under the ultrasound quality statement 2 or 3.<br>2. As above – we question why is this not part of QS2 or 3?<br>3. Local arrangements – here again this is quite an open statement. Is it the GP or should it be the imaging department that should refer? The CA 125 value would need to be available to the imaging department if it is responsible for referral to the MDT, considering what has been stated under QS3. | 1/2) The structure measures have been aligned to the most appropriate statement to avoid any duplication of measures.<br>3) It will be up to local teams to decide who should be doing the referral. |

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| 70 | Royal College of Radiologists | QS6 | Malignancy Indices<br>The RCR suggests that it would have been worthwhile to state how the risk of malignancy index (RMI) is assessed and this should be inserted on page 17. | The risk of malignancy calculation has now been included in the definitions. |
| 71 | Sussex Cancer Network | QS6 | Cancer waits data does not help to measure this standard | The topic expert group considered the data sources for all statements and included those that were relevant. Cancer waits are no longer referenced in the final quality statement. |
| 72 | Target Ovarian Cancer | QS6 | Should the RMI I calculation not be included in the definitions box maybe? | The risk of malignancy calculation has now been included in the definitions. |
| 73 | Target Ovarian Cancer | QS6 (&QS5) | It would be more logical if section 6 (Malignancy indices) came before section 5 (other imaging) since RMI I is calculated using CA125 and TVU data alone without the requirement for other screening modalities. Further imaging is used once risk of malignancy has been established to give more definitive information about the extent of disease spread prior to treatment commencing. | The order of the statements has been revised; the quality statement on malignancy indices now precedes other imaging. |
| 74 | Airedale NHS Foundation Trust | QS7 | The commissioning of support services, Clinical Nurse Specialists and Clinical Psychologists in all healthcare providers should be undertaken with care; adequate capacity is essential but this capacity can be shared between cancer sites. | Thank you for your comment. It is expected quality standards will be considered in the context of local circumstances. |
| 75 | British Pain Society | QS7 | Information about specialist pain and palliative care services should be offered to the patient for early input for managing pain and other symptoms alongside treatment of the cancer. | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in all quality standards (for adults), covered this area in more detail. |
| 76 | International Ovarian Tumour Analysis (IOTA) Group | QS7 | We fully agree with these statements | Thank you for your response. |
| 77 | Macmillan Cancer Support | QS7 | We are very pleased to see the inclusion of a quality statement on information and we would strongly endorse the continued inclusion of this statement. This statement however is weak in comparison to those included in other Quality Standards and needs to be significantly strengthened. Firstly, we believe that it must refer to the provision of personalised information, alongside appropriate support given to the patient so that they can | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', |

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| | | | understand this information. Secondly it must include reference to the completion of a full assessment of all the patient's needs and to these needs and how they will be met being captured in a care plan.<br>Firstly, we believe it is important that patients receive information throughout their cancer journey alongside support from a trained worker to understand this information, and that the information and support they receive is relevant for them at that time in the journey. As such the quality statement should refer to 'personalised' information and support, and should also make reference to the need to offer this at key points in their cancer journey. Information Prescriptions, which are currently being rolled out across England, provide a key way in which providers can offer this continual support.<br>Secondly, we would like to see that ovarian cancer patients receive individualised care plans at key points in their cancer journey, including at the end of treatment. The care plan should be based on a holistic and structured assessment of their needs (i.e. not just clinical needs, but also psychosocial, practical and financial needs) and should set out how these needs will be met. This would help to identify which care pathway is most suitable for each patient, based on the treatment and the patient's ability to manage, and therefore what level of professional involvement will be required. | which is cross-cutting and referenced in all quality standards (for adults), covered this area in more detail. |
| 78 | Ovarian Cancer Action | QS7 | Information. The inclusion of information on Family History and the Genetic predisposition of Breast and Ovarian Cancer. This information is critical for younger women diagnosed with Ovarian Cancer and Healthcare professionals. This offers an opportunity to prevent cancer or diagnose it earlier. | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in all quality standards (for adults), covered this area in more detail. |
| 79 | PharmaMar | QS7 | The statement currently does not require that women with suspected or diagnosed ovarian cancer are given any information about their treatment or treatment options. We would suggest that 'treatment' should be added to the list of areas on which information should be provided so that patients are enabled to make an informed choice about their treatment. Providing this type of information is in line with the Cancer Patient Information Prescriptions programme which is currently being rolled out across the NHS. | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in all quality standards (for adults), covered this area in more detail. |

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| 80 | Roche Products Ltd | QS7 | Roche firmly believes in patient involvement in treatment decision making and suggest that this quality statement is expanded to do more than just provide information. We recommend the statement is amended as follows: 'Women with suspected or diagnosed ovarian cancer are provided with opportunities, at the appropriate times, to discuss the disease, (including psychological, social and sexual issues), tests and the risks and benefits of treatment options, and are offered information that supports them to make informed choices.<br>This amended statement is closely aligned to draft quality statement 4 in the draft lung cancer quality standard and would demonstrate consistency in quality expectations across cancer care pathways. | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross-cutting and referenced in all quality standards (for adults), covered this area in more detail. |
| 81 | Roche Products Ltd | QS7 | To measure this QS we believe 'patient satisfaction with involvement in decision making and information received' should be included as a key outcome. | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross cutting and referenced in all quality standards (for adults), covered this area in more detail. |
| 82 | Royal College of Nursing | QS7 | We would like to see a little more added to this statement.<br>We would like to see mention of the role of a nurse specialist as the appropriately trained staff and as well as providing information regarding tests and disease, also discussion of the follow up after treatment, the holistic assessment and living with and beyond cancer needs of women with ovarian cancer. | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross cutting and referenced in all quality standards (for adults), covered this area in more detail. |
| 83 | Sussex Cancer Network | QS7 | The role of the Clinical Nurse Specialist should be mentioned much sooner – if the intention is to ensure all women have access to a CNS at the breaking bad news stage the standard should say so – this would be easier to measure | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross cutting and referenced in all quality standards (for adults), covered this area in more detail. |

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| 84 | Target Ovarian Cancer | QS7 | We are concerned that this will be interpreted to mean that women undergoing tests should be given information about the psychosocial/sexual aspects of the disease, which would not be appropriate at this point in the patient pathway. Women undergoing tests for suspected ovarian cancer should be given details about the tests and why they are being done, but nothing more at that point in time. 7a) needs altering, but 7b) is fine. | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross cutting and referenced in all quality standards (for adults), covered this area in more detail. |
| 85 | PharmaMar | QS7 (&QS8 &QS9) | The Quality Standard in its current form seems to have undue focus on women with stage 1 ovarian cancer (statements 7, 8 and 9).<br>According to statistics prepared by Cancer Research UK only 29% of all cases of ovarian cancer are detected at stage 1 (Cancer Research UK, Ovarian cancer survival statistics, 8 March 2011). Ovarian cancer is difficult to detect at this stage of the disease due to the lack of evident symptoms.<br>We would suggest that the Quality Standard would be improved if the skew towards ovarian cancer detected at stage 1 is reduced. For example, in statement 8 this could be broadened to include all women with ovarian cancer who are undergoing surgery having optimal surgical staging. | Draft quality statement 7 did not progress to the final quality standard. Provision of patient information is an important theme for all NHS care. The topic expert group decided the NICE quality standard on 'patient experience in adult NHS services', which is cross cutting and referenced in all quality standards (for adults), covered this area in more detail. |
| 86 | Airedale NHS Foundation Trust | QS8 | It has to be remarked that the way services for patient with ovarian cancer are being designed tends to disadvantage those who undergo surgery *without* cancer being suspected; the RMI is not 100% sensitive. It would be better if the surgical skills to fulfil the requirement of this statement were present in all gynaecological services with all operations on adnexal masses being conducted by gynaecologists who can stage early-stage disease. | Thank you for your comments. Operations on adnexal masses are outside the scope of this quality standard which concerns only those women undergoing surgery for suspected ovarian cancer. |
| 87 | International Ovarian Tumour Analysis (IOTA) Group | QS8 | We fully agree with these statements. | Thank you for your response. |
| 88 | Roche Products Ltd | QS8 | Roche welcome this QS on optimal surgical staging to ensure patients are staged accurately and offered appropriate treatment. We therefore believe surgical staging should not be limited to women with suspected stage I ovarian cancer, but should also be considered in women with suspected stages II-III. | There are no recommendations in the underpinning guidance used in the development of the quality standard to support broadening the quality statement to include other stages of disease. The scope of the ovarian cancer quality standard states the use of staging in reference to stage I disease only. |
| 89 | Roche Products Ltd | QS8 | We suggest the following process measures are included to support this QS:<br>a) Proportion of women with staging recorded at diagnosis | Please see response to comment 88. |

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| | | | b) Proportion of women who had laparoscopical staging<br>Proportion of women with suspected stage II-III disease who receive surgical staging or at the very least the Evidence of local arrangements to ensure women with suspected stage II-III disease are considered for surgical staging | |
| 90 | Royal Cornwall Hospital NHS Trust | QS8 | Women with suspected stage I ovarian cancer should have optimal surgical staging.'<br>Staging is associated with potential operative morbidity and is inappropriate in benign disease. Frozen section is the norm in the US and many parts of Europe and Asia and it is disappointing that it is not mentioned here.<br>A recent publication from the Queen Elizabeth Hospital in Gateshead (attached) on the use of frozen section in 1439 cases of suspected ovarian cancer found it resulted in appropriate surgery in 93% of cases, with staging avoided in 769 cases with benign pathology. We also use frozen section in Cornwall to good effect and it doesn't prolong surgery as the results are usually back by the time the hysterectomy is completed.<br>It would seem sensible in the statement to advocate the use of frozen section to confirm a malignancy prior to undertaking optimal staging. | Frozen section is not recommended in the guideline, so cannot therefore form part of the statement. |
| 91 | PharmaMar | QS8 (&QS7 &QS9) | The Quality Standard in its current form seems to have undue focus on women with stage 1 ovarian cancer (statements 7, 8 and 9).<br>According to statistics prepared by Cancer Research UK only 29% of all cases of ovarian cancer are detected at stage 1 (Cancer Research UK, Ovarian cancer survival statistics, 8 March 2011). Ovarian cancer is difficult to detect at this stage of the disease due to the lack of evident symptoms.<br>We would suggest that the Quality Standard would be improved if the skew towards ovarian cancer detected at stage 1 is reduced. For example, in statement 8 this could be broadened to include all women with ovarian cancer who are undergoing surgery having optimal surgical staging. | There are no recommendations in the underpinning guidance used in the development of the quality standard to support broadening the quality statement to include other stages of disease. |
| 92 | Airedale NHS Foundation Trust | QS9 | To specify carboplatin is very proscriptive; was it meant to exclude combination chemotherapy as this wording does?<br>In any case, any specification regarding chemotherapy should be worded to encourage clinical trials participation. | Draft quality statement 9 did not progress to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 93 | British Pain Society | QS9 | Patients should have information and access to specialist pain clinics that has expertise to diagnose and treat complex pain including chemotherapy-induced neuropathic pain following Taxol and Carboplatin chemotherapy. | Draft quality statement 9 did not progress to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 94 | International Ovarian | QS9 | We fully agree with these statements | Thank you for your response. |

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| | Tumour Analysis (IOTA) Group | | | |
| 95 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS9 | There is agreement that some patients with stage I disease should be offered adjuvant chemotherapy – we are aware that the RCR point out that good evidence exists both from the ICON1 and the ACTION trials for carboplatin. However, many experts strongly believe that the choice of chemotherapy should not be so dogmatic. Carboplatin may be suitable for some but for others combination chemotherapy with paclitaxel should be available. Currently, NICE guidance recommends a discussion of the benefits/ risks of single agent versus combination chemotherapy to Stage II-IV disease but does not give such choice to high risk stage I disease. Our experts would like to see this changed. There is a paucity of trials literature on treatment on early stage disease and the only trials that have been published were conducted more than a decade ago. The tumour biology in a patient with Grade III stage Ic disease with tumour growing through the capsule and positive peritoneal washings is very different from a patient with Stage Ia Grade III disease, or stage Ic Gd 1 or II disease. To group together all stage I patients (IA, IB Ic together) makes no sense and is not based on any sound evidence. A prescriptive comment that carboplatin alone is suitable for all stage I patients, is considered by many, to be misguided, and potentially harmful. The evidence from a large series published by Vergote et al in the Lancet in 2001 showed a 8.8 fold increase in risk of death between G1 and G3 disease, and a 2.65 fold increase in risk of death in the presence of stage I c v I a or b disease (not surgical rupture). Furthermore, the HR difference in long- term outcome for high risk stage I disease (G3 or Ic) from ICON 1 ( ASCO 2007 ) was 0.52 in favour of chemotherapy- the survival at 5 years in the chemotherapy group ( carboplatin) was about 80 % and 70 % at 10 years. In the absence of clear data and poor survival in this group patients with high risk stage I disease should be afforded the same opportunities as those with stage II, or III disease, namely, a discussion of the pros and cons of single agent versus combination chemotherapy. Failure to provide such choice and promotion of broad brush recommendations that ignores differences in biological behaviour of tumours will help to perpetuate the poor survival figures seen in the United Kingdom compared with other Western World Countries.<br>There are staffing implications, if CNS are used to counsel women with suspected cancer rather than those with confirmed cancer. | Draft quality statement 9 did not progress to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 96 | Roche Products Ltd | QS9 | According to NICE TA55 it is recommended ‘paclitaxel in combination with a | Draft quality statement 9 did not progress |

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| | | | platinum based compound or platinum-based therapy alone (cisplatin or carboplatin) are offered as alternatives for first-line chemotherapy (usually following surgery) in the treatment of ovarian cancer." Further, NICE TA91 recommends "**platinum-sensitive or partially platinum-sensitive, except women who are allergic to platinum-based drugs,** paclitaxel in combination with a platinum-based drug (carboplatin or cisplatin) as an option for second-line (or subsequent) treatment should be considered". We therefore suggest that this is reflected in this QS. Moreover, since there is no distinction within TA55 on stage of disease this is offered to and TA91 refers to patients with advanced disease this QS should not be restricted to stage 1 patients. | to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 97 | Roche Products Ltd | QS9 | Based on our comments for this statement we recommend the addition of a measure on proportion of women who receive a platinum based compound and paclitaxel and a further measure on how many receive platinum based compound alone. | Draft quality statement 9 did not progress to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 98 | Royal College of Radiologists | QS9 | Adjuvant systemic chemotherapy<br>The RCR agrees with the statement that women with high risk stage 1 disease should be offered adjuvant chemotherapy and this should be only carboplatin as there is good evidence from both the ICON1 and the ACTION trials. We feel that carboplatin alone is adequate in this group of patients and increases survival by 10%. However, the RCR is aware that others may suggest that combination chemotherapy with paclitaxel should be available for some women. | Draft quality statement 9 did not progress to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 99 | Royal Cornwall Hospital NHS Trust | QS9 | '…women with suboptimal surgical staging who appear to have stage I disease have the opportunity to discuss the possible benefits and side effects of adjuvant chemotherapy.'<br>The statement should say these women should be offered the opportunity to discuss the possible benefits and side effects of a staging procedure as well as just adjuvant chemotherapy.<br>Optimal staging as described by NICE can often be performed laparoscopically often as a day-case procedure. The advantage is that low grade true stage IA/B tumours can be managed without adjuvant chemotherapy whilst those low grade tumours with disease elsewhere (stage II-III) must be offered chemotherapy. With high grade tumours with disease found elsewhere (stage II-III), many clinicians would consider it inappropriate to use single agent carboplatin as adjuvant chemotherapy. | Draft quality statement 9 did not progress to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 100 | Target Ovarian | QS9 | Think they should be the other way around because the tissue diagnosis will | Draft quality statement 9 did not progress |

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| | Cancer | (&QS10) | inform treatment i.e. whether or not to give chemo | to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 101 | PharmaMar | QS9 (&QS7 &QS8) | The Quality Standard in its current form seems to have undue focus on women with stage 1 ovarian cancer (statements 7, 8 and 9).<br>According to statistics prepared by Cancer Research UK only 29% of all cases of ovarian cancer are detected at stage 1 (Cancer Research UK, Ovarian cancer survival statistics, 8 March 2011). Ovarian cancer is difficult to detect at this stage of the disease due to the lack of evident symptoms.<br>We would suggest that the Quality Standard would be improved if the skew towards ovarian cancer detected at stage 1 is reduced. For example, in statement 8 this could be broadened to include all women with ovarian cancer who are undergoing surgery having optimal surgical staging. | Draft quality statement 9 did not progress to the final quality standard. The topic expert group decided this statement was already being fulfilled and therefore was not aspirational. |
| 102 | Airedale NHS Foundation Trust | QS10 | This permits cytological diagnosis if tissue biopsy is not appropriate; this is to be welcomed. | Thank you for your comments. |
| 103 | International Ovarian Tumour Analysis (IOTA) Group | QS10 | We fully agree with these statements | Thank you for your response. |
| 104 | Target Ovarian Cancer | QS10 | We think this statement would benefit from clarifying which histological method is preferred i.e. percutaneous image guided biopsy, and only laparoscopic biopsy if this is not available. | Draft quality statement 10 did not progress to the final quality standard. The topic expert group decided there was little variation in practice and therefore the statement was not aspirational. |
| 105 | Target Ovarian Cancer | QS10 (&QS9) | Think they should be the other way around because the tissue diagnosis will inform treatment i.e. whether or not to give chemo | Draft quality statement 10 did not progress to the final quality standard. The topic expert group decided there was little variation in practice and therefore the statement was not aspirational. |
| 106 | Airedale NHS Foundation Trust | QS11 | This wording seems to state that when complete resection of all macroscopic disease is not possible but substantial debulking may be feasible no surgery should be undertaken. Is this intended? | Draft quality statement 11 did not progress to the final quality standard. |
| 107 | British Pain Society | QS11 | Patients who are scheduled for surgery should have the input from acute pain services to manage their pain in the peri-operative period and the use of epidural analgesia and patient controlled analgesia are to be encouraged. | The use of analgesia is not recommended in the NICE clinical guideline 122, as the main development source therefore is outside the scope of the quality standard. Draft quality statement 11 did not progress to the final quality standard. |

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| 108 | International Ovarian Tumour Analysis (IOTA) Group | QS11 | We fully agree with these statements | Thank you for your response. Draft quality statement 11 did not progress to the final quality standard. |
| 109 | Ovarian Cancer Action | QS11 | Surgery. It should be noted that a Gynaecological surgeon should perform complete resection of all macroscopic disease in every possible case. | Thank you for your comment. Draft quality statement 11 did not progress to the final quality standard. |
| 110 | Roche Products Ltd | QS11 | It is our understanding that gynaecological surgeons aim to undertake a complete resection of all microscopic disease, as well as all macroscopic disease. This is because of clinical evidence showing microscopic residual disease imparts a prognosis almost as poor as that with macroscopic residual disease. We suggest the inclusion of the wording “complete resection of all macroscopic and microscopic disease” in the QS. | Draft quality statement 11 did not progress to the final quality standard. The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 which recommends complete resection of all macroscopic disease only. |
| 111 | Roche Products Ltd | QS11 | We suggest the inclusion of a further process measure that records the proportion of women with microscopic residual disease, as well as those with macroscopic residual disease. | Draft quality statement 11 did not progress to the final quality standard. The Ovarian Cancer quality standard reflects the content of NICE clinical guideline 122 which recommends complete resection of all macroscopic disease only. |
| 112 | Royal College of Obstetricians and Gynaecologists | QS11 | In this statement the measure will be the percentage of women having no residual macroscopic disease after surgery. Whilst plaudable, one potential impact could be that Centres decide to operate only on a highly selected patient cohort (using – for example – imaging and laparoscopy) in whom macroscopic disease clearance is highly likely. The remaining patients then only have chemotherapy. This could lead to a skewed picture and I would suggest that the denominator is considered carefully – or to include those who had optimum debulking ( i.e. no residuum greater than 1 cms) which may faciliate in preventing this potential problem. Of note, the evidence base for no macroscopic disease and optimum debulking [<1cms residdum] is the same. | Draft quality statement 11 did not progress to the final quality standard. |
| 113 | Sussex Cancer Network | QS11 | Don’t all cancer surgeons want clear margins every time? The challenge is to achieve it. | Thank you for your comment. Draft quality statement 11 did not progress to the final quality standard. |
| 114 | Target Ovarian Cancer | QS11 | There is no mention of fertility conserving surgery. No recommendation in CG122 however it does say the following (page 40, section 4.1) ‘In women where the disease appears to be confined to one ovary and who wish to | a) The topic expert group prioritised the areas of care they felt were most important, based on the development |

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| | | | conserve fertility then conservative surgery can be considered where the uterus and contra-lateral ovary are conserved.<br>Also given that around 10% of women diagnosed with ovarian cancer die within one month of diagnosis, the Quality Statement does not give an indication that in some cases, surgery is for palliative care reasons only. In this context we also believe that the QS on Palliative Care should be cross referenced in a more obvious way. | sources listed.<br>b) The End of Life quality standard has been referenced in the final ovarian cancer quality standard.<br>Draft quality statement 11 did not progress to the final quality standard. |
| 115 | Airedale NHS Foundation Trust | QS12 | Any specification regarding chemotherapy should be worded to encourage clinical trials participation. | Draft quality statement 12 did not progress to the final quality standard as the use of NICE-approved treatments is mandated and therefore the statement was not aspirational. |
| 116 | International Ovarian Tumour Analysis (IOTA) Group | QS12 | This is reasonable. However, there must be flexibility to allow for participation in clinical trials and for the exercise the patient's choice | Draft quality statement 12 did not progress to the final quality standard as the use of NICE-approved treatments is mandated and therefore the statement was not aspirational. |
| 117 | National Cancer Research Institute Gynaecological CSG, Royal College of Physicians, Association of Clinical Pathologists, Joint Collegiate Council for Oncology | QS12 | Unless women were in portfolio trial. | Draft quality statement 12 did not progress to the final quality standard as the use of NICE-approved treatments is mandated and therefore the statement was not aspirational. |
| 118 | PharmaMar | QS12 | We do not believe that ensuring that patients are able to access NICE approved treatments should be included in the Ovarian Cancer Quality Standard. There a number of reasons for this:<br>• Patients should already be able to access all NICE approved treatments following a positive technology appraisal and the three month implementation period given to allow commissioners to ensure that funding is made available. We are aware of reports that in some areas commissioners are restricting access to these treatments regardless of the mandatory funding signal. However, this is a problem for all cancer patients and not just those with ovarian cancer. We therefore believe that the Department of Health needs to tackle restrictions to NICE approved medicines across the board and not in a piecemeal way for each different type of disease through individual quality | Draft quality statement 12 did not progress to the final quality standard as the use of NICE-approved treatments is mandated and therefore the statement was not aspirational. |

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| | | | standards<br>• Guidance issued by the General Medical Council is clear that doctors should inform patients of all appropriate treatment options to meet their clinical needs and this has been reiterated in the Department of Health (Department of Health, Improving access to medicines for NHS patients, November 2008)<br>• We are concerned that by specifying patients are offered appropriate NICE-approved treatments this will limit the scope of clinician's decision-making and will limit conversations about other appropriate treatments which are not NICE-approved | |
| 119 | Roche Products Ltd | QS12 | Whilst we whole-heartedly agree that access to NICE approved treatment is important particularly in light of substantial variation in treatment practice (Uptake of NICE Approved Cancer Drugs 2007/2008; 2009; http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_098856), we feel that limiting this QS to 'NICE approved treatment' may inhibit access and limit patient choice to all licensed and clinically appropriate treatment available via alternative funding routes, now and in the future. Therefore we suggest that this quality statement is redefined as 'Access to NICE approved and clinically appropriate treatment' and the statement reads as 'Women with ovarian cancer are offered appropriate NICE approved treatment, and are informed of all clinically appropriate treatments, with due consideration to stage of disease, risks and benefits, and patient choice.'<br>We request NICE considers the following evidence that supports the suggested amendments:<br>a) According to the NHS Constitution: "You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you." Based on this right, patients should at the very least be 'informed' of all treatment options and be allowed to take part in the decision making around appropriate treatment options and explore the alternative funding routes that exist to access treatment that currently sit outside NICE recommendations/review.<br>b) The NHS Constitution is supported by DH guidance to Chief Executives regarding their responsibilities in decision making processes about medicines outside of NICE recommendations:<br>http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsP | Draft quality statement 12 did not progress to the final quality standard as the use of NICE-approved treatments is mandated and therefore the statement was not aspirational. |

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| | | | olicyAndGuidance/DH_093413<br>c) Uptake of cancer medicines in the UK is significantly lower than its international peers. One of the key principles of the Cancer Drugs Fund (CDF) is to ensure that access to cancer drugs is improved. In line with the report, 'Extent and causes of international variations in drug usage' published by Professor Sir Mike Richards it paves the way over the next three years for clinicians to prescribe the previously difficult to access cancer drugs that they believe will help their patients, and offers the opportunity to align access and usage in England with that of Europe. DH CDF guidance and the international variations report can be found on the following links:<br>http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_125445<br>http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117962<br>With the recent joint publication of the Strategy for UK Life Sciences and Innovation Health and Wealth from the Department of Business Innovation and Skills and Department of Health the intention is to ensure that NHS managers at all levels are 'hard wired' to promote innovation. The reports also announced an early access scheme that may allow patients to benefit from access to innovative treatment prior to licensing where the MHRA is satisfied that the clinical benefits outweigh the risks for patients with considerable unmet need. In addition plan is to launch a new app and web portal providing a database of where clinical trials are going on; where members of the public will be able to log in and ask to participate. To ensure the planned Quality Standard for ovarian cancer encourages behaviour consistent with supporting the uptake and diffusion of innovation we suggest that provision of information covering all treatment options, including all medicines from phase III development onwards, is explicitly encouraged. | |
| 120 | Roche Products Ltd | QS12 | We suggest the inclusion of further process measures that ensure:<br>• Patients are actively consulted on their choice of therapy and there is evidence that this has been done<br>• Multi-Disciplinary Teams have the core attendance and relevant test results to optimise evidence-based treatment decisions.<br>• Evidence of local arrangements to ensure that treatments that are currently not NICE recommended/reviewed have been given proper consideration based on the evidence and available funding routes.<br>Suggestions for data to support this quality statement include relevant metrics from the: | Draft quality statement 12 did not progress to the final quality standard as the use of NICE-approved treatments is mandated and therefore the statement was not aspirational. |

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| | | | • National Cancer Patient Experience Survey<br>The NHS Information Centre for Health and Social Care's "Use of NICE-appraised medicines in the NHS in England" annual reports; Use of NICE Appraised Medicines in the NHS – 2009, Experimental Statistics. http://www.ic.nhs.uk/statistics-and-data-collections/primary-care/prescriptions/use-of-nice-appraised-medicines-in-the-nhs-in-england--2009-experimental-statistics. | |
| 121 | Sussex Cancer Network | QS12 | Too vague to measure | Draft quality statement 12 did not progress to the final quality standard as the use of NICE-approved treatments is mandated and therefore the statement was not aspirational. |

**These organisations were approached but did not respond:**

A Little Wish
Abbott GmbH & Co KG
Abbott Laboratories
African HIV Policy Network
Almac Diagnostics
Amgen UK
Anglia cancer network
Arden Cancer Network
Association for Palliative Medicine of Great Britain
Association of British Healthcare Industries
Association of British Insurers
Association of Cancer Physicians
Association of Chartered Physiotherapists in Oncology and Palliative Care
Association of Genetic Nurses and Counsellors
Astrazeneca UK Ltd
Barnsley Hospital NHS Foundation Trust
Beckman Coulter
Belfast Health and Social Care Trust
Betsi Cadwaladr University Health Board
Birmingham Women's Health Care NHS Trust
Boehringer Ingelheim
Bradford District Care Trust
Brighton and Sussex University Hospital NHS Trust
Bristol and Avon Chinese Women's Group
British Dietetic Association
British Gynaecological Cancer Society
British Medical Association
British Medical Journal
British National Formulary
British Nuclear Medicine Society
British Psychological Society
British Society for Human Genetics
British Society for Immunology
British Society of Urogynaecological Radiology
BUPA Foundation
Cambridge University Hospitals NHS Foundation Trust
Camden Link
Cancer Research UK
Cancer Services Co-ordinating Group
Cancer Voices
Care Quality Commission (CQC)
CLIC Sargent
College of Emergency Medicine
College of Occupational Therapists
Cook Medical Inc.
County Durham Primary Care Trust
Daiichi Sankyo UK
Deltex Medical
Department for Communities and Local Government
Department of Health, Social Services and Public Safety - Northern Ireland
Derby-Burton Cancer Network

Derbyshire Mental Health Services NHS Trust
Dorset Cancer Network
Dorset Primary Care Trust
Dudley PACT Patient Advisory Cancer Team
East Lancashire Hospitals NHS Trust
East Midlands Cancer Network
Energy Therapy World-Wide Net
Equalities National Council
Essex Cancer Network
Eusapharma
GE Healthcare
George Eliot Hospital NHS Trust
GlaxoSmithKline
Gloucestershire Hospitals NHS Foundation Trust
Gloucestershire LINk
Great Western Hospitals NHS Foundation Trust
Greater Manchester and Cheshire Cancer Network
Greater Manchester and Cheshire Cardiac and Stroke Network
Greater Midlands Cancer Network
Grunenthal Ltd
Guerbet Laboratories Ltd
Guy's and St Thomas' NHS Foundation Trust
Gynaecological Cancer Network Leads Group
Harrogate and District NHS Foundation Trust
Health Protection Agency
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Hospira UK Limited
Human Fertilisation Embryology Authority
Humber and Yorkshire Coast Cancer Network
Imaging Equipment Ltd
Institute for Womens Health
Institute of Biomedical Science
James Cook University Hospital
Janssen
Johnson & Johnson
KCARE
Kent & Medway Cancer Network
Knowsley Primary Care Trust
Lancashire Care NHS Foundation Trust
Leeds Primary Care Trust (aka NHS Leeds)
Leeds Teaching Hospitals NHS Trust
Leicestershire, Northamptonshire and Rutland Cancer Network
Liverpool Community Health
Lothian University Hospitals Trust
Luton and Dunstable Hospital NHS Trust
Lymphoedema support network
Medicines and Healthcare products Regulatory Agency
Ministry of Defence
MRC Clinical Trials Unit
National Cancer Action Team
National Clinical Guideline Centre

National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Council for Palliative Care
National Forum of Gynaecological Oncology Nurses
National Institute for Health Research Health Technology Assessment Programme
National Patient Safety Agency
National Public Health Service for Wales
National Radiotherapy Implementation Group
National Treatment Agency for Substance Misuse
NHS Bournemouth and Poole
NHS Clinical Knowledge Summaries
NHS Connecting for Health
NHS Improvement
NHS Kirklees
NHS National Programmes
NHS Plus
NHS Sefton
NHS Sheffield
North East London Cancer Network
North Tees and Hartlepool NHS Foundation Trust
North Trent Cancer Network
North West London Cancer Network
North Yorkshire & York Primary Care Trust
Northern Ireland Cancer Network
Nottingham City Hospital
Novartis Pharmaceuticals
Novo Nordisk Ltd
Oxfordshire Primary Care Trust
Pan Birmingham Cancer Network
Patients Watchdog
Pelvic Pain Support Network
PERIGON Healthcare Ltd
Peterborough and Stamford Hospitals NHS Foundation Trust
Pfizer
Pilgrims Hospices in East Kent
Randox Laboratories Limited
Roche Diagnostics
Roy Castle Lung Cancer Foundation
Royal Berkshire NHS Foundation Trust
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Psychiatrists
Royal College of Psychiatrists in Scotland
Royal College of Surgeons of England
Royal Pharmaceutical Society
Royal Society of Medicine
Sandwell Primary Care Trust
Sanofi

Schering-Plough Ltd
Scottish Clinical Biochemistry Managed Diagnostic Network
Scottish Intercollegiate Guidelines Network
Sheffield Primary Care Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Shropshire & Mid Wales Cancer Forum
SNDRi
Social Care Institute for Excellence
South Asian Health Foundation
South Staffordshire Primary Care Trust
South Tees Hospitals NHS Trust
South Wales Cancer Network
Southend Hospitals NHS Foundation Trust
Southport and Ormskirk Hospital NHS Trust
Step4Ward Adult Mental Health
Teenagers and Young Adults with Cancer
Thames Valley Cancer Network
The Association for Clinical Biochemistry
The Association of the British Pharmaceutical Industry
The British Association of Gynaecological Pathologists
The British In Vitro Diagnostics Association
The Eve Appeal
The National LGB&T Partnership
The Rotherham NHS Foundation Trust
The University of Glamorgan
UCL Partners
UK Clinical Pharmacy Association
UK National Screening Committee
UK NEQAS for Immunology and Immunochemistry
United Lincolnshire Hospitals NHS
University Hospital Birmingham NHS Foundation Trust
Welsh Cancer Services Coordinating Group
Welsh Government
Welsh Scientific Advisory Committee
West Hertfordshire Primary Care Trust
Western Cheshire Primary Care Trust
Western Health and Social Care Trust
Whitehouse Consultancy
Wirral University Teaching Hospital NHS Foundation Trust
Wrightington, Wigan and Leigh NHS Foundation Trust
York Hospitals NHS Foundation Trust