Renal and ureteric stones: assessment and management (Feb 2019)

Consultation on draft guideline - Stakeholder comments table
18/07/2018 – 29/08/2018

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1	SH	Beat Kidney Stones	Guideline	12	4, 5, 6, 7, & 8	Why did the committee not recommend that further research was needed. Patients accepted this recommended guideline on face value but were concerned that if this diagnostic tool was in fact best practice, then the guideline in its present state would not be a strong enough justification to either use or purchase high value capital equipment?	Thank you for your comment. Although CT was found to be more accurate in terms of diagnosing renal and ureteric stones, it is well known that it carries greater radiation exposure than ultrasound, and there are risks in terms of exposure to children and young people. The Committee decided that the increased accuracy did not outweigh these risks. They concluded that these risks are well established and therefore further research would not add significant knowledge to make a research recommendation justifiable. Further, they also concluded that research for CT in a paediatric population would not be ethical given the known associated risks.
2	SH	Beat Kidney Stones	Guideline	20	25 & 26	Patients welcomed the committee's recommendation, however, for the information of non-Urologists and non-sufferers; some patients who have experienced SWL before have chosen urine expulsion and analgesics rather than SWL treatment.	Thank you for your comment. We have recommended watchful waiting as an option for people with renal stones to be considered, so patients can be managed conservatively. Choice of treatments should be made after an informed discussion between

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							the patient and health professional as part of the decision making process.
3	SH	Beat Kidney Stones	Guideline	26	4,5,6	A number of patients have made the point that long term cost savings invariably disappear because goal posts always move.	Thank you for your comment.
4	SH	Beat Kidney Stones	Guideline	26	4,5,6	Patients also wondered when the economic analysis took place, if the following was allowed for: the pain experienced during the SWL treatment when the anvil for shock waves is an organ and particularly a kidney; the short and long term damage to that organ; if the spine is used as an anvil for the shock waves and patients suffer pain for life as a consequence?	Thank you for your comment. The analysis was a cost analysis, however it was discussed narratively how the interventions themselves might have quality of life impact, for example, there is generally no anaesthetic with SWL so the pain may be more memorable, although with URS there may be post-operative pain and functional impact. The costing analysis only used the time horizon of the trials, and no long term trial data was available to identify any long term effects that you mention, but adverse events were included as part of the economic analysis.
5	SH	British Association of Paediatric Urologists	Guideline	4	7	Concern has been raised over the wording of section 1.3.1 There is a single evidence base which has been extrapolated to paediatric practice. Alpha blockers in children are problematic.	Thank you for your comment. The evidence base for the recommendation for alpha blockers in the paediatric population was not extrapolated, but based on a separate meta-analysis showing a clinical benefit of alpha blockers (see Evidence review D, section E.4). It has been acknowledged that alpha

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						Tamsulosin is available in a modified release format, so cannot be given in an appropriate dose for a child under the age of 12 Doxasocin can be given in an appropriate dose for paediatric practice but patient needs to have blood pressure monitored We would suggest that this section that the recommendation changes so that alpha blockers can be CONSIDERED in children, rather than offered.	blockers in paediatric practice is off licence, however this is common practice for this population. As per the Mokhless 2012 study, tamsulosin can be given in an appropriate dose (0.4 mg was given to children older than 4 years and 0.2 mg was given to younger children. Those who could swallow the whole capsule were allowed to do so otherwise the content of the capsule was evacuated in water or juice). Further, doxazocin is available as another option. The Committee acknowledged that BP monitoring could be needed for children with doxazocin but this may be just for the first dose. The Committee reviewed the evidence for medical expulsive therapy, and agreed that due to some uncertainty around the size of stones that derive benefit of alpha blockers, the recommendation should be amended to 'consider alpha blockers', rather 'offer alpha blockers'.
6	SH	British Association of	Guideline	5	General	The guideline only refers to 3 surgical forms of treatment modality – SWL, URS, PCNL. IN the paediatric population none of these modalities may be	Thank you for your comment. The Committee identified three surgical modalities to focus on, and these were

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		Paediatric Urologists				appropriate as the stone may have been caused by an anatomical abnormality which in turn may require an alternative modality of surgery – e.g. pyeloplasty (open, laparoscopic or robotic) for a PUJ obstruction which has resulted in stones. In small children the size of the available equipment may mean that some of these options are not available to the clinicians. We would like to see a comment which recognises that there may be a need in paediatric patients to use an alternative surgical treatment modality due to size or underlying anatomical abnormality.	thought to be applicable to the paediatric population as well as the adult population. The Committee agreed to exclude open, laparoscopic and robotic surgery from the guideline. They thought that open surgery is no longer appropriate or commonly used so this was not a relevant inclusion. Laparoscopic surgery is cross referred to (IPG212, 2007). The Committee noted that there is insufficient evidence for robotic surgery. As these modalities were not considered in the guideline the Committee was unable to make a comment, however this does not preclude the use of these methods. The Committee did however look at evidence for mini and ultra mini PCNL in the paediatric population and recommended that clinical judgement should be used when considering these methods.
7	SH	British Association of Paediatric Urologists	Guideline	5	9	We are concerned that certain families will use this document to try and force high risk surgery for their children. In the Paediatric Population there are a number of patients who have complex co-morbidities that make them unfit / high risk for surgery, whilst their stone is asymptomatic. The wording of this section implies that	Thank you for your comment. Recommendation 1.6.1 states that watchful waiting should be considered for all adults, children and young people for asymptomatic stones. A sentence has been added to the rationale and impact section in the

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						by refusing to offer surgery (which the clinician views as being in the patient's best interest) going against the wishes of the family means that we will be in breach of this guideline. It would be useful to have this recognised in the comments regarding watchful waiting	short version of the guideline to highlight that watchful waiting might be particularly beneficial to people with complex co-morbidities that making them unfit/high risk for surgery.
8	SH	British Association of Paediatric Urologists	Guideline	9	1	A strong feeling from the group was that all children should be referred to a clinician with expertise for assessment and metabolic investigation.	Thank you for your comment. The Committee agreed that many centres have paediatricians with an interest in nephrology. They also noted that there is an online protocol used by secondary care paediatricians to perform the metabolic evaluation, and children are only referred to specialist centres if an abnormality is identified. The Committee agrees that this is reflective of most centres. Therefore, the Committee agreed that children should get adequate metabolic assessment. They agreed that the current recommendation also gives clinicians necessary flexibility and would avoid unnecessary over referral to specialist centres. Based on this, and the fact that there was no evidence found to inform the recommendation, the recommendation has not been amended to be stronger.
9	SH	British Association of	Guideline	9	12	Suggestion that this should specifically mention Cola drinks which contain phosphoric acid and increase urinary oxalate excretion.	Thank you for your comment. The evidence found did not specify the type of carbonated drink consumed,

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		Paediatric Urologists				Avoiding carbonated drinks (especially Cola Drinks)	therefore the Committee agreed not to specify a particular type in the recommendation. The Committee was aware that there is conflicting evidence surrounding the various benefits and harms of different carbonated drinks, and as this was not reviewed they agreed not to specify any particular carbonated drinks.
10	SH	British Association of Urological Surgeons	Guideline	General	General	We feel that some of the recommendations in these guidelines are markedly at odds with some aspects of current practice by endourologists with an interest in stone disease in the United Kingdom. We have all been elected to the committee of the Section of Endourology of BAUS and represent current, mainstream opinions in British endourology. We are arguably the main stakeholders – it is us and the constituency we represent – that would have to make any guidelines produced work. It is in this context that we make our comments. We feel that that in some areas that have been reviewed too great a weight has been placed on poorly conducted studies. It should be emphasised that in our view it would appear that these guidelines apply only to patients with a single stone in the kidney or ureter at the time of presentation; many patients however have multiple stones at the time of presentation. The presence of a	Thank you for your comment. The Committee acknowledges that some of the evidence was of very low and low quality, and in these instances took this into account when making recommendations. Where evidence was low quality, the Committee also considered factors such as current practice, and clinical experience. NICE guidelines are evidence based and therefore recommendations have been based on the available evidence. Bilateral and multiple stones were not specifically excluded from the review, but are often an exclusion criteria of Randomised Control Trials due to their variability, in terms of size and location for example, and therefore the Committee was not able to comment on the treatment of these stones. The

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						second stone or indeed multiple stones in the patient at the time of initial evaluation may hugely influence any treatment recommendations. This is not acknowledged in these guidelines. Similarly there is no recognition of the role of the patient in the decision making about their treatment. In an era when the NHS , and indeed NICE, have put so much emphasis on the importance of shared decision making in modern patient care and indeed when NICE have published on it previously (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making), it is extremely disappointing that there is no mention of shared decision making in the context of urinary tract stone disease where patient factors are often key elements of the clinical decision making. The guidelines do make repeated reference to health economics. Though recognising the importance of economic choices in healthcare, we feel that a report from the National Institute for Health & Care Excellence should focus on clinical excellence, and not cost effectiveness when clinical excellence is compromised. Again, disappointingly, we feel that these guidelines fail to do this. This is particularly important as these guidelines could potentially be used by trusts in the UK to suggest to urologists how patients should be managed. We feel the care of patients with stone	Committee does acknowledge that people with multiple or bilateral stones may be treated differently than people with a single stone because of their stone burden, and this may impact on decisions made about treatment. Multiple stones should be judged on a case by case basis and the recommendations may not be applicable to these stones, this is acknowledged in the rationale and impact section for surgical treatments in the short version of the guideline. However, they also noted that it may still be appropriate to treat the target stone as per the recommendations. This rationale has been added to the discussion of evidence in evidence review F. NICE recognises the importance of shared decision making and patient choice in all of its guidance. The Patient experience in adult NHS services guideline, which includes the recommendations on shared decision making is highlighted in the guideline scope, as well as medicines optimisation, service user experience in adult mental health and medicines

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						disease could be severely compromised by trusts pushing urologists to follow these guidelines. It should also be noted that the European Association of Urology and the American Urological Association have both produced internationally recognised guidelines for the treatment of urolithiasis. To justify the expense of the use of taxpayers money to produce these guidelines they had to offer something uniquely appropriate for British urology. We are not sure that these guidelines offer a British perspective that is helpful to urologists beyond the aforementioned guidelines that pre-existed the initiation of the process that produced this draft document. We recognise that these guidelines are produced by a methodology that adheres strictly to a designated process. We believe this process has produced guidelines that are in many recommendations clinically inappropriate and will not offer excellence in patient care. It is our understanding that these draft guidelines have been produced after a lengthy process of consultations, meetings, data analysis and reviews in time dedicated to their production. We have had to produce this response in a short time frame (over the summer holiday period) and with no time allocated for meetings arranged to generate a response. It is possible with	adherence. All of these guidelines should be considered and followed alongside the current guideline. Links to these are provided in the NICE short version in the 'your care' section along with an outline of the broad principles around decision making. Please see https://www.nice.org.uk/about/nice-communities/public-involvement/your-care. No additional recommendations on these topics were included unless there are specific issues related to renal and ureteric stones. The Committee agreed that the shared decision making recommendations were directly applicable to the renal and ureteric stone population without the need for additional recommendations. NICE recommendations are worded 'offer' and 'consider' to indicate the need for a discussion with the patient about the treatment options and the importance of shared decision making. NICE, unlike other international guidelines, does take into account cost

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						further time that we may have additional comments beyond those we have listed.	effectiveness as well as clinical effectiveness. It is key to decision making on a national level that treatments recommended are based on evidence of cost effectiveness as well as clinical effectiveness, as the NHS has a limited budget and the opportunity cost of investment has to be considered. Although clinical excellence is of course the aim, there are not unlimited resources available to be able to support this, and the best balance between costs and benefits underpins NICE recommendations. With regards to the surgery recommendations, SWL was a scenario where a treatment was less effective but also less costly overall, and therefore the benefit of the more expensive interventions were not thought to justify their cost. These cost savings have an opportunity cost within other areas of the NHS. The NICE process aims to produce high quality, evidence based recommendations and places clinical excellence as a top priority.
11	SH	British Association of	Guideline	General	General	The document places PCNL firmly as a "reserve" treatment. PCNL is not a treatment that should be	Thank you for your comment. The Committee reviewed the available

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		Urological Surgeons				"considered only if URS or SWL have failed". This will increase the duration and cost of treatment. A PCNL for an 18mm lower pole or even renal pelvis stone is a good treatment – no stent, discharged stone free – for the appropriately chosen patient. In addition, in a set of guidelines that will be published in 2019, there is no mention of the possible role of mini-PCNL, or ultra-mini PCNL.	evidence and found that both URS and SWL were more effective than PCNL. Further, economic evidence demonstrated that PCNL wasn't as cost effective as SWL or URS. Mini and ultra mini PCNL were considered but there was limited evidence, and only in some stone sizes (larger stones). This is mentioned in the footnotes to table 1. It is reasonable to consider these in smaller stones but there was no evidence on which to make a recommendation.
12	SH	British Association of Urological Surgeons	Guideline	General	General	A number of statements are made in the discussion that we believe are incorrect. As an example "No evidence was found for the use of stents before URS" (p18 line 16). There is, and it is summarised in International Collaboration in Endourology: Multicenter Evaluation of Prestenting for Ureterorenoscopy. Jessen JP, Breda A, Brehmer M, Liatsikos EN, Millan Rodriguez F, Osther PJ, Scoffone CM, Knoll T. J Endourol. 2016 Mar;30(3):268-73.	Thank you for your comment. **NICE guidelines prioritise evidence from randomised controlled trials, as these are viewed as the most rigorous design and are least susceptible to bias. In this review, RCT evidence was available for SWL but not for URS, and the Committee agreed that this was sufficient to base recommendations on. This RCT evidence showed no benefit of stent use before SWL. As no RCT evidence was identified for URS, no recommendation was made for this. The cited study**

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							(Jessen 2016) is a retrospective, non-randomised observational study, therefore was not considered by the Committee.
13	SH	British Association of Urological Surgeons	Guideline	General	General	Finally, there is no suggestion or recommendations on whether PCNL is best performed in units performing a certain number annually; no comment on the role of the multi-disciplinary meeting in the treatment of stone disease; the role of local audit or the appropriateness of submission of data to national audits; there is no guidance about the appropriateness of the use of mobile lithotripsy although mobile units rarely offer treatment within 48 hours as is suggested in these guidelines. This has huge cost implications. There are no recommendations on which patients should be referred on for a tertiary opinion; no suggestions who should be sent for metabolic investigations; no comment on the role of modern percutaneous techniques; no comment on access to emergency interventional radiology. Comments or an opinion on many of these subjects would have added a British perspective and justified the time and cost of producing these guidelines.	Thank you for your comment. The configuration and delivery of services is not covered by this guideline and would need to be determined locally. The Committee agrees that as part of good practice the MDT delivering care should meet to discuss management options. You are correct that the guideline has not made a distinction between static or mobile lithotripters as this distinction was not made in the evidence. The cost of implementing the recommendation on SWL within 48 hours is dependent on the model of implementation used. The 'Getting It Right First Time' project has recently also published recommendations for urology and recommends networked models of care. The NICE Resource Impact work has also demonstrated that treating people with ureteric stones less than 10mm using SWL instead of ureteroscopy would be cost saving, although this excludes network costs. The Resource Impact tools are

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							available on publication of the guideline to help trusts and commissioners with planning implementation in their area. The guideline does include modern PCNL techniques (i.e. mini, ultra mini). This evidence can be found in evidence review F. However, as there was not much evidence regarding these techniques, the Committee concluded that clinical judgement should be used when considering these techniques, as outlined in footnotes 1 and 2 of the surgery recommendations table. No recommendation was made on who should be sent for metabolic investigations as no evidence was found to base this on. The Committee made a research recommendation to inform future practice.
14	SH	British Association of Urological Surgeons	Guideline	3	11	1.2 Pain relief The recommendation instructs the use of NSAIDs in the first instance and only opioids if NSAIDs and paracetamol have failed. There is no recommendation about how long should be allowed to test if these so called first line medications	Thank you for your comment. The committee decided not to specify the length of time to wait to see if first line medication has been effective. The amount of time for an NSAID to work will depend on the route of administration. The committee also

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						have been effective. Under these recommendations it is conceivable that a patient suffering with the intense pain of ureteric colic could be given NSAIDs, time given to see if this effective, followed by intravenous paracetamol and then time given to see if this is effective, before being given an opioid. This treatment plan could conceivably leave a patient in pain for over 1.5 hours or more before more potent analgaesic is given. Our first responsibility as doctors is to relieve pain. The recommended treatment plan potentially leaves patients with one of the worst pains that humans can experience in severe pain for far longer than I suspect any member of the committee would wish for themselves. A statement that starts "Do not use opiates…" will stop this group of medicines, often very appropriate for patients in severe pain, from being used unless in a last resort. This is poor medicine and not patient centred.	recognised that often these pain medications are given in parallel, and thought that the wording of the current recommendation still allows for this, whereas specifying timings would limit the recommendation, and potentially make unnecessary protocols, which the committee was keen to avoid. They concluded that clinicians should be allowed to base these decisions on the clinical situation, using their judgement and expertise. The evidence shows that NSAIDs and paracetamol are more effective than opioids in terms of pain relief. Based on this evidence, patients are likely to have their pain managed by the first or second line treatment (NSAID or paracetamol). Only in cases where both first and second line treatment has not worked would a patient be in pain for the amount of time that you have suggested, however the evidence suggests that this is not likely as NSAIDs or paracetamol are likely to resolve the pain. The Committee discussed recommendation 1.2.3 based on

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							stakeholder feedback. Although it was originally worded as 'do not offer…' to highlight that opioids should only be used if NSAIDs and paracetamol has been tried first and have not been effective, and to hopefully reduce the number of people receiving inappropriate opioids, the Committee concluded that this was too strong and open to misinterpretation. They amended the wording to 'consider opioids' with the original caveats.
15	SH	British Association of Urological Surgeons	Guideline	4	6	1.3 Medical expulsive therapy A large multicentre trial, published in the Lancet, should be the best evidence upon which we base current practice. Its results should carry more weight than a number of other poorly conducted trials with poor pre-study statistical advice. This study concluded that MET with tamsulosin or nifedipine results in: No change in spontaneous stone passage at 4 weeks for either drug vs. placebo or compared against each other. No difference when analysed by stone size or location. No difference in analgesic use or time to stone passage. We are fully aware of all the other studies published on this subject. We feel a meta-analysis of a number of poorly conducted studies serves to confuse the issue	Thank you for your comment. The Committee are aware that there is a high quality study that generally showed no difference between alpha blockers and placebo or calcium channel blockers and placebo. However, it is NICE methodology to consider all available and relevant evidence that meets the review protocol. NICE do not exclude studies based on study size or quality, as this is taken into account when each study and study outcome is assessed for the risk of bias. To exclude these studies would be inconsistent with all other NICE guidance.

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						(rubbish in results in rubbish out – poor data produces poor and incorrectly drawn conclusions in any meta-analysis) and as with any meta-analysis is subject to publication bias. We are not sure that correct critical processes have been applied to all the studies on this matter. Recommending the use of either medication, particularly nifedipine which is, I suspect, not used by any urologist in the UK, is very questionable. The evidence for tamsulosin is poor, generally evidence from small poorly conducted and statistically weak; in contrast the Lancet paper is large, statistically robust and well conducted. Further, recommending the use of off licence medication in children of a drug for which there is no evidence is very questionable.	The Committee did reconsider the evidence for tamsulosin, and concluded that as they were not able to consider <5mm compared to 5-10mm stone sizes separately, there was some uncertainty about the population that would benefit from alpha blockers, therefore they amended the recommendation to 'consider alpha blockers' rather than 'offer alpha blockers'. They also reconsidered the evidence for calcium channel blockers, and concluded that as there was no difference found between nifedipine and placebo, the intervention didn't meet the criteria of being effective; therefore they removed this recommendation. The Committee concluded that off licence medication use is common in paediatric practice, and that the recommendation allows clinical judgement to be used. Further, this recommendation was based on a separate meta-analysis which included evidence in the paediatric population that demonstrated a clinical benefit of alpha blockers.
16	SH	British Association of	Guideline	4	7 and more	1.3.1 (and others) Stone size	Thank you for your comment. The Committee agreed to use stone size

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		Urological Surgeons			generally	All recommendations for the determination of stone treatment are based on a single measurement of stone size. There is no mention of stone volume in these guidelines. Stone volume is a major factor in determining treatment. There is a huge difference in volume between a 15mm linear stone and a 15mm spherical stone.	rather than stone volume to categorise the evidence. This is because stone volume is rarely reported in the evidence. Stone volume is also difficult to measure compared to stone size and so potentially less helpful.
17	SH	British Association of Urological Surgeons	Guideline	4	13	1.4 Timing of Surgical Treatment 1.4.1 This needs to be clearer. The indications are *not* the same. Unrelenting pain should be treated urgently; stones that are having treatment recommended as they are "unlikely to pass" do not need urgent treatment clinically, although the socio-economic advantages of doing so are fully understood. Given that ESWL is the first line for all ureteric stones according to these guidelines, this means that all ureteric stones larger than 8mm or so should be treated within 48 hours. It is illogical to state that treatment (presumably including ESWL) should be commenced within 48 hours, then stating ESWL should be performed within 4 weeks (table) but simultaneously mandate surgical treatment (i.e. a URS and laser) within 48 hours. If timing is paramount, how can a four week time frame appear acceptable for one treatment modality whilst mandating a 48 hour treatment plan for another. Furthermore, there are *very significant* service implications with the statement that stones unlikely to pass should be treated within 48 hours. This means	Thank you for your comment. The Committee considered that people with ureteric stones and renal colic with: ongoing pain that is not tolerated, or stones unlikely to pass are both urgent populations, therefore the population referred to in recommendation 1.5.4 is a specific sub-set of the population referred to in table 1. There are risks associated with waiting for a stone to pass such as kidney obstruction. The reviewed evidence showed that the quicker a person with a stone is treated, the better the outcomes for that person. The timing of surgery recommendation (1.5..) specifies that the treatment should be offered within 48 hours which is the time frame based on the evidence.

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						URS and Laser needs to be available 7 days a week (such that patients admitted on a Friday afternoon would need to be treated by Sunday afternoon). Furthermore, since the first line treatment is ESWL, this implies that all units should have access to ESWL through the weekend.	The recommendations in the tables refer to a wider population, The timing of surgery recommendation of within 48 hours is referring to the first session only, this is explained in the Committee's discussion of the evidence. Table 2 of the surgery recommendations refers to the stone being cleared within 4 weeks. SWL is not the first line for all ureteric stones but is offered for those with ureteric stones <10mm, but it is only considered for those with ureteric stones 10-20mm, therefore it is not first line for all ureteric stones. The service implications of initiating the recommendations will be dependent on the model of implementation used. The 'Getting It Right First Time' project has recently also published recommendations for urology and recommends networked models of care. The NICE Resource Impact work has also demonstrated that treating people with ureteric stones less than 10mm using SWL instead of ureteroscopy would be cost saving, although this excludes network

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							costs. The Resource Impact tools are available on publication of the guideline to help trusts and commissioners with planning implementation in their area. NHS is a 7 day working service, therefore the committee view was that it is likely to be feasible to offer a first treatment within 48 hours.
18	SH	British Association of Urological Surgeons	Guideline	5	5	1.5.2 Staghorn stones in children ESWL is an increasingly outdated intervention for staghorn stones in children. If a child is to be anaesthetised, the aim should be to clear stone volume with a PCNL rather than simply stenting a child for subsequent ESWL which also requires general anaesthesia in the most part in children. Staghorn stones – and other stones – in children should be referred to a unit with a particular interest in paediatric stone disease. Increasingly these units offer a service with a paediatric urologist and adult stone surgeon working together so that modern stone treatment is available for children.	Thank you for your comment. There was no evidence for staghorn stones in the paediatric population, and the Committee considered that treatment for these stones may be similar to the treatment of >20mm stones. The Committee also considered current practice and clinical experience. Because of the lack of certainty they agreed that all surgical options should be considered, including SWL but also URS and PCNL. This allows the clinician to choose the most appropriate surgical option based on the clinical situation. The Committee concluded that if SWL is selected for children with renal stones >20mm, including staghorn stones, it should be performed in specialist centres with appropriate levels of expertise. This outlined in section 1.10.2 of evidence

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							review F, and has also been added into section 1.10.1 for additional clarity.
19	SH	British Association of Urological Surgeons	Guideline	5	8	1.6 Treatment Options The section on treatment reduces the treatment of stones to a set of pixels on a screen, without recognising that patients should be offered a number of options and should be involved with the decision making about which treatment is right for them as an individual. Indeed, quoting the NHS website, "Shared decision making is now consistently quoted as a '*key tenet*' of modern healthcare but is too often still not fully practised by clinicians or experienced by patients". Treatment decisions should be determined not only by the stone but also by other priorities of the patient. In an era where we must discuss consent in detail including discussing all other possible treatment options, the importance of offering choice to patients in the treatment of their particular stone in their particular situation is not suggested in these guidelines. This set of guidelines is a recommendation for British practice, yet they fail to put the guidelines in the context of British medicine, and key tenets of the NHS. There is no mention of the importance of patient choice in their treatment and that treatment is dependent on many other factors other than the stone. Failure to mention shared decision making represents a real missed opportunity to educate about this fundamental process of healthcare through these	Thank you for your comment. NICE recognises the importance of shared decision making in all of its guidance. The Patient experience in adult NHS services guideline, which includes the recommendations on shared decision making is highlighted in the scope, as well as medicines optimisation, service user experience in adult mental health and medicines adherence. All of these guidelines are expected to be considered and followed alongside the current guideline. Links to these are provided in the NICE short version in the 'your care' section along with an outline of the broad principles around decision making. Please see https://www.nice.org.uk/about/nice-communities/public-involvement/your-care. No additional recommendations on these topics were included unless there are specific issues related to renal and ureteric stones. The Committee concluded that the shared

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						guidelines in a condition where patient choice in their treatment is so relevant.	decision making recommendations were directly applicable to the renal and ureteric stone population without the need for additional recommendations.
20	SH	British Association of Urological Surgeons	Guideline	6	Table 1	Section on ureteric stones 10-20mm adults. Considering ESWL should not be the first treatment option. We do not know of many people who would do this, do not think that this is supported by the evidence, and this is not supported by EAU guidelines. Evidence in the guidance has shown that ureteroscopy is more effective with regard to stone removal and repeat treatments. There may be a shorter hospital stay, less pain and fewer adverse events with ESWL, but this does not make it a reasonable treatment option. Section on renal stones: Seems odd that PCNL is not first line consideration (with ureteroscopy (and ESWL)) for stones 10-20mm given the evidence outlined, and it is surprising that the balance of benefits leads the committee to ureteroscopy or ESWL for these stones. It is not a surprise that the cost argument for these two treatments wins over PCNL, and this seems to have swayed the committee incorrectly in our opinion.	Thank you for your comment. The recommendation on SWL for ureteric stones 10-20mm is a 'consider' recommendation (if local facilities allow), whereas the first line treatment is URS which is an 'offer' recommendation. You are correct the SWL is less effective but more favourable when it comes to adverse events; however there is also a cost difference between the two types of treatments. Even when considering retreatments of SWL for some people, SWL is still likely to be the less costly option. This was proven for the ureteric stones <10mm, and based on that, but also considering that larger stones are likely to have more risks, the Committee acknowledged that there could be a use for SWL in this group, which is why the recommendation takes a weaker form for SWL than URS, and caveated with a timeframe to ensure timely treatment. It was also acknowledged

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							that the range of stone sizes within a subgroup (10 to 20) is large, and SWL may well be a feasible option for a stone at the lower end of the range. In the renal stones 10-20mm subgroup, the evidence showed little difference in effectiveness between URS and PCNL. This was contrary to what the Committee was expecting, and therefore on balance PCNL did not offer enough additional benefit to justify the cost.
21	SH	British Association of Urological Surgeons	Guidel ine	8	8	1.7 Use of Stents after Ureteroscopy 1.7.1 The phrasing of this important sentence should be adjusted. It is easy to read this as "patients should not be stented" for stones <20mm. Whilst longer, something along the lines of *"The decision to insert a stent after ureteroscopy should be an active decision, based upon the specific pre-operative imaging and intra-operative findings, and should be documented as part of the operation note. This should include the intended duration of drainage and state the plans for its removal. Stenting all patients as a matter of routine should be avoided."* Furthermore, the recommendation that patients should not be stented for stones less than 20mm is unfortunately an example of a set of guideline produced by a committee looking at papers on a subject which	Thank you for your comment. The Committee agreed that routine stenting is not supported by the evidence. The 'Committee's discussion of the evidence' section in evidence review I outlines when a stent would be considered, including when there is evidence of infection or obstruction. Choice of treatments should be made after an informed discussion between the patient and health professional as part of the decision making process.

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						are often small series not addressing the real question as to why we stent. This recommendation in the view of many urologists lacks clinical realism. We recognise that stents cause frequency, urgency and dysuria as you state in your evidence. Stents prevent the devastating complication of post-operative sepsis with obstruction. No study to date has been done to show this as the study would need to be very large, but failure to stent could result in patients with severe sepsis post-operatively needing lifesaving emergency intervention. Additionally, stents help prevent post-operative renal pain, the pain with which the patients present and the pain clinicians hope to relieve by their intervention.	
22	SH	British Association of Urological Surgeons	Guideline	8	11	1.8.1"Consider" stone analysis is weak and there is no suggestion in which patients it should be 'considered'. When there is a stone available to send, it should be analysed. This is the equivalent of our histological diagnosis, and the opportunity to have it should not be given up. There may be limited "evidence" but surely a stronger recommendation should be made. We doubt there is any good evidence for sending a removed appendix for histology in patients who have it removed for right iliac fossa pain, but cannot imagine that guidelines saying "consider sending the appendix for analysis" would be well received by general surgeons!	Thank you for your comment. No evidence was identified to evaluate the clinical or cost effectiveness of stone analysis on a renal stones population level. An economic analysis would involve taking into account the cost of testing everyone, in order to identify metabolic abnormalities in a smaller proportion of people. For the largest stone composition group (calcium formers), additional tests would also be required to form a full picture on why the patient formed a stone which means larger costs can accrue as metabolic testing can be quite patient

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							specific depending on the results of different tests. An analysis would also need to consider the treatment that those individuals would receive for the underlying conditions identified and the future stones avoided and quality of life improvement. Therefore evidence required would need to show the balance between the cost of testing all, and the benefits of improvement in the proportion picked up with an abnormality. A test and treat type trial is needed to provide the clinical data required to prove both clinical and cost effectiveness of metabolic testing, and why a research recommendation was made.
23	SH	British Association of Urological Surgeons	Guideline	8	12	1.8.2 Similarly, "consider" sending blood for Calcium sounds like this is not that important. Hyperparathyroidism is quite common, particularly in stone formers, and cannot be detected without serum Calcium assessment as the initial step. A delayed diagnosis risks recurrent stones, and even nephrocalcinosis and renal impairment. Missing this diagnosis has huge clinical and cost implications for the NHS. A simple blood test should be sent, in all patients but particularly in patients who have recurrent or large volume stones. Again, there is no advice in which patient group it should be 'considered'.	Thank you for your comment. The Committee considered this recommendation and noted that there is variation in current practice, with a full range of metabolic tests being done in some areas and fewer tests in others. However, the Committee also considered that PHPT is an underdiagnosed condition that often is indicated by the presence of stones.. Based on this, and the fact that it is an inexpensive test the Committee agreed to change the recommendation

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							from 'consider…', to a stronger recommendation to 'measure calcium…'. As there was no evidence found, the Committee was not able to specify a particular patient group.
24	SH	British Association of Urological Surgeons	Guideline	9	1	1.8.3 All children with stones should have specialist referral and treatment. The surgery is bespoke, and the likelihood of metabolic abnormalities, and of future recurrence, much greater. "Young people" should stipulate the actual age – perhaps <16?	Thank you for your comment. The Committee agreed that many centres have paediatricians with an interest in nephrology. They also noted that there is an online protocol used by secondary care paediatricians to perform the metabolic evaluation, and children are only referred to specialist centres if an abnormality is identified. The Committee agrees that this is reflective of most centres. Therefore, the Committee agreed that children should get adequate metabolic assessment. They agreed that the current recommendation also gives clinicians necessary flexibility and would avoid unnecessary over referral to specialist centres. Based on this, and the fact that there was no evidence found to inform the recommendation, the recommendation has not been amended to be stronger.

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							A definition of the age of children and young people has been added to the 'terms used in the guideline' section which has been linked from the short version of the guideline.
25	SH	British Association of Urological Surgeons	Guideline	9	7	1.9.1 The recommendation of "2.5 to 3 litres of water" per day – does this really mean water? And other liquid as well? Stone risk is based on the volume of urine produced, not the amount of fluid consumed, and this might be better as aiming to produce 2.5 L of urine per day, for which a fluid intake of 2.5-3L is generally required on average, but this will vary according to patient factors including weight, daily activities, etc. Where does the recommendation of "avoiding carbonated drinks" come from? There is evidence that supports their use (e.g. diet 7 up for its citrate content). Is the carbonated issue so strong that it mitigates the extra 330ml of fluid intake? Is this because of pH? If so is it for all stones?	Thank you for your comment. The reviewed evidence was only for water. The Committee considered that other types of fluid (such as coffee, alcohol, fruit juice) may be associated with various advantages and disadvantages and may differ from water in terms of their effectiveness at preventing a recurrence of stones. However the Committee specified water only because this was the only type of fluid that had evidence of effectiveness. Measuring urine volume is difficult for patients to do, and although the Committee acknowledge that fluid output may be a better indicator of stone risk, they agreed that this is often impractical, and so decided not to amend the recommendation. A RCT showed a benefit of not drinking carbonated drinks in terms of stone recurrence when they compared outcomes in a group of people who did

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							not drink carbonated drinks to a group of people who could drink carbonated drinks, although the type of carbonated drinks consumed was not reported. Advice to avoid carbonated drinks reflects current practice. The Committee noted that there is no available evidence on whether the harm of carbonated drink mitigates the advantages of the extra fluid intake and so could only comment based on the available evidence.
26	SH	British Association of Urological Surgeons	Guideline	9	22	1.9.3 The recommendation to treat calcium oxalate stones with potassium citrate is placed in these guidelines in a context of barely recommending any metabolic investigations. The only way of confirming that a stone is calcium oxalate is by sending a piece for analysis. Putting such an emphasis on metabolic treatment with such low emphasis on metabolic investigation is an unusual suggestion of how medicine should be practiced. What about the use of Potassium citrate in Uric acid stones and cystine stones for alkalinisation?	Thank you for your comment. Stone analysis has been recommended as a 'consider' therefore the stone composition will be identifiable for those who provide these tests. The guideline acknowledges that there are limited recommendations regarding metabolic testing. This was due to a lack of evidence to base recommendations on. The Committee agreed to make a research recommendation to inform practice in future to allow for stronger recommendations to be made.
27	SH	British Association of Urological Surgeons	Guideline	10	1	1.9.4 There is no suggestion of which cohort of patients with stone disease should be 'considered' for metabolic investigations to identify hypercalciuria or hypocitraturia. Indeed there is no mention of more complex metabolic	Thank you for your comment. It is acknowledged in the guideline that although recommendations have been made to consider treatment, this can

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						testing. Yet there is a suggestion of treatment for patients with these metabolic conditions. This is extremely odd to say the least.	only be given to the populations in question if they are found to have certain metabolic abnormalities. Although treatment may be cost effective, the step before this on whether metabolic testing of everyone in order to provide treatment to a small proportion still remains uncertain and therefore agreed that a research recommendation would be beneficial in this area . As recommendations for both testing and treatment are consider recommendations, then people can still provide these if they are already doing so.
28	SH	British Association of Urological Surgeons	Guideline	10	7	1.9.5 What about the use of thiazides in patients with hypercalciuria with a normal daily sodium excretion to start with (no sense adjusting their salt intake)? And why only for calcium oxalate stones and hypercalciuria? What about calcium phosphate stones?	Thank you for your comment. The recommendation states that sodium should be restricted to no more than 6g per day. If the sodium intake already meets this criteria then it would not need to be restricted further. The evidence for thiazides was based primarily on those with predominantly calcium oxalate stones and hypercalciuria, therefore the recommendations were based on this evidence. There was not enough evidence found for calcium phosphate stones for thiazides therefore the Committee did not feel they could

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							make a recommendation for this population.
29	SH	British Dietetic Association	Guideline	General	General	In relation to question one above: Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. We think that considering referral to a Renal Dietitian in complex/recurrent stone formers for a full dietetic review as a GOOD PRACTICE element would have the biggest impact on practice for the patient. It would enable patient-specific dietetic advice to help prevent reoccurrence of stones in the future.	Thank you for your comment. **A sentence has been added to the discussion of the evidence section in evidence review C to say that people with recurrent or complex stones may need specific dietary/lifestyle review and advice from a MDT (including a dietician with an interest in renal stone disease, specialist nurse, chemical pathologist etc.).**
30	SH	British Dietetic Association	Guideline	22	23	1.9.2 Impact of the recommendations on practice: For these recommendations to be successful there should be the consideration of a change in practice where a referral should be made to a Renal Dietitian/metabolic stone clinic in the complex/recurrent stone former. Recurrent stone formers can present with complex malabsorption (pancreatic insufficiency/diet lifestyle habits) that can be addressed efficiently by an experienced Registered Dietitian. There can be many barriers to changing diet and lifestyle that cannot be fully addressed without thorough dietary assessment. In order for the patient to reach their best in terms of clinical outcomes, complex stone formers should have access to a Registered Dietitian. Dietitians are not only equipped to educate patients, they have the skills to employ motivational interviewing	Thank you for your comment. A sentence has been added to the discussion of the evidence section of evidence review C stating that referral to a MDT including a renal dietician may be necessary for those with complex or recurrent stones.

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						and behaviour change thus helping to overcome barriers and facilitate change. It should also be considered that the Renal Dietitian can take a careful history which may reveal a number of dietary and lifestyle risk factors which contribute to the individual's risk of recurrent stone formation. In addition a Registered Dietitian is able to interpret the 24 hour urinalysis in the context of the patients overall health (including bowels, diabetes, and obesity), and be able to offer tailored advice using an approach that makes this information relevant and useful for the individual	
31	SH	British HIV Association	Guideline	General	General	BHIVA has looked at the guidance and there are no specific points to make in terms of HIV infection or antiretroviral treatment, other than stopping atazanavir if the stones emerge on this treatment.	Thank you for your comment.
32	SH	British Society of Interventional Radiology	Guideline	3	2-10	I agree with the recommendations with regard to diagnostic imaging, it would be helpful to define the clinical scenario of suspected renal colic - colicky loin to groin pain with haematuria. As in radiology practice the variation in symptoms that lead to '? renal colic' on the request card is large, a number of which are not indicated.	Thank you for your comment. A definition of renal colic has been added to the glossary. The Committee discussed this and concluded that it was not necessary to define 'suspected renal colic' in the recommendation, as the clinicians treating these patients would be aware of the presentations. They acknowledge that this may not be the case in every circumstance , but were reluctant to be too prescriptive or restrictive within the recommendation

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							by providing a definition of the clinical scenario of renal colic.
33	SH	British Society of Interventional Radiology	Guideline	4	12-16	There is no mention of nephrostomy (PCN) insertion within the section on surgical treatment or anywhere in the document. Nor is there any discussion on differing management in patients with acute kidney injury, hydronephrosis or sepsis - are these patients not included in this guidance, if so I think this needs to be stated (sorry if I have missed this). At present I feel the guidance suggests that PCN has no role in the management of ureteric stones - currently many patients with complications of ureteric stones are managed initially with PCN.	Management of obstructed and infected kidney is not included in this guideline, so treatments for this presentation (such as a percutaneous nephrostomy tube) were not considered.
34	SH	Great Ormond Street Hospital NHS Foundation Trust	Guideline	9	1-3	We are concerned that this recommendation is too weak and that children and families will remain undiagnosed, poorly assessed and miss out on appropriate treatment (including if relevant, genetic counselling for genetic disorders). The Committee has recognised that renal stones are much rarer in children, though the age of first renal stones is falling particularly in females in whom about 15% of first stones form under 16y. This changing epidemiology is likely reflecting dietary and lifestyle changes and merits recognition. Secondly, there are numerous evidence that the proportion of children with stones who have an underlying biochemical or metabolic disorder is high (e.g. BMC Nephrol. 2017 Apr 18;18(1):136. doi: 10.1186/s12882-017-0505-x.) and some of these disorders cause major morbidity. For instance, 50% cystinuria patients present in childhood (from birth	Thank you for your comment. When considering recommendation 1.7.3, the Committee agreed metabolic assessment of all children with renal tract calculi is important. They also noted that many secondary centres have paediatricians with an interest in nephrology and use a regionally agreed protocol to perform metabolic evaluation in all children with stones. The Committee considered that the current recommendation gives clinicians some flexibility before referring to specialist tertiary centres, which remains common practice anyway. Based on this, and the fact that there was no level 1 clinical or

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						screening data in Quebec) and this disorder is both treatable but also associated with a high risk of renal functional loss over time. Primary hyperoxlauria has a poor prognosis with some Registry data (Mayo Clinic) indicating a 50% risk of end stage renal failure by early 40s. Primary screening can start with stone analysis (if available) and /or a single blood biochemical profile and urine tests (random, followed up by 24h as needed) for oxalate, cysteine, urate, calcium can identify such disorders. In the Evidence review A, Page 10, line 47 states that the Committee indicated it was 'established practice' to refer children and young people for specialist review and went further to state on P11, Line 1, that 'ideally children should be referred'. These statements are not consistent with the weaker recommendation in the Guideline. (The comment below adds weight to this concern)	cost effectiveness evidence (i.e. based on randomised controlled trials or systematic reviews of randomised controlled trials) found to inform the recommendation, this has not been revised to be stronger. The wording in Evidence review A has been amended to reflect the strength of the recommendation.
35	SH	Great Ormond Street Hospital NHS Foundation Trust	Evidence review A	9	42	This states that "many centres have paediatricians with an interest in nephrology who share care with a paediatric nephrologist who could undertake such investigations themselves." We are concerned that this is an overstatement of the general expertise of paediatricians who see children with stone problems. Likewise a proportion of stones in children are referred to adult urologists who, in general, have less experience or capacity for metabolic evaluation and may not appreciate the specific diagnostic requirements in children.	Thank you for your comment. The Committee disagrees that it is an overstatement to say that many centres have paediatricians with an interest in nephrology, or that a significant proportion of children with stones are treated by adult urologists. There is an online protocol used by secondary care paediatricians to perform the metabolic evaluation, and children are only referred if an

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						We believe this comment, matched to the comment above, should lead to a stronger recommendation that children and young people with renal or ureteric stones should be referred to a paediatric nephrologist with experience in managing these disorders	abnormality is identified. The Committee agrees that this is reflective of most centres. From their collective clinical experience, the Committee agreed that adult urologists do not solely manage children with stones, and that many do not have adequate child protection training, therefore are not able to have involvement in paediatric practice. Based on this, and the fact that there was no evidence found to inform the recommendation, the recommendation has not been amended to be stronger.
36	SH	Guys and St Thomas Hospital NHS Foundation Trust	Guideline	4	6-11	This recommendation is very odd and a throwback to expert guidelines from 10 years ago. There have been several high quality randomised controlled trials in the last few years which have found limited benefit to MET. If there is a benefit it is smaller than originally thought and restricted to stones in the distal ureter >5mm. The meta-analyses on this subject are flawed by incorporating trials of poor quality and limited numbers. All the quality trials (especially NIHR and NIH) were negative. The emergency department has only recently stopped prescribing this for all and this contradictory guideline will confuse.	Thank you for your comment. The NICE process for systematic review and meta-analysis is to include all relevant evidence providing it meets the review protocol. The high quality RCTs were included, however we are unable to exclude other studies based on quality and size. This is taken into account when the risk of bias assessment for each study is carried out. This applies to all NICE guidance therefore to exclude studies based on their quality and size in this review would be inconsistent.

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							The Committee was unable to look at the less than 5mm and the 5-10mm stone population separately. The committee decided to split the evidence into 10mm groups (<10, 10-20, >20, staghorn) rather than 5mm groups because it was felt that having too many strata would make the data difficult to manage and interpret. In this review there were also location (renal or ureteric) and age (adult or children and young people) strata, giving a potential of 14 separate strata for the committee to consider. It was agreed that adding extra strata by breaking down the sizing to 5mm groups would be unmanageable and not feasible. Further, this would reduce the amount of evidence available for each group, and would lead to excluding a large number of studies that did not report stone size in this way. However they acknowledged that because of this there was uncertainty regarding the exact population that may benefit from alpha blockers, and so they have amended the recommendation to a 'consider', rather than 'offer'. The rationale for this has been added to the rationale

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							and impact section of the short version document, and the discussion of evidence section of evidence review D.
37	SH	Guys and St Thomas Hospital NHS Foundation Trust	Guideline	5	8-18	The offering of treatment within 48 hours is a laudable aim. Given that the NICE guidance advocates ESWL for this as the preferred treatment, there are significant logistical and cost pressures that make this difficult to achieve. I appreciate the guidance does acknowledge this but there is going to have to be significant investment in both equipment and personnel to run the equipment. Most ESWL in children has to be done under a GA. This makes this more challenging to deliver especially when the lithotripter is not in the paediatric hospital. The cost of delivering this is high with specialised anaesthetists and nursing staff required in the adult hospital.	Thank you for your comment. The recommendation to offer treatment within 48 hours only refers to those with renal or ureteric stone and renal colic when either pain is ongoing and not tolerated, or the stone is unlikely to pass. There are separate recommendations for all other patients (see tables 1 and 2 and recommendations 1.5.1-1.5.3). The Committee acknowledges that there may be service delivery and implementation implications. However, this recommendation is based on evidence that people with stones who are treated within 48 hours have better outcomes. How challenging and costly implementing the recommendation on SWL within 48 hours will be is dependent on the model of implementation used. The 'Getting It Right First Time' project has recently also published recommendations for

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							urology and recommends networked models of care. The NICE Resource Impact work has also demonstrated that treating people with ureteric stones less than 10mm using SWL instead of ureteroscopy would be cost saving, although this excludes network costs. The Resource Impact tools are available on publication of the guideline to help trusts and commissioners with planning implementation in their area. The timing of surgery recommendations do not apply to children, as there was no paediatric evidence. Further, because children are more likely to pass stones quickly, a watch and wait strategy may be more likely. The Committee acknowledged that SWL may be more challenging to deliver to children due to the need for general anaesthetic for example. The recommendations for surgery for children gives a choice of two or three treatments, to allow for more flexibility and clinical judgement to be used
38	SH	Guys and St Thomas	Guidel ine	7	Table	As a urologist I find this too simplistic. The grey area of 10-20mm renal stone is not discussed and there are	Thank you for your comment. The evidence available has been used in

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		Hospital NHS Foundation Trust				various factors e.g. lower pole / stone density / previous treatments that might guide one treatment over another. Recent evidence has questioned the true stone-free rates with flexible ureteroscopy to be only 50% (Abstract: https://www.jurology.com/article/S0022-5347(17)33626-1/abstract - paper in press). Thus it is likely miniaturised PCNL techniques may become more important in the future in this stone size offering superior stone-free rates and thus recurrence rates with minimal inpatient stay.	the review. We are not able to look at abstracts. New evidence will be picked up when this guideline is updated. Please see the guidelines manual for more information on how evidence is identified and included. https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview.
39	SH	Guys and St Thomas Hospital NHS Foundation Trust	Guideline	8	7-9	As a urologist I find the wording odd and sounds like it is written by non-urologists who do not understand the clinical situation. Whilst I agree with reducing stenting after 'routine' ureteroscopy, the actual phrasing of "Do not routinely offer post-treatment stenting …" is too strong and implies it is not needed. The NICE panel need to understand that this is likely to reduce daycase ureteroscopy rates as people are kept in for post-operative pain or observation.	Thank you for your comment. The evidence showed that there was no benefit of stenting after surgery. The Committee discussed that there are some instances where stenting may be appropriate, however they were keen to reduce the practice of routine stenting. Therefore they concluded that 'do not routinely offer' was appropriate wording for this recommendation. The Committee did not agree that this would lead to a reduction in day-case URS based on their clinical experience.
40	SH	Guys and St Thomas Hospital NHS Foundation Trust	Guideline	8	10-12	I feel stone analysis should be mandatory when possible; checking serum calcium should be mandatory in all adults if not previously checked.	Thank you for your comment. There was no evidence looking at the effectiveness of stone analysis, therefore the Committee could not make a judgement on the clinical or cost effectiveness of stone analysis for

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							everybody who has a stone. This means that the Committee was unable to make a stronger recommendation. The recommendation on measuring serum calcium has now been made stronger as it is an inexpensive test and can pick up hyperparathyroidism which is commonly associated with the increased risk of renal stones.
41	SH	Guys and St Thomas Hospital NHS Foundation Trust	Guideline	9	19-23	I agree with the advice of using potassium citrate. However it should be noted that most potassium citrate that is prescribed is in the liquid form and this has a poor compliance rate due to side-effects. It would be useful if this NICE guidance were to be used as a driver to obtain other preparations (e.g. such as UroCit-K tablets which are routinely available in other countries). The tablets are only available on a named patient basis only in the UK although an effervescent form can sometimes be obtained. Licencing of the tablet form would increase compliance and thus potentially reduce stone episodes. Currently if this guidance were to be followed this would increase the cost pressure on the Trust as we often take on prescribing the tablets for patients from other areas (as a tertiary/ quaternary referral centre) and GP's won't prescribe it.	Thank you for your comment. The Committee recognised that the taste of potassium citrate might be a negative factor for treatment adherence. Potassium citrate is currently used in UK clinical practice off-licence for calcium oxalate stones. Although other forms of the treatment may be available elsewhere the licensing of medications is not within the remit of NICE.
42	Non-reg	Homerton Hospitals NHS Foundation Trust	Guideline	3	9	It would be useful to define an age range for "young people" – I normally assume this to mean those between 16 and 18 years?	Thank you for your comment. In this guideline we have grouped children and young people together as anyone under the age of 16. This has been

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							specified in the beginning of the document.
43	Non-reg	Homerton Hospitals NHS Foundation Trust	Guideline	4	4	It would be useful to define the term "muscle relaxants" – I normally assume the general term to refer to anaesthetic agents which I imagine is not the appropriate group of drugs here	Thank you for your comment. Muscle relaxants refers to antispasmodics. This has been amended throughout the document.
44	Non-reg	Homerton Hospitals NHS Foundation Trust	Guideline	6	Table 1	The table is divided into two columns for adults (16 years and older) and children and young people – this implies that young people are <16 – again it would be useful to define an age range for "young people"	Thank you for your comment. A sentence has been added to the beginning of the document to clarify that children and young people have been grouped together to mean anyone aged under 16 years.
45	SH	Hyperparathyroid UK Action 4 Change	Guideline	General	General	Before I had my successful parathyroid surgery last year I had been suffering from kidney stones. I was told that after my op as my calcium had returned to normal I wouldn't make any more stones but the ones I had already made would still be there in my kidneys unless they passed. I had a scan last month and have found out that I am still making more stones. Kidney stone patients should still be monitored post parathyroidectomy until stone production ceases.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and incudes the frequency of monitoring. This guideline will be available for consultation in November 2018 The Committee acknowledged there is variation in practice with regards follow-up imaging post treatment for stones. As no evidence was found the Committee made a research recommendation to inform future guidance.

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46	SH	Hyperparathyroid UK Action 4 Change	Guideline	General	General	I was pregnant when I first passed a stone 30 years ago. I'd had episodes of unexplained pain during and before my previous pregnancy which they put down to a grumbling appendix, that's going back 39 years ago and over 75 stones. I was diagnosed with primary hyperparathyroidism over 15 years ago and have had 2 failed ops, waiting for my 3rd. If only a connection between kidney stones and hyperparathyroidism had been made years sooner.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
47	SH	Hyperparathyroid UK Action 4 Change	Guideline	General	General	Magnesium binds oxalate in the digestive tract and inhibits the formation of calcium oxalate crystals in urine. Why is there no mention of magnesium in dietary advice or through the guideline? Surely a magnesium supplement would be beneficial to those with calcium oxalate stones.	Thank you for your comment. Magnesium was included in the review protocol however no evidence was found (see sections 1.3 and Appendix A of evidence review C). Magnesium supplement was considered a pharmacological substance and was included in evidence review K – Prevention of recurrence. One study was identified that compared magnesium to placebo, and another study compared magnesium + thiazide to thiazide alone or to no intervention. This evidence was in people with majority calcium oxalate or 'calcium' stones. The evidence showed some benefit of magnesium, however the Committee noted that this was based on single studies, was very low quality and there was concern about potential serious side effects about which there

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							was no evidence. They concluded that they could not justify recommending magnesium based on such limited evidence and with no evidence regarding potential serious adverse events.
48	SH	Hyperparathyroid UK Action 4 Change	Guideline	General	General	I had 14 years of kidney stones and slightly elevated ionised calcium. It was the ionised calcium level and stones that got my diagnosis of primary hyperparathyroidism.	Thank you for your comment. **The Committee has recommended that serum calcium be measured. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.**
49	SH	Hyperparathyroid UK Action 4 Change	Guideline	General	General	I had 2 kidney scans pre-op (parathyroidectomy) and have had another 2 kidney scans post op. I passed my first stone 2 months after my op. I had a scan then which showed 7mm in right kidney. My most recent scan showed the 7mm in right kidney and 4mm and 6mm stones in the left! I don't understand how I'm still making more stones when my calcium is back to normal	Thank you for your comment. **Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes preoperative imaging and ongoing monitoring. This guideline is available for consultation in November 2018.**
50	SH	Hyperparathyroid UK	Guideline	General	General	I never had a pre surgery (parathyroidectomy) kidney scan as I did not have stones coming out, but after surgery I had two episodes, meaning the stones were in	Thank you for your comment. **Recommendations for imaging have been made if renal colic is**

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		Action 4 Change				my kidneys from the disease; primary hyperparathyroidism, just did not come out yet. My surgery was 2011. First stone episode was 4 months post-surgery, 2nd episode 6 months later. I still feel stones in my kidneys; dull ache.	**suspected. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and preoperative imaging. This guideline will be available for consultation in November 2018.**
51	SH	Hyperparathyroid UK Action 4 Change	Guideline	General	General	People with parathyroid hyperplasia should continue to be monitored periodically for stones after parathyroid surgery, even with only one or half a gland remaining.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and incudes monitoring. This guideline will be available for consultation in November 2018.
52	SH	Hyperparathyroid UK Action 4 Change	Guideline	3	2	Diagnostic imaging. I've just come out of hospital due to urosepsis caused by a blocked kidney due to stones. I had to have an emergency nephrostomy tube placed (removal in roughly 6 weeks along with stones). Originally, I had a scan and was told my stones were only 1-2mm big so I ignored the pain. Wow, 8mm stone had totally blocked my kidney...	Thank you for your comment and sharing your experience with the Committee. The Committee has made the recommendation for imaging to be completed within 24 hour hours if renal colic is suspected because of the risks to kidney function if this is not carried out quickly.
53	SH	Hyperparathyroid UK Action 4 Change	Guideline	3	2	I passed a stone 3 years post-op (parathyroidectomy). My latest scan shows no more stones, but I now have a cyst on my kidney.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed

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							on this topic and includes ongoing monitoring of patients. This guideline will be available for consultation in November 2018.
54	SH	Hyperparathyroid UK Action 4 Change	Guideline	3	2	We have many members with multiple cysts revealed on scans, some with stones and calcification, others without, We would like to know if they are related to hyperparathyroidism, if they can cause discomfort or any other reason for kidney cysts	Thank you for your comment Unfortunately this clinical question is beyond the scope of this guideline, therefore the Committee would suggest a patient seeks advice from their GP or hospital specialist.
55	SH	Hyperparathyroid UK Action 4 Change	Guideline	3	3	It took years to get a diagnosis and if it hadn't been for my Mum insisting I be hospitalised till they got to the bottom of why I was always in chronic pain goodness knows how much longer I would have waited. No scans were offered previously.	Thank you for your comment. A recommendation for imaging within 24 hours has been made if renal colic is suspected. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
56	SH	Hyperparathyroid UK Action 4 Change	Guideline	3	6	When I was offered the renal colic CT scan, I did get one, but not on any sort of urgent basis.	Thank you for your comment. The Committee has specified a timeframe of imaging within 24 hours if renal colic is suspected because renal function can decline quickly.
57	SH	Hyperparathyroid UK	Guideline	3	6	I was about 14 in 2006 when I was first taken to A&E with renal colic, I didn't get any scans back then or	Thank you for your comment. Recommendations have been made

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		Action 4 Change				blood tests was just given pain killers and there was no follow up after I left hospital. I was admitted 3 or 4 times over the next 5 years, when hypercalcemia was found but no connection made to my kidney pain.	for imaging when renal colic is suspected. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis and ongoing monitoring. This guideline will be available for consultation in November 2018.
58	SH	Hyperparathyroid UK Action 4 Change	Guideline	3	11	30 years of renal stones. I have primary hyperparathyroidism. Way back it was Coproxamol (no longer available) or Dr would come to the house and give me morphine injections. Now it's cocodamol.	Thank you for your comment. Recommendations have been made to consider an opioid if both NSAIDs and intravenous paracetamol are contraindicated or are not giving sufficient pain relief.
59	SH	Hyperparathyroid UK Action 4 Change	Guideline	3	11	26 years of stones and undiagnosed primary hyperparathyroidism: Pain management 1991-present day: 1.liquid morphine. 2. Slow release morphine tablets. 3. Diclofenac. 4. Cocodamol 30/500. 5. Codeine phosphate 60mg. 6.ibuprofenc 400mg. 7. Paracetamol 500mg	Thank you for your comment. A stepped approach to pain relief has been recommended beginning with NSAIDs. Recommendations have been made to consider an opioid if both NSAIDs and intravenous paracetamol are contraindicated or are not giving sufficient pain relief.
60	SH	Hyperparathyroid UK Action 4 Change	Guideline	4	13	I was off work for 12 weeks on opioids waiting for removal of a stone. After surgery I was told the stone was gone when in actual fact it was stuck in my urethra. Why did they not scan me before the surgery? It took another week of peeing fire for it to pass. The 45 minute drive home was unbearable feeling I would wet myself.	Thank you for your comment. The Committee has made recommendations to help address the situation you describe. A recommendation for imaging has been made if renal colic is suspected

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							and for surgery to take place within 48 hours for people with ureteric stones and ongoing pain or the stone is unlikely to pass.
61	SH	Hyperparathyroid UK Action 4 Change	Guideline	4	16	This is not always the case, I have had to wait up to 4 days being monitored in hospital in considerable pain before emergency surgery. Another occasion my GP told me all was OK but I knew from experience it wasn't as the stone was too big to pass. That was another emergency surgery via A&E.	Thank you for your comment. The Committee has made recommendations to help address the situation you describe. A recommendation for imaging within 24 hours has been made if renal colic is suspected and for surgery to take place within 48 hours for people with ureteric stones and ongoing pain or the stone is unlikely to pass.
62	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	11	26 years of stones. Mine are made of 97% phosphate.	Thank you for your comment.
63	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	11	I produce two different type of stones. Calcium stones and ones that come from uric acid. Uric acid ones if I remember rightly are a brown colour and softer than calcium stones. I am now on tablets to sort out the uric acid levels so hopefully won't get them again. I have primary hyperparathyroidism.	Thank you for your comment. The Committee has recommended that serum calcium be measured. Hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
64	SH	Hyperparathyroid UK	Guideline	8	11	We surveyed 100 people in our organisation with kidney stones. Only 57 had their stones analysed. Their	Thank you for your comment and for sharing the results of your survey with

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		Action 4 Change				results: 36 had calcium and oxalate stones (63.16%), 15 had calcium and phosphate stones (26.32%), 4 had struvite (7.02%1 had uric acid stones (1.75%), 1 had cysteine stones (1.75%), 1 (1.75) had uric acid stones.	the Committee. A recommendation to consider stone analysis has been made and because of the absence of evidence in this area the Committee has made a research recommendation on metabolic workup. A separate guideline is currently being developed on Hyperparathyroidism. This guideline will be available for consultation in November 2018.
65	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	My stones were the trigger to my diagnosis and treatment of primary hyperparathyroidism.	Thank you for your comment. A recommendation to consider stone analysis has been made and because of the absence of evidence in this area the Committee has made a research recommendation on metabolic workup. A separate guideline is currently being developed on Hyperparathyroidism. This guideline will be available for consultation in November 2018.
66	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	My calcium was first found high back in 2011. I had been admitted to hospital 3 or 4 times previous to this with renal colic, but I wasn't diagnosed with phpt until 2016. No doctor seemed to see any relation between my high calcium and the kidney pain and nobody bothered to check my calcium and parathyroid hormone. If this had been done back in 2011 when I first had high calcium then it could have prevented 7 more years of ongoing pain. I think it is so important that people who have had kidney stones, especially	Thank you for your comment. The Committee has recommended that serum calcium be measured. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be

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						when they are reoccurring for so long, get proper blood tests to look for a cause.	available for consultation in November 2018.
67	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I had kidney stones but no connection was made to Primary Hyperparathyroidism which was diagnosed 2 years later after I complained of headaches.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
68	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I passed my first kidney stone in 1983. I had kidney stones after that but didn't have to have kidney stone surgery until 2007. The calcium labs I can get, go back to 2004 with high calcium. I passed kidney stones regularly until my surgery (parathyroidectomy) in 2017. Since my surgery I have passed a calcium oxalate stone about every 2 weeks. They are very small so pass but are still bothersome and shut me down.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
69	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I had a stone and kidney calcification seen on a scan after pain in my left kidney area in 2009. I painfully passed the stone eventually over a period of several hours where I could barely stand (although I didn't know at the time what was happening). A repeat scan 3 months later and my GP was astonished the stone had gone. A further stone was seen in 2011 but no action taken. An incidental blood test later that year revealed hypercalcemia. I believe it is so important for our	Thank you for your comment. The Committee has recommended that serum calcium is measured.

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						doctors to know to test calcium in the presence of kidney stones.	
70	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I wish someone had mentioned primary hyperparathyroidism or tested my calcium four years ago when I got my first stone	Thank you for your comment. The Committee has recommended that serum calcium is measured. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
71	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	My issues are the time it took to get diagnosed with primary hyperparathyroidism after my first kidney stone. Urology found the high calcium and high parathyroid hormone. They wrote to my GP to get referred to an endocrinologist. I was with the endocrinologist less than 10 mins but it took a year and one day to be diagnosed. Why couldn't urology diagnose me? It was they who had to keep me as an outpatient for 3 years to get rid of my collection of stones and they were the department that picked up the primary hyperparathyroidism in blood tests.	Thank you for your comment. The Committee has recommended that serum calcium is measured. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
72	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	High normal adjusted calcium (with high normal parathyroid hormone) - i.e. non-suppressive relationship. During investigation period, I also had excruciating pain in my left lower quadrant (combined with back and hip pain). GP referred me for an ultrasound of my ovary/uterus. Night before scan I	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications

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						almost went to Accident and Emergency as it became excruciating and I felt very sick and faint. Then suddenly the pain disappeared. Scan of ovary/uterus was unremarkable so it was assumed I had a small ovarian cyst ruptured and cleared. I am post menopause at 48. It wasn't until similar pain started higher up on same side and then moved down to same area , and having read of others' experiences with hyperparathyroidism and kidney stones that it occurred to me that my problem could be kidney stones moving down and then being passed which would provide relief. GP is unaware of possible links so I am now having to make appointment to ask for CT scan and 24 hour urine test. Surely GP should be guided to look for a possible/likely connection rather than this being patient led.	for diagnosis. This guideline will be available for consultation in November 2018.
73	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I was only tested for calcium levels after 8 months of kidney troubles and even then it was reluctantly by the urologist as they didn't seem to believe me that I didn't have this unhealthy lifestyle/diet he was blaming for my stones! It should be standard to check these levels with kidney problems	Thank you for your comment. The Committee has recommended that serum calcium is measured.
74	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I believe that everyone who has kidney stones should be checked for hyperparathyroidism and everyone with hyperparathyroidism should be checked for kidney stones. I'm not sure if I have permanent kidney damage at this point but my hyperparathyroidism could have been diagnosed and my kidney damage could have been avoided had my serum Calcium and parathyroid hormone been checked in 1983.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be

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							available for consultation in November 2018.
75	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I think everyone who is diagnosed with kidney stones should be tested to rule out Parathyroid Disease. I was pregnant when I got my first stone, I was seeing a primary doctor, a gynaecologist, a high risk specialist, and an urologist. Not one of them thought to check my calcium levels. I feel like urologists definitely should be educated on Parathyroid Disease. If they truly care about their patients and want to help them, they would want anyone with this disease to be cured. If urologists knew to test people, many cases could be caught and cured earlier.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
76	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I found this site: NHS.UK Kidney stones, NHS Choices. They have a symptom checker you can fill in, it mentions various other diseases but nothing about the parathyroid. This must be amended surely.	Thank you for your comment.
77	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	Urologists could save patients the pain and time plus the NHS time and money by diagnosing stone patients with phpt sooner, why not perform the one blood test for calcium when first presenting with stones?	Thank you for your comment. The Committee has recommended that serum calcium is measured. Hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
78	SH	Hyperparathyroid UK	Guideline	8	12	Knowing the problems and delays that can be caused by doctors testing calcium without pth and consequently	Thank you for your comment. The Committee has recommended that

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		Action 4 Change				failing to understand the suppressive relationship between the two, I believe this sentence could be improved upon and would benefit patients if it were to read 'Consider checking serum calcium and EDTA (ethylenediaminetetraacetic acid) Parathyroid hormone together to determine or rule out primary hyperparathyroidism as a cause'.	serum calcium is measured. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
79	SH	Hyperparathyroid UK Action 4 Change	Guideline	8	12	I was only diagnosed with a kidney stone after phpt diagnosis. I was advised no further action unless it moves by the ultrasound staff and nothing since.	Thank you for your comment. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis and ongoing monitoring. This guideline will be available for consultation in November 2018.
80	SH	Hyperparathyroid UK Action 4 Change	Guideline	9	5	(preventing recurrence) - I think even if someone has had just one kidney stone they should get their calcium checked. I mean how much does it cost to do a blood test? I must have had my bloods done 50 times in the past couple of years, if not more. If primary hyperparathyroidism is found then it could prevent more stones! I believe if my primary hyperparathyroidism had been diagnosed earlier then I wouldn't still be suffering with bilateral stones.	Thank you for your comment. The Committee discussed this recommendation and considered that PHPT is an underdiagnosed condition that often is indicated by the presence of stones. Based on this, and the fact that it is an inexpensive test the Committee agreed to change the recommendation from 'consider…', to a stronger recommendation to 'measure calcium…'. This means that

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							people with a stone should get their calcium measured.
81	SH	Hyperparathyroid UK Action 4 Change	Guideline	9	11	My stones are calcium oxalate so I eat a low oxalate diet and drink lemon water. I also take magnesium and Vitamin K2 mk7 which is information I have gathered from my own research.	Thank you for your comment. The guideline includes information on diet and lifestyle to prevent recurrence of stones. Information and support for people with hyperparathyroidism will also be provided in the guideline on this topic that is currently in development. This guideline will be available for consultation in November 2018.
82	SH	Hyperparathyroid UK Action 4 Change	Guideline	11	18	I found diclofenac suppository is better than morphine for kidney stone pain.	Thank you for your comment. The Committee noted that the evidence found did not reflect the route of NSAID administration now commonly used to manage pain and chose to recommend NSAIDs by any route which may include suppositories.
83	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	I had a stent fitted on 12 August and I'm in agony. Constant spasms around kidney. Stent and stone stuck in tube not being removed until 21st September	Thank you for your comment. The Committee discussed the adverse effects that stents can cause patients and this is described within the guideline. Limited evidence was found for the use of stents before or after surgery. The Committee recommended that stents are not used prior to shockwave lithotripsy and should not be used routinely after

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							ureteroscopy in patients who have ureteric stones.
84	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	I hate stents but have to admit it did help a lot of small pieces of stone to pass. My urologist gave me meds to deal with the stent. One was for spasms and one for burning I believe.	Thank you for your comment. The Committee discussed the adverse effects that stents can cause patients and this is described within the guideline. Limited evidence was found for the use of stents before or after surgery. The Committee recommended that stents are not used prior to shockwave lithotripsy and should not be used routinely after ureteroscopy in patients who have ureteric stones.
85	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	Diclofenac suppositories are very good for kidney pain taken with cocodamol. I am stent intolerant, I refuse to ever have one again as they are more painful than stones. The minute I have a stent, my body tries to get rid of the foreign object and goes into spasms nonstop until it is removed.	Thank you for your comment. The Committee noted that the evidence found did not reflect the route of NSAID administration commonly used to manage pain and chose to recommend NSAIDs by any route which may include suppositories. The Committee discussed the adverse effects that stents can cause patients and this is described within the guideline. Limited evidence was found for the use of stents before or after surgery. The Committee recommended that stents are not used prior to shockwave lithotripsy and should not be used routinely after

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							ureteroscopy in patients who have ureteric stones.
86	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	I had lithotripsy yesterday, a stent was mentioned beforehand, I said I'd refuse to sign permission for a stent to be fitted and kept my nephrostomy tube. OK, no one wants a tube coming out of their back attached to a pee bag but, compared to the pain of a stent, it's 100 times better.	Thank you for your comment. The Committee discussed the adverse effects that stents can cause patients and this is described within the guideline. Limited evidence was found for the use of stents before or after surgery. The Committee recommended that stents are not used prior to shockwave lithotripsy.
87	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	I just had my 10th kidney stone surgery on Friday. I was absolutely miserable and this was without any stents. I can't tolerate the stents. The worse pain I have ever had is with them and immediately after them being yanked out.	Thank you for your comment. The Committee agrees stents can cause pain and they discussed the adverse effects experienced by patients and this is described within the guideline.
88	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	I've only ever had one stent and it was awful. It ended up working its way out on its own so I didn't have to have the doctor remove it.	Thank you for your comment. The Committee discussed the adverse effects that stents can cause patients and this is described within the guideline.
89	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	Stent pain is awful I was walking around like John Wayne. And I needed to wee every five minutes and that would burn. No one tells you just how awful stents are. I still have bad dreams about them. I would also advise taking medication for the pulling it out process as they don't give you anything for that either and that's s whole different story.	Thank you for your comment. The Committee agrees stents can cause pain and they discussed the adverse effects experienced by patients and this is described within the guideline.
90	SH	Hyperparathyroid UK	Guideline	19	13	Never again will anyone put a stent near me! Last Friday my urology dr mentioned a stent. Told him I'd	Thank you for your comment. The Committee discussed the adverse

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		Action 4 Change				rather go on dialyses or have my kidney removed than ever have a stent.	effects that stents can cause patients and this is described within the guideline.
91	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	I know stents are not fun, but with three meds; one for spasms, one for burning and one for pain, they are more tolerable. I hated the one I had for a month after surgery. But tons of small stones passed with the stent so it's worth it	Thank you for your comment. The Committee discussed the adverse effects that stents can cause patients and this is described within the guideline. Limited evidence was found for the use of stents before or after surgery. The Committee recommended that stents are not used prior to shockwave lithotripsy and should not be used routinely after ureteroscopy in patients who have ureteric stones.
92	SH	Hyperparathyroid UK Action 4 Change	Guideline	19	13	My first stent removing session was before diagnosis of primary hyperparathyroidism and I pushed to get it removed after 2 weeks because of the pain. The urologist was having a right old time trying to get it out and I was in a state and crying. I peed all over the bed and then he had a go at me for not drinking enough water because the stent had calcified inside me. It was obviously the hyperparathyroidism that calcified the stent. It was the most traumatic experience getting it out. After diagnosis of primary hyperparathyroidism I reminded him of shouting at me for not drinking enough water and said 'You know now that a kidney stone plus a stent that gets calcified in 2 weeks probably means some calcium issue'? He replied 'I hear you'.	Thank you for your comment. The Committee agrees stents can cause pain and they discussed the adverse effects experienced by patients and this is described within the guideline. A recommendation has also been made for serum calcium to be measured in all patients with a renal or ureteric stone. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic. This guideline will be available for consultation in November 2018.

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93	SH	Hyperparathyroid UK Action 4 Change	Guideline	29	19-22	The tests that are most useful are serum calcium and EDTA parathyroid hormone to look for a non-suppressive relationship which indicates primary hyperparathyroidism, either classic elevated calcium or normocalcemic primary hyperparathyroidism. We have members with both classifications who have a history of renal stones.	Thank you for your comment. A recommendation has been made for serum calcium to be measured in all patients with a renal or ureteric stone. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
94	SH	Hyperparathyroid UK Action 4 Change	Guideline	29	4-6	Primary hyperparathyroidism is mentioned briefly but it is not 'rare', it is the 3rd most common endocrine disease as will be described in the forthcoming guidelines for Primary Hyperparathyroidism currently under consideration due for publication 23.05.19	Thank you for your comment. We agree and have removed this, as suggested.
95	SH	Hyperparathyroid UK Action 4 Change	Guideline	29	5-6	Primary Hyperparathyroidism is mentioned by name only but considering all these comments, I believe it deserves a more considerable mention here and earlier (page 12, line 8) when mentioning testing for serum calcium, and also to include parathyroid hormone testing at the same time as a high normal calcium may inadvertently rule out a cause by a doctor not educated on normocalcemic primary hyperparathyroidism.	Thank you for your comment. The Committee has recommended that serum calcium is measured. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
97	SH	Hyperparathyroid UK	Guideline	29	5-6	Much more emphasis needs to be included regarding primary hyperparathyroidism. We conducted a renal	Thank you for your comment and for sharing the results of your survey.

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		Action 4 Change				stone survey of 100 people to determine how long they had suffered stones before being diagnosed with primary hyperparathyroidism. The results are incredibly sad and just not good enough. 97 of them had a confirmed diagnosis of primary hyperparathyroidism: 23 (23.71%) had stones 1-2 years, 22 (22.68%) had stones +2-5 years, 20 (20.62%) had stones for +5-10 years, 21 (21.65%) had stones +10-20 years, 7 (7.22%) had stones +20-30 years, 4 (4.12%) had stones over 30 years before diagnosis of primary hyperparathyroidism. These results and charts are available on our website.	Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
98	SH	Hyperparathyroid UK Action 4 Change	Guideline	29	5-6	We asked our members with renal stones and primary hyperparathyroidism at what stage their doctors alerted them to primary hyperparathyroidism as a cause. An alarming 48% responded that Primary hyperparathyroidism was not indicated by their consultants or doctors and they had to do their own research. Perhaps if Primary Hyperparathyroidism was not incorrectly classed in this guideline as rare, they might be diagnosed sooner?	Thank you for your comment. We agree it is a common endocrine disorder and have therefore removed this text. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
99	SH	Hyperparathyroid UK Action 4 Change	Guideline	29	10	My endocrinologist recently stated 'Well you certainly have a lot of calcium in your urine' but has not requested a kidney scan despite scans in 2009 and 2011. More emphasis here would be appreciated on both the 24 hours scan and underlying metabolic diseases.	Thank you for your comment. This section is about the frequency of follow-up imaging and unfortunately we did not find any evidence. The Committee has made research recommendations to inform future

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							practice for both imaging and metabolic testing in a general stone population. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic and includes indications for diagnosis. This guideline will be available for consultation in November 2018.
100	SH	Hyperparathyroid UK Action 4 Change	Guideline	29	10	Despite a high calcium level in my 24 hour urine recently, I was told by a surgeon 'Oh I don't pay much attention to the 24 hour urine as it could be caused by a high calcium diet' Clarification would be appreciated here.	Thank you for your comment. No evidence was found for 24 hour urine testing and therefore the Committee decided they could not recommend this, but acknowledged in current practice hypercalciuria is diagnosed with a 24 urine test. The Committee has recommended that serum calcium is measured. The use of thiazides was discussed by the Committee who agreed thiazides could be considered for adults with hypercalciuria and recurrent calcium oxalate stones.
101	SH	Hyperparathyroid UK Action 4 Change	Guideline	31	22	Thiazides should be prescribed with caution and only to those who do not have hypercalcemia and have had primary hyperparathyroidism ruled out. Serum calcium should be monitored regularly for those prescribed thiazides.	Thank you for your comment. The Committee has recommended that serum calcium is measured. The use of thiazides was discussed by the Committee who agreed thiazides could be considered for adults with hypercalciuria and recurrent calcium

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							oxalate stones, but only after reducing salt intake to recommended levels. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic. This guideline will be available for consultation in November 2018.
102	SH	Hyperparathyroid UK Action 4 Change	Guideline	31	22	I was prescribed Bendroflumethiazide for over 4 years. Nobody had noted my serum calcium of 2.91. I was very poorly for years I was taking a thiazide. I had a large parathyroid adenoma removed a year after stopping the thiazide.	Thank you for your comment. The Committee has recommended that serum calcium is measured. The Committee agreed thiazides could only be considered for adults with hypercalciuria and recurrent calcium oxalate stones, but only after reducing salt intake to recommended levels. Assessment and management of hyperparathyroidism is not within the scope of this guideline as a separate guideline is currently being developed on this topic. This guideline will be available for consultation in November 2018.
103	SH	NHS GRIFT	Guideline	3	12	Concerned about the recommendation for use of NSAID as first line of treatment as long -term use can cause renal problems. duration of its use is not stated	Renal colic is an acute condition and so pain medication for this condition would not be long term. The Committee agreed not to specify the length of time to wait to see if first line medication has been effective. The

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							amount of time for an NSAID to work will depend on the route of administration. The Committee also recognised that often these pain medications are given in parallel, and thought that the wording of the current recommendation still allows for this, whereas specifying timings would limit the recommendation, and potentially make unnecessary protocols, which the Committee was keen to avoid. They concluded that clinicians should be allowed to base these decisions on the clinical situation, using their judgement and expertise.
104	SH	NHS GRIFT	Guideline	4	7& 9	Concerned about the recommendation for the use of non UK licenced medication alpha blockers and nifedipine for medical expulsive therapy	The Committee did reconsider the evidence for tamsulosin, and considered that as they were not able to consider <5mm compared to 5-10mm stone sizes separately, there was some uncertainty about the population that would benefit from alpha blockers, therefore they decided to amend the recommendation to 'consider alpha blockers' rather than 'offer alpha blockers'. They also reconsidered the evidence for calcium channel blockers, and agreed that as there was no difference found between nifedipine and placebo, the

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							intervention didn't meet the criteria of being effective; therefore they agreed to remove this recommendation. The Committee has acknowledged that alpha blockers are not licenced in the UK and there is information about the use of off label medications as footnotes for the MET recommendation (recommendation 1.3.1, short version document).
105	SH	NHS GRIFT		Rec 1.1.1		Rec 1.1.1 re CT. Could the recommendation emphasise experienced clinical assessment before CT. As worded, a CT may be ordered urgently in abdominal pain where renal colic might be low on a list of possible diagnoses. Also, people with repeated admissions may end up having multiple CT scans. The GIRFT discussions with clinicians made it clear that CT scans are used to triage patients into or away from acute urology services in some Trusts. This can mean that relatively junior medical staff can end up ordering CT scans in order to move the patient along a pathway, rather than from a clear clinical indication. I am also concerned about the risk of women of childbearing years being subjected to repeat scans as a result of their having chronic non-specific abdominal pain or recurrent urinary infections.	The Committee decided not to emphasise experienced clinical assessment before CT as it would be standard practice to carry out a clinical assessment first and the Committee did not consider a recommendation to be necessary. The Committee disagrees that the recommendation may lead to a CT being ordered urgently where renal colic is low on the list of possible diagnoses. This is because the recommendation specifies that CT should not be offered to everyone with abdominal pain, but only those with suspected renal colic. They also agreed that most centres have local protocols about who can order a CT scan, and this would avoid junior medical staff ordering a CT. The Committee discussed both pregnant

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							women and women of childbearing age and agreed that whilst pregnant women should have ultrasound and not CT, it would disadvantage women of child bearing age to not have CT, when renal colic is suspected.
106	SH	NHS GRIFT		Recs 1.1.1 and 1.1.2		Recs 1.1.1 and 1.1.2 The 24 hour timeframe is supported by GIRFT Urology	Thank you for your comment.
107	SH	NHS GRIFT		Section 1.2		Section 1.2 Pain management. The recommendations could usefully emphasise the timeframe for trying an alternative drug if the initial choice is not providing pain relief.	The Committee decided not to specify the length of time to wait to see if first line medication has been effective. The amount of time for an NSAID to work will depend on the route of administration. The Committee also recognised that often these pain medications are given in a staged manner, and thought that the wording of the current recommendation still allows for this, whereas specifying timings would limit the recommendation, and potentially make unnecessary protocols, which the Committee was keen to avoid. They concluded that clinicians should be allowed to base these decisions on the

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							clinical situation, using their judgement and expertise.
108	SH	NHS GRIFT		Rec 1.4.1		Rec 1.4.1 Timing: there is a group of patients with likely infection in whom stenting and treatment of the infection takes precedence over definitive surgery. This doesn't seem to be covered here or in 1.5.1. Otherwise NHS GIRFT Urology fully supports the aim for definitive treatment within 48 hours. It seems odd that the guideline does not cover the issue of the infected and obstructed kidney as this is a life-threatening emergency condition – there is a very real risk that the patient progresses to full-blown sepsis, particularly if inappropriate invasive stone treatment is attempted, or drainage of the obstructed upper urinary tract is delayed.	Thank you for your comment. A sentence has been added to beginning of the guideline to clarify that the guideline does not cover the infected obstructed kidney, and that this needs urgent drainage. A link to the NICE guideline on sepsis management has also been added.
109	SH	NHS GRIFT		Rec1.5 .1		Rec1.5.1 see comment on stenting in patients with likely infection above. Also, it would be useful for 1.5.1 to emphasise that stenting before URS for logistic reasons e.g. theatre time availability should not be directing treatment, and there is no real clinical indication for stenting before surgery in the absence of infection. A key finding of the GIRFT review has been that a large number of patients are treated by insertion of a ureteric stent, rather than definitive stone treatments, for logistic reasons. We found that unacceptable as this subjects patients to two general anaesthetic procedures and	The committee agrees that routine stenting is not acceptable, and that stenting before SWL should only be done in circumstances such as infection or obstruction. However there was no available RCT evidence for the clinical or cost effectiveness of stenting before URS and so the committee is not able to comment. The recommendation about timing of surgery states that those with ongoing pain or a stone not likely to pass

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						delays definitive stone treatment. GIRFT is keen to move the specialty to a position that regards inappropriate stenting as being seen as substandard care, rather than a fact of life. However, as mentioned above, there is a small number of patients for whom a stent is indicated in order to manage coexisting infection and obstruction.	should have treatment within 48 hours, which emphasises the need for quick treatment for these patients and should lead to decreases in stenting generally.
110	SH	NHS GRIFT		Rec 1.6.2 and table 1		Rec 1.6.2 and table 1. NHS GIRFT Urology is pleased to see the increased profile of SWL as a treatment option for patients as part of shared decision making, while recognising that this will be a challenge for services to implement in some areas.	Thank you for your comment.
111	SH	NHS GRIFT		Section 1.8		Section 1.8: there does not seem to be an option here to refer adults for metabolic investigation and treatment if, for example, an endocrine problem is suspected.	Thank you for your comment. In line with guidelines currently being development, the recommendation for calcium checking has been amended to a stronger recommendation. However, there was no evidence for stone analysis or urine testing, therefore no strong recommendations could be made. A research recommendation has been made to inform practice in the future.
112	SH	Paramount Medical Solutions Ltd	Guideline	8	11	This recommendation has some challenges. In practice, many people may not return their stones for analysis. One factor that may contribute to this is sub-optimal	Thank you for your comment. The Committee acknowledges that stone collection for people with stones may

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						methods/advice regarding enabling patients to catch the stone. NHS Direct website suggests that people urinate through a stocking. Many hospitals suggest the patient buys a tea strainer or urinates into a bottle and then sieve contents- all of which are sub-optimal. Purpose made consumable products for collecting stones do exist and if stone analysis is an important test, the patient should be better equipped to comply with the test by providing an appropriate collection container.	be challenging. Specific methods of collecting stones were not reviewed, and therefore the Committee is unable to comment.
113	SH	Polycystic Kidney Disease Charity	Guideline	General	General	We welcome the new guideline. We represent children and adults with polycystic kidney disease (PKD). An estimated 70,000 individuals in the UK may have polycystic kidney disease (PKD), of whom around 66,000 are affected by ADPKD (autosomal dominant polycystic kidney disease). We noticed that there are NO references in the draft guideline to the diagnosis and treatment of patients with ADPKD and would like to request these are added, because ADPKD patients have clinical challenges not seen in non-ADPKD patients. It's believed that around 2–3 in every 10 people with ADPKD get a kidney stone at some time (refs: Ars E, et al. Spanish guidelines for the management of autosomal dominant polycystic kidney disease. Nephrology Dialysis and Transplantation. 2014;29:iv95–105.	Thank you for your comment. The diagnosis and treatment of patients with polycystic kidney disease is outside of the scope of this guideline. The guideline recommendations are applicable to the group of ADPKD patients who develop stones.

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						http://ndt.oxfordjournals.org/content/29/suppl_4/iv95.long; Nishiura JL, et al. Evaluation of nephrolithiasis in autosomal dominant polycystic kidney disease patients. Clinical Journal of the American Society of Nephrology. 2009;4:838–834. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2666433/; Rangan GK, Alexander SI, Campbell KL, Dexter MAJ, Lee VW, Lopez-Vargas P, Mai J, Mallett A, Patel C, Patel M, Tchan M, Tong A, Tunnicliffe DJ, Vladica P, Savige J. KHA-CARI guideline recommendations for the diagnosis and management of autosomal dominant polycystic kidney disease. Nephrology. 2016;21(8):705-716.) A patient with ADPKD is 5 to 10 times more likely to get a kidney stone than someone without ADPKD (KHA-CARI 2016). If a patient gets kidney stones, they may become more frequent as ADPKD progresses and kidneys enlarge (KHA-CARI 2016; Nishiura 2009). Although only a minority will have complications from stones, some evidence shows that ADPKD patients with stones have co-morbidities not seen in ADPKD patients who don't get stones – such as pain and urinary infections (Levine E, Grantham JJ. Calcified renal stones and cyst calcifications in autosomal dominant polycystic kidney disease: clinical and CT study in 84 patients. AJR Am J Roentgenol.1992;159:77-81).	

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114	SH	Polycystic Kidney Disease Charity	Guideline	5-7	1.6	There is no evidence that surgical treatment of stones in ADPKD patients should differ from non-ADPKD patients. However, the presence of multiple renal cysts can complicate surgical interventions because of the risk of cyst rupture and possible subsequent infection. UK ADPKD patients have shared their stones' experiences with the PKD Charity. A number were successfully treated using the standard interventions. However, those with very cystic kidneys had encountered problems. In one case, a patient had been prepared for lithotripsy but the procedure was "aborted" once the surgeon had seen the number of kidney cysts and the "risk of hitting a cyst". Two further attempts were made later but eventually abandoned and the patient drank water until the stones passed painfully. This patient also experienced a stone rupturing a cyst, which eventually resulted in sepsis. Another patient, a 'stone-former' who had a previous poor experience of lithotripsy, was successfully treated with Flexible Ureteroscopy & Laser. This patient commented that the hospital team has a good understanding of the complications in ADPKD patients and this has resulted in good outcomes.	Thank you for your comment. The guideline recommendations are applicable to the group of ADPKD patients who develop stones. The guideline recommends a stepped approach to surgical treatment. If one type of procedure is contraindicated or has failed alternative procedures are recommended.

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115	SH	Polycystic Kidney Disease Charity	Guideline	3	1.1.1	At the time of presentation, a urinary or cystic infection should also be considered as a possible reason for renal colic in addition to investigation for stones in ADPKD patients. The KHA-CARI 2016 guidelines also suggest "screening for underlying urinary metabolic abnormalities in ADPKD patients presenting with their first stone".	Thank you for your comment. The Committee has not made any recommendations concerning the signs and symptoms of renal colic. The Committee has made recommendations to consider stone analysis and measure serum calcium to identify underlying metabolic abnormalities, as well as making a research recommendation about the effectiveness of a full metabolic workup including urine analysis. However, the Committee has not made recommendations specifically for ADPKD patients as this population was not included in the scope.
116	SH	Polycystic Kidney Disease Charity	Guideline	9	19	It has been suggested that "lithiasis may benefit from potassium citrate when hypocitraturia is present, as well as from urine alkalinisation" (Ars E, et al. Spanish guidelines for the management of autosomal dominant polycystic kidney disease. Nephrology Dialysis and Transplantation. 2014;29:iv95–105. http://ndt.oxfordjournals.org/content/29/suppl_4/iv95.long)	Thank you for your comment. The Committee has not commented on a metabolic abnormality for the potassium citrate in adults recommendation due to the fact that the reviewed evidence involved participants with a mix of metabolic abnormalities. This meant that the Committee was unable to determine which specific abnormality benefits the most from potassium citrate. We are not able to include other guidelines as part of the NICE evidence review process.

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117	SH	Polycystic Kidney Disease Charity	Guideline	10	10	We'd like to see a recommendation for a national registry of stones patients to record incidents and treatment outcomes to help inform future guidelines and shared decision making. We read on the British Association of Urological Surgeons website that they were undertaking a 'snapshot audit of ESWL practice in the UK during 2016 & 2017', but no reports have been published. There is a stent registry. ADPKD patients can be registered on the Rare Renal Disease Registry (RaDaR), part of the UK Renal Registry, but the data is mainly entered by nephrologists or comes from renal systems. Most stones patients will see urologists and this data is unlikely to be recorded on RaDaR unless verbally provided by the patient. Further research is required into the outcomes of correcting predisposing urinary metabolic circumstances for stones in ADPKD patients.	Thank you for your comment. A registry to collect data on surgical treatments already exists and information about this is available on the British Association of Urological Surgeons website. The diagnosis and treatment of patients with polycystic kidney disease is outside of the scope of this guideline, however the Committee acknowledge the lack of evidence available on which metabolic tests are most useful and who they should be offered to and have made a research recommendation.
118	SH	Renal Association	Guideline	General	General	The Guideline Group are to be congratulated on their comprehensive approach to this report. A comprehensive look at the evidence underlying clinical practise in the care and management of patients with renal stone disease is welcome. This particular topic is full of "expert opinion" and often lacks	Thank you for your comment and for contributing to the consultation process. The Committee agree, and were pleased to create comprehensive

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						underlying evidence and clear rationale for the advice given. I am especially pleased that the guidelines offers management advice for both adult and paediatric stone forming patients. The management for each of these groups does often differ and the draft provides clear signposting of when adult and paediatric management differs.	evidence based guidelines in this area. They acknowledge that where there is insufficient evidence, recommendations were based, in part, on the expertise of the Committee. A detailed rationale of all recommendations is provided in the 'Committee's discussion of the evidence' section of each evidence review. The Committee further agrees that it was important to cover both adult and paediatric populations.
119	SH	Renal Association	Guideline	9	General	The dietary and lifestyle advice seem straightforward but again a 24 h urine collection would allow this to be more individualise to each patient. It is not stated who is best to give this advice (urologist/nephrologist/dieitician) but clearly it can be given by all healthcare professionals. Was consideration of high fructose corn syrup intake discussed? Taylor EN, Curhan GC. Fructose consumption and the risk of kidney stones. Kidney Int. 2008 Jan;73(2):207-12. Epub 2007 Oct 10. PubMed PMID: 17928824.	Thank you for your comment. A recommendation on 24 h urine collection could not be made as there was no clinical or cost effectiveness evidence. The Committee hasn't specified in the recommendation who should give dietary advice, however a sentence has been added to the discussion of evidence section of evidence review C which says that a MDT including a renal dietician for example may be needed to review or

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							give advice for those with complex or recurrent stones. High fructose corn syrup intake was not identified by the Committee as an intervention for inclusion in this review.
120	SH	Renal Association	Guideline	8, 9, 10	General	Metabolic testing for renal stones seems to be very minimalistic and the word "consider" to be too ambiguous. In my view each stone should be sent for analysis in a new stone former, and in recurrent stone formers repeat analysis may also be indicated if there is a change in appearance. Stone analysis will help identify rare stones where specific treatments are indicated (e.g. cystine stones, 2,8, DHA stones, uric acid stones etc). I am not sure why stone analysis is not extended to paediatric samples also – as many DGH urologists will deal with paediatric stones and is secondary referral to a specialist is required the chemical ID of the stone in a child is extremely valuable information. Serum calcium analysis is perhaps the bare minimum and if this elevated then specific diagnoses can be reviewed (e.g. primary hyperparathyroidism). I was sorry to see a 24 h urine was not suggested as part of the metabolic evaluation. I realise that there may be lacking evidence in this area. In my own clinical practise a 24 h urine evaluation can be extremely informative – in terms of renal volume alone – it can provide the answer, Poor urine volumes is a frequently identified risk factor for stone formation. The guidelines do	Thank you for your comment. The Committee agrees that stone analysis, serum calcium and urine testing are informative and helpful tests, however due to a lack of evidence they were unable to strong recommendations for stone analysis or urine analysis. The Committee considered the calcium recommendation and noted that PHPT is an underdiagnosed condition that often is indicated by the presence of stones. Based on this, and the fact that it is an inexpensive test the Committee agreed to change the recommendation from 'consider…', to a stronger recommendation to 'measure calcium…'. They also agreed to make a research recommendation to address this, in the hope that strong recommendations for a full metabolic testing will be able to be made in the future. We hope that this research will be able to

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						provide some advice regarding drinking volumes (2.5-3L per day but this advice remains critical for patients with poor volumes, and without 24 h collections it is difficult to see whether the advice (the stone clinic affect) has been taken on board. The evidence for low urine volumes is quoted in Evidence review A to be 5.6%(Ferraro 2015 QJM). This is likely to be an underestimation given other studies have found low urine volumes to be present in 12-25% (Curhan GC, Willett WC, Speizer FE, Stampfer MJ. Twenty-four-hour urine chemistries and the risk of kidney stones among women and men. Kidney Int. 2001;59(6):2290–8.) I would agree that the place for a metabolic assessment should be researched in more detail.	demonstrate whether full metabolic testing for everyone who has a stone is both clinically and cost effective. A sentence has been added to acknowledge that other studies have found a larger percentage of low urine volume in stone formers.
121	SH	Renal Association	Evidence review A	3	General	Low urine volumes is quoted in Evidence review A to be 5.6%(Ferraro 2015 QJM). This is likely to be an under estimation given other studies have found low urine vols to be present in 12-25% (Curhan GC, Willett WC, Speizer FE, Stampfer MJ. Twenty-four-hour urine chemistries and the risk of kidney stones among women and men. Kidney Int. 2001;59(6):2290–8.)	Thank you for your comment. A sentence has been added to acknowledge that other studies have found a larger percentage of low urine volume in stone formers.
122	SH	Royal College of General Practitioners	Guideline	8	10	Can you specifically advise re 24 urine testing for calcium at this part of guideline? It is explained on page 29 line 6 but it is unlikely all readers will find this easily that there is insufficient evidence to recommend it	Thank you for your comment. There is insufficient evidence to make a recommendation for 24 hour urine testing as outlined on page 28. The Committee did not make a practice recommendation but this does not

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							preclude clinicians from doing this testing when clinically indicated.
123	SH	Royal College of General Practitioners	Guideline	9	15	Can you specifically advise why calcium restriction is not advised as I suspect many clinicians and patients may assume that this would prevent stones? There is some evidence that dietary calcium intake is a protective factor against stone formation. It is important to emphasise that dietary calcium restriction is no longer recommended as it may lead to increased stone formation potentially through increased oxalate absorption, and may cause bone demineralization. Further efforts are needed to educate patients not to restrict calcium intake. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4708574/	Thank you for your comment. The recommendation has been adjusted to make clear that people should not restrict their calcium intake, and that it should be within a normal range. The Committee has emphasised in the discussion that a normal calcium intake may help prevent stone recurrence.
124	SH	Royal College of Pathologists	Guideline	9	1	Is 'consider' a strong enough recommendation? Given that inherited stone disease is more likely to present in childhood with implications for renal failure, I would be concerned that children may not get the metabolic assessment they need.	Thank you for your comment. The Committee agreed that many centres have paediatricians with an interest in nephrology. They also noted that there is an online protocol used by secondary care paediatricians to perform the metabolic evaluation, and children are only referred to specialist centres if an abnormality is identified. The Committee agrees that this is reflective of most centres. Therefore, the Committee agreed that children should get adequate metabolic

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							assessment. They agreed that the current recommendation also gives clinicians necessary flexibility and would avoid unnecessary over referral to specialist centres. Based on this, and the fact that there was no evidence found to inform the recommendation, the recommendation has not been amended to be stronger.
125	SH	Royal College of Pathologists	Guideline	10	3	This recommendation recommends potassium citrate treatment in the case of hypercalciuria and hypocitraturia. However, the guidelines (metabolic testing) do not make the measurement of either urine calcium or citrate a requirement as there is no clinical cost effectiveness data. It would therefore be impossible to comply with this recommendation in the absence of these metabolic tests.	Thank you for your comment. It is acknowledged in the guideline that although recommendations have been made to consider treatment, this can only be given to the populations in question if they are found to have certain metabolic abnormalities. Although treatment may be cost effective, the step before this in terms of whether testing everyone to provide treatment to a small proportion still remains uncertain. As recommendations for both testing and treatment are consider recommendations, then people can still provide these tests of treatments if they are already doing so.
126	SH	Royal College of Pathologists	Guideline	10	8	Similar to the point above, thiazides are recommended with hypercalciuria but urine calcium is not part of the metabolic assessment so would be difficult to comply with this recommendation.	Thank you for your comment. Urine calcium was not included in the recommendations as a research recommendation was made due to

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						Hypercalciuria should be defined.	there being a lack of evidence. However, this does not preclude urine calcium testing being carried out as part of the metabolic assessment. Hypercalciuria is defined within the glossary.
127	SH	Royal College of Pathologists	Evidence review A	10	10	The committee indicated that stone analysis might be as useful as urinary tests but this is very dependent on the methodology used to analyse the stones and the proportion of components. For example, a stone containing calcium phosphate and calcium oxalate with no indication as to the quantities of each compound would not help elucidate whether hypercalciuria or hyperoxaluria was the underlying cause. The stone content should be used as part of the investigation only.	Thank you for your comment. As there was no evidence for stone analysis the Committee is unable to comment on the methodology used to analyse the stones. The Committee also agreed that commenting on the methodology of stone analysis was beyond the scope of the guideline. Many laboratories do report the proportion of components/ compounds; however this alone does not indicate whether hypercaliuria or hyperoxaluria is present. This is done by urine analysis. The Committee noted that stone content can be helpful for planning management for the patient, but it is known that the same stone with different densities and compositions can yield different results on subsequent stone analyses of fragments obtained as it can differ with the fragment that was sent for analysis and the urological procedures used. It was acknowledged in the

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							committee's discussion of the evidence that stone analysis is useful as part of other investigations.
128	SH	Royal College of Surgeons of Edinburgh	Guideline	General	General	"Consider checking calcium" - i would have thought that a serum calcium check is required for all those with a stone presentation -	Thank you for your comment. The Committee considered this recommendation and noted that there is variation in current practice, with a full range of metabolic tests being done in some areas and fewer tests in others. However, the Committee also considered that PHPT is an underdiagnosed condition that often is indicated by the presence of stones. Based on this, and the fact that it is an inexpensive test the Committee decided to change the recommendation from 'consider…', to a stronger recommendation to 'measure calcium…'.
129	SH	Royal College of Surgeons of Edinburgh	Guideline	General	General	The recordation for using much more in situ ESWL is impractical unless you have an onsite lithotripter - so will have significant implications for delivery certainly in Scotland. This is acknowledged in the document but would currently be impossible to implement in many parts of Scotland at present.	Thank you for your comment. Cost of implementation will depend on the implementation model used. Increased use of SWL could be achieved with networked models, as recommended in the 'Getting It Right First Time' project. NICE guidelines only apply to England, although we acknowledge that logistical difficulties particularly in more rural areas can also apply to England.

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130	SH	Royal College of Surgeons of Edinburgh	Guideline	3	3	I appreciate the push for CTKUB within 24hrs may be difficult but we seem to manage in Edinburgh without too much difficulty in most cases, so I don't think this is a major problem for us. I do wonder whether there needs to pre-text confirming that this is aimed at those presenting as an emergency with acute loin pain thought to be renal colic? There is a risk that this could increase referrals for hospital assessment and imaging based on the requirement of CTKUB within 24hrs, by GPs who see patients with ?renal colic which are normally assessed and investigated in the community. It does not mention that this is an off-licence use of these medications.	Thank you for your comment. The Committee acknowledge that the recommendation may lead to an increase in referrals, but concluded that all suspected renal colic should be imaged with CT. The Committee felt that a CT within 24 hours should be achievable for the majority of areas covered by this guideline. Offering CT within 24 hours will not mean that renal colic cannot be managed outside of the emergency department. This was discussed at length and although it was agreed that imaging should happen urgently, it was accepted that this isn't feasible in all locations and therefore within 24 hours was agreed upon. Doing a CT within this time does not require admission to hospital, as long as patients are imaged within this timeframe. This means that patients may be sent home and asked to return as an outpatient the next day for imaging Pain medication is not off licence. The off-licence use of alpha blockers and calcium channel blockers are mentioned in the footnotes for recommendations 1.3.1 and 1.3.2..

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							Therefore we are not sure what medication you are referring to.
131	SH	Royal College of Surgeons of Edinburgh	Guideline	4	6	This is obviously very controversial and this is acknowledged in the commentary. My reading of the recent literature is that there is probably benefit for stones 5-10mm but not <5mm. Should patients with a 2mm distal ureteric calculus be offered and prescribed an off licence medication? 'Consider' may be a more appropriate term to 'offer' for the guidelines?	Thank you for your comment. The Committee was unable to look at the less than 5mm and the 5-10mm stone population separately. The committee decided to split the evidence into 10mm groups (<10, 10-20, >20, staghorn) rather than 5mm groups because it was felt that having too many strata would make the data difficult to manage and interpret. In this review there were also location (renal or ureteric) and age (adult or children and young people) strata, giving a potential of 14 separate strata for the committee to consider. It was agreed that adding extra strata by breaking down the sizing to 5mm groups would be unmanageable and not feasible. Further, this would reduce the amount of evidence available for each group, and would lead to excluding a large number of studies that did not report stone size in this way. . However they acknowledge that because of this there was uncertainty regarding the exact population that may benefit from alpha blockers, and so they amended the

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							recommendation to a 'consider', rather than 'offer'. The rationale for this has been added to the rationale and impact section of the short version document, and the discussion of evidence section of evidence review D.
132	**SH**	**Society and College of Radiographers**	**Guideline**	**3**	**2-10**	**The Society and College of Radiographers supports the use of appropriately Justified and Optimised (in accordance with IR(ME)R 2017) low-dose non-contrast CT by adequately trained and entitled Operators as an urgent (within 24 hours of presentation) investigation in adults with suspected renal colic. If a woman is pregnant, we support the use of ultrasound instead of CT.** **The Society and College of Radiographers supports the use of urgent (within 24 hours of presentation) ultrasound as first-line imaging for children and young people with suspected renal colic. If there is still uncertainty about the diagnosis of renal colic after ultrasound, we support consideration of the use of appropriately Justified and Optimised (in accordance with IR(ME)R 2017) low-dose non-contrast CT by adequately trained and entitled Operators.** **The Society and College of Radiographers suggests that referral for paediatric CT should be made at Consultant level and preferably to a specialist Paediatric Consultant Radiologist or entitled Radiographer Practitioner.**	**Thank you for your comment. Referral to services and delivery of care should be made by health professionals with the necessary qualifications and competencies. This is a decision to be made by at a local level.**

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						Professionals undertaking ultrasound examinations of the renal tract whether medically qualified or not must be properly trained. **https://www.rcr.ac.uk/publication/standards-provision-ultrasound-service** **https://www.rcr.ac.uk/publication/standards-interpretation-and-reporting-imaging-investigations-second-edition** **https://www.rcr.ac.uk/publication/ultrasound-training-recommendations-medical-and-surgical-specialties-third-edition**	
133	SH	Society and College of Radiographers	Evidence review J	7	14	1.8.1 Research recommendations – The Society and College of Radiographers supports and welcomes the research recommendations: What is the clinical and cost effectiveness of 6-monthly imaging for 3 years for people with 16 recurrent calcium renal or ureteric stones?	Thank you for your comment.
134	SH	University Hospital of South Manchester NHS Foundation Trust	Guideline	4	1	In "real world" situations of acute colic in A&E or the ward this does not serve our patients well. In theory a NSAID/IV paracetamol may have a stronger evidence base, but given the severity of colic pain I believe this could lead to unacceptable delays in effective analgesia. It is effectively saying that a patient has to wait (?how long) to see if an NSAID is effective before considering further analgesia. Given NHS nursing staff shortages this will inevitably lead to delays.	Thank you for your comment. The Committee decided not to specify the length of time to wait to see if first line medication has been effective. The amount of time for an NSAID to work will depend on the route of administration. The Committee also recognised that often pain medications are given in a staged manner, and thought that the wording of the current recommendation still allows for this,

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							whereas specifying timings would limit the recommendation, and potentially make unnecessary protocols, which the Committee was keen to avoid. They concluded that clinicians should be allowed to base these decisions on the clinical situation, using their judgement and expertise. Evidence from a population with confirmed or suspected renal colic presenting at an emergency department demonstrated that NSAIDs and paracetamol are effective for this population. The Committee concluded that this population does represent real world settings.
135	SH	University Hospital of South Manchester NHS Foundation Trust	Guideline	4	7	I disagree. The two highest quality trials of MET (SUSPEND and Furyk: Ann Emerg Med. 2016 Jan;67(1):86-95) failed to show any benefit for alpha blockers in small stones (<5mm). There *may* be some benefit in larger stones (5-10mm), but this was based on subgroup analysis only in the Furyk trial. There was approximately 10% incidence of unacceptable side effects from tamsulosin in SUSPEND. There is a US based trial that is recruiting that I believe will look more at larger stones. Until that is published I don't think the risk/benefit ratio justifies its use.	Thank you for your comment. The Committee was aware that the SUSPEND trial and Furyk study tended to show no difference between interventions, however NICE methodology is to not exclude studies based on study size or quality, as this is taken into account in the risk of bias assessments. Taking all of the available evidence into account, the Committee agreed that overall, there was evidence of benefit of tamsulosin.

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							The Committee was unable to look at the less than 5mm and the 5-10mm stone population separately, however they acknowledge that because of this there was uncertainty regarding the exact population that may benefit from alpha blockers, and so they amended the recommendation to a 'consider', rather than 'offer'. The rationale for this has been added to the rationale and impact section of the short version document, and the discussion of evidence section of evidence review D. The US trial by Meltzer has been assessed for inclusion however it was excluded as the reported data wasn't usable. The authors were contacted however they were unable to supply the relevant information within the time constraints.
136	SH	University Hospital of South Manchester NHS Foundation Trust	Guideline	4	9	SUSPEND also failed to show any benefit for nifedipine.	Thank you for your comment. The SUSPEND trial authors were contacted for additional information to include data on stone location. The Committee reviewed this new evidence. When calcium channel blockers were compared to no treatment, there was a clinical benefit

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							of nifedipine, and when compared to placebo there was a no clinical difference for many outcomes. Because there was no benefit when compared to placebo, the Committee noted that the intervention didn't meet the criteria of being effective, therefore this recommendation was removed.
137	SH	University Hospital of South Manchester NHS Foundation Trust	Guideline	4	14	This is aspirational-facilities for SWL &/or URS within 48h of admission, including at weekends, do not exist in many (?any) centres in the UK.	Thank you for your comment. The Committee considered that the NHS is a 7 day working week and so offering treatment within 48 hours was not thought to be unreasonable. How challenging implementing the recommendations on treatment within 48 hours will be are dependent on the model of implementation used. The 'Getting It Right First Time' project has recently also published recommendations for urology and recommends networked models of care. The NICE Resource Impact work has also demonstrated that treating people with ureteric stones less than 10mm using SWL instead of ureteroscopy would be cost saving, although this excludes network costs. The Resource Impact tools are available on publication of the guideline to help trusts and

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							commissioners with planning implementation in their area.
138	SH	University Hospital of South Manchester NHS Foundation Trust	Guideline	8	4	The statement is rather neutral, but given that the authors recommend a clinical trial of its effectiveness as well as the existing evidence of lack of efficacy in conservative treatment, I don't see how a consideration of the overall risks/benefits can lead to any recommendation in this regard.	Thank you for your comment. Recommendation 1.8.3 refers to children, whereas the research recommendation is for the adult population. Therefore they address two separate populations.
139	SH	University of Aberdeen	Guideline	4 15	7-10 23	We have concerns that this recommendation is not in agreement with the current European Association of Urology (EAU) Guidelines for Urolithiasis recommendations in adults (Retrieved from http://uroweb.org/guideline/urolithiasis/ 23 August 2108) which is to offer alpha-blockers as medical expulsive therapy (MET) as one of the treatment options only for large (distal) ureteral stones (≥ to 5mm). The EAU guidance was recently updated in response to changes in the evidence and is based on the two most recently published meta-analyses, Hollingsworth et al. (BMJ 2016; 355:i6112) and Campschroer et al. (Cochrane Database of Systematic Reviews 2018, Issue 4) both of which show no benefit of alpha-blockers to patients with smaller ureteric stones (<5 mm). There were 55 studies included in the Hollingsworth review and Campschroer et al. reviewed 67 studies in their Cochrane review, which showed a minimal effect for stones 5 mm or less	Thank you for your comment. The committee was unable to look at the less than 5mm and the 5-10mm stone population separately. The committee decided to split the evidence into 10mm groups (<10, 10-20, >20, staghorn) rather than 5mm groups because it was felt that having too many strata would make the data difficult to manage and interpret. In this review there were also location (renal or ureteric) and age (adult or children and young people) strata, giving a potential of 14 separate strata for the committee to consider. It was agreed that adding extra strata by breaking down the sizing to 5mm groups would be unmanageable and

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						(RR 1.06 (95% CI 0.98 to 1.15). In clinical practice in the UK NHS smaller stones (<5 mm) are far more prevalent than larger stones (Pickard et al., Lancet 2015; 386: 341–49). These draft NICE guidelines would therefore benefit from sub-group analyses for smaller stones which may be of greater relevance to the UK population. Leaving the guideline as is would mean over-treatment for a significant number of NHS patients and risk of harm from unnecessary side effects. In addition the committee could also consider the data from a recently published RCT (Meltzer et al., JAMA Intern Med. 2018;178(8):1051-1057) conducted in emergency departments in the USA, which showed the alpha-blocker tamsulosin did not significantly increase the stone passage rate compared with placebo and their findings do not support the use of tamsulosin for symptomatic urinary stones smaller than 9 mm. The findings are consistent with the SUSPEND (Pickard et al., Lancet. 2015; 386(9991):341-9) and Furyk studies (Ann Emerg Med. 2016 Jan;67(1):86-95), and the committee should consider whether the evidence from the three largest, well conducted and methodologically sound placebo controlled RCTs in the literature should be balanced against the numerous small, low quality studies included in the evidence review meta analyses. It is also worth mentioning that the NICE evidence systematic review includes data from two large pharmaceutical industry sponsored studies (Ye et al. 2011, 2018). Concerns have been raised about some aspects of these studies, including selection of the	not feasible. Further, this would reduce the amount of evidence available for each group, and would lead to excluding a large number of studies that did not report stone size in this way. r. However the committee acknowledge that because of this there was uncertainty regarding the exact population that may benefit from alpha blockers, so they amended the recommendation to a 'consider', rather than 'offer'. The rationale for this has been added to the rationale and impact section of the short version document, and the discussion of evidence section of evidence review D. Both the Hollingsworth and Campschroer reviews were picked up for examination by the technical team, and all included references were assessed for inclusion to the review. The Meltzer study was identified and assessed for inclusion however it was excluded as the reported data wasn't usable. The authors were contacted however they were unable to supply the relevant information due to time constraints.

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						study population, the low drop-out rate and the over-representation of larger stones compared to other studies (see letters to the editors European Urology: Volume 73, Issue 4, April 2018, Pages e91; Volume 74, Issue 2, August 2018, pages e40-e41 and e43-e44). To date although the authors have responded to the comments, some serious questions regarding the methodology of these large studies remain. The committee may wish to reconsider this evidence after consideration of the points raised.	The committee noted concerns regarding the Ye 2018 study, and considered the evidence both with and without this study included, however its inclusion did not impact the overall conclusions of the review. The Committee also noted that the SUSPEND trial and Furyk study tended to show no difference between interventions, however NICE methodology is not to exclude studies based on study size or quality, as this is taken into account in the risk of bias assessments. Further, NICE methodology is to pool all available studies meeting the protocol where possible, to get more precise estimates. Taking all of the available evidence into account, the Committee concluded that there was evidence of benefit of tamsulosin, however they acknowledged that there was some uncertainty surrounding its effect.
140	SH	University of Aberdeen	Evidence review D - Medical Expuls	23	Indirectness of population	In some cases the SUSPEND study results are not broken down into outcomes associated with stone location, which is the focus of the review and recommendations by the committee. Although not presented the SUSPEND trial team can provide this data for inclusion if the committee requests this.	Thank you for your comment. The SUSPEND trial team have provided this data and this has now been included.

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			ive Therapy				
141	SH	University of Aberdeen	Evidence review D - Medical Expulsive Therapy	80 & 81	Distal stones <10mm	Both the EAU and the American Urology Association guidelines state that medical expulsive therapy (MET) should only be used in an informed patient (meaning that the patient is informed of the side-effect profile of the drug and the fact that this is an off-label use of the drug). This is particularly pertinent in adult females and children where there is a lack of safety data. We have concerns that this will be challenging to implement in practice and that patients could be offered MET without a full realisation of the implications of off-label use. In the SUSPEND trial, a pragmatic study based in UK NHS hospitals, tamsulosin and nifedipine were associated with a greater rate of side effects compared to placebo (participant reported discontinuation of medication due to side effects). In addition nifedipine was associated with a greater rate of serious adverse reactions which involved attendances at emergency departments. Based on this we feel that the claim MET, and in particular nifedipine, has a benign adverse event profile is misleading, and ask the committee to reconsider the risk/benefit ratio for MET considering reported discontinuation of medication and additional hospitalisations due to adverse reactions.	Thank you for your comment. NICE recognises the importance of shared decision making in all of its guidance. The Patient experience in adult NHS services guideline, which includes the recommendations on shared decision making is highlighted in the scope, as well as medicines optimisation, service user experience in adult mental health and medicines adherence. All of these guidelines are expected to be considered and followed alongside the current guideline. Links to these are provided in the NICE short version in the 'your care' section along with an outline of the broad principles around decision making. Please see: https://www.nice.org.uk/about/nice-communities/public-involvement/your-care. No additional recommendations on these topics were included unless there are specific issues related to renal and ureteric stones. The Committee concluded that the shared decision making recommendations

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							were directly applicable to the renal and ureteric stone population without the need for additional recommendations. There is information about the use of off label medications as footnotes for the MET recommendation (recommendation 1.3.1, short version document). The SUSPEND authors were contacted to provide additional information which has allowed the adverse event data, as well as other outcomes, to be included. The Committee reviewed the new evidence and agreed to amend the recommendations to 'consider' alpha blockers, rather than 'offer'. The recommendation for nifedipine was removed.