Quality Standards Ovarian Cancer Topic Expert Group

Minutes of the TEG3 meeting held on 2nd February 2012 at the NICE Manchester office

Attendees	**Topic Expert Group Members** Sean Duffy (SD) [Chair], Charles Redman (CR), Laurence Brown (LB), Frances Reid (FR), Linda Facey (LF), Doug Wulff (DW), Jurjees Hasan (JH), Derek Cruickshank (DC), Marcia Hall (MH), Cathy Hughes (CH), Evis Sala (ES), Robin Crawford (RC), Ian Manifold (IM), Nathan Bromham (NB), Azim Lakhani (AL) **NICE Staff** Mark Baker (MB), Andy McAllister (AMA), Cheryl Thorne (CT), Edgar Masanga (EM), Nicola Greenway (NG), Dan Sutcliffe (DS), Lucy Spiller (LS) [Minutes]
Apologies	**Topic Expert Group Members** Audrey Bradford, Craig Dobson, Michael Scanes

Agenda item	Discussions and decisions	Actions
1. Introductions and apologies	SD welcomed the attendees, noted the apologies and reviewed the agenda for the day. The group confirmed the minutes from the meeting held on 29th September 2011 were an accurate record.	
2. Declarations of interest	SD asked the group whether they had any new interests to declare since the last meeting. LB advised the group that he had been asked to sit on a Target Ovarian Cancer advisory panel. No other group members had any additional interests to declare.	
3. Review of progress so far and objectives of the day	DS reviewed the progress made on the quality standard (QS) so far. He advised the group that the main objectives of the day were to discuss the results of the consultation and agree up to 15 quality statements for progression into the final QS. DS advised the group that the NICE QS team will respond to each stakeholder comment received during consultation and these responses will be published on the NICE website. DS told the group that the NICE senior management team had reviewed the QS earlier than usual in order to allow the group to discuss the feedback received and agree how to address it. DS advised the group that the final QS will include all the information the group considers important but advised them that the final version may look different due to the NICE editorial process. He also confirmed that the group will have the opportunity to see the final version of the QS before publication.	
4. Support for commissioners and others using the quality standard	EM outlined the role of the costing and commissioning team and advised the group that they will develop a support document for commissioners and other users to accompany the QS. He said the purpose of this document is to help commissioners and service providers consider the commissioning implications and potential resource impact of using the QS. EM advised the group that they may need to provide input during its development. He also told them that they will have the opportunity to comment on the document during a 2	

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	week consultation period. He asked the group to contact himself or CT if they have any questions.	
5. Presentation and discussion of consultation feedback	NG gave a brief overview of the consultation, focussing on the positive themes and the areas for consideration. She said that the positive comments generally focussed around these areas: • The QS is welcomed by stakeholders. • The stakeholders were pleased with the emphasis on early diagnosis. • The stakeholders were glad that the RCR guidance is featured prominently in the QS. The areas which require further consideration were highlighted as: • The scope does not cover the entire patient pathway and as a result of this the balance of statements seems uneven. – The group acknowledged this but highlighted that this results from the scope of CG122 and therefore cannot be addressed. • Further clarity required around some statements. • Further clarity required around some measurements. • Guideline evidence does not incorporate recent studies. – The group considered this but highlighted that the QS development process does not allow for inclusion of other evidence unless it is NHS Evidence accredited. They could not identify any additional NHS Evidence approved sources. • The implications of the statements on ultrasound and CT services, particularly due to current staff shortages and difficulty in service provision. • No reference to RCR cancer staging guidance and risk of malignancy index. NG advised the group that they would consider statement-specific comments received throughout the day. She also said there would be time at the end of the day to cover any outstanding general issues.	
	Please note that further changes may be made to the QS following this meeting, subject to discussion with and agreement of the TEG Chair.	
6. Presentation, discussion and	The TEG felt that the ‘serum CA125’ could be replaced with ‘CA125’ as CA125 levels could not be tested in any other way.	Remove ‘serum’ throughout the QS.

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agreement of final statements	**Draft Quality Statement 1:** Women reporting one or more of the following symptoms on a persistent or frequent basis are offered a serum CA125 test: persistent abdominal 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). The group discussed stakeholder comments relating to this statement. They did not feel stakeholder concerns regarding sensitivity/specificity of the serum CA125 test could be addressed as there is no alternative test. NG told the group that stakeholders had called for definitions of 'persistent' and 'frequent' but advised that these were already included in the definitions section. NG highlighted that the statement was quite long and suggested including the symptoms list in the definitions section rather than the statement itself. The group agreed to change the wording of the statement to 'reporting one or more symptoms suggestive of ovarian cancer on a persistent or frequent basis'. NG advised the group that stakeholders had suggested that back pain and bloating were omitted from the symptoms list. The group discussed this and agreed to reference bloating in the symptoms list but did not think it was appropriate to include back pain. NG said stakeholders had suggested including an age limit in this statement. The group discussed this at length and agreed to include	Change the wording of the statement to 'reporting one or more symptoms suggestive of ovarian cancer on a persistent or frequent basis' and move the symptoms list to the definitions section. Include 'bloating' in the symptoms list. Include 'aged 50 or over' in the

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	‘aged 50 or over’ in the statement.	statement. Reference the use of a serum CA125 test in younger women where clinically appropriate in the definitions and equality and diversity considerations sections.
	The group agreed to progress the statement with the following revised wording: **Revised Quality Statement 1:** Women aged 50 or over reporting one or more symptoms suggestive of ovarian cancer on a persistent or frequent basis are offered a serum CA125 test.	Progress the statement with the revised wording.
	Draft Quality Statement 2: 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. NG said some stakeholders were supportive of the two week timescale however others felt this would be difficult to meet. Following discussion the group felt this timescale should remain as this makes the statement aspirational. NG advised the group that stakeholders were concerned with the accuracy of the ultrasound and the experience of the sonographer. However the group felt experience was a core requirement for any sonographer. The group agreed to remove ‘symptoms suggestive of ovarian cancer and’ from the statement.	Remove ‘symptoms suggestive of ovarian cancer and’

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		from the statement.
	The group agreed to change the wording of the second half of the statement to 'have an ultrasound of their abdomen and pelvis via direct access from primary care within two weeks of receipt of results.'	Change the second half of the statement to 'have an ultrasound of their abdomen and pelvis via direct access from primary care within two weeks of receipt of results.'
	The group agreed to progress the statement with the following revised wording: **Revised Quality Statement 2:** Women with serum CA125 of 35 IU/ml or greater have an ultrasound of their abdomen and pelvis via direct access from primary care within 2 weeks of receipt of results.	Progress the statement with the revised wording.
	Draft Quality Statement 3: Women with serum CA125 of 35 IU/ml or greater whose ultrasound suggests ovarian cancer, as defined by RCR guidance, are referred urgently within 2 weeks for further investigation. NG advised the group that stakeholders had suggested including specialist referral in this statement as well as urgent referral however the group did not feel this was appropriate as specialist referrals should be urgent. NG said stakeholders had raised concerns over resource issues which may result from an increased number of ultrasounds. The group discussed this did not feel this could be addressed as the QS is aspirational. The group agreed to remove 'with serum CA125 of 35 IU/ml or greater' from the statement.	Remove 'with serum CA125 of 35 IU/ml or greater' from the

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		statement.
	Following stakeholder feedback the group agreed to remove the reference to the RCR guidance as this guidance does not give diagnostic information as the statement suggests. The group agreed to replace 'urgently within 2 weeks' with 'on a suspected cancer pathway' in the statement. The group agreed to progress the statement with the following revised wording: **Revised Quality Statement 3:** Women whose ultrasound suggests ovarian cancer are referred on a suspected cancer pathway for further investigation.	Remove 'as defined by RCR guidance' from the statement. Replace 'urgently within 2 weeks' with 'on a suspected cancer pathway' in the statement. Progress the statement with the revised wording.
	Draft Quality Statement 4: 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. NG advised the group that stakeholders were unsure whether the intent of this statement was for the GP to repeat investigations or to consider another diagnosis. The stakeholders also suggested that the onus should be on the GP to reassess the patient, rather than on the patient to book another appointment. The group felt the intent of the statement was to ensure those patients whose symptoms persist are reassessed. They therefore decided to change the wording of the second half of the statement to 'with no confirmed diagnosis for their symptoms, are reassessed by their GP within 1 month if the symptoms persist.' Following stakeholder comments the group agreed to include a	Change the second half of the statement to 'with no confirmed diagnosis for their symptoms, are reassessed by their GP within 1 month if the symptoms persist.' RC to develop a list

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	definition of other causes of their symptoms in the definitions section.	of other causes of these symptoms and share with NG and DS.
	The group agreed to include '(less than 35 IU/ml) and 'of 35 IU/ml or greater' in the definitions section, and use 'raised serum CA125' instead of 'serum CA125 of 35 IU/ml or greater' to be consistent with the use of 'normal serum CA125' earlier in the statement.	Include '(less than 35 IU/ml) and 'of 35 IU/ml or greater' in the definitions section. Use 'raised serum CA125' instead of 'serum CA125 of 35 IU/ml or greater'.
	NG advised the group that stakeholders had also suggested providing advice for GPs in the event of raised serum CA125 but normal ultrasound and referencing the use of a symptom diary for evidence and monitoring. The group considered these suggestions but did not feel they could be incorporated within the statement.	
	The group agreed to progress the statement with the following revised wording: **Revised Quality Statement 4:** Women with normal serum CA125, or raised serum CA125 but normal ultrasound, with no confirmed diagnosis for their symptoms, are reassessed by their GP within 1 month if the symptoms persist.	Progress the statement with the revised wording.
	Draft Quality Statement 5: Women with suspected ovarian cancer are offered computed tomography (CT) of the abdomen and pelvis, reported by a radiologist who is a core member of the multidisciplinary team, as the initial staging investigation. If required, other types of imaging should be used in accordance with RCR guidance. NG highlighted that stakeholders had suggested including ultrasound	

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	markers in this statement but the group felt this was adequately covered by statements 2 and 3. Stakeholders also suggested considering MRI for women under 35 but the group did not feel this was appropriate.	
	Following stakeholder comments and on consideration of the patient pathway the group agreed to place this statement after the following statement, meaning this statement becomes quality statement 6.	Reorder the statements so draft statement 5 becomes quality statement 6.
	Following stakeholder comments the group discussed the intent of this statement and felt there were three main concepts to address. They therefore decided to change the wording of this statement to **'**Women with suspected ovarian cancer on US are offered computed tomography (CT) of the abdomen and pelvis as the initial staging investigation.' and to add two additional statements (for details, please see below).	Change the wording to **'**Women with suspected ovarian cancer on US are offered computed tomography (CT) of the abdomen and pelvis as the initial staging investigation.'
	The group agreed to progress the statement with the following revised wording: **Revised Quality Statement 5 (now Quality Statement 6):** Women with suspected ovarian cancer on US are offered computed tomography (CT) of the abdomen and pelvis as the initial staging investigation.	Progress the statement with the revised wording.
	Following stakeholder comments and the changes made to draft statement 5 the group decided to include a statement on the reporting of CT staging.	

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	In relation to draft statement 5, stakeholders suggested using the term 'reviewed' instead of 'reported', however the group felt that in order to improve quality of patient care, the term 'reported' should remain. The NICE team were unsure of the evidence to support this but RC said he would share this with DS.	RC to share evidence to support the use of a radiologist with DS.
	Regarding draft statement 5, stakeholders suggested that it would be beneficial to define the term 'specialist MDT'. The group agreed it would be useful to reference the definition included in the National Cancer Peer Review Programme in this new statement as well.	Reference the definition included in the National Cancer Peer Review Programme.
	The group agreed to include a statement with the following wording: **New statement (now Quality Statement 7):** Women with suspected ovarian cancer have their CT staging reported by a radiologist who is a core member of the specialist multidisciplinary team.	Progress the statement as it stands.

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	Following stakeholder comments and the changes made to draft statement 5 the group decided to include a statement on the use of MRI for women with an indeterminate adnexal mass.	
	New statement (now Quality Statement 8): Women with an indeterminate adnexal mass on ultrasound have magnetic resonance imaging (MRI) for further characterisation.	Progress the statement as it stands.
	Draft Quality Statement 6: Women with suspected ovarian cancer who undergo an ultrasound have their risk of malignancy index I (RMI I) score calculated and those with an RMI I score of 250 or greater are referred to a specialist multidisciplinary team.	
	Following stakeholder comments and on consideration of the patient pathway the group agreed to place this statement after the following statement, meaning this statement becomes quality statement 5.	Reorder the statements so draft statement 6 becomes quality statement 5.
	NG advised the group that stakeholders had raised concerns over the accuracy of RMI I and the group acknowledged that this is a mechanism of triage, not a precise tool. In response to other stakeholder comments the group agreed to include the RMI I calculation in the definitions section.	Include the RMI I calculation in the definitions section.
	Stakeholders also suggested that it would be beneficial to define the term ‘specialist MDT’. The group agreed it would be useful to reference the definition included in the National Cancer Peer Review Programme.	Reference the definition included in the National Cancer Peer Review

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		Programme.
	Stakeholders also raised queried who should refer the patient to the MDT but the group did not feel this was relevant to this statement. The group agreed to progress the statement without altering the wording: **Quality Statement 6 (now Quality Statement 5):** Women with suspected ovarian cancer who undergo an ultrasound have their risk of malignancy index I (RMI I) score calculated and those with an RMI I score of 250 or greater are referred to a specialist multidisciplinary team.	Progress the statement as it stands.
	Draft Quality Statement 7: Women with suspected or diagnosed ovarian cancer are offered information about the tests and the disease, including psychological, social and sexual issues, from appropriately trained staff. The NICE team advised the group that the patient experience in generic terms QS will be published shortly. The group were shown the contents of the new QS. They discussed the overlap and concluded that the majority of the components of draft statement 7 were covered by the patient experience QS. The group felt the only areas not specifically covered were psychosexual issues, sexuality and sexual activity. The NICE team acknowledged the importance of this information but highlighted that could be covered by the term 'potential consequences' and reminded the group that this information is specifically referenced in CG122. The group therefore decided that draft statement 7 will not be progressed.	Remove draft statement 7.
	Draft Quality Statement 8: Women with suspected stage I ovarian cancer should have optimal surgical staging. NG advised the group that stakeholders had suggested broadening this statement to include other stages however the group said this was not possible as it goes beyond the scope of CG122. The group also considered stakeholder suggestions to include the use of frozen section, however they did not think that would be appropriate within	

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	this quality standard. The group also considered a stakeholder suggestion that the statement should refer to the surgical skills required, however they did not feel this would enhance the statement. The group agreed to change the wording of the statement from 'should have' to 'have'. The group agreed to progress the statement with the following revised wording: **Revised Quality Statement 8 (now Quality Statement 9):** Women with suspected stage I ovarian cancer have optimal surgical staging.	Change the wording from 'should have' to 'have'. Progress the statement with the revised wording.
	Draft Quality Statement 9: Women with high-risk stage I disease are offered adjuvant chemotherapy consisting of six cycles of carboplatin and 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. Following consideration of stakeholder comments and further discussion the group agreed to remove this statement.	Remove draft statement 9.
	Draft Quality Statement 10: Women offered chemotherapy have a confirmed tissue diagnosis by histology (or by cytology if histology is not appropriate). Following consideration of stakeholder comments and further discussion the group agreed to remove this statement.	Remove draft statement 10.
	Draft Quality Statement 11: Women with ovarian cancer who undergo surgery, either before chemotherapy or after neoadjuvant chemotherapy, have surgery in which complete resection of all macroscopic disease is the objective. NG said stakeholders had suggested specifying that gynaecological surgeons should perform surgery and including a reference to fertility conserving surgery however the group did not feel these suggestions were relevant to the purpose of this statement. The group did not feel the current wording was in line with the intention of the statement. They therefore agreed to change the	Change the wording to 'Women with

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	wording of the statement to 'Women with ovarian cancer who undergo surgery as part of their initial treatment plan, have surgery where the outcome is complete resection of all macroscopic disease.' The group agreed to progress the statement with the following revised wording: **Revised Quality Statement 11 (now Quality Statement 10):** Women with ovarian cancer who undergo surgery as part of their initial treatment plan, have surgery where the outcome is complete resection of all macroscopic disease.	ovarian cancer who undergo surgery as part of their initial treatment plan, have surgery where the outcome is complete resection of all macroscopic disease.'
	Draft Quality Statement 12: Women with ovarian cancer are offered appropriate NICE-approved treatments. Following consideration of stakeholder comments and further discussion the group agreed to remove this statement.	Remove draft statement 12.
	NG advised the group that stakeholders had suggested the following additional areas for inclusion in the QS: • Early involvement of pain and palliative care services • Follow up care/survivorship agenda • Continence, mobility and general issues of daily living • Management of ascites • Clinical nurse specialist • Teenage and young adult MDT The group discussed whether these additional statements should be included in the QS but felt they were either not appropriate for inclusion or were already covered by other existing statements.	
7. Equality impact assessment	The group considered the equality and diversity issues and highlighted the following issue in relation to statement 1: Although the epidemiological profile of ovarian cancer means the risk is higher in women aged 50 and over, it may be appropriate to offer a serum CA125 test to those under 50 in some circumstances, based on clinical judgement.	

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8. Next steps	AMA outlined the next steps, including key dates in the QS development process. He gave a brief outline of the endorsement process and told the group which organisations have expressed an interest in endorsing the QS to date. AMA asked the group to contact any further relevant organisations who had not already expressed an interest in endorsing the QS. SD thanked the group for their hard work and closed the meeting. The TEG was reminded that the date for the next meeting, to begin working on the Commissioning Outcomes Framework indicators, will be on 5th July 2012 in the NICE Manchester office.	