Renal Stones

Consultation on draft scope
Stakeholder comments table

20/01/17 to 17/02/17

ID	Type	Organisation name	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
15	SH	British Association of Urological Surgeons	1	15-16	We think that "Urolithiasis" would be a better general term. Or even "Urinary Tract Stones". "Renal stone" as a generic term works does not work, because it is not very precise, and may cause confusion when the final document is generated. There were the same problems with developing later iterations of the European guidelines. Why not use the term "renal stone" for a stone in the kidney, or even "kidney stones" which would be better understood by the public, and "ureteric stone" for a stone in the ureter? This would avoid any confusion, since the treatment for these, and the timing of it, are potentially different. Most people would agree that conservative management for a 10mm asymptomatic renal (as in kidney) stone with repeat imaging in six months would be reasonable; most people would not use this approach for the same "renal" stone in the ureter.	Thank you for your comment. For clarity, we have removed the phrase "the term 'renal stones' should be taken to include ureteric stones" and specified 'renal and ureteric stones' throughout the document.
16	SH	British Association of Urological Surgeons	3	74-75	Another question relates to the monitoring of radiation exposure for females of childbearing age. Given all patients are at a degree of risk from radiation, including young men, who have a slightly higher likelihood of getting a stone in the first place, would seem appropriate. Why not broaden this to include men too?	Thank you for your comment. We have amended the wording to clarify that the guideline will look at the management of renal and ureteric stones in women of child bearing age. We also consider the risk of radiation exposure during imaging to be the same for men and non-pregnant women, and the risk is to the foetus, in cases of pregnancy. This paragraph was amended and made more generic, with pregnant women identified as a subgroup needing special consideration.
17	SH	British Association of Urological Surgeons	4	80-81	If mentioning pregnant women on the groups needing specific consideration, we should probably also mention children and also cystinuria is not specifically mentioned as a subgroup.	Thank you for your comment. Children are included in the guideline and this has been clarified in the scope. We consider Cystinuria to be a very rare condition that will be managed differently. Although the guideline will identify people with Cystinuria, it will not address how the person is managed.

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18	SH	British Association of Urological Surgeons	4	95	Would it be worth specifically mentioning "observation / monitoring" as an option for the asymptomatic renal (as in kidney) stone? This is obviously not suitable as a long-term strategy for an asymptomatic ureteric stone (other than in very exceptional cases) Some guidance over the timing for second-phase treatment would be useful. e.g. When to do SWL for Residual Fragments after a PCNL; when is the best time for a "second phase" flexible ureterorenoscopy after an initial one with stone fragmentation and JJ stent insertion. What is the best time for the second session of SWL in a patient being treated by shockwave. How long is too long between these sessions? What if there is a stent in situ??	Thank you for your comment. We have amended the question in 3.5 to "What is the most clinically and cost-effective management (surgical and non-surgical) of asymptomatic renal stones? The details of the review questions and protocols will be discussed and finalised by the Guideline Committee. Regarding your comment on 'second phase treatment', timing of interventions will be discussed with the committee, when the evidence has been reviewed.
19	SH	British Association of Urological Surgeons	5	101	Consider changing remit to pharmacological treatment for patients **with and without** clear metabolic results, not all patients have a metabolic screen. Empirical use of potassium citrate has a role - it would be useful to define this.	Thank you for your comment. This section has been amended. We are looking at pharmacological treatments for both groups. Details on the review protocols, including which pharmacological treatments to review, will be discussed and finalised by the guideline committee.
20	SH	British Association of Urological Surgeons	5	120-126	Would be interested if economic considerations could evaluate estimated economic impact of stone disease on the UK economy, as well as costs of treatment. Can this include an estimate of days lost in work due to stone disease and delays in its treatment?	Thank you for your comment. During the development of the guideline, the cost-effectiveness of alternative treatments/strategies/interventions will be considered rather than the 'cost of illness' of the disease area. In accordance with the NICE guidelines manual (2014) this guideline should take a NHS and personal social services perspective in line with the NICE reference case for interventions with health outcomes in NHS settings. Furthermore, productivity costs are not included in any NICE reference case. Exceptions do exist, for example where interventions in the workplace are being evaluated; however, this is not the case in this guideline. The impact of an individual's ability to work should be addressed through quality of life measures which will be incorporated in reviews of published evidence.
21	SH	British Association of Urological	6	127-156 Section 3.5	Key issues, will the guideline cover two stone related but important issues – management of obstruction and management of sepsis?	Thank you for your comment. NICE has developed guidance on the management of sepsis. Please see: www.nice.org.uk . We consider it unnecessary to

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		Surgeons				include the management of obstruction, because current practice is considered to be established in this area.
22	SH	British Association of Urological Surgeons	6	141-142	"What are the most clinically and cost-effective options for surgical treatment of symptomatic renal stones?" If we ask this question we know that the answer in terms of clinical effectiveness (i.e. rendering the patient stone free) will be PCNL>URS>SWL. A more relevant question to ask is "Which surgical treatments provide the best balance of clinical effectiveness, treatment risk and cost-effectiveness for patients with symptomatic urolithiasis?"	Thank you for your comment. The clinical question is worded according to the standard framework established by NICE. All questions will consider both the clinical and cost effectiveness. Details on the review protocols will be discussed and finalised by the Guideline Committee. The main outcomes listed in section 3.6 include adverse events.
23	SH	British Association of Urological Surgeons	6	137-145 Sections 3 & 4	As above, we suggest these should be divided into symptomatic and asymptomatic renal (kidney) and ureter. Section 5 would then be follow up in patients who have had "urolithiasis" or "urinary tract stones" according to the decision above.	Thank you for your comment. This guideline will cover management and follow up of both, renal and ureteric stones. And section 3.5 has been amended to clarify this. Details on the review protocols will be discussed and finalised by the Guideline Committee.
24	SH	British Association of Urological Surgeons	6	146-156	We think there is general agreement, which is evidence-based and reflected in other guidelines, that enhanced metabolic testing should be carried out on patients after a basic risk assessment. We would suggest that sending stones for biochemical analysis should be encouraged as the first part of a metabolic risk assessment. Furthermore, we recommend that section 5.2 should be preceded with a commentary on which patients (including based on stone biochemical type) more detailed metabolic tests should be performed for. IE define the "high risk" groups who might benefit (young, bilateral, early recurrence, pure stone composition etc)? As it stands the scoping question 5.2 seems to treat all patients the same. Lines 149-150 could be changed to "5.2 Which metabolic investigations should be performed on which patients presenting with urolithiasis?"	Thank you for your comment. 'Metabolic workup' has now been added as a separate key issue in section 3.5 of the scope and includes stone analysis and which metabolic investigations should be carried out. Details on the review protocols will be discussed and finalised by the Guideline Committee.
25	SH	British Association of Urological Surgeons	general		One (slightly pedantic) point on nomenclature: "ESWL" is a trade name registered to Dornier and the correct abbreviation for generic shockwave lithotripsy should be "SWL" and this is normally used (by organisations such as Endourological Society/ WCE).	Thank you for your comment. This has been amended to SWL throughout the scope.

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26	SH	British Association of Urological Surgeons	general		Overall we think that the document has a comprehensive feel and should make an excellent resource for stone patients and the Endourologists who treat them.	Thank you for your comment and for your contribution to the consultation process.
6	SH	British HIV Association	General	General	Please find below a summary of comments from the British HIV Association. The draft scope was circulated to our multi-disciplinary BHIVA Antiretroviral Treatment Guidelines Writing Group and the comments incorporate feedback from clinicians, pharmacists and patient representatives: . We suggest that HIV-positive individuals are included as one of the specific subgroups of people needing specific consideration, whether as a standalone topic or within a section on drug-related renal stones. HIV per se may increases the risk of renal stone formation and patients treated with the protease inhibitor class, in particular those on atazanavir, have a higher risk of renal stones. There is a higher risk of radiolucent stones which are poorly visible on CT and stones that are pure crystallised drug have been described. Based on this we suggest a low threshold for ureteroscopy for HIV-positive individuals presenting with renal colic with no visible stones on imaging to ensure radio-opaque stones are not missed and to enable stone analysis.	Thank you for your comment. We agree with your view and we have now added people who are HIV positive and having treatment with protease inhibitors as a specific subgroup of people identified as needing specific consideration as they have a higher risk of developing renal stones.
1	SH	Cambridge Healthcare Supplies Limited	2	30	Include provision for the primary care treatment of stones sized <5mm through pharmacological, dietary or lifestyle interventions. Although the working group have identified as 'no need to include' for this size of stone, if left untreated, in a significant proportion of patients the stones will progress to a relevant size.	Thank you for your comment. We are including people with stone sizes of less than 10mm. Also, both pharmacological and lifestyle interventions will be considered.
2	SH	Cambridge Healthcare Supplies Limited	4	95	Managing asymptomatic renal stones should also include pharmacological treatment e.g. potassium citrate. Such treatment should be included for symptomatic stones also. European Association of Urology Urolithiasis Guidelines.	Thank you for your comment. We amended the section 3.5 'Key issues and questions' to include pharmacological treatments in people who have or have had renal stones. Details on the review protocols, including which pharmacological treatments to review, will be discussed and finalised by the Guideline Committee during the development process.
3	SH	Cambridge Healthcare Supplies	6	143	Include metabolic analysis followed by cost effective pharmacological treatments, dietary and lifestyle changes.	Thank you for your comment. We have amended the scope to include surgical and non-surgical management of asymptomatic renal stones. Timing of when metabolic

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		Limited				investigations will be carried out will be discussed by the committee when the evidence has been reviewed.
4	SH	Cambridge Healthcare Supplies Limited	6	151	The most clinically- and cost-effective pharmacological treatments are not licensed for the treatment of renal stones e.g. potassium citrate. These are licensed for lower tract urinary infections (in general not limited to females) or for the alkalisation of urine hence a metabolic marker. The plethora of clinical data supporting the use of potassium/sodium citrate or potassium/sodium bicarbonate for the treatment of responsive renal stones could be used by NICE to request that the MHRA (Medicine and Healthcare products Regulatory Agency) licence these medicines for this indication. Currently provision of new clinical trial data is cost prohibitive but would be a requirement for the licence indication.	Thank you for your comment. Pharmacological treatments are included in the 'Key issues and questions' section of the scope. Details on the review protocols, including which pharmacological treatments to review, will be discussed and finalised by the Guideline Committee.
5	SH	Cambridge Healthcare Supplies Limited	General	General	GC membership should include a Renal Pharmacist and a Consultant in Chemical Pathology and Metabolic Medicine	Thank you for your comment. We have advertised for the positions suggested in your comment and will finalise the recruitment process in March 2017.
27	SH	Kidney Research UK	General	General	We are happy with the scope as it stands. The comments made by our representative at the scoping meeting have been incorporated.	Thank you for your comment and for your contribution to the consultation process.
8	SH	Newcastle University Hospitals of NHS Foundation Trust (Great North Childrens Hospital, Newcastle upon Tyne)	3	59	People with renal stones, including families and carers***.*** ***Does this include children too?***	Thank you for your comment. Children are included and this has been clarified in the scope.
9	SH	Newcastle University Hospitals of NHS Foundation Trust	3	69	explains why any groups are excluded from the scope. ***I think a line to explain exclusion of open surgery for renal stones and bladder stones needs a mention. Also a mention as to why children with renal stones were excluded from this draft needs a mention in The Equality assessment page.***	Thank you for your comment. Open surgery has been excluded from the scope as very few operations are performed per year and as the majority of surgical stone management is minimally invasive there would be insufficient up-to-date evidence for open surgical techniques.

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		(Great North Childrens Hospital, Newcastle upon Tyne)				Bladder stones are outside the remit of the guideline. NICE have been commissioned to develop a guideline on renal stones which is the general term form renal and ureteric stones. We consider the aetiology of bladder stones to be different and people with bladder stones would be managed differently. Additionally, children are included in the scope and this has been clarified.
10	SH	Newcastle University Hospitals of NHS Foundation Trust (Great North Childrens Hospital, Newcastle upon Tyne)	4	80	Specific subgroups of people identified as needing specific consideration. ***Does this include children with renal stones?***	Thank you for your comment. The scope includes children and this has been clarified. However, please note, children are not considered a special subgroup as they are part of the main population.
33	SH	Royal College of Pathologist	6	146	The scope should include more thorough investigation of recurrent stone formers who may have an inherited cause for their disease and may consequently be at risk of renal failure.	Thank you for your comment. We have included a separate section in the 'key issues and questions' to cover metabolic workup. Details on the review questions and protocols will be discussed and finalised by the Guideline Committee.
28	SH	Royal College of Pathologists	general	general	What is the rationale for excluding bladder stones? The same issues arise from these in terms of causation.	Thank you for your comment. This is outside the remit of the guideline. NICE have been commissioned to develop a guideline on renal stones which is the general term form renal and ureteric stones. We consider the aetiology of bladder stones to be different and people with bladder stones would also be managed differently.
29	SH	Royal College of Pathologists	4	97	The draft scope implies that no 'metabolic' (=biochemical) investigations are done prior to stone removal. Biochemical investigations should be done at the outset as may identify treatable causes (e.g. hyperparathyroidism). I suggest an additional section is inserted that includes biochemical investigation of renal stone formers PRIOR to	Thank you for your comment. We have edited the scope to clarify that metabolic investigations for people who have or have had renal stones are included.

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					treatment	
30	SH	Royal College of Pathologists	6	149 and section 3.5	As above, metabolic investigations are only considered post stone removal. Biochemical analysis should be done prior to interventions.	Thank you for your comment. We have included a separate section in the 'key issues and questions' to cover metabolic workups. Details on the review protocols will be discussed and finalised by the Guideline Committee. Timing for metabolic investigations will be discussed with the committee when the evidence has been reviewed.
31	SH	Royal College of Pathologists	General	General	There is no mention of paediatric stone disease and the importance of thorough metabolic investigations to exclude the possibility of inherited disorders that can have a greater impact on renal health of the patient and also other family members	Thank you for your comment. This has been amended to clarify that children are included.
32	SH	Royal College of Pathologists	6	143	Managing asymptomatic stones: presumably these are incidental findings on imaging. Is treatment necessary at all? This section should include assessment of relevant biochemistry and dietary advice prior to any other intervention.	Thank you for your comment. We have amended the scope to include surgical and non-surgical management of asymptomatic renal stones. Timing of when metabolic investigations will be carried out will be discussed by the committee when the evidence has been reviewed.
34	SH	Royal College of Pathologists	General	General	Analysis of renal stones should be carried out to direct treatment	Thank you for your comment. We are including the analysis of stones. Please see the draft question 6.2, which states: 'Which metabolic investigations, if any, should be performed for people who have had renal stones (including blood, urine and stone analysis)?'
7	SH	Royal Free London NHS Foundation Trust	5	101	Delete "without clear metabolic results", as this question will need to be asked for the groups with and without the results of a metabolic work-up.	Thank you for your comment. This section has been amended. We will look at pharmacological treatments for people with or without clear metabolic results.
11	SH	The Royal college of General Practitioners			In the draft scope it would be useful to evaluate clinical prediction score ssuch as STONE (Moore 2014) as there is concern about excessive radiation related to routine computed tomography scanning for patients with suspected renal stones. Moore CL et al. Derivation and validation of a clinical prediction rule for uncomplicated ureteral stone—the STONE score: Retrospective and prospective observational cohort studies. *BMJ* 2014 Mar 26; 348:g2191. (http://dx.doi.org/10.1136/bmj.g2191)	Thank you for your comment. Current UK practice is to take a history and conduct a clinical assessment of the patient before making a decision about imaging. , and We are not aware of any clinical prediction scores developed and validated in the UK, and the American prediction score is not widely used within the NHS, we therefore have not prioritised this as an area for inclusion in the guideline..
12	SH	The Royal	5	101	RCSEd believes there is a need for clear guidelines for patients with clear	Thank you for your comment. The identification of

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		College of Surgeons of Edinburgh			metabolic abnormalities. For example, what is best practice for patients with hypercalciuria and should all patienst with cytinuria be seen at a specialist clinic?	metabolic disorders will be included in the guideline but we will not cover the ongoing management of specific metabolic abnormalities.
13	SH	The Royal College of Surgeons of Edinburgh	General	General	Also clear guidelines on further metabolic tests – for example, if PTH is raised with normal calcium do we need to check Vit b12 prior to endocrine referral?	Thank you for your comment; 'metabolic investigations' are included in the scope in section 3.3. The available evidence will be reviewed and discussed by the guideline committee before making recommendations.
14	SH	The Royal College of Surgeons of Edinburgh	4	97	We also believe there is a need for clear guidance on frequency and duration of follow up protocols.	Thank you for your comment. This will be discussed with the committee, when the evidence has been reviewed.

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