Kidney Cancer: diagnosis and management

Consultation on draft scope
Stakeholder comments table

22/08/23 to 19/09/23

Stakeholder	Document	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Action Kidney Cancer	EHIA	1	10	Equality issues - EHIA document - 2.2 Age - please add that older people may not have access to technology or may find technology difficult to negotiate leaving them at a disadvantage when it comes to accessing online resources offering information and support. This may necessitate additional support from family, carers, and HCPs. Accessible formats for health care information and face-to-face appointments will need to be considered for these people. Information will need to be provided in an easy-to-read format to ensure older people are fully engaged in the decision-making process and can make informed choices about treatments. Difficulties travelling to tertiary referral centres due to cost, co-morbidities, disabilities, or the need to be accompanied by a family member or carer, may limit access to a broader range of treatment options. Older people are also more likely to have poor health literacy, resulting in them presenting with later stage cancers and limiting their ability to understand treatment options. Young adults (<45 years) diagnosed with kidney cancer or with a family history of kidney cancer	Thank you for your comments. The equalities issues that you have raised which are not already covered by the EHIA, have been added. The new additions are available in section 3.2 – the post-consultation version of the EHIA, under the sections for "age" and "other definable characteristics". Screening is excluded by the scope, and family members are not part of the included population. However, genetic assessment for people diagnosed with renal cell carcinoma is included under the area of 'Follow-up and monitoring'. Evidence will therefore be sought as part of an evidence review in this area. Question 5c in the scope includes the following draft review question 'Which adults with renal cell carcinoma should be offered genetic assessment and how does it influence treatment plans?' If evidence allows, the committee will be able to make recommendations in this area if they consider it appropriate.

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				should be screened for hereditary RCC. Young adults are also likely to experience financial toxicity because they are more likely to be on a lower income, zero hours contracts, or only have access to statutory sick pay. This will make it difficult for them to take time off work to attend appointments or if they need give up work due to side effects of treatment. Meeting the costs of travel to hospital appointments, accommodation and childcare when attending appointments will also be difficult for these people.	
Action Kidney Cancer	EHIA	1	10	Equality issues - EHIA document - 2.2 Race - please add a line about translation of information resources into different languages. Please add a line about black people with sickle cell disease have a predisposition to renal medullary carcinoma. Black people with sickle cell disease and a kidney tumour should be assessed for renal medullary carcinoma.	Thank you for your comments. The EHIA has been updated and notes that information and support materials may be needed in alternative formats and languages. In section 2.2 of the EHIA under 'Race', it is noted that renal medullary carcinoma predominantly affects young adults with African and African Caribbean heritage who have sickle cell trait, sickle cell disease or other hemoglobinopathies that cause sickling of the red blood

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					cells. The purpose of the EHIA is to highlight equalities issues the committee should take into account when making recommendations. We will raise this equality issue with the committee when we review the evidence around the diagnosis of renal cell carcinoma and make guideline recommendations on this topic.
Action Kidney Cancer	EHIA	1	10	Equality issues - EHIA document - 2.2 Religion or belief - some people have cultural/religious barriers to talking about toilet habits that prohibit them from discussing symptoms with their doctor.	Thank you for your comment, the EHIA has been updated to reflect this issue.
Action Kidney Cancer	EHIA	1	10	Equality issues - EHIA document - 2.2 Age - please add that older people may not have access to technology or may find technology difficult to negotiate leaving them at a disadvantage when it comes to accessing online resources offering information and support. This may necessitate additional support from family, carers, and HCPs. Accessible formats for health care information and face-to-face appointments will need to be considered for these people. Information will need to be provided in an easy-to-read format to	Thank you for your comments. The equalities issues that you have raised which are not already covered by the EHIA, have been added. The new additions are available in section 3.2 – the post-consultation version of the EHIA, under the sections "age" and "other definable characteristics". Screening is excluded by the scope but genetic assessment is included under the area of 'Follow-up and monitoring'. Evidence will therefore be sought as part of an evidence review in this area. Question 5c in the scope

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				ensure older people are fully engaged in the decision-making process and can make informed choices about treatments. Difficulties travelling to tertiary referral centres due to cost, co-morbidities, disabilities, or the need to be accompanied by a family member or carer, may limit access to a broader range of treatment options. Older people are also more likely to have poor health literacy, resulting in them presenting with later stage cancers and limiting their ability to understand treatment options. Young adults (<45 years) diagnosed with kidney cancer or with a family history of kidney cancer should be screened for hereditary RCC. Young adults are also likely to experience financial toxicity because they are more likely to be on a lower income, zero hours contracts, or only have access to statutory sick pay. This will make it difficult for them to take time off work to attend appointments or if they need give up work due to	includes the following draft review question 'Which adults with renal cell carcinoma should be offered genetic assessment and how does it influence treatment plans?' If evidence allows, the committee will be able to make recommendations in this area if they consider it appropriate.

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				side effects of treatment. Meeting the costs of travel to hospital appointments, accommodation and childcare when attending appointments will also be difficult for these people.	
NHS England	Scope	General	General	We strongly suggest the document makes reference to making reasonable adjustments. This is a legal requirement as stated in the Equality Act 2010. Adjustments aim to remove barriers, do things in a different way, or to provide something additional to enable a person to receive the assessment and treatment they need. Possible examples include; allocating a clinician by gender, taking blood samples by thumb prick rather than needle, providing a quiet space to see the patient away from excess noise and activity. We recommend including reference to the Reasonable Adjustment Digital Flag (RADF) and the RADF Information Standard which mandates all providers and commissioners of health services	Thank you for your comment. We have added a reference to the Reasonable Adjustment Digital Flag as suggested to section 3.2 of the EHIA under the section for disability. We will draw the committee's attention to the point about reasonable adjustments when drafting recommendations during development of the guideline.

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				and publicly funded social care to identify, record, flag, share, meet and review Reasonable Adjustments, including details of their underlying conditions. DAPB4019: Reasonable Adjustment Digital Flag - NHS Digital	
NHS England	Scope	General	General	We recommend including reference to the importance of Communication: Using simple, clear language, avoiding medical terms and 'jargon' wherever possible. Some people may be non-verbal and unable to describe verbally how they feel. Pictures may be a useful way of communicating with some people, but not all.	Thank you for your comments. 'Information, communication, advice and support for adults with suspected or confirmed renal cell carcinoma' is an area that is included in the scope for the guideline and if evidence allows, the committee may make recommendations in this area. The EHIA is intended to capture issues relating to equalities considerations that the committee may need to take into account when drafting recommendations. The issues you have raised around non-verbal communication have been added to the updated EHIA.
NHS England	Scope	General	General	Please note recent LeDeR research: kcl.ac.uk/ioppn/assets/fans-dept/leder-main-report-hyperlinked.pdf	Thank you for this information, which has been highlighted in the updated EHIA. The added information is available in section 3.2 under the section disability – the post-consultation version of the EHIA

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NHS England	Scope	General	General	The draft scope should consider cancer predisposition syndromes such as Von Hippel Lindau (VHL) in the section on genetics, in particular to consider making recommendations about how such patients should be managed and followed up in a multidisciplinary way.	Thank you for your comment. The scope includes genetic assessment under the area of 'Follow-up and monitoring'. Evidence will therefore be sought as part of an evidence review in this area. The scope includes draft review question 5c 'Which adults with renal cell carcinoma should be offered genetic assessment and how does it influence treatment plans?' If evidence allows, the committee will be able to make recommendations about cancer predisposition syndromes if they consider it appropriate.
NHS England	Scope	General	General	The draft scope should consider a service specification for services dealing with locally advanced renal cancer (e.g., multi-disciplinarity of surgical teams).	Thank you for your comment. We will not be covering service delivery and organisation in the guideline as there is already existing guidance that covers this, such as the Getting it right first time report published in June 2023. If the committee consider it appropriate they may cross refer to this or other suitable guidance.
NHS England	Scope	General	General	The draft scope should consider making recommendations about clinical trial recruitment in renal cancer teams to ensure access for all appropriate patients via MDT to agreed clinical trials portfolio.	Thank you for your comment. We will not be covering recruitment to clinical trials in the guideline as there is already existing guidance that covers this, such as the Getting it right first time report published in June 2023. Recruitment to clinical trials is discussed in section 4.6 of the GIRFT report 'Clinical trial discussion throughout the

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					treatment journey'. If the committee consider it appropriate they may cross refer to this or other suitable guidance.
NHS Wales Executive - Wales Cancer Network	Scope	General	General	I have read the guidelines sent and have no specific comments but will be very interested in reading the conclusions including which patients should have biopsies prior to surgery. Â Since we have been referring patients to London for surgery the percentage of patients having to undergo biopsy has massively increased and yet the number of patients having the surgery remains unchanged but surgery is delayed and biopsies are invasive and expensive, we only used to biopsy those with tumours under 4 cm but London seem to want everyone to have biopsy. Will be very interested to see what guidelines come from this.	Thank you for your interest in this guideline. As you will be aware from draft question 2b in the draft scope, it is intended that the evidence will be reviewed assessing biopsy versus no biopsy in adults with suspected renal cell carcinoma. All registered stakeholders will be notified when the guideline is published. We would welcome your feedback during consultation prior to publication.
Action Kidney Cancer	Scope	1	6	Please make it clear that this includes all rare subtypes of RCC, e.g., papillary RCC,	Thank you for your comments. We have amended the statement to make it clear that we will look at "Adults (18

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				chromophobe RCC, collecting duct RCC etc., and hereditary RCC e.g., von Hippel Lindau, Birt-Hogg-Dube, hereditary leiomyomatosis etc. We assume people with sarcomatoid RCC will also be covered by these guidelines? Should this definition include oncocytomas? Although mostly benign, a small proportion of oncocytomas can metastasise: https://pubmed.ncbi.nlm.nih.gov/9255250/ Oncocytomas follow the kidney cancer treatment pathway through diagnosis, biopsy and, sometimes, surgery. Likewise for category IIF, III or IV Bosniak cysts, which can turn malignant: https://radiopaedia.org/articles/bosniak-classification-system-of-renal-cystic-masses?lang=gb	years and older) with suspected or confirmed renal cell carcinoma, including all subtypes". Furthermore, the notes of the stakeholder workshop, which are available on the consultation page of the website, state that the intention is to include all sub-types of renal cell carcinoma in the searches for evidence. However, as they are rarer, there may be less evidence available on which to base recommendations relating to specific sub-types of renal cell carcinoma. The various sub-types of renal cell carcinoma that will be included in the searches will be detailed in the review protocols. We are covering the active surveillance of oncocytomas under section 5. 'Follow-up and monitoring' in the scope.
Action Kidney Cancer	Scope	1	9	Please add transitional cell carcinoma (TCC) to the list of exclusions.	Thank you for your comment. It has been clarified in the final scope that 'transitional cell carcinoma' is an alternative term for 'urothelial cell carcinoma'
Eisai	Scope	1	9	In exclusions - to be consistent. will it be good to include children and young people <18	Thank you for your comment. The scope for NICE guidelines does not specify obvious exclusions, for

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					example that children are excluded when the included population is stated as adults (18 years and older).
Kidney Cancer UK	Scope	1	16	(See P4 Ln89 comment below). We agree that the setting should include confirmed and suspected kidney cancer. However, there is a crucially important stage before this, which is the period in which the suspicion of kidney cancer is arrived at and the decision to refer for specialist diagnosis is taken. Our 2022 patient survey shows a high proportion of patients are initially misdiagnosed (22%) or diagnosed at a relatively late stage (43% said their cancer had already reached stage 3 or 4 at diagnosis. Ensuring they are referred for specialist investigation as early as possible is likely to help reduce these figures. The section on kidney cancer in the NICE clinical guideline NG12 Suspected Cancer: Recognition and referral does not include a full set of symptoms associated with kidney cancer and this	Thank you for your comments on NG12 Suspected Cancer. The suspected renal cancer recommendations on signs and symptoms for referral in this guideline are outside the scope of the kidney cancer guideline. We will pass on your comment to surveillance to be considered for future updates of NG12 Suspected Cancer. NICE Surveillance monitors guidelines to make sure they are up to date and decide what action to take if it is no longer valid or accurate. Thank you for highlighting the ongoing NHS Galleri trial, however this relates to population level screening which is outside of NICE's remit. NICE guideline NG12 Suspected Cancer covers identifying adults, young people and children with symptoms that could be caused by cancer. It outlines appropriate investigations in primary care and the selection of people to refer for specialist opinion. It

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				should be updated in line with this guideline to ensure rapid referral takes place. We have one additional point regarding the Galleri test, which is presently undergoing clinical trials (the NHS-Galleri Trial). This may have an impact on early diagnosis of kidney cancer, depending on the trial's results. Depending on the results of the trials and on if and how the test is approved for NHS use, we would simply like to draw attention to the possibility that the kidney cancer guideline might need to have inserted a comment regarding this test during the guideline's development. In addition, NG12 Suspected Cancer: Recognition and referral, might need to be updated with regard to the Galleri test. Kidney Cancer UK Patient Survey Report 2022. Published 2023. https://www.kcuk.org.uk/wp-content/uploads/2023/02/KCUK_Report-2022_EMAIL-1.pdf	aims to help people understand what to expect if they have symptoms that may suggest cancer.

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Eisai	Scope	1	16	Settings- it will be good to state the settings - primary, secondary, tertiary	Thank you for your comment. 'All healthcare settings' include primary, secondary and tertiary settings. Thus, no changes were made to the scope.
British Nuclear Medicine Society	Scope	2	6	With regards to imaging, we would like to ask the committee to consider the clinical and cost effectiveness of 99mTc-sestamibi SPECT-CT in the diagnosis of kidney tumours. Studies have shown that 99mTc-sestamibi SPECT-CT has a sensitivity of 92% and specificity of 88% for detecting renal oncocytomas compared to other lesions, and a sensitivity of 89% and specificity of 67% for detecting renal oncocytomas compared to chromophobe renal cell carcinoma. We would like to ask the committee to consider whether 99mTc-sestamibi SPECT-CT should be used in the risk stratification of renal masses. ref: Wilson MP, Katlariwala P, Murad MH, Abele J, McInnes MDF, Low G. Diagnostic accuracy of 99mTc-sestamibi SPECT/CT for detecting renal	Thank you for your comments. Area 2 of the scope 'Diagnosis and assessment of renal cell carcinoma' includes imaging. Review question 2a aims to assess the clinical and cost effectiveness of imaging for diagnosis in adults with suspected renal cell carcinoma. In addition, it seeks to identify which imaging investigations should be offered, to whom and under what circumstances. If evidence is identified on 99mTc-sestamibi SPECT-CT scans that meets the inclusion criteria in the review protocol for this topic, it will be included in the evidence review and considered by the committee when it makes recommendations.

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				oncocytomas and other benign renal lesions: a systematic review and meta-analysis. Abdom Radiol (NY). 2020 Aug;45(8):2532-2541. doi: 10.1007/s00261-020-02469-8. PMID: 32193593.	
Action Kidney Cancer	Scope	2	21	Treatment of kidney cancer can be difficult to understand for patients and their families, especially treatment of metastatic disease. Access to systemic anti-cancer treatments in the second line and beyond is complicated and dependent on what the patient had as their first-line treatment. This requires careful planning on behalf of the medical oncologist with respect to the ordering of drugs to get the most benefit from systemic anti-cancer treatment for advanced/metastatic RCC. This situation is often not adequately explained to patients before they start first-line treatment with systemic anti-cancer treatments. Lack of information prevents patients from making informed decisions about their treatment options from the outset. Many patients are unaware of the treatment options available to them when	Thank you for your comments. Area 1 of the scope recognises the importance of information, communication, advice and support needs and a draft review question is included on this area. NICE guideline NG197 Shared decision making, published in 2021, includes existing recommendations on patient decision aids (see section 1.3 of the guideline). The evidence will not therefore be reviewed in this area, but the committee may decide to draw on or cross refer to the existing recommendations in this area. The committee will also consider where patient decision aids could be of benefit and they can be developed where possible. In addition, if the committee consider it appropriate it may cross refer to other existing guidance in this area,

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				they start first-line treatment. Informed shared decision-making with their clinician would help make patients more aware of their treatment options and enable the patient and clinician to work in partnership to make the best possible decisions for the patient. Informed decision-making brings together the clinician's expertise, treatment options, evidence, risks, and benefits with the patient's individual preferences, personal circumstances, goals, values, and beliefs. Patient decision aids should be made available to patients to help them make informed decisions about their treatment. These guidelines should include the use of patient decision aids throughout the kidney cancer pathway, including when, where, and how decision aids are made available to patients.	such as the Getting it right first time report published in June 2023. This report highlights the role of a urological cancer clinical nurse specialist for the provision of information, communication, advice, and support in section 3.5. It also includes a section on shared decision making in section 3.5.

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				Patients should be under the care of a clinical nurse specialist throughout their treatment pathway, for the provision of information, communication, advice, and support.	
Kidney Cancer UK	Scope	2	21	We agree that the scope for information, communication, advice and support must cover suspected and confirmed renal cancer. In addition, we recommend adding two specific bullet points that will emphasise two specific areas within this scope that are particularly important: The period from diagnosis of suspected cancer (i.e. the scan) to the first consultant appointment. Many patients are told they might have kidney cancer from a scan but probably won't see a consultant for some weeks after that, even though primary care will have referred the patient on to a specialist. The period post-treatment - particularly after management of localised kidney carcinoma. This	Thank you for your comments. The two periods you identify are clearly times at which support and reassurance are of particular importance to patients and to their families and carers. For that reason, the draft review question specifies 'before, during and after treatment', in recognition of patients' needs at these times and the committee will endeavour to ascertain how those needs can best be met during development of the recommendations for this section of the guideline.

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				is an important time when patients need reinforcement that their treatment has been successful, but that they are also being monitored to ensure their cancer does not return.	
Action Kidney Cancer	Scope	2	24	Should informed consent for biopsy and surgery be covered here?	Thank you for your comment. This area of the scope describes the areas in which evidence will be reviewed. As it is standard practice to obtain informed consent for all procedures, including biopsy, the evidence will not be reviewed in this area.
Kidney Cancer UK	Scope	2	25	Under 'Diagnosis' we would strongly suggest management of symptoms pre-treatment is covered. This is something which often gets forgotten but for those who have, in particular blood clots, no one seems to manage it, despite it often needing hospitalisation when a clot blocks the ureter. Similarly, flank pain can be extreme, but pain management often does not happen. Patients are not given information about what to do if they get these symptoms so documenting this in the consultation will help to ensure that this aspect is not missed.	Thank you for your comment. Patient information and support is an important area and is captured under Area 1 of the scope which focuses on Information, communication, advice and support. The draft review question covers the period before treatment as well as during and after treatment. The committee noted that there are many pre-treatment symptoms that are managed outside of the kidney cancer pathway, which is why the guideline will focus on providing support and information for establishing these onward referrals and contact with other specialists.

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					Where management of specific symptoms are covered in other guidelines, we may cross refer as appropriate.
Eisai	Scope	2	27	Do we need to include staging?	Thank you for your comment. As noted in the 'Areas that will not be covered' of the scope, evidence on the accuracy of systems for classifying and staging tumours will not be reviewed. This is because systems such as the World Health Organisation Classification of renal tumours and the Tumour, Node and Metastasis (TNM) classification system are well established and in common use. However, the committee may choose to cross refer to these systems when making recommendations, where appropriate.
Action Kidney Cancer	Scope	2	31	Following diagnosis of kidney cancer, the care and treatment of all patients should be discussed by an MDT.	Thank you for your comment. As outlined in the scope, the guideline will not cover service delivery and organisation but if the committee consider it appropriate may cross refer to other existing guidance in this area, such as the Getting it right first time report published in June 2023.
British Society of Interventional	Scope	2	36	Please include non-thermal ablation into the non-surgical options	Non-thermal ablation in the form of irreversible electroporation is covered by NICE interventional procedures guidance IPG443 which advises that this intervention should only be used in the context of

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Radiology (BSIR)				Non-surgical interventions, including thermal (radiofrequency ablation, cryoablation and microwave ablation) and **non-thermal ablation (Irreversible Electroporation**) and stereotactic ablative therapy	research. NICE will continue to monitor new evidence in this area to inform its surveillance of the guidance. The evidence base for procedures with recommendations for 'research only' usually reflects the fact that they are not established procedures. As such, this will not form part of a review question in a guideline.
Action Kidney Cancer	Scope	2	40	Neoadjuvant therapy for RCC is not approved for use in the UK by the MHRA or NICE. Neoadjuvant therapy is not recommended in the EAU guidelines.	Thank you for your comment. While it is acknowledged that currently neoadjuvant therapies for renal cell carcinoma are not approved for use in the UK, stakeholders attending a scoping workshop noted that there is ongoing research in this area. Although the findings of that research may not be published before the guideline is published, the inclusion of neoadjuvant therapies in the scope provides an option to include them in future updates if there is evidence to support their use.
Action Kidney Cancer	Scope	2	48	Non-surgical interventions for locally advanced RCC also include thermal ablation in addition to stereotactic ablative radiotherapy. Remove	Thank you for your comments. Committee members confirmed that section 4 of the scope focuses on the management of locally advanced renal cell carcinoma. Thermal ablation has not been included as an

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				'radiotherapy' and refer to stereotactic ablative radiotherapy only.	intervention in this section as it is used for the treatment of small renal masses or cancers, usually of less than 3.5cm. In locally advanced renal cell carcinoma, the cancers are usually larger and have invaded the surrounding vasculature and so thermal ablation is not possible. Regarding radiotherapy, committee members confirmed that stereotactic ablative radiotherapy may be used to treat patients in the initial-stages of locally advanced renal cell carcinoma, but that conventional radiotherapy would be used for palliative care. As palliative care will not be included, radiotherapy has been removed from area 4 of the scope and as an example in review question 4a.
Action Kidney Cancer	Scope	2	51	Neoadjuvant therapy for RCC is not approved for use in the UK by the MHRA or NICE. Neoadjuvant therapy is not recommended in the EAU guidelines.	Thank you for your comment. While it is acknowledged that currently neoadjuvant therapies for renal cell carcinoma are not approved for use in the UK, stakeholders attending a scoping workshop noted that there is ongoing research in this area. Although the findings of that research may not be published before the guideline is published, the inclusion of neoadjuvant therapies in the scope provides an option

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					to include them in future updates if there is evidence to support their use.
Action Kidney Cancer	Scope	3	65/66/67	Clarify monitoring for long-term consequences of treatment for localised/locally-advanced RCC â€“ we need guidelines for frequency of monitoring, methods used and by whom?	Thank you for your comment. We aim to cover monitoring for long-term consequences for treatment of localised or locally advanced RCC in review question 5b: 'For adults who have had treatment for localised or locally advanced renal cell carcinoma, what is the most clinically and cost-effective follow-up strategy (based on method, duration, and frequency) for monitoring any long-term consequences of treatment and for early detection of recurrence or progression of disease?'
Action Kidney Cancer	Scope	3	68/69	Clarify monitoring for local recurrence and monitoring for distant metastases. Is this just chest/abdomen/pelvis scans or does it include bone scan for bone metastases, brain MRI for brain metastases etc. Please can we have some guidelines for monitoring for brain and bone	Thank you for your comments. As outlined in the scope under 'Follow-up and monitoring' evidence will be reviewed in the area of monitoring for local recurrence and for distant metastases. The committee agreed this is an important area and further detail such as the points you suggest, will be discussed during development of the protocols for the review questions. There is an existing

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				metastases?	NICE guideline, which includes recommendations on the investigation, management and monitoring of brain metastases which may be of interest. Please see recommendations 1.6 - 1.8 in NICE guideline NG99 Brain tumours (primary) and brain metastases in over 16's. The committee may cross refer to this guideline if appropriate.
Kidney Cancer UK	Scope	3	61	It would be useful to add an additional bullet point on the need to cover subsequent recurrence or spread as anecdotally we hear that sometimes there is inconsistency in referral from Urology to Oncology Please also refer to comments above on P2 Ln21	Thank you for your comment. The importance of follow-up after treatment is recognised in the scope and section 5 includes monitoring for local recurrence and for distant metastases.
University Hospitals Birmingham NHS Foundation Trust	Scope	3	65	I'd like to see a little more in the scope about the impact of the various treatments on renal function, and the implications of decreased renal function in this cohort. Whilst there is a mention of follow-up for long-term consequences for local disease, there are	Thank you for your comments. This section of the scope outlines the areas in which the evidence will be reviewed. The committee noted that while there may be some short term or acute consequences of treatment on kidney function, there is existing NICE guidance in this area (see NICE guideline NG148 Acute kidney injury: prevention, detection and management,

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				acute consequences and we're also involved with people with more advanced disease.	recommendations 1.5 and 1.6). The committee agreed that for this guideline, the priority is to review the evidence and make recommendations relating to any long-term consequences of treatment on kidney function. They agreed that they would cross refer to the sections of the NICE guideline on acute kidney injury where relevant and therefore we have not expanded the scope to cover acute consequences.
Action Kidney Cancer	Scope	3	75	Systemic treatment - mention combination therapies and impact of adjuvant therapy on subsequent sequencing of systemic treatments.	Thank you for your comment. Review question 6a will cover pharmacological systemic treatments (as monotherapy and in combination) recommended by NICE technology appraisal guidance and the guideline will cross refer to this guidance. Review question 6b will cover the positioning of non-pharmacological interventions amongst pharmacological treatments within the metastatic pathway. Evidence on effectiveness after adjuvant therapy will be considered for question 6b where relevant. For convenience, review questions 6a and 6b are as follows:

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					6a. What is the clinical and cost effectiveness of different pharmacological treatment regimens (for example immunotherapies and targeted drug therapies) for metastatic renal cell carcinoma in adults? (Relevant NICE technology appraisal recommendations will be incorporated into the guideline). 6b. What is the clinical and cost effectiveness of non-pharmacological interventions when used in combination with, or separate from pharmacological treatments, at different positions within the treatment pathway for metastatic renal cell carcinoma in adults? For example, cytoreductive nephrectomy, removal of lymph nodes, surgical removal of metastases, thermal ablation of metastases and radiotherapy (including stereotactic ablative radiotherapy).
Action Kidney Cancer	Scope	3	77	Need to clarify what treatment is given if adjuvant immunotherapy fails and the impact of adjuvant immunotherapy on subsequent sequencing of systemic treatments, i.e., rechallenge with immunotherapy if adjuvant immunotherapy fails?	Thank you for your comment. Review question 6a will cover pharmacological systemic treatments (as monotherapy and in combination) recommended by NICE technology appraisal guidance and the guideline will cross refer to this guidance. Review question 6b will cover the positioning of non-

					pharmacological interventions amongst pharmacological treatments within the metastatic pathway. Evidence on effectiveness after adjuvant therapy will be considered for question 6b where relevant. For convenience, review questions 6a and 6b are as follows: 6a. What is the clinical and cost effectiveness of different pharmacological treatment regimens (for example immunotherapies and targeted drug therapies) for metastatic renal cell carcinoma in adults? (Relevant NICE technology appraisal recommendations will be incorporated into the guideline). 6b. What is the clinical and cost effectiveness of non-pharmacological interventions when used in combination with, or separate from pharmacological treatments, at different positions within the treatment pathway for metastatic renal cell carcinoma in adults? For example, cytoreductive nephrectomy, removal of lymph nodes, surgical removal of metastases, thermal ablation of

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					metastases and radiotherapy (including stereotactic ablative radiotherapy).
Action Kidney Cancer	Scope	3	79	Ablation (cryotherapy, radiofrequency ablation, stereotactic ablative radiotherapy) can be used to treat oligometastatic disease. Oligometastatic disease can also be treated with metastasectomy, and systemic treatments. Stereotactic ablative radiotherapy is often used to treat single or small numbers of metastases in the brain. Whole brain radiotherapy is used for widespread brain metastases.	Thank you for your comment. The committee considered whether oligometastatic disease should be included as a separate area of the scope. However, it was agreed that there is no single definition of oligometastatic disease and that it is part of the spectrum of metastatic renal cell carcinoma. The treatments you suggest for the management of oligometastatic disease are the same as those that will be included and reviewed for metastatic renal cell carcinoma, so we expect any evidence on oligometastatic disease to be included in these questions. For these reasons, the committee did not consider that oligometastatic disease needed to be considered separately.
British Society of Interventional	Scope	3	82	Please include non-thermal ablation into the non-surgical options	Non-thermal ablation in the form of irreversible electroporation is covered by NICE IPG443 which advises that this intervention should only be used in the context of research. NICE will continue to monitor new evidence

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Radiology (BSIR)					in this area to inform its surveillance of the guidance. The evidence base for procedures with recommendations for 'research only' usually reflects the fact that they are not established procedures. As such, this will not be part of a review question in a guideline.
Action Kidney Cancer	Scope	4	89	Referral from primary care - Suspected cancer - recognition and referral - 1.6.6 Renal cancer - the list of sign/symptoms for referral for suspected renal cancer is incomplete and only includes haematuria. These guidelines should be enhanced to include back/flank pain, lump in the abdomen, night sweats, high blood pressure, fatigue, weight loss, anaemia, persistent cough etc. Action Kidney Cancer, Kidney Cancer UK and Cancer Research UK.	Thank you for your comments on NG12 Suspected Cancer. The suspected renal cancer recommendations on signs and symptoms for referral in this guideline are outside the scope of the kidney cancer guideline. We will pass on your comment to surveillance to be considered for future updates of NG12 Suspected Cancer. NICE Surveillance monitors guidelines to make sure they are up to date and decide what action to take if it is no longer valid or accurate.
Kidney Cancer UK	Scope	4	89	We note that this scope does not include referral from primary care. We agree with this, provided the guideline process will consider including a recommendation that NICE guideline NG12 Suspected Cancer: Recognition and referral be updated to include more information on potential early kidney cancer. (Please see comments above	Thank you for your comments on the NICE guideline NG12 on Suspected Cancer. The suspected renal cancer recommendations on signs and symptoms for referral in this guideline are outside the scope of the kidney cancer guideline. We will pass on your comment to surveillance to be considered for future updates of NG12 Suspected Cancer. NICE Surveillance monitors guidelines to make

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				on P1 Ln16). The NICE guideline on suspected cancer does not cover all symptoms of kidney cancer and must be updated in line with this guideline if referral from primary care is not to be covered herein. There should be a recommendation made to this effect.	sure they are up to date and decide what action to take if it is no longer valid or accurate.
Eisai	Scope	4	91	Is there a reason - accuracy of systems for classifying and staging tumors will not be included?	Thank you for your comment. As noted in the 'Areas that will not be covered' of the scope, evidence on the accuracy of systems for classifying and staging tumours will not be reviewed. This is because systems such as the World Health Organisation Classification of renal tumours and the Tumour, Node and Metastasis (TNM) classification system are well established and in common use. However, the committee may choose to cross refer to these systems when making recommendations, if appropriate.
Kidney Cancer UK	Scope	4	92	Whilst agreeing that palliative and end of life care are covered elsewhere in other NICE guidance, this guideline should at least acknowledge the need for palliative care to be integrated throughout the patient's treatment pathway. At	Thank you for your comments. While this guideline will not review the evidence in the area of palliative and end-of-life care, the committee may cross-reference to any relevant related guidance (including but not limited to

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				points in the pathway where this is particularly important, reference should be made to the relevant NICE guidance. It is particularly important to include the use of drug treatment relating to kidney cancer to preserve the quality of life rather than being curative, despite treatment for a cure being withdrawn. We believe it is important include this in the scope of this guideline because the nature of the treatments may be specific to kidney cancer.	palliative care), when making recommendations if it considers it appropriate to do so. Regarding using drug treatments to preserve the quality of life as opposed to using drug treatments with the intention to cure, the outcomes listed in the scope include quality of life and so where evidence is available, this will be considered.
Kidney Cancer UK	Scope	4	104	Please refer to P2 Ln21 comments. This question should include: * Information about diagnosis, treatment options, and potential side effects such as: - Biopsy effectiveness and risks	Thank you for your comments. This level of detail is not included in the scope, but your comments will be considered when the protocol for this review question is developed.

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				-The full range of applicable treatment options and their pros and cons -Pros and cons of receiving some treatments before or after surgery - Follow up and monitoring plans for patients with untreated kidney lesions. * Emotional support throughout the patient journey * Measures to tackle inequalities * Mental health support	
Action Kidney Cancer	Scope	4	116	Should we also ask about the risks of biopsy here? They are minimal, but it is still worth discussing. Also, what happens to the biopsy sample, how is it stored and how long is it kept, etc.? Given the heterogenous nature of kidney cancer, what is the sensitivity and reliability of the biopsy results, i.e., the rate of false positives?	Thank you for your comment. As is noted in the main outcomes section of the scope, adverse events and complications will be considered for all relevant review questions and for the question on biopsy this would include potential risks. The management of the biopsy sample would be determined by standard operating procedures at local service level and will not be covered by this guideline. Regarding the sensitivity and reliability of biopsy results, the committee discussed whether this

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					area of the scope should focus on the accuracy of diagnostic testing. It noted there are several existing systematic reviews of the evidence in this area, for example Marconi et al 2016. However, it also noted there is a gap in the evidence around the effectiveness and cost effectiveness of biopsy compared with no biopsy for adults with suspected renal cell carcinoma and agreed that the existing review question is a priority for the guideline.
Action Kidney Cancer	Scope	5	139/151	Neoadjuvant therapy for RCC is not approved for use in the UK by the MHRA or NICE. Neoadjuvant therapy is not recommended in the EAU guidelines.	Thank you for your comment. While it is acknowledged that currently neoadjuvant therapies for renal cell carcinoma are not approved for use in the UK, stakeholders attending a scoping workshop noted that there is ongoing research in this area. Although the findings of that research may not be published before the guideline publishes, the inclusion of neoadjuvant therapies in the scope provides an option to

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					include them in future updates if there is evidence to support their use.
Action Kidney Cancer	Scope	5	126	For all techniques and treatments, should we be asking about the risks/side effects of each treatment?	Thank you for your comment. As is noted in the main outcomes section of the scope, adverse events and complications will be considered for all relevant review questions.
British Society of Interventional Radiology (BSIR)	Scope	5	134	Consider including thermal and non-thermal ablation for evaluation	Thank you for your comment. Thermal ablation is included in this question as an example of a non-surgical intervention. Non-thermal ablation in the form of irreversible electroporation is covered by NICE IPG443 which advises that this intervention should only be used in the context of research. NICE will continue to monitor new evidence in this area to inform its surveillance of the guidance. The evidence base for procedures with recommendations for 'research only' usually reflects the fact that they are not established procedures. As such, this will not form part of a review question in a guideline.

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Eisai	Scope	6	173	Do we need to include management of recurrent renal cell carcinoma	Thank you for your comment. The evidence for the effectiveness of the interventions which would be used to manage localised recurrence of renal cell carcinoma after partial or radical nephrectomy (for example surgery, thermal ablation, stereotactic ablative radiotherapy) will be reviewed under area 3 of the scope, 'Management of localised renal cell carcinoma'. The interventions that would be used to manage recurrence as metastases to lymph nodes or other organs (e.g. systemic treatments, surgery, thermal ablation of metastases and radiotherapy), will be reviewed under area 6 of the scope 'Management of metastatic renal cell carcinoma'.
Eisai	Scope	7	193	The KCUK audit showed disparity in access to treatments and inequality within country. It also looked at gaps in early identification. Will it be good to consider these points?	Thank you for your comments. We will not be covering service delivery and organisation or reviewing the evidence around recruitment to clinical trials in the guideline as there is already existing guidance that covers this such as the Getting it right first time report published in June 2023. If the committee consider it appropriate they may cross refer to this or other suitable guidance. However, the findings of the Kidney Cancer UK audit are noted in the Equalities and Health Inequalities Assessment (EHIA). It may not be possible to address

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					some of the issues raised in the EHIA directly by making guideline recommendations (where they cover areas outside NICE's remit). However, the committee will consider the equality issues raised and endeavour to address them where possible in drafting recommendations.
Action Kidney Cancer	Scope	8	218	The main emphasis throughout these guidelines is on clinical and cost effectiveness. However, the most important outcome of treatment for both the patient, family members and carers are living for as long as possible with a good quality of life. Being able to go back to doing the things that they could do before their diagnosis, such as working, enjoying holidays, and socialising with family and friends, without the constant worry of the cancer returning or progressing. Quality of life (and side effects of treatment) should be given equal standing with clinical and cost effectiveness.	Thank you for your comments. As you will see from the main outcomes listed in the scope, quality of life is included with coping with side-effects of treatment given as one of the examples of how this measure may be reported in some studies. Where validated measures of quality of life are reported by studies, they will be extracted and synthesised in the same way as measures of effectiveness and cost effectiveness and presented to the committee to consider when making recommendations. Furthermore, it is worth highlighting that cost effectiveness analyses take into account multiple factors including quality of life, patient-reported outcomes, as well as clinical effectiveness.
Kidney Cancer UK	Scope & EHIA	General	General	We would like to draw attention to two pieces of evidence that, to date, have not been published in	Thank you for your comments and this helpful information. You will see the findings of the audit report

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				peer review journals: 1. The two-year retrospective audit, plus addendumA. We are planning to submit for publication a paper on this audit and we will keep NICE updated on progress. The reports can be accessed directly from our website by clicking on 'audit' and 'addendum' above, and the raw data are available on the CancerStat 2 database, which is only accessible to individuals who have an NHS email address. 2. The Kidney Cancer UK Patient Survey 2014 - 2023. All survey reports can be found on our website by clicking here and scrolling down. The latest report is directly available here. Please note that we will be publishing another survey report early in February 2024.	are reflected in the Equalities and Health Inequalities Assessment and reference has been made to the addendum to the audit report and the findings of the patient survey in the updated EHIA.

Registered stakeholders

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