National Institute for Health and Clinical Excellence

Bladder Cancer
Scope Consultation Table
19 July - 30 August 12

Type (NB this is for internal purposes – remove before posting on web)

SH = Registered Stakeholders. These comments and responses will be posted on the NICE website after guideline development begins.
GRP = Guidelines Review Panel member. These are added to this table for convenience but will not be posted on the web.
NICE = Comments from NICE. These are added to this table for convenience but will not be posted on the web.
Non Reg = Comments from organisations and people who have not registered as stakeholder. These are added for convenience but will not be posted on the web.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Abbott Molecular	1	General	We would agree that that this covers all key areas, we note the much needed review of the most effective technologies for both monitoring and diagnosis with non-invasive urine tests. We would propose that the scope should also include a review of current best practice for diagnosis and monitoring in developed healthcare markets overseas.	Thank you for your comment. Evidence will be sought worldwide. However, the recommendations within this guideline will only apply to the NHS in England, Wales and Northern Ireland
SH	Association of Anaesthetists of Great Britain and Ireland	1	General	The AAGBI does not wish to comment on this guideline	Thank you.
SH	British Uro-oncology Group	15	General	Could include upper tract TCC	Thank you for your comment. We do not consider upper tract TCC to be within the remit of the bladder cancer guideline. The treatment is very different to bladder cancer and therefore this could be a suitable topic for a NICE guideline in the future.
SH	British Uro-	16	General	Could include management of toxicity e.g. cystitis	Thank you for your comment. We

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	oncology Group				acknowledge the importance of the adverse effects of the diagnosis and treatment of bladder cancer. We have added a topic on treatment of toxicities, including cystitis.
SH	Department of Health	1	General	Thank you for the opportunity to comment on the draft scope for the above clinical guideline. **I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.**	Thank you.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	22	General	At present, systemic therapies for urothelial cancer are lagging behind other tumour types in their incorporation of (expensive) novel, molecularly-targeted agents. However, this is likely to change in the near future, as current or imminent clinical trials produce new data. There are obvious implications for the use of predictive molecular and imaging biomarkers in guiding individual treatment decisions ("personalised medicine"), either for maximising efficacy and/or minimising toxicity. These can potentially impact on patients' quality of life (on an individual level) or on health economics (on a population level). Guidance would be welcome on a framework for the use of predictive biomarkers, as evidence emerges on novel agents, perhaps including recommendations for future biomarker research within clinical trials.	Thank you for your comment. We acknowledge the importance of this area for determining the future management of bladder cancer. The guideline will be covering chemotherapy for metastatic disease and will look for evidence on novel agents. However, the area of predictive biomarkers was not considered a high priority for inclusion within this guideline and will not be included as a topic.
SH	Pierre Fabre Ltd	1	General	Bladder cancer management will benefit greatly from NICE Review and Guidelines. Management may appear complex but, as we have seen with other tumour types, a complex task is only a sequence of smaller tasks performed to a consistent standard and in the right order. Good communication with all stakeholders is essential.	Thank you for your comment.
SH	Royal College of	1	General	All histopathological reports should comply with the latest version	Thank you for your comment. We will

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	Pathologists			of the Royal College of Pathologists dataset (2007), which is currently under review.	be recruiting a histopathologist to be a member of the GDG who we expect to keep us appraised with the update of the dataset.
SH	Society and College of Radiographers	1	General	• It is good that the information and support needs are included in the Qs. • Of concern that BCG is in short supply at the moment .	Thank you for your comment.
SH	Society and College of Radiographers	3	General	Clear guidance on follow up of patients will be very useful, as we suspect centres are going to be challenged to reduce follow up appts and convert to patient self management for some patients. Clear guidance of where follow up is required will provide the framework for appropriate use of resources etc	Thank you for your comment. We will be investigating optimal follow up within topic K of the draft scope.
SH	British Uro-oncology Group	6	3.1	Epidemiology does not mention the scenarios of locally advanced and metastatic urothelial cancer. Although metastatic disease is partly included locally advanced disease is not mentioned	Thank you for your comment. The epidemiology section of the scope is not comprehensive and a full needs assessment will be carried out as part of guideline development. The issues you have raised will be covered in the guideline. Muscle invasive disease will be considered from apparently organ confined disease through to metastatic disease.
SH	NCRI bladder	1	3.1	Epidemiology section does not mention the (relatively-rare, but	Thank you for your comment. The

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	cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology			clinically important) scenarios of locally-advanced and metastatic urothelial cancer. Metastatic disease is partly covered later, but locally-advanced disease is not.	epidemiology section of the scope is not comprehensive and a full needs assessment will be carried out as part of guideline development. The issues you have raised will be covered in the guideline. Muscle invasive disease will be considered from apparently organ confined disease through to metastatic disease.
SH	Pierre Fabre Ltd	2	3.1 a	Survival in women (5 year) appears to be 10% lower than for men (61% v 71%). This dramatic imbalance should be highlighted as it is unlike any other tumour type and merits investigation.	Thank you for raising this fundamental issue. We will be considering the reasons for this and what could be done to address it when reviewing the evidence.
SH	Royal College of Pathologists	2	3.1 c	Line 4 should state '(stages pTa, pTis and pT1 respectively)'.	Thank you for your comment – we have amended the scope.
SH	Pierre Fabre Ltd	3	3.2 c	Bladder cancer patients survive with good function for many years with appropriate observation and interventional management. There is an annual cost for maintaining patients in this long survival state but this appears to be very good value for money. The cumulative cost can appear high because many patients survive longer than with other tumour types (20 years). Bladder cancer management should not be branded as "expensive" until properly analysed.	Thank you for your comment. The term we used was reflecting the overall health care cost of managing bladder cancer.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of	2	4.1.1 b	In addition to urothelial carcinoma, rare histologies (e.g. squamous, adenocarcinoma, small cell carcinoma), are covered (sarcoma is not – section 4.1.2) but mention is not made of mixed histologies, involving one of the rarer types with urothelial carcinoma. Whilst this is understandable in epidemiological terms, guidance would be particularly welcome in a relatively	Thank you for your comment. We would expect the management of mixed histologies to be highlighted in the evidence review if they are of importance. We are also recruiting a histopathologist to the GDG.

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	Cancer Physicians, Joint Collegiate Council for Oncology			evidence-poor area, with wide variations in practice.	
SH	Royal College of Pathologists	3	4.1.1 c, d	Although urethra is said to be included, there are no specific management questions regarding this. Possible considerations might be 'How should treatment be modified for patients with disease in both the bladder and urethra or urethra only disease?' (This may be pertinent since intravesical therapy is less effective in the urethra.)	Thank you for your comment. The evidence that looks at the comparative outcomes for topics F, G and H will guide us to the appropriate management of this population.
SH	Royal College of Pathologists	4	4.1.1 e	Such a group might include patients with adenocarcinoma of urachal origin.	Thank you for your comment. We agree, and this population is covered within the scope.
SH	Action on Bladder Cancer	3	4.1.2	Guidance on management of patients with synchronous upper and low tract TCC	Thank you for your comment. This is covered by 4.1.2c.
SH	British Uro-oncology Group	7	4.1.2	There is no mention of important rare histologies such as adenocarcinoma, small cell carcinoma etc or of mixed histologies. Guidance is important as this area has little evidence available and there is considerable variation in practice. In metastatic disease, palliative chemotherapy is given often using the same regime as for urothelial pathology but this may not be evidence based.	Thank you for your comment. This is correct as this section covers groups that will not be covered. However, rare histologies are covered in section 4.1.1b. We would expect the management of rare bladder cancer including mixed histologies to be reported in the evidence review if they are of importance. We are also recruiting a histopathologist to be a member of the GDG
SH	British Uro-oncology Group	8	4.1.2	Upper tract urothelial cancer is not covered. There is a paucity of clinical data in this area and it is unclear as to whether these	Thank you for your comment. We do not consider upper tract TCC to be

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				tumours should be treated in the same manner as the same pathology (urothelial) in the bladder itself. There is ongoing UK lead research in this setting looking at the potential benefit of adjuvant chemotherapy (the POUT trial) and this NICE review should be an ideal opportunity to evaluate the data for upper tract urothelial tumours	within the remit of the bladder cancer guideline. The treatment is very different to bladder cancer. Upper tract TCC could be a suitable topic for a NICE guideline in the future.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	3	4.1.2	It is stated that (urothelial) carcinoma of the upper urinary tract (ureters and renal pelves) will not be covered. This seems rather surprising, particularly in the context of muscle-invasive and metastatic disease where there is a lack of clarity on whether it is or is not appropriate to treat tumours of similar histology but different clinical behaviour in the same way as lower tract tumours). Active research is under way in this field (e.g. the POUT trial of adjuvant chemotherapy for upper tract urothelial carcinoma, resected with curative intent). We would strongly recommend that management of the upper tracts is included.	Thank you for your comment. We do not consider upper tract TCC to be within the remit of the bladder cancer guideline. The treatment is very different to bladder cancer. Upper tract TCC could be a suitable topic for a NICE guideline in the future.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	4	4.1.2	There is no mention of important rare histologies such as adenocarcinoma, small cell carcinoma etc or of mixed histologies. Guidance is important as this area has little evidence available and there is considerable variation in practice. In metastatic disease, palliative chemotherapy is given often using the same regime as for urothelial pathology but this may not be evidence based.	Thank you for your comment, rare histologies are covered in section 4.1.1b. We would expect the management of rare bladder cancer including mixed histologies to be highlighted in the evidence review if they are of importance. We are also be recruiting a histopathologist to the GDG
SH	NCRI bladder cancer Clinical Studies Group,	5	4.1.2	Upper tract urothelial cancer is not covered. There is a paucity of clinical data in this area and it is unclear as to whether these tumours should be treated in the same manner as the same	Thank you for your comment. We do not consider upper tract TCC to be within the remit of the bladder cancer

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	Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology			pathology (urothelial) in the bladder itself. There is ongoing UK lead research in this setting lloking at the potential benefit of adjuvant chemotherapy (the POUT trial) and this NICE review should be an ideal opportunity to evaluate the data for upper tract urothelial tumours	guideline. The treatment is very different to bladder cancer. Upper tract TCC could be a suitable topic for a NICE guideline in the future.
SH	National Cancer Intelligence Network	2	4.1.2 c	We note that pelvic and ureteric tumours are specifically excluded from the scope. We believe this is an error as the two diseases commonly coexist and management of the kidney will be directly influenced by the management of the bladder and vice versa.	Thank you for your comment. We do not consider pelvic and ureteric tumours to be within the remit of the bladder cancer guideline. The treatment is very different to bladder cancer. Pelvic and ureteric tumours could be a suitable topic for a NICE guideline in the future.
SH	Pierre Fabre Ltd	5	4.3	These Guidelines will form a basis for future commissioning guidelines and the responsibility of primary care to identify relevant symptoms of bladder cancer and the appropriate time line for referral to secondary care should be specified. This may dictate the entry point into the treatment algorithm (and associated outcome) and is an essential part of the "contract" between primary and secondary care in a commissioning culture.	Thank you for your comment. We agree. Referral between primary and secondary care is dealt with by the NICE guideline on referral for suspected cancer. The GDG will be looking at the diagnosis and management of bladder cancer.
SH	Pierre Fabre Ltd	11	4.3	Follow up of patients after radical treatment is inconsistent across the country. What to do with patient without a bladder, how frequently do we follow-up after chemo-radiotherapy (bladder preserving) and who should follow up after chemo-radio.	Thank you for your comment; this is covered within topic K of the scope.
SH	Action on Bladder Cancer	1	4.3.1	Guidance on management of urethra at time of cystectomy, When should we do it and when should we leave it	Thank you for your comment. The evidence that looks at the comparative outcomes for the scope topics F, G and

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					H will guide us to appropriate management of this population.
SH	Action on Bladder Cancer	2	4.3.1	Follow-up of urethra after cystectomy how, how often in patients with conduits and neobladders	Thank you for your comment. The evidence that looks at the comparative outcomes for the scope topics F, G and H will guide us to appropriate management of this population.
SH	Action on Bladder Cancer	6	4.3.1	We discussed upper tract TCC only to exclude it, do we need a paragraph to that effect in the document as it is unlikely to be covered in any other guidelines	Thank you for your comment. We do not consider upper tract TCC to be within the remit of the bladder cancer guideline. The treatment is completely different to bladder cancer and therefore this could be a suitable topic for a NICE guideline in the future. The patient population has been excluded under section 4.2.1c.
SH	Action on Bladder Cancer	7	4.3.1	Clear and separate management pathway for low risk NMIBC would be good vs high risk NMIBC and MIBC	Thank you for your comment. Low risk NMIBC and high risk NMIBC and MIBC are covered within the scope. The final guideline will produce management pathways for these patient groups according to the evidence.
SH	Action on Bladder Cancer	8	4.3.1	Shortage of BCG may have influenced current practice and may dictate future BCG regimes/recommendations	Thank you for your comment. This has been acknowledged in the scope. The recommendations in the guideline will be based on the best available evidence.
SH	Allergan Ltd UK	1	4.3.1	The guideline committee may wish to consider evaluating the treatment outcomes for intermediate risk non-muscle invasive bladder cancer* to add to low and high risk already being considered.	Thank you for comment. We will review this terminology as part of the evidence.

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				*-M. Babjuk, W. Oosterlinck, R. Sylvester, E. Kaasinen, A. Böhle, J. Palou, M. Rouprêt. Guidelines on Non-muscle-invasive Bladder Cancer (TaT1 and CIS). Uroweb 2012. Available at http://www.uroweb.org/guidelines/online-guidelines/ (last accessed 20/8/2012)	
SH	Allergan Ltd UK	2	4.3.1	The guideline committee may wish to evaluate and separate the evidence for patients that are being treated following diagnosis versus those that are being treated for recurrence	Thank you for your comment. This patient group is included within the scope of the guideline (section 4.1.1d) and will be evaluated under the appropriate topics.
SH	Allergan Ltd UK	3	4.3.1	Will the guideline aim to make specific recommendations on the chemotherapy regimens to be used and whether they should be used as single instillation, multi instillation, adjuvant or neo-adjuvant for the different risk grading of bladder cancer?	Thank you for your comment. The guideline recommendations will be based on the analysis of the evidence.
SH	National Cancer Intelligence Network	1	4.3.1	There seems a basic question missing in the scope and that is: 'What is the optimum management for patients with locally advanced bladder cancer?'	Thank you for your comment. This question is covered in the scope under section 4.3.1H.
SH	Abbott Molecular	2	4.3.1 b	We would propose that this technology review should include commercially available 'molecular' in vitro diagnostics particularly in the light of proposed European Regulation relating to 'in-house' IVDs.	Thank you for your comment. Further interventions will be prioritised by the GDG for inclusion in the guideline based on criteria such as a) the likelihood that they have significant resource issues and b) there is variation in clinical practice, recommendations will then be based on the analysis of the evidence.
SH	Ipsen Ltd	1	4.3.1 c	We would recommend this key clinical issue is re-worded to include "the diagnosis and management of bladder cancer" rather than simply the diagnosis.	Thank you for your comment. The management of bladder cancer is covered in section 4.3.1 F, G and H. We have amended section 4.3.1c to include optimal endoscopic techniques

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					for diagnosing new and recurrent bladder cancer.
SH	Pierre Fabre Ltd	7	4.3.1 f, g, h.	Accurate and consistent intra- and inter-institutional assessment of stage and performance status has been an essential step towards uniform standards of treatment for other cancers. Specific measures to highlight the importance and skill of stage and PS assessment should be included.	Thank you for your comment. The importance of stage and performance status assessment in determining management will be analysed as part of the evidence review.
SH	British Uro-oncology Group	9	4.3.1 h	There is significant uncertainty with regard to the optimum systemic regime for chemoradiotherapy and variation in practice across the UK and this is an area where guidance is required.	Thank you for your comment. We agree.
SH	British Uro-oncology Group	10	4.3.1 j	Despite the lack of randomised data, adjuvant chemotherapy is still given in centres across the UK despite published guidelines from the EAU and UK based guidance is imperative.	Thank you for your comment. We agree.
SH	British Uro-oncology Group	11	4.3.1 j	Palliative chemotherapy is not mentioned for second line treatment. The use of second line chemotherapy in appropriately selected patients is in widespread use in the UK< with a number of agents under evaluation and the subject of ongoing trials . Outside of a clinical trial, a number of regimens are in widespread use eg weekly taxol and although the scope comments that second line treatment with vinflunine is excluded as it is the subject of its own guidance, second line chemotherapy for metastatic disease includes drugs other than vinflunine. It is therefore vital to include the area of second line chemotherapy in detail.	Thank you for your comment. We have added a topic on second-line chemotherapy (4.3.1j) but will not be able to consider vinflunine as it is being addressed by a NICE technology appraisal.
SH	British Uro-oncology Group	13	4.3.1 j	Elderly patients with metastatic disease unsuitable for cisplatin based chemotherapy need to be included	Thank you for your comment. We expect this patient population to be covered in the evidence review for section 4.3.1j.
SH	Ipsen Ltd	2	4.3.1 k	We kindly request that this recommendation also includes the endoscopic techniques used, for example…blue light cystoscopy	Thank you for your comment. We have amended section 4.3.1c to include optimal endoscopic techniques for

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					diagnosing new and recurrent bladder cancer.
SH	British Uro-oncology Group	1	4.3.1 a	Information needs including bladder preservation advantages and disadvantages and potential late toxicity of radiotherapy	Thank you for your comment. We have revised section 4.3.1a in order to consider what information and support may be required for the patient pathway rather than pre-judging the information needs of patients.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	6	4.3.1 a	Information needs including bladder preservation advantages and disadvantages and potential late toxicity of radiotherapy	Thank you for your comment. We have removed the examples from section 4.3.1a in order not to pre-judge the information needs of patients.
SH	Royal College of Pathologists	5	4.3.1 a	Another example might include impact on continence.	Thank you for your comment. We have removed the examples from section 4.3.1a in order not to pre-judge the information needs of patients.
SH	Pierre Fabre Ltd	6	4.3.1 b, c, d	This guideline should set out to identify the optimum diagnostic pathway for bladder cancer without being restricted to a limit to the diagnostic tools. Which specialties are involved (urology, pathology, radiology, oncology), what are the key decision points and what clinical skills will allow specific tests or procedures to be activated, delayed or omitted. This list should not be limited at this stage in the process.	Thank you for your comment. The final guideline will produce diagnostic and management pathways according to the evidence on clinical and cost effectiveness. The list is not exhaustive.

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SH	British Uro-oncology Group	2	4.3.1 d	Role of isotope bone scan for staging MIBC?. Role of PET scan.	Thank you for your comment. Further interventions will be prioritised by the GDG for inclusion in the guideline based on criteria such as a) the likelihood that they have significant resource issues and b) there is variation in clinical practice, recommendations will then be based on the analysis of the evidence.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	7	4.3.1 d	Role of isotope bone scan for staging MIBC?. Role of PET scan.	Thank you for your comment. Further interventions will be prioritised by the GDG for inclusion in the guideline based on criteria such as a) the likelihood that they have significant resource issues and b) there is variation in clinical practice, recommendations will then be based on the analysis of the evidence.
SH	Royal College of Pathologists	6	4.3.1 e	The presence or absence of muscle in the histological sample is imperative information.	Thank you for your comment. We agree.
SH	Royal College of Pathologists	7	4.3.1 e	Other examples include pathological stage, presence of CIS (local or distant), multifocality, presence of necrosis and histological subtype of tumour	Thank you for providing us with this information.
SH	British Uro-oncology Group	3	4.3.1 g	Role of radiotherapy for high risk NMIBC – especially patients not fit for surgery	Thank you for your comment. We have amended the scope of the guideline to include radiotherapy for high risk NMIBC (section 4.3.1g)
SH	NCRI bladder cancer Clinical	8	4.3.1 g	Role of radiotherapy for high risk NMIBC – especially patients not fit for surgery	Thank you for your comment. Whilst we acknowledge the importance of this

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	Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology				area, it was not considered a high priority for this guideline and will therefore not be included as a topic.
SH	Pierre Fabre Ltd	8	4.3.1 general	There is a great need for reliable systems to track patients with bladder cancer over many years so that those who subsequently go on to develop higher risk or muscle invasive disease can be identified early for treatment escalation. There are some examples of high quality practice that could be shared.	Thank you for your comment. We feel this issue will be covered under section 4.3.1K, but accept that we may not be able to make recommendations for all patient groups due to lack of evidence.
SH	British Uro-oncology Group	4	4.3.1 h	Health economics of different bladder preservation strategies	Thank you for your comment. A health economic review for published economic literature will be conducted for each question being addressed. De novo modelling will be undertaken for those topics considered to be a high priority by the GDG.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for	9	4.3.1 h	We welcome the inclusion of chemo-radiotherapy in the list of issues to be considered. There have been recent important additions to the evidence base, in the last few years, including UK-led studies which have resulted in UK practice being ahead of some other geographical areas. With the recent release of data from multiple studies in this area, there is uncertainty on the optimum systemic therapy to accompany radical radiotherapy (and consequent significant variations in practice across the UK) and guidance based on a thorough review of the available literature would be particularly valuable.	Thank you for your comment.

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	Oncology				
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	10	4.3.1 h	We welcome the inclusion of guidance on both neoadjuvant and adjuvant systemic chemotherapy for potentially-curable muscle-invasive disease. The evidence base is considerably stronger for neoadjuvant therapy than for adjuvant therapy, resulting in a higher uptake of neoadjuvant therapy than in almost any other geographical region, globally. However, there is still surprisingly widespread use of adjuvant chemotherapy on an individualised, off-trial basis, despite advice to the contrary in international guidelines and meta-analyses. Clear guidance is imperative. There is also widespread debate about the role of multi-modality management of loco-regionally advanced, node-positive (N1-3, M0) disease. It is clear that this is a poorer prognosis group and areas of unresolved debate include a) the role of nodal clearance and/or radiotherapy and b) the role of primary chemotherapy, prior to possible subsequent surgery or radiotherapy, the value of which is much less clear than for neoadjuvant chemotherapy. Recommended national standards would be of significant value.	Thank you for your comment. Thank you for this information. Both topics will be included in the evidence review for section 4.3.1h, and the GDG will make evidence based recommendations where possible**.**
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	12	4.3.1 h	There is significant uncertainty with regard to the optimum systemic regime for chemoradiotherapy and variation in practice across the UK and this is an area where guidance is required.	Thank you for your comment. This topic will be covered in the evidence review for section 4.3.1h, but accept that we may not be able to make recommendations for all patient groups due to lack of evidence.
SH	NCRI bladder	11	4.3.1 h	Health economics of different bladder preservation strategies	Thank you for your comment. We do

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	cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology				not know at this stage which topics will be a high priority for health economic analysis. This will be determined following a review of published economic literature and completion of a health economic plan.
SH	British Uro-oncology Group	12	4.3.1 j	Patients with incurable locally advanced bladder cancer or with metastatic disease who are unfit or unsuitable for cisplatin based chemotherapy are not included in the scope. Whilst there are currently ongoing clinical trials, guidance is required in this area.	Thank you for your comment. We expect this patient population to be covered in the evidence review for section 4.3.1j, but accept that we may not be able to make recommendations for all patient groups due to lack of evidence.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	13	4.3.1 j	Palliative chemotherapy other than first-line treatment for metastatic disease does not seem to have been considered. It is stated, later, that 2nd-line therapy with vinflunine is (rightly) excluded, because of separate guidance, under development. However the issue of 2nd-line systemic therapy is much larger than just vinflunine alone. There is widespread belief amongst UK non-surgical oncologists that chemotherapy can be of clinical benefit in this setting, and a variety of regimens are used, outwith clinical trials, on this basis, without any clear evidence of benefit. It seems imperative to explore this area and to issue guidance, perhaps including recommendations for prioritisation of future research.	Thank you for your comment. We have added a topic on second-line chemotherapy (section 4.3.1j) but will not be able to consider vinflunine as it is being addressed by a NICE technology appraisal.
SH	NCRI bladder cancer Clinical	14	4.3.1 j	A particular area requiring guidance, pending the results of on-going clinical studies, is the issue of appropriate systemic	Thank you for your comment. We expect this patient population to be

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	Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology			chemotherapy regimens for patients who have incurable locally-advanced or metastatic disease and whose renal function and/or whose performance status is not considered adequate for the safe administration of cisplatin-based chemotherapy . We would welcome specific guidance on how the group of patients with impaired renal function should be defined, in light of recent international attempts to address this.	covered in the evidence review for section 4.3.1j but accept that we may not be able to make recommendations for all patient groups due to lack of evidence.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	15	4.3.1 j	Similarly to point 7, above, guidance would be welcome on the administration of palliative systemic chemotherapy for patients who are outside the age ranges covered by the existing literature (particularly elderly patients).	Thank you for your comment. We expect this patient population to be covered in the evidence review for section 4.3.1j, but accept that we may not be able to make recommendations for all patient groups due to lack of evidence.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	16	4.3.1 j	Despite the lack of randomised data, adjuvant chemotherapy is still given in centres across the UK despite published guidelines from the EAU and UK based guidance is imperative.	Thank you for your comment. We will make evidence based recommendations where possible.

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SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	17	4.3.1 j	Palliative chemotherapy is not mentioned for second line treatment. The use of second line chemotherapy in appropriately selected patients is in widespread use in the UK< with a number of agents under evaluation and the subject of ongoing trials . Outside of a clinical trial, a number of regimens are in widespread use eg weekly taxol and although the scope comments that second line treatment with vinflunine is excluded as it is the subject of its own guidance, second line chemotherapy for metastatic disease includes drugs other than vinflunine. It is therefore vital to include the area of second line chemotherapy in detail.	Thank you for your comment. We have added a topic on second-line chemotherapy to the scope (section 4.3.1j) but will not be able to consider vinflunine as it is being addressed by a NICE technology appraisal.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	19	4.3.1 j	Elderly patients with metastatic disease unsuitable for cisplatin based chemotherapy need to be included	Thank you for your comment. We expect this patient population to be covered in the evidence review for section 4.3.1j, but accept that we may not be able to make recommendations for all patient groups due to lack of evidence
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate	18	4.3.1 j	Patients with incurable locally advanced bladder cancer or with metastatic disease who are unfit or unsuitable for cisplatin based chemotherapy are not included in the scope. Whilst there are currently ongoing clinical trials, guidance is required in this area.	Thank you for your comment; we expect this patient population to be covered in the evidence review for section 4.3.1j but accept that we may not be able to make recommendations for all patient groups due to lack of evidence.

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	Council for Oncology				
SH	British Uro-oncology Group	5	4.3.1 k	Frequency of cystoscopy in bladder preservation and length of follow up	Thank you for your comments. We expect this issue to be covered by section 4.3.1k, but accept that we may not be able to make recommendations for all patient groups due to lack of evidence.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	20	4.3.1 k	Frequency of cystoscopy in bladder preservation and length of follow up	Thank you for your comments. We expect this issue to be covered by section 4.3.1k, but accept that we may not be able to make recommendations for all patient groups due to lack of evidence.
SH	Royal College of Pathologists	8	4.3.1 l	Line 2 should have 'bladder' omitted, since the intractable pain may be due to secondary disease elsewhere.	Thank you for your comment. This guidance will focus on bladder cancer specific issues. There is existing NICE guidance on management of cancer pain. These include, Improving Supportive and Palliative Care for Adults with Cancer - Supportive and palliative care: the Manual http://www.nice.org.uk/nicemedia/live/10893/28816/28816.pdf and Opioids in palliative care - CG140 - Opioids in palliative care: safe and

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					effective prescribing of strong opioids for pain in palliative care of adults - National Institute for Health and Clinical Excellence
SH	Allergan Ltd UK	4	4.4	An additional outcome to consider may be time to recurrence or recurrence at 1 year, 2 years etc	Thank you for your comment. We feel these outcomes are already covered by disease free survival.
SH	British Uro-oncology Group	14	4.3.2 b	Vinflunine as second line chemotherapy. Please see point 11 above. Other agents are in widespread use in this setting	Thank you for your comment. We have added a topic on second-line chemotherapy (section 4.3.1j) but will not be able to consider vinflunine as it is being addressed by a NICE technology appraisal.
SH	NCRI bladder cancer Clinical Studies Group, Royal College of Physicians, Association of Cancer Physicians, Joint Collegiate Council for Oncology	21	4.3.2 b	Vinflunine as 2nd-line therapy – see point above. Other agents are in widespread use in this setting	Thank you for your comment. We have added a topic on second-line chemotherapy (section 4.3.1j) but will not be able to consider vinflunine as it is being addressed by a NICE technology appraisal.
SH	Pierre Fabre Ltd	9	4.3.2 b	The subject of 2nd line chemotherapy should be included in the scope for this Guideline. Patients that relapse after chemotherapy are not abandoned if they are considered likely to benefit from further treatment with alternative chemotherapy. The nature and quality of this chemotherapy is inconsistent. Access to this treatment is also geographically variable and would benefit greatly from an informed, structured review by NICE.	Thank you for your comment. We have added a topic on second-line chemotherapy (section 4.3.1j) but will not be able to consider vinflunine as it is being addressed by a NICE technology appraisal.

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SH	Pierre Fabre Ltd	10	4.3.2 b	Guidelines for 2nd line chemotherapy already exist elsewhere in Europe (EAU, ESMO) and we should not be left behind with this important gateway for treatment innovation.	Thank you for your comment. We have added a topic on second-line chemotherapy (section 4.3.1j) but will not be able to consider vinflunine as it is being addressed by a NICE technology appraisal.
SH	Action on Bladder Cancer	4	4.5	What chemo regimes are available for recurrent/metastatic disease. Vinflunine is not very good and not the only choice chemo, most oncologists would favour paclitaxel	Thank you for your comment. We have added a topic on second-line chemotherapy (section 4.3.1j) but will not be able to consider vinflunine as it is being addressed by a NICE technology appraisal.
SH	Action on Bladder Cancer	5	4.5	Management of toxicities of treatments, e.g BCG or radiation cystitis	Thank you for your comment. We amended the scope of the guideline to include interventions for bladder toxicity following radiation or BCG therapy. (Section 4.3.1m)
SH	Alliance Pharmaceuticals Ltd	1	4.5	In this section the following question is asked 'What are the most effective adjuvant intravesical chemotherapy regimens for low-risk and for High-risk non-muscle invasive bladder cancer?' We wondered whether in addition to this question, you would also consider ''What are the most effective adjuvant intravesical BCG regimens for low-risk and for High-risk non-muscle invasive bladder cancer?'', this question would then consider the evidence of the maintenance schedule vs. induction only.	Thank you for your comment. We have revised this draft question to "What are the most effective adjuvant intravesical therapy (chemotherapy or immunotherapy) regimens for low-risk and for high-risk non-muscle invasive bladder cancer?"
SH	Alliance Pharmaceuticals Ltd	2	4.5	We were wondering whether you would consider looking in to comparative studies reviewing efficacy of different strains of BCG? Only a small number of published studies have compared different BCG strains, however the publication of a prospective randomized comparison of induction BCG Connaught and induction BCG TICE is expected soon (Thalmann).	Thank you for your comment. We have reworded the draft question and this should allow inclusion of issues raised in your comment.

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SH	Society and College of Radiographers	2	3.2 d (page 2)	Interesting to note comment : The significant disease and treatment-related morbidity, the substantial use of NHS resources and the wide variation in practice makes a guideline on the diagnosis and management of bladder cancer a high priority. There is likely to be variation in current practice at every stage and with every intervention Knowing there is a tendency for variation in practice with RT # prescribing then careful wording within these guidelines will be essential to eliminate / reduce this, which will be helpful.	Thank you for your helpful comment. We agree.
SH	Pierre Fabre Ltd	4	4.1.1 & 4.1.2	Why are Renal Pelvis (C65) Ureter (C66) and Other Urinary cancers (C68) not included in this guideline? This exclusion will leave patients with cancer between Renal Cell (C64) and Bladder (C67) without structured NICE Guidelines or Guidance. These patients are managed by the same MDT and a small extension to this scope for this Guideline would cover the urinary tract and eliminate the risk of some patients not being covered by some form of NICE review.	Thank you for your comment. We do not consider upper tract TCC to be within the remit of the bladder cancer guideline. The treatment is completely different to bladder cancer and therefore this could be a suitable topic for a NICE guideline in the future.

These organisations were approached but did not respond:

ADDEPT
Allocate Software PLC
Amgen UK
Anglia cancer network
Association of Chartered Physiotherapists in Women's Health
Barnsley Hospital NHS Foundation Trust
Bladder and Bowel Foundation

British Association for Cytopathology
British Association of Urological Surgeons
British Medical Association
British Medical Journal
British Medical Ultrasound Society
British National Formulary
British Nuclear Medicine Society
British Pain Society
British Psychological Society
British Society of Interventional Radiology
Cambridge University Hospitals NHS Foundation Trust
Camden Carers Centre
Camden Link
Cancer National Specialist Advisory Group
Cancer Phytotherapy Service
Cancer Research UK
Capsulation PPS
Care Quality Commission (CQC)
Central Manchester and Manchester Children's Hospital NHS Trust
Central South Coast Cancer Network
Chartered Society of Physiotherapy
CLIC Sargent
Coloplast Limited
Department of Health, Social Services and Public Safety - Northern Ireland
East and North Hertfordshire NHS Trust
Greater Manchester and Cheshire Cancer Network
Greater Midlands Cancer Network
Hammersmith and Fulham Primary Care Trust
Health Quality Improvement Partnership
Healthcare Improvement Scotland
Hinchingbrooke Healthcare NHS Trust
Hindu Council UK
Independent Healthcare Advisory Services
Institute of Biomedical Science
Integrity Care Services Ltd.

Johnson & Johnson Medical Ltd
King's College Hospital NHS Foundation Trust
Lancashire Care NHS Foundation Trust
London Cancer
Luton and Dunstable Hospital NHS Trust
Medicines and Healthcare products Regulatory Agency
Mid Yorkshire Hospitals NHS Trust
Milton Keynes Hospital NHS Foundation Trust
Ministry of Defence
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 Institute for Health Research Health Technology Assessment Programme
National Patient Safety Agency
National Treatment Agency for Substance Misuse
NHS Connecting for Health
NHS Direct
NHS Plus
NHS Sheffield
North Essex Partnership Foundation Trust
North Trent Cancer Network
Northern Ireland Cancer Network
Nova Healthcare
Pan Birmingham Cancer Network
Parenteral and Enteral Nutrition Group
Partneriaeth Prifysgol Abertawe
Peninsula Cancer Network
Pfizer
Public Health Wales NHS Trust
Public Health Wales NHS Trust
Queen's University Belfast

Randox Laboratories Limited
Roche Diagnostics
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Midwives
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Psychiatrists
Royal College of Surgeons of England
Royal Derby Hospital
Royal Pharmaceutical Society
Royal Society of Medicine
Royal Surrey County Hospital NHS Trust
Salford Royal NHS Foundation Trust
Sandoz Ltd
Scottish Intercollegiate Guidelines Network
Sheffield Childrens Hospital
Social Care Institute for Excellence
South Tees Hospitals NHS Trust
South Wales Cancer Network
South West Yorkshire Partnership NHS Foundation Trust
Spectranetics Corporation
St Mary's Hospital
Tameside Hospital NHS Foundation Trust
UCL Partners
Urostomy Association
Walsall Local Involvement Network
Welsh Government
Welsh Scientific Advisory Committee
Western Cheshire Primary Care Trust
Westminster Local Involvement Network
Wirral University Teaching Hospital NHS Foundation Trust

York Hospitals NHS Foundation Trust
Yorkshire Cancer Network