NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION SUMMARY REPORT

1 Quality standard title

Bladder cancer

Date of Quality Standards Advisory Committee post-consultation meeting:
23 September 2015.

2 Introduction

The draft quality standard for bladder cancer was made available on the NICE website for a 4-week public consultation period between 23 July and 18 August. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 14 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

Stakeholders were also invited to respond to the following specific question:

4. Should a statement be included that focuses on discharge to primary care for adults with low-risk non-muscle-invasive bladder cancer if they have no recurrence of the bladder cancer within 12 months?

4 General comments

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

- Stakeholders considered that the quality standard would help to address variation in practice.
- A number of additional areas were suggested for inclusion in the quality standard.

Consultation comments on data collection

- A number of stakeholders considered that data collection would be possible for the proposed quality measures.
- Some stakeholders suggested that systems are required for prospective data collection, and designated people assigned to collect the data.
- Concern was expressed about the likely requirements on time for proposed quality measurement with other conflicting data collection priorities.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Adults who are having transurethral resection of bladder tumour (TURBT) have detrusor muscle obtained during the procedure.

Consultation comments

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

- Stakeholders commented that this is a useful marker of quality of resection and is required to accurately stage disease for high-risk cancer.
- The risk of bladder perforation was raised. Specific groups were highlighted where it was considered that risks might outweigh potential benefit, including:
  - People with low-risk bladder cancer (as low-risk cancers are not invasive)
  - Older people (at risk of bladder perforation with tumours on the dome of the bladder)
  - People requiring palliative resection
  - People with cancers arising within a diverticulum.
- Stakeholders commented that a statement on TURBT should reflect evidence of use of technology to improve diagnostic techniques as per NICE Guideline NG2 Bladder cancer: diagnosis and management (2015) priority recommendation 1.2.3: *"Offer white-light-guided TURBT with one of photodynamic diagnosis, narrow-band imaging, cytology or a urinary biomarker test (such as UroVysion using fluorescence in-situ hybridization [FISH], ImmunoCyt or a nuclear matrix protein 22 [NMP22] test) to people with suspected bladder cancer. This should be carried out or supervised by a urologist experienced in TURBT."*
- One stakeholder specifically highlighted that for all people undergoing TURBT, the procedure should be carried out or supervised by a consultant urologist with a clinical interest in bladder cancer.

5.2 Draft statement 2

Adults with suspected bladder cancer are offered a single dose of intravesical mitomycin C, given at the same time as the first transurethral resection of bladder tumour (TURBT).

Consultation comments

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

- Stakeholders highlighted that the term “at the same time” is ambiguous, as it could mean within surgery, or a number of hours or prior to discharge. The general consensus was that it should be administered within 24 hours.
- Stakeholders suggested that bladder perforation should be excluded from this quality statement, as it is unsafe to administer mitomycin C in those cases.
- Stakeholders reported that there is very limited evidence that mitomycin C given at the same time as TURBT is helpful for recurrent disease, and suggested that invasive, solid cancers should be excluded from the statement.

5.3 Draft statement 3

Adults with bladder cancer have a designated clinical nurse specialist.

Consultation comments

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

- The designated clinical specialist nurse might not necessarily be a single nurse for bladder cancer, however it was generally considered that people should have access to a designated clinical nurse specialist.
- Stakeholders commented that the statement would not currently measure quality of care. One stakeholder suggested that it should measure contact with a clinical nurse specialist rather than “being designated a clinical nurse specialist” so that actual support can be monitored.
- One stakeholder commented that the clinical nurse specialist should have contact with other services, e.g. community nurses and services to ensure support is seamless.

5.4 Draft statement 4

Adults with newly diagnosed non-muscle-invasive bladder cancer have prognostic information recorded and have a risk classification of their cancer completed.

Consultation comments

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

- Comments largely focused on data collection, including suggestions for data sources, such as multidisciplinary team data.
- One stakeholder commented that this statement is particularly relevant to histopathological staging and discussions at multidisciplinary meetings.

5.5 Draft statement 5

Adults with high-risk non-muscle-invasive bladder cancer have a discussion about intravesical Bacille Calmette Guérin (BCG) and radical cystectomy as treatment options.

Consultation comments

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

- Stakeholders commented that Bacille Calmette Guérin is only indicated for urothelial cancer and not all high risk non-muscle invasive disease.
- Stakeholders suggested that a shortage of Bacille Calmette Guérin might be an issue, and that alternatives are currently used in practice.
- One stakeholder highlighted that information about follow-up after treatment could be included within this statement.
- It was suggested that the outcome measures for this statement are too vague to measure the quality of care.

5.6 Draft statement 6

Adults with muscle-invasive urothelial bladder cancer have a discussion about neoadjuvant chemotherapy, radical cystectomy and radiotherapy with a radiosensitiser as treatment options.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- It was suggested that this statement could cause delays to some people receiving appropriate treatment in cases where they are clearly only suited for one of the two radical treatment options.
- One stakeholder suggested that therapeutic radiographers should be listed as part of the team discussing treatment options.
- One stakeholder suggested that synchronous chemoradiotherapy is the standard non-surgical treatment for people not undergoing radical surgery.
- One stakeholder suggested that biomarker testing should be included in discussions about the choice of treatment for adults with muscle-invasive urothelial bladder cancer.
- One stakeholder highlighted that information about follow-up after treatment could be included within this statement.
- It was suggested that data collection against the current outcome measures could be open to bias.

6 Suggestions for additional statements

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

- Stakeholders considered discharge to primary care of people with low risk non-muscle-invasive bladder cancer after one year of being recurrence-free to be an area where patient experience could be improved by reducing unnecessary hospital attendance. Cost-savings were also highlighted for this potential statement. Some stakeholders were concerned however that there is not strong evidence that this will improve quality and until evaluated it may in fact be detrimental to some. Other comments suggested that it will not make as much difference to care as other areas.
- One stakeholder suggested additional areas relating to diagnosis, including Fluorescence cystoscopy, random biopsies and antibody testing kits.
- One stakeholder considered that immunotherapy should be considered as part of treatment options.
- Stakeholders suggested time to definitive treatment, commenting that if definitive radical treatment is given more than 3 months after diagnosis, survival is adversely affected.
- Discussion about bladder reconstruction for appropriate people was suggested.
- Stakeholders highlighted neoadjuvant chemotherapy as a potential additional statement.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	*Stakeholder*	*Statement No*	**Comments**
1	Royal College of Pathologists	General	The quality standard is particularly welcome in this area of healthcare where there is considerable variation in clinical practice.
2	NHS England	General	All statements are well constructed and likely to help make a difference to patient care. These parameters can be added to the NHSE KBP specification when it is produced later this year, this will help collect data for the QS. The CRG are supportive of the NICE QS.
3	NCRI/ RCP/ ACP	Measures	The NCRI/RCP/ACP are grateful for the opportunity to respond to the draft Bladder Cancer QS consultation. Overall, we are broadly supportive of the standards, which appear reasonable. However, we are particularly concerned that the proposed quality measurement will rely on time within job plans to collect the data routinely – this does not currently exist. Clinicians are already progressing other audits in their own time (eg the National Prostate Cancer audit) and there appears to be no systems to automatically and prospectively capture the data. Within NHS units this is a huge issue and resource and appropriate systems are required to do this. We would also like to make the following joint comments.
4	NCRI/ RCP/ ACP	Measures	Data collection is a continuing issue in very busy NHS units. Physicians are struggling to keep up with data submission for mandatory audits like NPCA in addition to the COSD data set which partially overlaps with clinical time. It is difficult to answer the question 'if the systems and structures were available' without having knowledge of what these systems would look like. There does not appear to be any method of capturing this data prospectively and automatically within the current system.
5	NCRI/ RCP/ ACP	Measures	As noted above data collection is the biggest challenge. A further quality standard should be a structured process for data collection involving designated team members.
6	Royal College of Pathologists	Measures	The quality standards are measurable for clinical audit purposes and should be mandatory for centres providing specialist care.
7	RCGP's	Question 2	Potentially this is possible using hospital information IT systems and CPRD.

ID	*Stakeholder*	*Statement No*	**Comments**
8	British Uro-oncology Group	Questions 2 and 3	Data collection is the biggest challenge. A further quality standard should be a structured process for data collection – designated team members We should voice opinion that data should be collected, if clinician time is to be devoted to this, as is already being done eg in prostate cancer with the NCPA in addition to the COSD data set, there is partial overlap of data collection and also clinical time.
9	RCGP's	Question 3	Standardised national template for data collection with defined read codes.
10	NHS England	1	Agreed where possible bearing in mind the risk of bladder perforation in the elderly with tumours on the dome of the bladder
11	British Uro-oncology Group	1	This is a useful surrogate marker of quality of resection and for high risk cancer is required to accurately stage disease. Low risk cancers are not invasive and therefore the increased risk of bladder perforation in obtaining muscle is not justified, particularly for recurrent low risk disease. Other categories where this is not an appropriate standard are palliative resection and cancers arising within a diverticulum. A high rate of detrusor muscle in specimens, in association with high rates of bladder perforation would not be to the benefit of low risk patients.
12	NCRI/ RCP/ ACP	1	This is a useful surrogate marker of quality of resection and for high risk cancer is required to accurately stage disease. Low risk cancers are not invasive and therefore the increased risk of bladder perforation in obtaining muscle is not justified, particularly for recurrent low risk disease. Other categories where this is not an appropriate standard are palliative resection and cancers arising within a diverticulum. A high rate of detrusor muscle in specimens, in association with high rates of bladder perforation would not be to the benefit of low risk patients.
13	British Association of Urological Nurses	1	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Yes it is possible to measure this using histology from MDT, but the statement does not reflect evidence of use of technology to improve diagnostic techniques as per NICE Guideline NG2

ID	Stakeholder	Statement No	Comments
			Bladder cancer: diagnosis and management (2015) priority recommendation 1.2.3
14	British Association of Urological Nurses	1	What do you think could be done to support improvement and help overcome barriers? Inclusion of evidence of use of technology to improve diagnostic techniques.
15	British Association of Urological Surgeons	1	**Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement? Yes although consideration should be given to adding a caveat that muscle is not required if the surgeon can be confident that the tumour is not high risk. We appreciate this may cause problems but low risk cancers are not invasive and therefore the increased risk of bladder perforation in obtaining muscle is not justified, particularly for recurrent low risk disease. **Question 2** If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Yes **Question 3** For each quality statement what do you think could be done to support improvement and help overcome barriers? Ensure that for all patients undergoing TURBT, the procedure is carried out or supervised by a consultant urologist with a clinical interest in bladder cancer
16	The Royal College of Radiologists	1	*"Adults who are having transurethral resection of bladder tumour (TURBT) have detrusor muscle obtained during the procedure"*. The RCR feels this is essential to be able to ensure patients receive the most appropriate therapy for their stage of disease. Data are important and should be reasonably straightforward to collect.
17	Royal College of Pathologists	1 and 4	Inclusion of the muscularis propria as a quality indicator of TURBT specimens (statement 1) and risk stratification of bladder cancer (statement 4) are particularly relevant to histopathological staging and discussions at multidisciplinary meetings and these two quality standards are especially welcomed by the RCPath
18	British Uro-oncology Group	2	What is meant by "at the same time". It should be clarified whether this means administration within the operating theatre, or within 24 hours of TURBT. There is evidence that giving chemotherapy within 24 hours improves outcomes, but no evidence that giving the instillation in the operating theatre is required. Many clinicians do feel that intra-operative administration is good practice, but many units would not deliver it in this manner and are not disadvantaging their

ID	Stakeholder	Statement No	Comments
			patients. Mitomycin is the most commonly used intravesical chemotherapy currently, but there are others that are effective in reducing recurrence such as epirubicin. It is important to exclude bladder perforation from this standard – it is not safe to administer MMC if perforation suspected. Invasive, solid cancers should also be excluded. There is very limited evidence that MMC is helpful with TURBT for recurrent disease.
19	NCRI/ RCP/ ACP	2	The meaning of 'at the same time' within the statement should be clarified as to whether this means administration within the operating theatre, or within 24 hours of TURBT. There is evidence that giving chemotherapy within 24 hours improves outcomes, but no evidence that giving the instillation in the operating theatre is required. Many clinicians do feel that intra-operative administration is good practice, but many units would not deliver it in this manner and are not disadvantaging their patients. Mitomycin is the most commonly used intravesical chemotherapy currently, but there are others that are effective in reducing recurrence such as epirubicin. It is important to exclude bladder perforation from this standard – it is not safe to administer MMC if perforation suspected. Invasive, solid cancers should also be excluded. There is very limited evidence that MMC is helpful with TURBT for recurrent disease.
20	British Association of Urological Nurses	2	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures Yes, it would be possible to measure this standard using prescription data.
21	British Association of Urological Nurses	2	What do you think could be done to support improvement and help overcome barriers? The Statement needs clarification of "given at the same time as the first TURBT". Does this mean Peri-operatively? Within 1 hour, 6 hours, prior to discharge?. Leaving it so open to individual interpretation discounts the evidence re timing of 1st intravesical chemotherapy dose.

ID	*Stakeholder*	*Statement No*	**Comments**
22	British Association of Urological Nurses	2	***If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?*** Answered individually.
23	British Association of Urological Surgeons	2	**Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement? The phrase 'at the same time as TURBT' is somewhat imprecise, we understand that the intention in the NICE guideline was that this should mean in theatre and not in recovery or on the ward afterwards, although it is not being implemented as such due to local interpretations of what 'At the same time as TURBT' means. We would suggest this should say that MMC should be administered as soon as possible after TURBT and within 24 hours. There is evidence that giving chemotherapy within 24 hours improves outcomes, but no evidence that giving the instillation in the operating theatre is required. **Question 2** If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Not easily, see comment to Q1 above. It would be difficult to be sure the data was accurate, particularly not just whether the Mitomycin C was given but as importantly, where and when. **Question 3** For each quality statement what do you think could be done to support improvement and help overcome barriers? There are different barriers in different NHS trusts including reluctance of urologist to take on the extra work in theatre, theatre/recovery resistance, pharmacy resistance to give up making Mitomycin up in pharmacy which would lose them income. On the other hand this has been implemented successfully in many trusts for over a decade without any problems so it is achievable.
24	The Royal College of Radiologists	2	Data are important and should be reasonably straightforward to collect. Administration is very cost effective. The RCR suggests that exceptions are reported (that is, why dose not given/ clinical reason). The main valid reason is likely to be if there has been a risk of perforation but sites with high rates may be a concern.
25	NHS England	3	Many hospitals do not have enough clinical nurse specialists to have a single nurse for bladder cancer and many of the nurse specialists prefer a mixed practice. But agreed each patient should

ID	Stakeholder	Statement No	Comments
			have a designated nurse specialist.
26	British Association of Urological Nurses	3	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures Yes, it is possible to measure this statement via tick boxes in notes, on SCR etc, which document a named CNS. However currently this is too vague to be measurable in any meaningful way, as writing the name of a CNS in someones notes, does not equate to improvements in care.
27	British Association of Urological Nurses	3	What do you think could be done to support improvement and help overcome barriers? I would suggest amending the statement to "Has contact with a Urology CNS specialising in bladder cancer" and monitoring actual contacts that the person has with a CNS e.g. at least one of the following - Hollistic needs assessment, information prescriptions, clinical visits, telephone calls etc. Having a designated CNS is an entirely different thing to having contact with one.
28	British Association of Urological Nurses	3	***For each quality statement what do you think could be done to support improvement and help overcome barriers?*** Answered individually.
29	British Association of Urological Surgeons	3	**Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement? Yes **Question 2** If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Yes **Question 3** For each quality statement what do you think could be done to support improvement and help overcome barriers? Development of specific bladder cancer nurse specialists (rather than generic uro-oncology nurse specialists) for every trust dealing with bladder cancer
30	The Royal College of	3	*"Adults with bladder cancer have a designated clinical nurse specialist"*. There is a significant inequity between the access of bladder cancer patients and prostate patients to Clinical Nurse

ID	*Stakeholder*	*Statement No*	**Comments**
	Radiologists		Specialists (CNSs) which needs to be corrected. The RCR feels that bladder cancer patients' experience and adherence to treatment would be significantly improved with appropriate access to a CNS. Again, data are important. It can be difficult to record accurately and there is a need to ensure this is not a 'tick box exercise'. It may be there is a need to measure the number of patients with valid holistic needs assessments.
31	RCN	3	The nurse should have links with community services to ensure that services are available before advising the patient i.e. products. The nurse should liaise with the community nurse so that the patient has seamless care reducing anxiety.
32	Royal College of Pathologists	1 and 4	Inclusion of the muscularis propria as a quality indicator of TURBT specimens (statement 1) and risk stratification of bladder cancer (statement 4) are particularly relevant to histopathological staging and discussions at multidisciplinary meetings and these two quality standards are especially welcomed by the RCPath
33	NHS England	4	EAU app is freely available and should be used as standard
34	British Association of Urological Nurses	4	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures Yes, using a simple proforma
35	British Association of Urological Nurses	4	What do you think could be done to support improvement and help overcome barriers? Patient held records, detailing individual's clinical information, treatment and monitoring regimen.
36	British Association of Urological Surgeons	4	**Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement? Yes **Question 2** If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Yes **Question 3** For each quality statement what do you think could be done to support improvement

ID	*Stakeholder*	*Statement No*	**Comments**
			and help overcome barriers? As for the other quality statements, development of bladder cancer specific teams within each trust dealing with bladder cancer (as is already the case for prostate cancer) would ensure that this information is collected in a meaningful way and used to guide clinical decision making. Without this there is a risk that this information is collected for the purposes of audit and becomes a 'tick-box' exercise
37	The Royal College of Radiologists	4	Data are important and should be reasonably straightforward to collect from Multi-Disciplinary Team (MDT) data. The RCR suggests consideration is given to including an audit of accuracy of recording, or the impact of recording.
38	NHS England	5	This discussion may now include the use of hot Mitomycin C due to shortage of BCG and patest publications showing equal efficacy.
39	British Uro-oncology Group	5	BCG is only indicated for urothelial cancer – not all high risk non-muscle invasive disease appropriate.
40	NCRI/ RCP/ ACP	5	BCG is only indicated for urothelial cancer – not all high risk non-muscle invasive disease appropriate.
41	British Association of Urological Nurses	5	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Yes, via documentation of the discussion and use of information prescriptions.
42	British Association of Urological Nurses	5	For each quality statement what do you think could be done to support improvement and help overcome barriers? Clarification in the statement re discussion with whom? Family? GP? Suggest clarifying "with a urologist and CNS who specialise in this area"
43	British Association of Urological Surgeons	5	**Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement? This statement needs to be amended to say all patients "with high-risk non-muscle invasive **urothelial** (bladder) cancer…" In practice this quality standard is likely to be affected by the ongoing shortage of BCG. It is not

ID	*Stakeholder*	*Statement No*	**Comments**
			possible to have such a discussion when treatment options with BCG are often suboptimal and likely to remain so for some time. Consideration should be given to including options outlined by BAUS and European Urology for when BCG supplies are reduced or unavailable. **Question 2** If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Using 'reported understanding of treatment options' as a measure without a validated questionnaire is vague and open to bias. Using the ratio of BCG to Radical Cystectomy as a measure – what is the ideal ratio? There is no data that provides evidence for this **Question 3** For each quality statement what do you think could be done to support improvement and help overcome barriers? For the reasons outlined in the response to Q2, although the quality standard is laudable, the outcome measures are vague and may be a barrier in itself. Improving the objectivity of the measures and making them more evidence based should overcome this
44	The Royal College of Radiologists	5	The RCR feels it is quite difficult to see how this can be recorded/measured, especially if patients are moving between sites or seeing different specialists in different hospitals. It is not easy to show this from MDT data so it may only be assessable by manual audits. Many patients may be obvious for one or other treatment (that is, if not fit for cystectomy) so there may need to be some practical way of capturing this information.
45	Royal College of Pathologists	5 and 6	Access to relevant information related to treatment options to patients and their families by appropriately trained health care professionals is also endorsed.
46	MSD	5 & 6	MSD considers that both statements should include information on the recommended **follow up after treatment**, according to NICE guideline for Bladder cancer: diagnosis and management (NG2).
47	The Society and College of Radiographers	6	We would request that the role therapeutic radiographers as part of the health care professional team in discussions with patients who have muscle-invasive urothelial bladder cancer is acknowledged (extracts from page 22 & 23). Therapeutic radiographers are currently not listed along with urologists, oncologists, clinical oncologists and CNSs as part of the health care team that should be available to explain all treatment options, which includes radiotherapy, to these patients.
48	British Uro-	6	Whilst this is an admirable aim and for many patients is what one would wish to mandate, there

ID	*Stakeholder*	*Statement No*	**Comments**
	oncology Group		are some patient for whom radical cystectomy would be clearly the preferred option (eg significant lower urinary tract symptoms and small bladder capacity, previous radiotherapy, inflammatory bowel disease) or for whom radical cystectomy would be inappropriate based on advanced age or significant co morbidities. We would suggest that there should be effective "triage" in the sMDT to ensure that patient preference /co-morbidities etc are fully assessed. There is a concern that patients who are only fit/ appropriate for one of the two radical treatment options would have a potential pathway delay by adopting this statement without due consideration.
49	NCRI/ RCP/ ACP	6	Whilst this is an admirable aim and for many patients is what we would wish to mandate, there are some patients (eg those with significant lower urinary tract symptoms and small bladder capacity, previous radiotherapy, or inflammatory bowel disease) for whom radical cystectomy would clearly be preferred or for whom radical cystectomy would be inappropriate based on advanced age or significant co morbidities. We would suggest that there should be effective 'triage' in the sMDT to ensure that patient preference and the above mentioned factors are fully assessed. There is a concern that patients who are only suited for one of the two radical treatment options would have a potential pathway delay by adopting this statement without due consideration.
50	British Association of Urological Nurses	6	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures Yes, via documentation of the discussion and use of information prescriptions.
51	British Association of Urological Nurses	6	What do you think could be done to support improvement and help overcome barriers? Clarification in the statement re discussion with whom? Family? GP? Suggest clarifying "with a uro-oncologist and CNS who specialise in this area"
52	British Association of Urological Surgeons	6	**Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement? Yes **Question 2** If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

ID	*Stakeholder*	*Statement No*	**Comments**
			Yes **Question 3** For each quality statement what do you think could be done to support improvement and help overcome barriers? Using 'reported understanding of treatment options' as a measure without a validated questionnaire is vague and open to bias. The optimal ratio of NAC to no NAC and Cystectomy and radiotherapy is unknown. Without this information it is hard to see how collecting this information will improve quality standards – how will the optimal ratios of neoadjuvant chemotherapy and radical treatment be decided.
53	The Royal College of Radiologists	6	*"Adults with muscle-invasive urothelial bladder cancer (MIBC) have a discussion about neo adjuvant chemotherapy, radical cystectomy and radiotherapy with a radiosensitiser as treatment options".* The RCR fully supports this and suggests that all patients with MIBC should be seen by a Urological surgeon and a Clinical Oncologist prior to making an informed decision regarding definitive treatment and all patients should be considered for neoadjuvant cisplatin-based chemotherapy prior to definitive treatment. Synchronous chemoradiotherapy is the standard non-surgical treatment for patients not undergoing radical surgery. Patients should be given the option to participate in appropriate clinical trials (eg RAIDER study). The numbers for different treatments should be capable of being recorded and this may be important to compare different services. (See also comment above on QS5 about the difficulty of capturing consultations). It is also no good to have this conversation with patients if choices are closed – if quality is good, there should be variation in patients choices. Should patients be asked about this?
54	MSD	6	MSD suggests this should be re-worded to "Adults with muscle-invasive urothelial bladder cancer have a discussion about neoadjuvant chemotherapy, radical cystectomy **with lymphadenectomy** and radiotherapy with a radiosensitiser as treatment options." since radical cystectomy with extended lymphadenectomy is usually considered to be the standard treatment of muscle-invasive urothelial bladder cancer.

ID	*Stakeholder*	*Statement No*	**Comments**
55	MSD	6	Trials have confirmed a higher response rate of new immunotherapies in multiple tumour types (including bladder cancer) associated with differential expression levels of genetic biomarkers. Although further research into biomarkers that can predict the response of the patient's with bladder cancer is needed, NICE guideline for Bladder cancer: diagnosis and management (NG2) recognises that in the near future biomarker testing will be an important step toward individualised treatment. Therefore, MSD suggests the inclusion of "**Biomarker testing**" as one of the topics to include in the discussion of the choice of treatment for adults with muscle-invasive urothelial bladder cancer.
56	The Royal College of Radiologists	General and additional statement suggestions	The RCR strongly supports all of the quality measures proposed. The selected topics are important for high quality bladder cancer care and are key ones from NICE guidance. Their implementation should help to ensure standardisation of optimal treatment for patients and should, in turn, lead to improved outcomes both in terms of patient experience and cancer cure. However, the RCR suggests that follow-up and discharge policy are also worth monitoring.
57	RCGP's	Additional statement suggestions	The College feels additional areas that should be considered in diagnosis include Fluorescence cystoscopy, random biopsies and antibody testing kits. Immunotherapy should be considered as part of treatment options. Neoadjuvant chemotherapy is an important component that needs adoption by MDTs: Grossman HB, Natale RB, Tangen CM, et al: Neoadjuvant chemotherapy plus cystectomy compared with cystectomy alone for locally advanced bladder cancer. N Engl J Med 349:859-866, 2003. Kock pouchs need to be offered for patients who have radical cystectomy for extensive disease. Patients need access to community continence services.
58	British Association of Urological Surgeons	Additional statement suggestions	Would like to see the time to definitive treatment included as an important quality standard. This is likely to save more lives than any of the existing statements. If definitive radical treatment is given more than 3 months after diagnosis, survival is adversely affected. There should be a maximum time between TURBT and radical treatment such as 12 weeks. Would also like to see a standard including discussion of bladder reconstruction after radical cystectomy for appropriate patients. Also a standard offering neoadjuvant chemotherapy.

ID	*Stakeholder*	*Statement No*	**Comments**
59	British Association of Urological Surgeons	Additional statement suggestions	Data collection is one of the biggest challenges. A further quality standard should be a structured process for data collection – designated team members.
60	British Association of Urological Nurses	Additional statement suggestions	Does this draft quality standard accurately reflect the key areas for quality improvement? No The Quality Standards does not reflect current NICE Guideline NG2 Bladder cancer: diagnosis and management (2015) where priority recommendation 1.2.3, Offer white-light-guided TURBT with one of photodynamic diagnosis, narrow-band imaging, cytology or a urinary biomarker test (such as UroVysion using fluorescence in-situ hybridization [FISH], ImmunoCyt or a nuclear matrix protein 22 [NMP22] test) to people with suspected bladder cancer.
61	Ipsen	Additional statement suggestions	Ipsen welcomes the publication of the National Institute of Health and Care Excellence (NICE) Bladder Cancer Quality Standards to drive improvements in diagnostic techniques, treatment and care in bladder cancer which remains the seventh most common cause of cancer death in the UK. Ipsen agrees overall with the elements of the draft quality standards including patient safety, patient experience and clinical effectiveness. However, it is disappointing to see that the Quality Standards does not reflect current NICE's own Guideline NG2 Bladder cancer: diagnosis and management (2015) where priority recommendation 1.2.3, Offer white-light-guided TURBT with one of photodynamic diagnosis, narrow-band imaging, cytology or a urinary biomarker test (such as UroVysion using fluorescence in-situ hybridization [FISH], ImmunoCyt or a nuclear matrix protein 22 [NMP22] test) to people with suspected bladder cancer. Improved imaging techniques (Photodynamic diagnosis) shows the potential to reduce recurrence rates and thereby lowering the burden for the patients and treatment costs. Most patients present with early-stage non-muscle-invasive disease, between 13-61% will recur by 1 year post-transurethral resection of the bladder (TURB). Most cases of recurrence are due to incomplete visualization of the tumour at initial TURB and it is clear that the current standard of care for detection, white light cystoscopy (WLC), is inadequate.

ID	Stakeholder	Statement No	Comments
			Standard white light guided TURB has shown poor quality concerning complete removal of all tumour tissue. It is thought that up to 50% of high-grade Ta or T1 tumors are understaged at initial TURB following WLC which requires a second TURB to reassess resected areas incorporating this recommendation as a Quality Standard would prevent further investigations, further resources would mean that patients cancer is detected earlier and an appropriate treatment plan can be put into place. The NHS has a duty to deliver the best standard of care based on the latest evidence base and the role of NICE in developing evidence-based guidelines remains essential to achieve the ambition of the the recent Cancer Strategy, (Achieving world class outcomes, A strategy for England 2015-2020). Early diagnosis and patient experience are a priority within the strategy. Ipsen calls on NICE to revise quality statement 1 so that it clearly supports clinicians to use new imaging technologies to make a diagnosis in line with NICE Guidelines on Bladder Cancer. The urological cancers (which includes bladder cancer but excludes prostate) consistently appears at the bottom of table of patient satisfaction comparisons of all cancer types in the national patient survey. The prolonged pattern of intrusive procedures that dominate investigation, treatment and follow-up regimens for bladder cancer may contribute to this position. Improving the Quality Standard 1 to support new imaging technologies will improve diagnosis, treatment, care and outcomes of patients and will assist with delivering strategic priorities. The change in quality standard would be measurable (patient experience and outcomes), data can be collected using the Bladder Cancer audit tool already produced by NICE as part of the Guideline
62	The Royal College of Radiologists	Additional statement suggestions	The RCR notes that the briefing paper supplied with the draft Quality Standard suggests CT or MRI staging before transurethral resection of bladder tumour. However, this suggestion is not included in the draft Quality Standard. The RCR would query the reason for this. The RCR suggests that CT or MRI prior to TURBT will almost certainly lead to some patients with non-muscle-invasive cancer having an unnecessary staging scan and therefore an increase in demand

ID	Stakeholder	Statement No	Comments
			for CT and MRI in patients with bladder cancer.
63	British Uro-oncology Group	Additional statement suggestions	Would like to see the time to definitive treatment included as an important quality standard. This is likely to save more lives than any of the existing statements. If definitive radical treatment is given more than 3 months after diagnosis, survival is adversely affected. There should be maximum time between TURBT and radical treatment such as 12 weeks. Would also like to see a standard including discussion of bladder reconstruction after radical cystectomy for appropriate patients. Also a standard of offering neoadjuvant chemotherapy.
64	NCRI/ RCP/ ACP	Additional statement suggestions	We would like to see the time to definitive treatment included as an important quality standard. This is likely to save more lives than any of the existing statements. If definitive radical treatment is given more than 3 months after diagnosis, survival is adversely affected. There should be maximum time between TURBT and radical treatment, such as 12 weeks. We would also like to see a standard including discussion of bladder reconstruction after radical cystectomy for appropriate patients. Also a standard of offering neoadjuvant chemotherapy.
65	British Association of Urological Surgeons	Additional statement on discharge to primary care (Question 4)	We recognise that this was a cornerstone recommendation of the NICE guidelines with anticipated clinical and economic benefits but implementing it has been met with some reluctance by many urologists. Without including this in the quality standards there is a risk that it will not be implemented losing many of the benefits particulalrly in terms of work load that would result. However whilst discharge after 12 months makes a lot of sense, there is not strong evidence that this will improve quality and until evaluated it may in fact be detrimental to some. This measure is not going to save lives, or make as much difference to care as other areas, including those mentioned below.
66	Royal College of Pathologists	Additional statement on discharge to primary care (Question 4)	Data should be collected to support the recommendation of discharging patients with low risk NMIBC to primary care after one year of being recurrence-free.
67	British Association of	Additional statement on	Yes, there is very wide variation in practice nationally. This should improve with introduction of mandatory records as per statement 4.

ID	*Stakeholder*	*Statement No*	**Comments**
	Urological Nurses	discharge to primary care (Question 4)	
68	British Uro-oncology Group	Additional statement on discharge to primary care (Question 4)	Whilst discharge after 12 months makes a lot of sense, there is no strong evidence that this will improve quality and until evaluated it may in fact be detrimental to some. This measure is not going to save lives, or make as much difference to care as other areas.
69	NCRI/ RCP/ ACP	Additional statement on discharge to primary care (Question 4)	Whilst discharge after 12 months makes a lot of sense, there is no strong evidence that this will improve quality and until evaluated it may in fact be detrimental to some. This measure is unlikely to save lives, or make as much difference to care as other areas.
70	DH	N/A	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.

Registered stakeholders who submitted comments at consultation

- Association of Cancer Physicians
- British Association of Urological Nurses
- British Association of Urological Surgeons
- British Uro-oncology Group
- Ipsen
- Merck Sharp & Dohme Limited
- National Cancer Research Institute
- NHS England
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Pathologists
- Royal College of Physicians
- Royal College of Radiologists