

DIAGNOSTICS ASSESSMENT PROGRAMME

**Point of care tests for urinary tract infections to improve antimicrobial prescribing
Early Value Draft Guidance Consultation Document – Comments
Theme: Current practice**

Comment number	Name and organisation	Section number	Comment	NICE Response
1	Web comment	General	<p>You say the new POC dx takes too long or could be less accurate than current testing when in reality all of them are quicker and more accurate than gold standard which is not even fit for purpose since it misses circa 30% of infections, especially in those that are most susceptible.</p> <p>You talk about culture tests taking 24h but reality is with logistics and poor admin reporting results, sample storage/quality etc, the average wait time for results and subsequent prescribing is several days not 24h. Quite frankly ANY test would be better than what you have now which is not fit for purpose. You'd be better of treating based on symptoms alone rather than using the current tests you have which are outdated and lack scientific evidence with inappropriate cut-offs from the 1960s!</p> <p>Science shows polymicrobial infections are real but standard testing labels this as contamination. Why can't you reduce the culture testing cutoff to 10³ and eliminate dipstick tests as negative results are not diagnostic?</p>	<p>Thank you for your comment which NICE has considered.</p> <p>The committee's considerations of the time to results and accuracy of point of care tests are described in section 3.5 and section 3.6 of the guidance document. The committee said that how tests are implemented in practice, local demand for testing and how quickly a test can run may all affect how tests will impact patient outcomes. The committee concluded that some of the newer tests assessed (that take around 16 to 24 hours for results or that are unlikely to give same-day results) are unlikely to be useful in primary or community care (see section 3.4) but it also concluded that quicker tests show promise.</p> <p>Based on the data identified, the committee concluded that there is considerable uncertainty about how well the tests will perform in the NHS compared to current testing, and too much uncertainty about their performance to recommend use in the NHS at present. But if more data is generated (described in section 1, section 3.17, section 3.16, section 3.18 and section 4 in the guidance) to confirm the accuracy of these newer</p>

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			<p>Identifying bacteria quickly even without abx susceptibility testing is more useful than a dipstick to effect prescribing ! doctors just need to understand abx susceptibility better.</p>	<p>tests, the recommendations may be changed in the future. The committee noted that there are ongoing studies that could provide important data (see section 3.10 and section 3.16 of the guidance document).</p> <p>The committee discussed the limitations of current testing, which can be found in section 2.2, section 3.7 and section 3.17 of the guidance document. This included that laboratory-based testing may take longer than 24 hours to provide results. Knowledge of current testing was provided by healthcare professionals working in the NHS as well as Public Health England's Diagnosis of urinary tract infections (2020). It is outside the scope of this guidance to propose changes to current laboratory-based testing, as proposed in the comment. The scope of the assessment can be found here.</p> <p>The committee's discussion about what information from point of care tests may be most useful is in section 3.8 of the guidance document. The committee concluded that rapid tests that can test for antibiotic susceptibility are</p>

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				likely to have the greatest potential to improve antibiotic prescribing decisions.
2	Web comment	2.3	<p>While waiting for laboratory-based culture test results, people are often prescribed antibiotics empirically.</p> <p>This statement appears, incorrectly, to suggest that urine cultures are normal on first presentation. In keeping with guidance (Public Health England), many with lower UTI are prescribed antibiotics empirically and no culture test is arranged.</p>	<p>Thank you for your comment which NICE has considered.</p> <p>Additional wording has been added to section 2.3 of the guidance to add clarification of the differences between diagnosis and treatment pathways in current practice.</p>
3	Web comment	3.5	<p>A clinical expert explained that dipstick tests give quick results during a GP appointment.</p> <p>Though dipsticks are rarely indicated - see PHE guidance quoted in section 2.</p>	<p>Thank you for your comment which NICE has considered.</p> <p>The groups that dipstick tests are not recommended for and the limitations of dipstick testing are highlighted in section 2.2, section 3.7 and 3.17 of the guidance document.</p>
4	Web comment	3.6 and 3.7	<p>In all patients with UTI symptoms, current medical practice involves initial urinary dipstick testing for leucocyte esterase and nitrites. If acute symptoms are typical, a mid-stream, clean catch urine sample may be sent for culture, despite negative dipstick results. If the symptoms are equivocal (commonly occurring in</p>	<p>Thank you for your comment which NICE has considered.</p> <p>The committee discussed the limitations of current testing, which can be found in section 2.2, section 3.7 and section 3.17 of the guidance document. In its</p>

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			<p>chronic, non-dysuric LUTS patients) and the initial urinary dipstick is negative, the sample may not be sent for culture at all.</p> <p>Urine culture also has substantial limitations. For largely historical reasons, the gold standard has long been defined as bacterial growth of a single organism at more than 10⁵ CFU/ml, with epithelial cells indicating contamination from the perineum. The 10⁵ CFU/ml threshold was set out by Kass in 1957, and is widely criticised, as his patients' urine samples were collected from only 74 women with acute kidney infections, with bacteria thriving in their urine. Since the late 1950's there have been reports that such a threshold is not sufficiently sensitive to pick up all urinary infections, but the concerns of numerous scholars have been largely ignored by the medical community. In early reports, Stamm and colleagues have demonstrated that the threshold set out by Kass can only pick up 50% of urinary tract infections. They proposed a more sensitive diagnostic criterion of 10² CFU/ml, which has been supported by many other recent studies. It should also be noted that "mixed growth" culture with evidence of epithelial shedding, in the context of symptomatic,</p>	<p>considerations, the committee recognised that there are considerable potential benefits for newer point of care tests considered in this guidance (see section 3.2 of the guidance for further detail).</p> <p>The committee acknowledged that dipstick tests are unreliable in certain populations (such as people over 65 or who have a catheter). The committee agreed that it is important to assess new tests in groups that have limited options in current standard care, and highlighted people with recurrent or chronic UTIs as groups that may particularly benefit from improved testing.</p> <p>Issues with laboratory-based testing were highlighted by the EAG (see section 7.2 of the EAG's report) and considered by committee. Further detail has been added to section 3.6 of the guidance document to clarify where this information can be found.</p>

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			<p>pyuric patients, point to a very significant pathological state, and should not be dismissed as “contaminated samples”.</p> <p>Further, urinalysis, by dipstick within GP surgery only detects those bacteria which reduce nitrates to nitrites in the urine but several uropathogens do not reduce nitrate to nitrite, and therefore its utility is restricted to Enterobacteriaceae which give a positive test result. This makes the nitrite test considerably less useful. One study notes that dipstick tests were just 56% sensitive to leukocyte esterase and 10% sensitive to nitrites in a study of patients with chronic LUTS without dysuria. Meta-analyses of the use of urinary dipsticks in adults and in children have been reported concluding that dipsticks cannot exclude infection reliably in most clinical settings.</p> <p>There are serious shortcomings affecting the routine diagnostic tests health practitioners rely on to diagnose UTIs, with many health practitioners unaware of their frequent failures to detect or correctly identify pathogenic bacteria.</p>	

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			Heytens et al. Women with Symptoms of a Urinary Tract Infection but a Negative Urine Culture: PCR-based quantification of Escherichia coli suggests infection in most cases. Clinical Microbiology and Infection. 2017	
5	Web comment	3.6 and 3.7	<p>We are also concerned that there is implication in this initial consult paper that a single causative pathogen is responsible for uncomplicated UTI either acute, recurrent or chronic in nature. Infections are now multi-pathogenic. Even with a positive initial urine sample, if the infection is not cleared based on culture results, consideration by the GP must include not only the same pathogen but other causative low growth pathogens. We ask whether the tests currently under consideration reflect this single causative pathogen pathway or whether they will identify multiple pathogens. For those with chronic infections this is often reflected in more detailed testing not under consideration here such as PCR or next generation sequencing.</p> <p>Tenke P, Koves B, Nagy K, Hultgren SJ, Mendling W, Wullt B, et al. Update on biofilm infections in the urinary tract. World JUrol. 2011.</p>	<p>Thank you for your comment which NICE has considered.</p> <p>Section 3.6 of the guidance document has been amended to reflect the point made in the comment that UTIs may have more than a single causative pathogen.</p>

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			<p>Blango MG, Mulvey MA. Persistence of uropathogenic Escherichia coli in the face of multiple antibiotics. AntimicrobAgents Chemother. 2010;54(5):1855-63.</p> <p>Hoiby N, Bjarnsholt T, Givskov M, Molin S, Ciofu O. Antibiotic resistance of bacterial biofilms. Int J Antimicrob Agents. 2010;35(4):322-32. doi: 10.1016/j.ijantimicag.2009.12.011. PubMed PMID: 20149602.</p> <p>Anderson GG, Dodson KW, Hooton TM, Hultgren SJ. Intracellular bacterial communities of uropathogenic Escherichia coli in urinary tract pathogenesis. Trends Microbiol. 2004;12(9):424-30.</p> <p>Anderson GG, Palermo JJ, Schilling JD, Roth R, Heuser J, Hultgren SJ. Intracellular bacterial biofilm-like pods in urinary tract infections. Science. 2003;301(5629):105-7. Epub 2003/07/05. doi: 10.1126/science.1084550. PubMed PMID: 12843396.</p> <p>Reid G. Biofilms in infectious disease and on medical devices. IntJAntimicrobAgents. 1999;11(3-4):223-6.</p>	

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6	Web comment	3.6 and 3.7	<p>We have concern about the statement “many UTIs are caused by E-coli”. This is based on the assumption of current culture tests identifying e-coli within a 24 hour window. The bacterial culture numbers are likely to depend on the ease of growth of bacteria in a laboratory. Bacterial species react differently to an oxygenated environment. The bacteria residing in a bladder have a limited oxygen source but when a urine sample is placed on a petri dish in the laboratory, the oxygen they are exposed to increases. This means that bacteria which flourish beneficially in this type of environment will grow. An example of this is E-coli whereas those that prefer the ecosystem and oxygen levels of the bladder will grow in limited numbers and are often dismissed as contamination.</p> <p>However laboratory cultures detect as little as 12% of other clinically significant species (e.g., gram-positive bacteria; Enterococci and Group B streptococci). It has been demonstrated that the positive predictive value of midstream urine cultures was 93% and 99% for Escherichia coli growth of at least 10² CFU and 10⁴ CFU, respectively, but the positive predictive value was 10% and 33% for Enterococci growth and 8 and 14%</p>	<p>Thank you for your comment which NICE has considered. We have amended the guidance to remove reference to ‘many UTIs’ to leave this point as ‘UTIs can be caused by E. coli’ without any reference to the proportion of infections that are caused by E. coli.</p> <p>The extent that the newer tests may allow more slow-growing pathogenic bacteria to be detected, compared to laboratory-based testing, was not clear from data identified. Section 3.6 of the guidance has been amended to highlight this as a consideration for future work.</p>

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			<p>for Group B streptococci growth of at least 10² CFU and 10⁴ CFU, respectively.</p> <p>Will these new tests proposed allow for the inclusion of more slow-growing bacteria that are equally as pathogenic as faster growing bacteria more readily identified on short window time frames for laboratory culture?</p> <p>Price et al. The Clinical Urine Culture: Enhanced Techniques Improve Detection of Clinically Relevant Microorganisms. Journal of Clinical Microbiology. May 2016 (54) 5 Hooton, T.M.; Roberts, P.L.; Cox, M.E.; Stapleton, A.E.</p> <p>Voided midstream urine culture and acute cystitis in premenopausal women. N. Engl. J. Med. 2013, 369, 1883–1891</p>	
7	Web comment	3.8	<p>Particularly if results are given as quickly and if it has better performance in groups that dipsticks are not recommended for.</p> <p>See previous comments. Dipsticks have limited but specific uses in algorithms.</p>	<p>Thank you for your comment which NICE has considered.</p> <p>The groups that dipstick tests are not recommended for use and the limitations are highlighted in section 2.2 and section 3.17 of the guidance document.</p>

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8	NHS England	3.9	Dosing of ciprofloxacin would not be dependent on culture results.	Thank you for your comment which NICE has considered. Section 3.9 of the guidance document has been updated to reflect this comment.

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Early Value Draft Guidance Consultation Document – Comments

Theme: Populations and patient groups

Comment number	Name and organisation	Section number	Comment	NICE Response
9	Web comment	General	We need to get over this paranoia about antimicrobial resistance – in the case of recurrent/chronic uti you are doing more harm than good by withholding abx and it wouldn't harm to take a little more than needed if this is the ultimate consequence.you are causing more harm by making decisions based on outdated tests which were never designed with the entire population demographics in mind.	<p>Thank you for your comment which NICE has considered.</p> <p>The committee considered the potential benefits and risks of point of care tests and concluded that the uncertainties in the current evidence means it is difficult to assess the risks and benefits of using these tests in the NHS while further evidence is generated. It also agreed that delays to appropriate antibiotic prescribing because a GP is waiting for test results or because a test has given inaccurate results could harm patients. More detail about the why the committee made its decision can be found in section 1 of the guidance document. The committee also recognised the importance of considering the impact of the tests on people with recurrent and chronic UTIs separately from acute UTIs, because of differences between the conditions (see section 3.14 of the guidance document).</p>
10	Web comment	3.2	Faster access to effective treatment would also relieve symptoms more quickly and effectively. New point of care tests may reduce the need to provide repeat urine samples,	Thank you for your comment which NICE has considered.

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Theme: Populations and patient groups

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			Although this statement may be correct in more specific situations, it is misleading for the majority of those in primary care with infection - women aged 16-65 with occasional bouts of cystitis, who should be receiving quick treatment without the need to wait for test results.	Further detail has been added to section 3.2 to clarify that some groups will receive treatment without waiting for test results.
11	Web comment	3.2	<p>Patient experts noted that people with neurogenic bladder, diabetes, polycystic kidney disease, and people who are immunocompromised have a higher risk of complicated UTIs and need to receive treatment as soon as possible.</p> <p>Agree and anyone who possibly has Upper UTI, which would include high-risk children as well</p>	Thank you for your response which NICE has considered.
12	Web comment	3.7	<p>These groups are likely to have asymptomatic bacteriuria, which could lead to overdiagnosis.</p> <p>Agree - and in this situation the technology would exacerbate over diagnosis.</p>	Thank you for your comment which NICE has considered.
13	Web comment	3.9	<p>But they noted that an antibiotic susceptibility test may be needed to prescribe them if there is concern about resistance in the local population.</p> <p>There is significant evidence that resistance rates are of limited use in predicting clinical response to antibiotics in</p>	<p>Thank you for your comment which NICE has considered.</p> <p>Further detail has been added to section 3.9 of the guidance document to reflect the detail in this comment.</p>

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			simple cystitis, since some antibiotics (nitrofurantoin and trimethoprim most notably) concentrate in the bladder and achieve levels well above that applied in laboratory resistance tests. Laboratory based (or POC) resistance status is, however, very useful for Upper UTI or in other situations where one would wish to avoid mis-treatments (you have listed examples above)	
14	NHS England	3.9	Tests identifying bacteria would also pick up asymptomatic bacteruria and, as with dipsticks, give false positives in some populations.	<p>Thank you for your comment which NICE has considered.</p> <p>Clinical experts agreed that urine samples from some populations, such as people who have a catheter or are over 65, are often polymicrobial. These groups are likely to have asymptomatic bacteriuria, which could lead to overdiagnosis. The committee's consideration of this is in section 3.7 of the guidance document.</p>
13	Web comment	3.14	As noted in the Consultation document Chronic UTIs have a significant health and economic impact on lives. We are grateful to the clinical experts involved in this consultation that acknowledge the separate clinical symptoms of acute, recurrent and chronic and how diagnostic/clinical care must differentiate. It is clearly a knowledge and evidence gap that	Thank you for your comment which NICE has considered.

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Theme: Populations and patient groups

Comment number	Name and organisation	Section number	Comment	NICE Response
			<p>must be investigated further to ensure diagnostic and treatment options accurately reflect the differences in patient cohorts. If emphasis continues to be placed on acute UTI in primary and secondary care then the patient burden will increase both on health services and economic burden on state support resources.</p> <p>At present sufferers of Chronic UTI may not receive an official diagnosis of the disease for up to 7 years after symptoms have commenced. The global burden of this disease is rising – 16.1% increase in age-standardised incidence between 1990 and 2013. With 58,000 years lost to disability (YLD) in 2003 alone</p> <p>Global Burden of Disease Study 2013 Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet. 2015 Aug 22;386(9995):743-800. doi: 10.1016/S0140-6736(15)60692-4.</p>	
14	Web comment	3.17	The accuracy of tests and how they affect prescribing choices may vary in different populations and data is unlikely to be generalisable across groups	Thank you for your comment.

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Comment number	Name and organisation	Section number	Comment	NICE Response
			Agree	
15	Web comment	3.17	People with recurrent or chronic UTIs were highlighted as a group that may particularly benefit from improved testing. Children?	Thank you for your comment. The wording in section 3.17 of the guidance has been updated to reflect this comment.

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Theme: Implementation

Comment number	Name and organisation	Section number	Comment	NICE Response
16	Web comment	3.5	<p>We are in agreement with the clinician comments made about the lack of need for a second appointment to discuss diagnostic results. With modern communications technology and electronic prescription services, diagnostic services and prescribing options should allow for treatment to be dispensed same day. We understand the concern that primary care practitioners have given most appointment last a maximum of 10 minutes but would recommend that practice organisation would mean that nurse practitioners alongside primary care physicians would manage local testing using these new diagnostic measures. Only patients with a chronic history of illness or other co-morbidities should receive a second appointment and that can be via telephone.</p> <p>As per the comments above, we believe that a patient who is sent away because the current dipstick analysis indicates no infection is in a worse position than a patient with access to the new testing protocols under consideration where diagnosis may take slightly longer. It is short sighted to</p>	<p>Thank you for your comment which NICE has considered.</p> <p>The committee discussed the implementation of new point of care tests (see section 3.5) and concluded that how testing was implemented in practice could influence how quickly results are available and how they are acted on but agreed that more rapid tests that give results on the same day show promise.</p>

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			<p>assume that a same day time delay is a negative. Bacterial development is often every 20 minutes and a more accurate longer test could prove of more benefit in the long run particularly if the patient has a history of recurrent or chronic infections. Each time a urinary tract infection occurs it can make susceptibility to a further infection more likely.</p>	
17	Web comment	3.5	<p>One significant area that is not addressed in this consultation document is patient education by healthcare practitioners as to how to obtain a urine sample. 1 in 4 urine samples sent for analysis are rejected due to “contamination” and at present there is no established protocol or standard for collection of urine by Public Health England other than the recommendation of a clean catch, mid-stream urine sample. For women this can prove to be a particularly difficult process. It requires starting the urine flow whilst parting the labia, stopping urination to position a small tube to collect the urine whilst keeping the labial folds open, removing the sample pot and finishing urinating. Spillage or splashing must be avoided and all of this often in a cramped GP surgery toilet or urgent care centre. More</p>	<p>Thank you for your comment which NICE has considered.</p> <p>Additional detail has been added to section 3.2 of the guidance document to highlight the importance of education for patients and GPs.</p>

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			<p>often or not there are little or no instructions from the GP or Nurse as to how to collect a “clean catch” sample. We would ask that education of the patient and GP be a key part of any potential introduction of new tests so that accuracy can be improved and a right first time diagnosis be given to a patient with clear symptoms of a UTI.</p>	
18	Web comment	3.6 and 3.7	<p>When analysing these new diagnostic tests for inclusion in primary and secondary care health support, we would question whether the parameters for each test will continue to reflect the 10⁵ threshold for positive identification of a UTI. Would these tests provide for lower thresholds if requested particularly for patients with recurrent or chronic infections. We would draw the committee’s attention to the fact that most GPs would not have the knowledge to request a lower CFU count for a patient, particularly if the initial dipstick or urine analysis was unclear or negative. We thus recommend that signs and symptoms of infection should be equally weighted and GPs not just be guided by dipstick or culture results which would include these new</p>	<p>Thank you for your comment which NICE has considered.</p> <p>Tests are assessed in line with how manufacturers indicate they should be used (including thresholds for what constitutes a positive result, which also may not be modifiable for all technologies) because this is how health care professionals would understand them to be intended to be used. The committee noted the importance of understanding how the tests impact on decisions about antibiotic prescribing made by health care professionals, alongside other information such as symptoms (described in sections 3.3 and 3.4 of the guidance)</p>

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Theme: Implementation

Comment number	Name and organisation	Section number	Comment	NICE Response
			diagnostic tests currently under consideration by this committee.	and concluded that further research on this is needed (see section 4.2).

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Theme: Test costs and cost modelling

Comment number	Name and organisation	Section number	Comment	NICE Response
19	Web comment	General	<p>Cost effectiveness is short sighted – for the particular cohort of chronic/recurrent uti patients, the cost-saving for subsequent years of prescribing/suffering are clear, and this is a patient group increasing in size due to initial acute utis not being treated adequately.</p>	<p>Thank you for your comment which NICE has considered.</p> <p>The specified time horizon for cost effectiveness analysis in the assessment is that it should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Any cost savings or benefits to health-related quality of life would therefore be important considerations in an assessment of cost effectiveness of the tests for people with recurrent or chronic UTI. However, at present the committee concluded there is too little evidence to be able to assess cost effectiveness of the tests to assess cost effectiveness in this way (see sections 1 and 3.15 in the guidance for more detail). Further research was recommended in the guidance to provide such evidence and allow cost effectiveness to be estimated.</p>

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Early Value Draft Guidance Consultation Document – Comments

Theme: Test costs and cost modelling

Comment number	Name and organisation	Section number	Comment	NICE Response
20	Web comment	3.12	<p>The committee considered that more detail was needed on what other changes in antibiotic use point of care tests could contribute to, beyond empirical or targeted use.</p> <p>It is very necessary that the modelling mirrors best practice in the management of UTI, rather than the practice that has been assumed throughout this document.</p>	Thank you for your comment which NICE has considered.
21	Llusern Scientific (company)	Page 77, EAR	<p>The document “early value assessment” Page 77, which is part of the committee paper assumed Lodestar distribution cost on the basis of FlexiCult costs of £43.90. This appears to have been derived from processing costs as follows:</p> <ul style="list-style-type: none"> • 9 minutes preparation, • 6 minutes to obtain results and • 7 minutes to discuss the results. <p>However, Lodestar test takes only 2 minutes preparation, results reading is instantaneous and would take less than a minute to record. Therefore, on the assumption of a similar</p>	<p>Thank you for your comment which NICE has considered.</p> <p>Test costs from the company for the Lodestar test were provided to NICE as commercial in confidence, so could not be published in the EAG’s external assessment report or be included in the guidance document. However, provided costs were provided to committee to aid decision making and were included in the external assessment report (the values were redacted for public release as they were provided as confidential).</p>

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Theme: Test costs and cost modelling

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			<p>patient discussion time of 7 minutes, the total processing time will be 10 minute resulting in a cost of about £20 (than £43.90).</p> <p>If we include a maximum-end price of the test (£12), a total combined cost of £32 is therefore a reasonable estimate for Lodestar test.</p>	

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Early Value Draft Guidance Consultation Document – Comments

Theme: Equality

Comment number	Name and organisation	Section number	Comment	NICE Response
22	Web comment	General	You talk the EDI talk but your committee is overwhelmingly white including your specialist lay members when you've already acknowledged that certain demographics have worse outcomes. Why don't you have any ethnic minority female patients on your advisory panel?!	<p>Thank you for your comment which NICE has considered.</p> <p>Positions on the committee (both for standing and specialist committee members) are advertised on NICE's website (https://www.nice.org.uk/Get-Involved/our-committees) and NICE has worked with former and current committee members to co-produce an action plan around increasing diversity within our advisory groups. Further detail on the NICE equality scheme and reports related to committee membership can be found on the following page: https://www.nice.org.uk/about/who-we-are/policies-and-procedures/nice-equality-scheme.</p>

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Early Value Draft Guidance Consultation Document – Comments

Theme: Further evidence generation

Comment number	Name and organisation	Section number	Comment	NICE Response
23	Web comment	3.5	<p>The committee concluded that how testing was implemented in practice, and local demand for testing, could influence how quickly results are available and how they are acted on.</p> <p>Real world studies needed before tests are recommended.</p>	<p>Thank you for your comment which NICE has considered.</p> <p>The committee agree that further research is needed and will allow the risks and benefits of early routine use of the technologies in the NHS to be understood more clearly. The committee's recommendations for further research are in section 1.2, section 3.17, section 3.18 and section 4 of the guidance document.</p>

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Early Value Draft Guidance Consultation Document – Comments

Theme: Comparator

Comment number	Name and organisation	Section number	Comment	NICE Response
24	Web comment	2.6	<p>The comparators are: dipstick testing, then laboratory-based testing (if necessary) or laboratory-based testing alone.</p> <p>Clinical symptom based diagnosis should also be a comparator.</p>	<p>Thank you for your comment which NICE has considered.</p> <p>Section 2.6 of the guidance document has been updated to note that diagnosis using clinical symptoms could be considered as a comparator in future assessments. Section 3.18 of the guidance also notes that a clinical expert also highlighted in the committee meeting that it may be useful to assess test performance in groups who currently have no testing, for example women over 18 with 2 or 3 symptoms of UTI.</p>

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Early Value Draft Guidance Consultation Document – Comments

Theme: General

Comment number	Name and organisation	Section number	Comment	NICE Response
25	British society of urogynaecology (BSUG)	General	<p>Thank you for inviting the British Society of Urogynaecology to comment on this consultation. We have reviewed the documents and have no specific comments. We are satisfied with the conclusions reached by the advisory committee and with the recommendations. We are not aware of any other evidence that would have changes the conclusions.</p>	Thank you for your comment.
26	Web comment	General	<p>It is encouraging that NICE is addressing the issue of primary and secondary care diagnostic investigations into acute, recurrent and chronic urinary tract infections.</p> <p>Comments are as follows:</p> <ul style="list-style-type: none"> * 1.7 million women in the UK and a significant number of men and children suffer from Chronic Lower Urinary Tract symptoms * Around 70% of those who experience an acute UTI will find their symptoms resolve with short course antibiotic 	<p>Thank you for your comment which NICE has considered.</p> <p>The committee discussed the impact of urinary tract infections and agreed that UTI's, particularly recurrent or chronic UTIs, can have a large mental and financial burden. The committee's discussion about the impact of UTIs is in section 3.1 of the guidance document.</p>

DIAGNOSTICS ASSESSMENT PROGRAMME

Point of care tests for urinary tract infections to improve antimicrobial prescribing

Early Value Draft Guidance Consultation Document – Comments

Theme: General

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			<p>treatment. However a further 30% will not achieve symptom resolution.</p> <p>* Approximately one in four people with a previous history of UTI will develop either recurrent or Chronic UTI</p>	