NICE National Institute for Health and Care Excellence

NICE guidance

Point-of-care tests for urinary tract infections to improve antimicrobial prescribing: early value assessment

HealthTech guidance
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Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces HTE7.

1 Recommendations

1.1 The following point-of-care tests are not recommended for early routine use for suspected urinary tract infections (UTIs) in primary or community care settings in the NHS while further evidence is generated:

- Astrego PA-100 analyser with the PA AST panel U-0501 (Sysmex Astrego)
- Uriscreen (Savyon Diagnostics).

They show promise in guiding antimicrobial prescribing, and further research and completion of ongoing studies would allow the risks and benefits of early routine use in the NHS to be understood.

1.2 Further research is recommended on how:

- accurate the tests are in detecting and identifying bacteria and testing for antibiotic susceptibility (depending on the test's functions; see section 4.1)
- the tests affect antibiotic prescribing (see section 4.2).

1.3 The following culture-based point-of-care tests are not recommended for early routine use in NHS primary or community care settings for suspected UTIs:

- Diaslide, DipStreak and ChromoStreak (Novamed)
- Flexicult Human (SSI Diagnostica)
- Uricult, Uricult trio and Uricult plus (Aidian).

They are not expected to give results quickly enough to improve antimicrobial prescribing in these settings.

Why the committee made these recommendations

Newer point-of-care tests for UTIs that give faster and more accurate results compared with current testing could improve outcomes and reduce the risk of antimicrobial resistance. Clinical experts agree that these tests show promise, particularly if they can show which antibiotics the infection will respond to (antibiotic susceptibility testing).

The tests are in the early stages of development and research is still being done. Uncertainties in the current evidence mean it is difficult to assess the risks and benefits of early routine use in the NHS while further evidence is generated.

The tests vary in how quickly they give results. There is not much evidence for the more rapid point-of-care tests (Astrego, and Uriscreen), including if these tests give results quickly enough to improve antibiotic prescribing. Delays to appropriate antibiotic prescribing because a GP is waiting for test results or because a test has given inaccurate results could harm patients, so it is uncertain if the tests will improve care. Costs were only available for some of the tests so the cost to the NHS is also uncertain.

So, rapid point-of-care tests cannot be recommended for early routine use in the NHS while further evidence is generated. Further research, for example on test accuracy, is recommended for these tests to see if this recommendation can be changed in the future. Ongoing studies may soon provide this for at least some groups of people (for example the TOUCAN study).

Some of the tests considered in this assessment are still awaiting regulatory approval. Tests are only included in the final guidance if they have appropriate regulatory approval by the date of final guidance publication.

Evidence suggests that culture-based point-of-care tests that take around 16 to 24 hours to give results do not give results quickly enough to improve antibiotic prescribing in primary or community care. Clinical experts agree that these tests may be less useful in these settings. So they are not recommended for use in primary or community care settings.

2 The technologies

Clinical need and practice

2.1 Urinary tract infections (UTIs) are commonly diagnosed in primary care. They contribute to a large proportion of antibiotic use. UTIs are currently diagnosed using a combination of clinical symptoms, dipstick tests (if appropriate) and laboratory-based culture testing.

2.2 Dipstick tests are rapid and can be done in a GP surgery. But they may not accurately diagnose UTIs, are not recommended for all populations (such as people aged over 65 or who have a catheter) and cannot identify the type of bacteria causing the infection. Laboratory-based culture tests can identify bacteria and test for antibiotic susceptibility. But they do not detect all types of bacteria, and the results can take 24 to 72 hours depending on locally available facilities, geographical location, and the day of sample collection. Laboratory test results may sometimes take longer (up to a week) if there are delays in getting samples to the laboratory or a delay in processing.

2.3 People are often diagnosed with a UTI based on clinical symptoms alone, and may be prescribed antibiotics empirically (that is, based on the likely cause of the infection in the absence of definite information about what has caused it). When testing is done, people could also be prescribed antibiotics while waiting for test results. NICE's guideline on antimicrobial prescribing for lower UTIs recommends reviewing the choice of antibiotic when microbiological results are available and changing the antibiotic according to the susceptibility results if bacteria are resistant and symptoms are not already improving. It recommends using a narrow-spectrum antibiotic if possible. Clinical experts explained that the first course of antibiotics has often finished by the time laboratory-based culture results are returned.

2.4 How UTIs are diagnosed can differ depending on a person's sex, age and if they have a catheter. Public Health England's guidance on diagnosis of urinary tract infections (2020) sets out several flow charts to guide

diagnosis for people with suspected acute UTIs. Separate pathways are presented for:

- women under 65 years with suspected UTI
- men under 65 years with suspected UTI
- adults who have a catheter or over 65 years with suspected UTI
- infants (from birth) and children under 16 years with suspected UTI.

The tests

2.5 NICE has assessed 12 point-of-care technologies that can be used for testing in people with suspected UTIs. Based on the features of the tests included in this assessment, the external assessment group (EAG) grouped them into rapid tests (results in less than 40 minutes) and culture-based tests (results in around 16 to 24 hours).

Rapid tests

2.6 The following rapid tests were assessed:

- Astrego PA-100 analyser with PA AST panel U-0501 (Sysmex Astrego) detects the presence of bacteria in a urine sample in 10 to 15 minutes. If the urine sample is positive, it assesses the susceptibility of the bacteria to 5 antibiotics (amoxicillin-clavulanic acid, ciprofloxacin, fosfomycin, nitrofurantoin, trimethoprim). Full results take 30 to 45 minutes. The company says that it is CE-in vitro diagnostic (IVD) marked but is not currently available in the UK.
- Lodestar DX (Llusern Scientific) detects 6 common UTI-causing bacteria (*Escherichia coli [E. coli], Klebsiella spp, Proteus mirabilis, Staphylococcus saprophyticus, Enterococcus spp, Pseudomonas aeruginosa*). Results take approximately 40 minutes. The company says that the technology does not yet have regulatory approval.
- TriVerity (Inflammatix) is a blood test that identifies if an infection is bacterial or viral, and the severity of the infection. Results take approximately 30 minutes. The company says that the technology does not yet have regulatory approval.

- Uriscreen (Savyon Diagnostics) is an enzyme-based test that detects the presence of bacterial catalase in a urine sample. Results take approximately 2 minutes. The company says that the technology is CE-IVD marked.
- UTRiPLEX (Global Access Diagnostics) detects the presence of matrix metalloproteinase-8 (MMP8) and human neutrophil elastase (HNE) in a urine sample. Results take approximately 6 minutes. The company says that the technology does not yet have regulatory approval.

Culture-based tests

2.7 The following culture-based tests were assessed:

- Diaslide, DipStreak and ChromoStreak (Novamed) are 3 culture-based tests that detect and identify the presence of gram-negative bacteria in a urine sample. ChromoStreak also detects the growth of common UTI-causing bacteria (*E. coli, Proteus,* and enterococci). Results take about 16 to 24 hours. The regulatory status of the 3 tests is not clear.
- Flexicult Human (SSI Diagnostica) is a culture-based test that detects and quantifies the bacteria in a urine sample, and evaluates the susceptibility to 5 antibiotics (mecillinam, nitrofurantoin, ampicillin, sulfamethizol and trimethoprim). It must be incubated overnight and takes 16 to 24 hours for results. The company says that the technology is CE-IVD marked and is available in the UK.
- Uricult, Uricult trio and Uricult plus (Aidian) are 3 culture-based tests that detect and identify the presence of gram-negative bacteria in a urine sample. Uricult plus also detects enterococci and Uricult trio also detects gram-negative, beta-glucuronidase-producing bacteria, such as *E. coli*. Results take approximately 16 to 24 hours. The company says that the technology is CE-IVD marked and available in the UK.

The comparators

2.8 The comparators are:

- dipstick testing, then laboratory-based testing (if necessary) or

- laboratory-based testing alone.

  During consultation, a stakeholder highlighted that diagnosis using clinical symptoms could be included as a comparator in future assessments.

3 Committee discussion

The diagnostics advisory committee considered evidence on point-of-care tests for urinary tract infections (UTIs) from several sources, including an early value assessment (EVA) report by the external assessment group (EAG), and an overview of that report. Full details are in the project documents for this guidance.

Patient issues

Impact of urinary tract infections

3.1 Patient experts explained that having a UTI, particularly if it is recurrent or chronic, has a negative impact on people's social life and relationships, and can mean they need to take time off work. They explained that children with UTIs often have to miss school, which can affect their education and friendships. Patient and clinical experts said that current tests may not identify certain infections, even if a person has typical UTI symptoms, which can lead to a misdiagnosis and delayed treatment. This may increase pain and discomfort and can negatively affect people's mental health. Clinical experts explained that acute lower UTIs usually have mild, but uncomfortable, symptoms. They noted that most people do not go on to develop complications, such as pyelonephritis or bacteraemia. Delays to diagnosis of chronic UTI were highlighted as a particular issue. Clinical and patient experts noted that people are often willing to pay for private tests so that they can get a diagnosis and return to work sooner. Clinical experts explained that people with chronic UTI symptoms but negative tests are often referred to secondary care, where misdiagnosis is common. They noted that referral to tertiary care for further testing can improve diagnosis and treatment, but access to this in the NHS is extremely limited. This may increase the time to diagnosis while the person has to live with ongoing symptoms. The committee agreed that UTIs, particularly recurrent or chronic UTIs, can have a large mental and financial burden.

Potential impact of new point-of-care tests

3.2 Patient experts explained that new point-of-care tests that can more accurately diagnose UTIs will improve patient outcomes and quality of life, and reduce side effects from taking unnecessary antibiotics. Faster access to effective treatment would also relieve symptoms more quickly and effectively, although some groups may receive antibiotics before test results are received in current care. New point-of-care tests may reduce the need to provide repeat urine samples, which may benefit groups who find this difficult, such as people who are pregnant, older people, people who are incontinent or people with dementia. Reductions in the need to travel to appointments (and associated costs), drop off samples, and pick up prescriptions may also benefit people with a lower income and disabled people. 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. They said that more accurate tests that could lead to quicker treatment may particularly help these groups. Clinical and patient experts also noted that there may be greater benefits for people who cannot have dipstick testing. Any improvements in antibiotic prescribing could reduce the risk of antimicrobial resistance, benefiting wider society. The committee accepted the potential benefits of newer point-of-care tests but acknowledged that less accurate results or delays to prescribing compared with current testing could lead to increased patient distress. A comment received at consultation highlighted the importance of educating patients and GPs, for example on collecting urine samples if new tests were introduced, to ensure any potential benefits are realised.

Clinical effectiveness

Impact of test use on antibiotic prescribing

3.3 UTIs are currently diagnosed using a combination of clinical symptoms, dipstick tests (if appropriate) and laboratory-based culture testing (see section 2). Two randomised controlled trials, Butler et al. (2018) and Holm et al. (2017), evaluated how the culture-based Flexicult Human test

affected antibiotic use. Both studies reported that there was no statistically significant difference in overall antibiotic use. Clinical experts said that, because the test takes up to 24 hours (and at least overnight) for results, clinicians may have continued to prescribe antibiotics if participants did not want to wait for test results before getting treatment. Clinical experts said that faster point-of-care tests could have a different effect on antibiotic use. The EAG said that the clinical and patient experts who they had consulted said that tests that gave results on the same day were likely to have the largest effect on antibiotic prescribing and patient outcomes.

3.4 The point-of-care tests evaluated for this guidance varied in how long they took to give a result. The EAG grouped them into rapid tests (results in less than 40 minutes) and culture-based tests (results in around 16 to 24 hours) in its assessment. It explained that this was a pragmatic choice based on the tests included in the scope for this assessment. It did not find any data on how the rapid tests affected antibiotic use. The committee concluded that the impact of tests on antibiotic use may be proportional to how quickly results can be returned, with quicker tests likely to have greater impact. It also concluded that, based on available data and expert opinion, the tests described as culture based by the EAG (taking around 16 to 24 hours for results) and tests that are unlikely to give same-day results are unlikely to be useful in primary or community care.

Using test results in clinical practice

3.5 A clinical expert explained that dipstick tests give quick results during a GP appointment. They noted that even if a point-of-care test returned results in 40 minutes, that would be after the appointment was finished so that the patient may need to come back for another appointment or have a phone call to discuss it. This would mean extra staff time and patients waiting for results. Other clinical experts disagreed that a second appointment would be needed, pointing out that electronic prescribing and better ways to communicate with patients, for example, text messaging, are now in place. They noted the importance of having good systems and pathways in place to achieve this. A clinical expert also noted that tests may only be able to run 1 sample at a time which,

depending on how many samples need to be run a day, could affect the time to get results. 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. This, alongside how quickly a test can be run, is likely to affect how much the tests can affect antibiotic prescribing.

Test accuracy

3.6 Only 3 studies with test accuracy data identified were considered at low risk of bias by the EAG. Of these, only 1 (Boon et al. 2022) reported accuracy data for UTI detection for rapid tests (Uriscreen and UTRiPLEX). This study assessed the test in children. Six studies compared point-of-care tests to dipstick testing done in the same population (including Boon et al. 2022). Three studies evaluating Uriscreen reported higher sensitivity but lower specificity than dipstick testing. One study evaluating UTRiPLEX reported it to be less sensitive but more specific than dipstick testing. The committee noted that there is also very limited data on how well rapid tests identify bacteria or do antibiotic susceptibility testing. The EAG did not find any accuracy data for the Astrego PA-100 system and TriVerity rapid tests. The committee concluded that there is limited good quality data on test accuracy. Particularly, to identify bacteria, assess susceptibility to antibiotics (for tests that can do this), and directly compare tests with dipstick testing. The committee noted that the EAG had raised issues with reference standards that were used to produce accuracy estimates for the tests (this is described further in section 7.2 of the diagnostics assessment report). Issues with detecting slower growing bacteria by laboratory-based tests were also raised during consultation on the draft guidance. At consultation, a commentator also highlighted that a UTI may be caused by more than a single causative pathogen and it is important to consider causative slow growth pathogens. The committee agreed that there was considerable uncertainty about how well the tests will perform if used in the NHS compared with current testing.

Generalisability of data

3.7 Clinical experts emphasised the limitations of current testing. They said

that dipsticks are unreliable in some populations (see section 2.2), which is important to consider when assessing new technologies. Populations in the identified studies were women with uncomplicated UTIs (3 studies), pregnant women (4 studies), people with a catheter (1 study) and children and babies (1 study in under 18 years, 1 study in under 16 years and 1 study in under 24 months). Five studies described having mixed populations but did not report any further detail. It was not clear if any studies assessed people with recurrent or chronic UTI. Clinical experts noted that urine samples from some populations, such as people who have a catheter or are aged over 65, are often polymicrobial. These groups are likely to have asymptomatic bacteriuria, which could lead to overdiagnosis. They noted that, as with dipstick testing, the accuracy of the newer point-of-care tests is likely to differ in these groups. Clinical experts also highlighted that differences in acute, recurrent and chronic infections mean tests may also perform differently in these groups. The committee concluded that accuracy data in the identified studies is not generalisable across the whole population of people with suspected UTIs (for example, people with suspected chronic UTI, people with catheters, men, and people aged over 65).

What information from tests is most useful

3.8 Some clinical experts said that just knowing the type of bacteria in a urine sample would not affect prescribing decisions. For example, UTIs can be caused by *Escherichia coli (E. coli)*, which has a broad antibiotic susceptibility profile. But other clinical experts said that it might affect prescribing if someone has a recurrent or chronic UTI. This is because it could identify the bacteria as one against which an antibiotic was previously effective. The EAG said that clinical experts had also considered that there would be some benefit from knowing the identity of bacteria present for prescribing decisions. A clinical expert said that bacterial identification may suggest what antibiotics are unlikely to work, but not what will work. Another said that tests that can more accurately rule out a UTI than dipstick testing may be useful as an initial tool to triage people for further testing, or to consider alternative diagnoses, and allow safe reduction of antibiotic use. Particularly if results are given as quickly and if it has better performance in groups that dipsticks are not recommended for.

3.9 Only 1 rapid test does antibiotic susceptibility testing (Astrego PA-100 analyser with the PA AST panel U-0501). No further tests were identified that have regulatory approval or expect to get it in the next 12 months, for inclusion in this assessment. Clinical experts said that rising resistance to trimethoprim has led to increased use of nitrofurantoin as a first-line empirical antibiotic choice for UTIs. This has led to a drop in trimethoprim resistance. Quicker identification of people whose infection is still susceptible to trimethoprim may allow it to be used more and allow for reduced use of nitrofurantoin (although potentially causing trimethoprim resistance to rise again). A clinical expert also highlighted that NICE's guideline on antimicrobial prescribing for lower UTIs recommends using a narrow-spectrum antibiotic if possible. But they noted that an antibiotic susceptibility test may be needed to prescribe them if there is concern about resistance in the local population. During consultation, a stakeholder said that antibiotic susceptibility information may be of limited use for uncomplicated lower UTIs because some antibiotics concentrate in the bladder and achieve levels well above that applied in laboratory resistance tests. They said it may be more useful for people with upper or complicated UTIs. Another clinical expert also highlighted concern about antibiotic susceptibility testing without bacterial identification, saying that you may need to know which bacteria it is to decide which dose of antibiotic to use. However, this was questioned by a stakeholder and another expert, who said that they did not think this would be done in primary care without clear guidance. The committee concluded that rapid tests that can test for antibiotic susceptibility (Astrego PA-100 analyser with the PA AST panel U-0501) are likely to have the greatest potential to improve antibiotic prescribing decisions. There is greater uncertainty about how antibiotic prescribing would be affected by tests that can identify bacteria but do not test for antibiotic susceptibility (Lodestar DX). But a clinical expert said that these tests could more accurately indicate the presence of bacteria in a reasonable timeframe for prescribing. Tests that can only identify if bacteria are present but do so very rapidly (UTRiPLEX and Uriscreen) may improve prescribing if they are more accurate and can be used more widely than dipstick tests.

Ongoing studies

3.10 The EAG identified ongoing studies for 2 of the included tests:

- the Astrego PA-100 system is being assessed in 1 study (the Astrego PA-100 study; submitted as commercial in confidence so it cannot be described here). It is also being assessed in the TOUCAN study, which is evaluating the accuracy of new point-of-care tests compared with current standard testing for women who consult their GP with symptoms of a UTI. The study protocol was provided to the committee as academic in confidence so cannot be described here.
- Lodestar DX is also being assessed in the TOUCAN study, as well as in an ongoing study exploring how the test affects treatment decisions when used by clinicians in Wales.

Cost effectiveness

Test price

3.11 Butler et al. (2018) reported that the cost of Flexicult Human was £48 per person. Few companies provided their test costs. Costs for the Astrego and Lodestar DX tests were provided as commercial in confidence, because costs for the UK have not yet been finalised, so cannot be reported here. Clinical experts said that dipstick tests currently cost about 50p each and laboratory-based culture tests cost about £10 to £20 per person. So, using the example of Flexicult Human, the tests included in this assessment may cost more than current testing. The committee noted that, although these tests could reduce costs incurred after testing and may improve patient outcomes, the greater the increase in cost of testing the less likely the tests are to be cost effective. It added that they may only be cost effective in some groups of people who get a particular benefit. Clinical experts also noted that GP practices may be reluctant to buy new point-of-care tests with much higher costs, particularly if the tests could be used for all people with suspected UTIs. A clinical expert said that 80% of antibiotics are prescribed for women with suspected uncomplicated UTI based on clinical symptoms alone, and improved testing may reduce the associated cost burden in the NHS.

The committee said that more information on the costs of new tests is needed to consider any recommendation for use in the NHS.

Proposed model for how the tests affect antibiotic use

3.12 The EAG's proposed modelling approach assessed how point-of-care tests affect empirical or targeted antibiotic use. It used test accuracy data and assumed that targeted antibiotics could always be used as the first antibiotic for rapid tests. It also assumed that tests that can identify the bacteria and tests that can assess antibiotic susceptibility affected prescribing in the same way. The committee recalled that how the test results affect prescribing decisions can be complex and may depend on local prescribing pathways (see sections 3.3 and 3.4). Also, the impact of tests that identify bacteria but do not identify antibiotic susceptibility was particularly uncertain (see section 3.8). The committee considered that more detail was needed on other ways that point-of-care tests could contribute to changes in antibiotic use, beyond empirical or targeted use. The committee concluded that there was too much uncertainty around the EAG's exploratory modelling to be able to accurately estimate how the test affects antibiotic prescribing. Direct data is needed. Clinical experts suggested that electronic prescribing meant that more detailed patient level data may be increasingly available, including age, sex and what antibiotics were prescribed. The committee also thought that future modelling work should give greater consideration to use of an individual patient simulation approach.

Clinical outcomes

3.13 The EAG explored using a linked evidence approach to assess how test-guided treatment decisions affect health outcomes, such as the incidence of pyelonephritis, sepsis and kidney failure. Clinical experts questioned the inclusion of pyelonephritis and sepsis, noting that these complications overlap. They also said that kidney failure was not a common outcome for people with UTI. The committee noted the importance of considering how the tests affected health outcomes as well as antibiotic use. It concluded that direct data on how test use affected clinical outcomes would be useful but agreed that a linked evidence approach could also be used. The EAG identified several areas

in which data may be needed for a linked evidence approach. These included the risk of complications for people with UTIs depending on the antibiotic they were treated with, or if they had no antibiotic treatment. But it highlighted that it had not done a systematic literature review, so it was possible that this data was available.

Modelling recurrent and chronic UTIs

3.14 The committee questioned the approach proposed by the EAG for modelling suspected recurrent or chronic UTIs. It noted that the EAG's model did not distinguish between first and repeat UTIs, or between recurrent and chronic UTIs. Clinical experts highlighted issues with this approach and said that there are meaningful differences between a first UTI and later UTIs. For example, each time someone has a UTI, the risk of having another increases. Decisions about antibiotics are also different for recurrent or chronic UTIs, which can be influenced by which antibiotics have already been used. The committee recalled that chronic UTIs can have a substantial impact on people's health-related quality of life (see section 3.1) and said that this should be considered in future modelling work. The EAG did not specifically search for this data and so it was not clear if data on the health-related quality of life for people with chronic UTI exists. The committee concluded that future modelling approaches should distinguish between acute and recurrent or chronic UTI.

Committee conclusions

3.15 The committee recalled that, based on the limited cost information available (see section 3.11), using the point-of-care tests assessed in this guidance may be more expensive than current tests. Because there is considerable uncertainty about whether even the rapid tests can give results quickly enough to change prescribing decisions, there is also uncertainty about whether the tests will improve clinical outcomes. There is also not a lot of data on test accuracy (see section 3.6), which made it difficult for the committee to assess the potential risks and benefits associated with introducing the tests into clinical practice. The committee concluded that there was currently too much uncertainty to recommend early routine use in the NHS while further evidence is

collected. It acknowledged that some of the included tests are in the early stages of development and research is ongoing. It recalled its conclusion that tests that are unlikely to give results on the same day are unlikely to be useful in primary or community care (see section 3.4) but that quicker tests show promise, particularly if they can test for antibiotic susceptibility (see sections 3.8 and 3.9). The committee recommended further research for these tests (see section 4).

Ongoing research

3.16 The committee recalled that there is ongoing research on some of the point-of-care tests (for example the TOUCAN study; see section 3.10) focusing mainly on test accuracy. The committee considered that data on how the tests affect antibiotic prescribing was needed to assess their potential impact in the NHS (see section 3.12). But better accuracy data may also help with assessing the benefits and harms of allowing early routine use in the NHS while further data is collected. The committee concluded that once the data from ongoing studies is available, it could be reviewed to decide if the NHS could be given early access alongside further data collection.

Research considerations

Populations for further research

3.17 There was limited data for some groups of people with suspected UTI. The accuracy of tests and how they affect prescribing choices may vary in different populations and data is unlikely to be generalisable across groups (see section 3.7). The committee concluded that further research should be done in populations that fully represent people who the test could be used for in the NHS. The committee noted that ongoing studies (see section 3.10) are mostly in women aged over 18 with acute UTI. It encouraged further research in other populations. Clinical and patient experts also highlighted that it was important to assess the new tests in groups that have limited options in current standard care; for example, dipstick tests are not currently recommended for use in certain groups (such as people aged over 65 or who have a catheter). People with

recurrent or chronic UTIs were highlighted as a group that may particularly benefit from improved testing. A comment received at consultation also highlighted that children may also benefit from improved testing. The committee concluded that it was important to evaluate the tests in groups for who current testing methods are known to be less accurate for. A clinical expert also highlighted that it may be useful to assess test performance in groups who currently have no testing, for example women aged over 18 with 2 or 3 symptoms of UTI.

Future evidence considerations

3.18 The committee concluded that further research was needed before it can recommend early routine use of the tests in the NHS while further evidence is collected (see section 4). It also discussed what further data may be needed to fully assess the clinical and cost effectiveness of the technologies. It concluded that further data is needed on:

- how local antibiotic resistance changes with test use
- how test-guided treatment affects clinical outcomes such as UTI-related complications
- the risk of complications for people with UTIs depending on the antibiotic they were treated with (for use in a linked evidence approach; see section 3.13)
- health-related quality of life for people with chronic UTI (see section 3.14).

4 Recommendations for further research

Further research is recommended for the following point-of-care tests:

- Astrego PA-100 analyser with the PA AST panel U-0501 (Sysmex Astrego)
- Uriscreen (Savyon Diagnostics).

Accuracy

4.1 The committee concluded that more data on test accuracy, including how well they identify bacteria and antibiotic susceptibility (if a test has these functions) is needed. It would be beneficial to see data comparing the new point-of-care tests with dipstick testing in the same population.

Antibiotic use

4.2 The committee would also like to see more data on how the new point-of-care tests affect decisions about antibiotic prescribing and antibiotic use. Clinical experts noted the importance of reporting the specific antibiotics used to help understand how the tests affect prescribing behaviour and antimicrobial resistance.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the test to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Specialist committee members

Additional specialist committee members took part in the discussions for this topic:

Sarah-Louise Bedford
Lay specialist

Alison Taylor
Lay specialist

Professor Gail Hayward
Associate professor of primary care, University of Oxford

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Miss Lauren Rose
Specialist clinical pharmacist, Nottingham University Hospitals

Dr Kiren Gill
Consultant obstetrician and gynaecologist, Whittington Health NHS Trust

NICE project team

Each diagnostics evaluation is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

Amy Barr
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Emma McCarthy
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Technical adviser

Harriet Wilson
Project manager

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