NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Diagnostics consultation document

Point-of-care creatinine devices to assess kidney function before CT imaging with intravenous contrast

The National Institute for Health and Care Excellence (NICE) is producing guidance on using point-of-care creatinine tests to assess kidney function before CT imaging with intravenous contrast in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the evidence (the diagnostics assessment report and the diagnostics assessment report addendum).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on people with a particular disability or disabilities.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on point-of-care creatinine tests to assess kidney function before CT imaging with intravenous contrast. The recommendations in section 1 may change after consultation.

After consultation, the committee will meet again to consider the evidence, this document and comments from the consultation. After considering the comments, the committee will prepare its final recommendations, which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the diagnostics assessment programme manual.

Key dates:

Closing date for comments: 11 July 2019

Second diagnostics advisory committee meeting: 20 August 2019

1 Recommendations

1.1 Point-of-care creatinine devices (ABL800 FLEX, i-STAT and StatSensor) that calculate estimated glomerular filtration rate (eGFR) are recommended to assess kidney function to guide decisions on whether to use intravenous contrast before an outpatient CT scan only if:

- current practice is that a recent eGFR result must be available before a person has a CT scan with intravenous contrast
- a person presents for a CT scan without a recent eGFR result and
- the person has risk factors for acute kidney injury.

1.2 Take age, sex and ethnicity into account when assessing risk of acute kidney injury using a questionnaire-based tool (see section 4.13).

1.3 Point-of-care creatinine devices (ABL90 FLEX PLUS, Dri-chem NX500, epoc Blood Analysis System, and Piccolo Xpress) are not recommended to guide decisions on whether to use intravenous contrast before an outpatient CT scan because there are insufficient data to assess their diagnostic accuracy.

1.4 Further research is recommended to:

- better understand the level of risk of contrast-induced acute kidney injury (see section 5.1)
- identify the most appropriate tool for identifying risk factors (see section 5.2) and
- monitor the effect of implementation on patient experience and efficiency in radiology departments (see section 5.3).

Why the committee made these recommendations

It is important to check whether the kidneys are working properly by measuring eGFR before a contrast-enhanced CT scan. This is because the contrast agent can cause acute kidney injury in people with low eGFR. Point-of-care creatinine devices measure creatinine levels and calculate eGFR rapidly. This means that people who do not have a recent eGFR result will not need to have their CT scan cancelled so that their creatinine can be measured in the laboratory.

Evidence suggests that the ABL800 FLEX, i-STAT and StatSensor all have acceptable accuracy in determining when eGFR is low (below 30 ml/min/1.73 m^2). It was not possible to determine whether one was more accurate than another. Economic modelling shows that all 3 devices offer value for money to the NHS when compared with delaying scans for laboratory creatinine testing, although more people with an eGFR of less than 30 ml/min/1.73 m^2 may be identified if they had laboratory testing. Using the devices can also avoid cancelling and rebooking CT

scans, which is important for patients. The devices offer the most value for money when:

- they are used only for people who have 1 or more risk factors for acute kidney injury and
- cancelled CT scan appointments cannot be offered to other people.

2 The diagnostic tests

Clinical need and practice

The problem addressed

2.1 Point-of-care (POC) creatinine devices allow rapid measurement of creatinine levels and calculation of estimated glomerular filtration rate (eGFR). This can show whether the kidneys are working properly. The focus of this assessment is POC creatinine testing to assess kidney function before people have intravenous contrast for CT imaging. Intravenous iodine-based contrast agents used in CT scans can cause acute kidney injury (AKI), particularly in people who are at high risk and those with known kidney dysfunction. If a person has a low eGFR, intravenous hydration can be offered before the scan to reduce the risk of AKI. If a person does not have a recent eGFR measurement, their CT scan could be cancelled and rescheduled while a creatinine test is processed in the laboratory.

2.2 In some NHS trusts, if a person is thought to be at low risk of kidney injury, they might be offered the contrast agent, risking kidney injury. Sometimes, to avoid the risk of kidney injury, people might have unenhanced imaging, which is less accurate than contrast-enhanced imaging. This could mean further tests are needed to confirm a diagnosis or make decisions about treatment.

2.3 Using POC creatinine tests before outpatient contrast-enhanced CT scans in the radiology department could minimise the risk of kidney injury. It could also reduce the number of cancelled scans, which is important for patients.

The condition

2.4 AKI covers injury to the kidneys from a number of causes; it often happens as a complication of another serious illness. If AKI is not treated promptly, levels of salts and chemicals in the body can increase, which affects the fluid balance in the body and how well other organs work.

2.5 Post-contrast AKI (PC-AKI) is a sudden deterioration in kidney function within 48 to 72 hours of administering intravenous iodine-based contrast agent. Incidence in patients having non-emergency CT scans with intravenous contrast agent is reported to be less than 1% (Ozkok et al. 2017). Risk factors for PC-AKI include chronic kidney disease, critical illness, contrast-enhanced imaging done as an emergency, older age, diabetes, use of nephrotoxic drugs and reduced kidney function (for example, if a person is dehydrated or has congestive heart failure). Short- and long-term mortality rates are significantly higher in patients with PC-AKI than in patients without PC-AKI. A history of PC-AKI may be also associated with development of chronic kidney disease and progression to end-stage renal disease.

The care pathways

2.6 NICE's guideline on acute kidney injury: prevention, detection and management says that before using iodinated contrast agents for imaging, kidney function should be checked and the risk of AKI assessed. It recommends that eGFR should be measured within 3 months of using iodinated contrast agents.

2.7 The threshold for eGFR at which there is a risk of developing PC-AKI varies across different guidelines, ranging between 30 ml/min/1.73 m^2

(The Royal Australian and New Zealand College of Radiologists guideline on iodinated contrast media, 2016, which has been endorsed by the Royal College of Radiologists) and 60 ml/min/1.73 m^2 (Renal Association guideline on the prevention of CI-AKI in adult patients, 2013). Clinical experts suggested that people with an eGFR of less than 30 ml/min/1.73 m^2 are at highest risk of developing PC-AKI.

2.8 Guidelines recommend that adults having iodinated contrast agents at increased risk of PC-AKI should:

- be offered intravenous volume expansion
- consider temporarily stopping angiotensin-converting enzyme inhibitors and angiotensin receptor blockers
- have a nephrology team discuss their care if there are contraindications to intravenous fluids.

2.9 If PC-AKI develops, NICE's guideline on acute kidney injury recommends:

- renal replacement therapy (dialysis) in some situations
- loop diuretics for treating fluid overload or oedema in people waiting to have dialysis, and in people who do not need dialysis.

The interventions

2.10 The POC creatinine devices included in table 1 are CE marked and measure creatinine using an enzymatic method. Devices are either handheld, table-top or portable and need very small samples of whole blood from either finger-prick or venous or arterial samples. Creatinine can be measured either as 1 component of a panel of parameters, or as a single measurement on a test card or cartridge specific for creatinine or kidney function.

Table 1 POC creatinine devices

Manufacturer and devices	Device format	Parameters measured	Sample volume	Analysis time	eGFR equation used
Nova Biomedical StatSensor	Handheld	Creatinine only	1.2 microlitres	30 seconds	MDRD, Cockcroft-Gault, Schwartz and Counahan-Barratt
Related models: StatSensor-i, StatSensor Xpress-i. All models allow offset adjustment of results. StatSensor and StatSensor-i also allow slope adjustment.					
Abbott i-STAT Alinity	Handheld	Multiple parameters	65 microlitres	2 minutes	MDRD
Related models: i-STAT 1, many studies simply state 'i-STAT'					
Radiometer ABL90 FLEX PLUS	Portable	19 parameters	65 microlitres	35 seconds	CKD-EPI, MDRD and Schwartz
ABL800 FLEX	Table-top	18 parameters	125 to 250 microlitres	1 minute	CKD-EPI and MDRD
Related models: ABL827, ABL837					
Siemens Healthineers Epoc Blood Analysis System	Handheld	11 parameters on 1 test card	92 microlitres	Less than 1 minute	CKD-EPI, MDRD and Schwartz
Abaxis Piccolo Xpress	Table-top	Multiple parameters	100 microlitres	Less than 14 minutes	MDRD
Fujifilm Dri-chem NX500	Table-top	Multiple parameters	1 microlitre	5 minutes	Expected
Abbreviations: CKD-EPI, chronic kidney disease epidemiology; eGFR, estimated glomerular filtration rate; MDRD, modification of diet in renal disease					

The comparators

2.11 There were 2 comparators used in the assessment:

- laboratory-based serum creatinine measurement and eGFR
- clinical judgement alone (no testing).

3 Evidence

The diagnostics advisory committee (section 8) considered evidence on point-of-care (POC) creatinine tests to assess kidney function before CT imaging with intravenous contrast from several sources. Full details of all the evidence are in the committee papers.

Clinical effectiveness

3.1 The external assessment group (EAG) systematically reviewed:

- studies comparing the results of POC creatinine tests with laboratory-based tests to assess kidney function in any non-emergency setting
- studies reporting clinical or implementation outcomes of POC creatinine tests to assess kidney function before CT imaging in a non-emergency, outpatient setting.

3.2 There were 54 studies in the review. Of those, 12 studies reported diagnostic accuracy data for estimated glomerular filtration rate (eGFR), 7 studies reported diagnostic accuracy data for serum creatinine, 50 studies presented data on correlation or measurement bias between a POC creatinine device and a laboratory reference test, and 6 studies reported data on workflow or implementation.

Correlation and measurement bias

3.3 Results from the StatSensor studies showed wide variation in the size and direction of measurement bias. StatSensor devices can be adjusted to correct for any bias seen, to align the POC creatinine device results with those from local laboratory methods. Only 2 StatSensor studies reported using an adjustment function for measurement bias. Although potentially important measurement bias was found in some studies of i-STAT and ABL devices, the concordance of results for these devices was generally better than for the StatSensor devices. A smaller number of studies were available on the epoc (1 study) and Piccolo Xpress (4 studies) devices.

3.4 There were 3 studies comparing different types of POC creatinine devices. Of these, 2 studies compared StatSensor, i-STAT and ABL800 FLEX. Both studies found that the ABL800 FLEX had the strongest agreement with laboratory serum creatinine, then the i-STAT and then StatSensor. There was 1 study comparing an ABL827 device with an i-STAT. It concluded that creatinine results from both devices correlated well with laboratory serum creatinine.

3.5 In some studies, measurement bias increased at higher creatinine levels (lower eGFR). This could affect care decisions for people at higher risk of kidney damage.

Diagnostic accuracy based on eGFR thresholds

3.6 There were 12 studies reporting diagnostic accuracy data on eGFR thresholds. Studies were of different devices, with some studies assessing more than 1 device:

- 7 i-STAT studies
- 7 StatSensor studies
- 3 studies included a Radiometer POC device (ABL800 or ABL827)
- 2 studies assessed 3 POC devices (ABL, i-STAT and StatSensor) and
- 1 study looked at 2 devices (ABL and i-STAT).

There were no studies of ABL90 FLEX PLUS, Dri-chem NX500, epoc Blood Analysis System and Piccolo Xpress. The eGFR equations used in the studies varied, with only 3 studies using chronic kidney disease epidemiology (CKD-EPI). There were 3 StatSensor and 2 i-STAT studies that used an adjustment function to correct for any measurement bias between the POC creatinine test results and laboratory test results from the study sample. Adjusted and unadjusted results were reported in all 3 StatSensor studies, but only adjusted results were presented in the 2 i-STAT studies. Most studies used an enzymatic method as the

laboratory reference, but the Jaffe method was used in 2 studies and the reference method was not reported in 1 study.

3.7 There were 6 studies at low risk across all risk of bias areas, including 2 studies of ABL800, 3 studies of i-STAT and 3 studies of StatSensor. The other 6 studies had at least 1 domain at unclear or high risk of bias. Risks of bias related to:

- how the adjustment function to correct for measurement bias was applied
- patient selection
- the use of a different modification of the diet in renal disease (MDRD) eGFR equation between the POC creatinine test and laboratory reference test and
- the use of a Jaffe method for the laboratory reference test (compared with an enzymatic method for the POC creatinine test).

3.8 There were low concerns about the applicability of results across all domains for only 2 studies, including 1 study of ABL800, i-STAT and StatSensor (Snaith et al. 2018), and 1 study of i-STAT (Snaith et al. 2019). The most common concern was the use of eGFR threshold; 3 studies used an eGFR cut-off of 60 ml/min/1.73 m^2 or above. Several studies included disease-specific populations, therefore their applicability to a broader population of outpatients referred for CT scan without a recent eGFR may be limited.

3.9 The EAG quantitatively analysed the study results. The probabilities of being in each eGFR category were calculated from the number of people in each category reported by all included studies (regardless of the device assessed). The pooled probabilities of being in each of the 4 categories are in table 2. Most studies only included a few people in category 1 (eGFR less than 30 ml/min/1.73 m^2) and more people in higher eGFR categories.

Table 2 Estimated probabilities of being in each eGFR category

Category	eGFR (ml/min/1.73 m^2)	All data	
		Median	95%CrI
1	0 to 29	0.014	(0.011, 0.017)
2	30 to 44	0.051	(0.039, 0.064)
3	45 to 59	0.143	(0.127, 0.159)
4	60 or higher	0.792	(0.780, 0.803)
Abbreviations: eGFR, estimated glomerular filtration rate; CrI, credible interval			

3.10 The pooled probabilities of having a classification by a POC creatinine device in each eGFR category (k) and in each laboratory-defined eGFR category (j) are given in table 3. The i-STAT and ABL devices have higher median probabilities of correct classification in each of the 3 lowest categories (p[1,1], p[2,2], p[3,3]) compared with the StatSensor. StatSensor was particularly poor at correctly classifying category 3 (eGFR 45 to 59 ml/min/1.73 m^2). However, there is considerable uncertainty in these probabilities for all devices.

Table 3 Estimated probabilities of being classified in each eGFR category by POC creatinine device

p[j,k]	StatSensor		i-STAT		ABL (Radiometer)	
	Median	95%CrI	Median	95%CrI	Median	95%CrI
p[1,1]	0.74	(0.61, 0.85)	0.85	(0.69, 0.94)	0.87	(0.75, 0.95)
p[1,2]	0.18	(0.08, 0.30)	0.04	(0.00, 0.18)	0.03	(0.00, 0.14)
p[1,3]	0.03	(0.00, 0.12)	0.04	(0.00, 0.18)	0.03	(0.00, 0.14)
p[1,4]	0.04	(0.01, 0.11)	0.04	(0.00, 0.16)	0.04	(0.00, 0.15)
p[2,1]	0.09	(0.03, 0.19)	0.10	(0.04, 0.21)	0.02	(0.00, 0.11)
p[2,2]	0.57	(0.42, 0.71)	0.77	(0.64, 0.87)	0.78	(0.61, 0.90)
p[2,3]	0.22	(0.12, 0.36)	0.10	(0.04, 0.21)	0.15	(0.05, 0.29)
p[2,4]	0.10	(0.03, 0.24)	0.01	(0.00, 0.06)	0.03	(0.00, 0.15)
p[3,1]	0.01	(0.00, 0.03)	0.01	(0.00, 0.05)	0.02	(0.00, 0.08)
p[3,2]	0.14	(0.09, 0.20)	0.10	(0.04, 0.17)	0.06	(0.01, 0.16)
p[3,3]	0.25	(0.16, 0.34)	0.81	(0.72, 0.88)	0.74	(0.62, 0.85)
p[3,4]	0.60	(0.51, 0.69)	0.08	(0.04, 0.13)	0.17	(0.09, 0.26)
p[4,1]	0.00	(0.00, 0.01)	0.00	(0.00, 0.01)	0.00	(0.00, 0.01)
p[4,2]	0.00	(0.00, 0.01)	0.01	(0.00, 0.02)	0.00	(0.00, 0.01)
p[4,3]	0.06	(0.04, 0.08)	0.08	(0.06, 0.10)	0.01	(0.00, 0.01)
p[4,4]	0.94	(0.91, 0.95)	0.91	(0.89, 0.93)	0.99	(0.98, 0.99)

eGFR categories (ml/min/1.73 m^2): 1=0 to 29; 2=30 to 44, 3=5 to 59; 4=60 or higher.
Abbreviations: CrI, credible interval.

3.11 Additional analyses were done to assess the effect of removing studies with limited applicability to clinical practice in the NHS. The pooled probabilities from these analyses were used in scenario analyses in the economic model:

- StatSensor devices allow a user-specified adjustment if systematic measurement bias is identified. An additional analysis including the adjusted data reported by Korpi-Steiner et al. (2009) and Shephard et al. (2010) was done. The Inoue et al. (2017) study was not included in this analysis because the reported adjustment could not be replicated in NHS practice.

- Only 2 studies used the CKD-EPI equation to calculate eGFR, all others used the MDRD equation. Of these studies, 1 included StatSensor, i-STAT and ABL800 FLEX devices (Snaith et al. 2018) and the other only included the i-STAT device (Snaith et al. 2019). An additional analysis using only the data in these 2 studies was done.

Clinical, workflow or implementation outcomes

3.12 There were 6 studies reporting a relevant outcome after using a POC creatinine device. The results showed variation in practice in both the proportions of patients who do not have a recent eGFR result and in the management decisions when a POC creatinine device shows an abnormal eGFR. For example, the proportion of people offered scans with or without contrast, or offered a reduced dose of contrast. Also, many of the studies were done several years ago so the value of their results is limited because eGFR thresholds for defining an abnormal result have decreased over time. No data were available on clinical outcomes such as need for renal replacement therapy or hospital admissions.

Cost effectiveness

3.13 The EAG identified existing studies on the cost effectiveness of POC creatinine tests in an outpatient non-emergency secondary care setting, to assess kidney function before contrast-enhanced CT imaging. Because only a single cost-consequence analysis was found, provided as an academic-in-confidence manuscript, the EAG also constructed a de novo economic model to assess the cost effectiveness of POC creatinine tests.

Model structure

3.14 The model assessed a cohort of outpatients presenting for a non-emergency contrast-enhanced CT scan without a recent eGFR measurement. Costs were presented from the perspective of the NHS and personal social services and were reported in UK pounds at 2018 prices.

Outcomes after the first year were discounted at a rate of 3.5% per year. Most costs happened in the first year and were therefore not discounted.

3.15 The model used a decision tree cohort approach to estimate the costs and health outcomes of the different testing and treatment strategies. The model captured:

- true eGFR status (less than 30 ml/min/1.73 m^2 or 30 ml/min/1.73 m^2 and above)
- how eGFR status is classified by different testing strategies, using the eGFR cut-off value of 30 ml/min/1.73 m^2 and probabilities conditional on true eGFR status
- any actions to reduce PC-AKI risk in patients with eGFR below the cut-off value (correct or incorrect eGFR)
- the subsequent risk of PC-AKI (depends on eGFR status and any actions to reduce PC-AKI risk)
- the risk of renal replacement therapy (depends on whether a patient had a PC-AKI).

3.16 The model assessed 6 strategies to identify and manage treatment for patients with an eGFR less than 30 ml/min/1.73 m^2:

- laboratory testing only
- risk factor screening with POC creatinine testing
- risk factor screening with laboratory testing
- risk factor screening with POC creatinine testing and laboratory testing
- POC creatinine testing only
- POC creatinine testing with laboratory testing.

3.17 For each strategy that includes POC creatinine testing, the model considered separate strategies for each of the POC devices, to give 14 alternative testing strategies. The 3 devices considered in the model

were i-STAT Alinity, ABL800 FLEX and StatSensor because only these had sufficient data available to calculate classification probabilities.

Model inputs

3.18 Population characteristics, including the probability of a patient being in 1 of 4 eGFR categories, are presented in table 4. The proportion of people attending a CT scan appointment without a recent eGFR measurement was used to estimate the throughput of POC creatinine devices.

Table 4 Population parameters used in the model

Parameter	Input	Source
Probability of estimated glomerular filtration rate (eGFR)	Below 30 ml/min/1.73 m^2: 0.006 30 to 45 ml/min/1.73 m^2: 0.063 45 to 60 ml/min/1.73 m^2: 0.154 60 ml/min/1.73 m^2 or higher: 0.777	Gamma distribution fitted to Mid Yorkshire NHS trust data
Age and proportion of men	65 years, 51.7%	Snaith et al. (2019)
% missing eGFR	34%	Cope et al. (2017)
Patients per site	272 per month	Mid Yorkshire NHS trust data

3.19 The diagnostic accuracy data used for each of the tests included in the model are in table 5. The cut-off used to define a positive result is eGFR less than 30 ml/min/1.73 m^2. The sensitivity of the tests is equivalent to the probability that a person with eGFR less than 30 ml/min/1.73 m^2 is correctly categorised as having eGFR less than 30 ml/min/1.73 m^2. The specificity of the POC creatinine devices was calculated by combining information on the distribution of population eGFR with the probability of having a classification of eGFR less than 30 ml/min/1.73 m^2 for a given true eGFR category (a weighted average).

Table 5 Diagnostic accuracy data

Test	Input	Source
Lab test	Sensitivity: 100% Specificity: 100%	Assumption
i-STAT	Sensitivity: 84.1% Specificity: 98.9%	Evidence synthesis of point-of-care diagnostic accuracy – main analysis
ABL80 FLEX	Sensitivity: 86.1% Specificity: 99.2%	
StatSensor	Sensitivity: 73.9% Specificity: 99.1%	
Risk factor questionnaire	Sensitivity: 100% Specificity: 65.2%	Too et al. (2015)

3.20 In the base-case analysis, an odds ratio of 0.97 (95% confidence interval [CI] 0.52 to 1.9) for the effect of preventative intravenous hydration was used for patients with an eGFR below 30 ml/min/1.73 m^2 (Ahmed et al. 2018). It was assumed there would be no effect of intravenous hydration on risk for patients with an eGFR above 30 ml/min/1.73 m^2 (AMACING trial). A scenario analysis was done using the lower bound of the odds ratio (0.52), implying a greater protective effect of intravenous hydration compared with the base-case analysis.

3.21 A fixed effects meta-analysis of 3 studies (Hinson et al. 2017; Davenport et al. 2013; McDonald et al. 2014) suggested no effect of contrast on PC-AKI risk (odds ratio [OR] 0.98; 95% CI 0.88 to 1.08). It was therefore assumed in the base case that there was no effect of contrast on the risk of PC-AKI. A scenario analysis exploring a greater risk of PC-AKI in people with an eGFR of less than 30 ml/min/1.73 m^2 was done.

3.22 The probability of having AKI after contrast for people with an eGFR of less than 30 ml/min/1.73 m^2 or 30 ml/min/1.73 m^2 and above depending on whether they had intravenous hydration or not is shown in table 6.

Table 6 Probability of AKI after contrast

eGFR (ml/min/1.73 m^2) and hydration	Probability of AKI	Source
eGFR below 30 and IV hydration	10.8%	Park et al. (2016)
eGFR below 30 and no IV hydration	11.1%	Park et al. (2010), Ahmed et al. (2018)
eGFR 30 and above with IV hydration	2.4%	Park et al. (2016)
eGFR 30 and above with no IV hydration	2.4%	Assumption
Abbreviations: eGFR, estimated glomerular filtration rate; AKI, acute kidney injury; IV, intravenous		

3.23 After having a CT scan, the probability that people who did not develop AKI after contrast needed renal replacement therapy was 0.014 and for people who did develop AKI after contrast was 0.111.

3.24 The model did not consider the effect of a delay in the planned CT scan on patient outcomes because of any change in their underlying condition during the waiting period.

3.25 It was assumed that 94.5% of people were alive 6 months after they had the CT scan, based on data reported in Park et al. (2016). The health-related quality-of-life data used in the base case are shown in table 7. No disutility from PC-AKI or intravenous hydration was included in the model.

Table 7 Health-related quality of life

Parameter	Value (QALYs)	Source
HRQoL adjusted life expectancy	9.80	Calculated from ONS mortality data and Ara and Brazier, 2010 general population utility equation
QALY loss from RRT	−0.0275	Wyld et al. 2012, and assuming 3 months of RRT
QALY loss from anxiety caused by delays	0	Assumption
Abbreviations: HRQoL, health-related quality of life; QALY, quality-adjusted life year; ONS, Office for National Statistics; RRT, renal replacement therapy		

3.26 Costs were calculated for each POC creatinine test, laboratory test, CT scans, intravenous hydration and for associated adverse events. The costs used in the model are shown in table 8. It was estimated that 92.6 patients per month would have a POC creatinine test. Risk factor screening before a POC creatinine test resulted in an estimated 32.6 patients per month having a POC test.

Table 8 Costs used in the model

Parameter	Value	Source
Laboratory test	£3.31	NHS reference costs 2017/18
Risk factor screening	£1.11	Lederman et al. (2010), NHS reference costs 2017/18
i-STAT without risk factor screening	£8.85	Calculated from company data
ABL800 FLEX without risk factor screening	£15.73	Calculated from company data
StatSensor without risk factor screening	£8.52	Calculated from company data
i-STAT with risk factor screening	£11.96	Calculated from company data
ABL800 FLEX with risk factor screening	£36.36	Calculated from company data
StatSensor with risk factor screening	£14.25	Calculated from company data
Contrast-enhanced CT scan	£111.65	NHS reference costs 2017/18
CT scan cancellation	£87.92	NHS reference costs 2017/18, assumed to be the cost of an unenhanced CT scan
Intravenous hydration	£340.89	NHS reference costs 2017/18
Adverse events from intravenous hydration	£32.76	Nijssen et al. (2017), NHS reference costs 2017/18
Renal medicine follow up if test positive (from last test in sequence)	£186.49	NHS reference costs 2017/18
Renal replacement therapy	£9,758	NHS reference costs 2017/18; assuming 3 sessions per week over 3 months

Base case assumptions

3.27 The following assumptions were applied in the base-case analysis:

- The laboratory test would have perfect diagnostic accuracy (100% sensitivity and specificity).
- Risk factor screening in the model would be done with a generic risk factor questionnaire.
- All patients having a laboratory test would have their CT scan cancelled and rebooked.

- A positive test result at the last step of the testing sequence resulted in the scan being cancelled and rebooked with intravenous hydration and contrast-enhanced CT scan.
- Adverse events from intravenous hydration were associated with costs but no health-related quality-of-life loss.
- Mortality in the model was the same for all patients regardless of PC-AKI status.
- Mortality was independent of eGFR levels and PC-AKI.
- Renal replacement therapy consisted of haemodialysis.

Base-case results

3.28 Deterministic and probabilistic results were presented as net monetary benefit and net health benefit using a maximum acceptable incremental cost-effectiveness ratio (ICER) of £20,000 per quality-adjusted life year (QALY) gained. Incremental net benefit was calculated for each strategy compared with laboratory testing. A fully incremental analysis was also done, but because the incremental cost and QALY differences between the strategies were so small, the ICERs are of limited use. This is because they are very sensitive to extremely small differences in the QALYs. If pairwise ICERs had been calculated, all strategies that include POC creatinine devices would cost less and be less effective than the strategy of laboratory testing for all. Full results of the base case are shown in tables 9 and 10. In general:

- Strategies that combine risk factor screening with POC creatinine testing and laboratory testing result in higher net benefit than other types of strategies, because they have a high positive predictive value. This avoids unnecessarily offering people who have false positive results intravenous hydration, which is associated with costs including cancelling and rebooking CT scans, giving intravenous hydration, treating intravenous hydration adverse events and patient follow up.

- Strategies that combine risk factor screening with POC creatinine testing, without confirmatory laboratory testing, are the next highest ranking. These have lower overall specificity and give more false positive results, which are associated with increased costs from unnecessary management for patients whose results were misclassified as eGFR less than 30 ml/min/1.73 m^2 (cancelling and rebooking CT scans, giving intravenous hydration, treating intravenous hydration adverse events and patient follow up).
- Strategies with POC creatinine testing that do not use risk factor screening have lower average net benefit than POC creatinine test strategies that do because of the higher costs of testing when all patients have POC creatinine testing.
- The strategies using POC creatinine in isolation are the lowest ranking strategies involving POC creatinine testing, because they misclassify more patients' results as false positives and all patients incur the cost of POC testing.
- Laboratory testing alone and risk factor screening then laboratory testing are the lowest ranking strategies. Although they have the highest QALY gains because they give no false positives or false negatives, they are associated with the highest costs, because of cancellation, rebooking and managing treatment for people who test positive.

Table 9 Base-case probabilistic cost-effectiveness results – net benefit

	Identification	Management	Total costs	Total QALYs	NHB [c] (QALYs)	NMB [c]	INHB [c] (QALYs)	INMB [c]	NB rank	Probability of being cost effective	
										£20,000/ QALY	£30,000/ QALY
1	Lab	Test negative[a] – contrast-enhanced CT scan Test positive[b] – intravenous hydration and contrast-enhanced CT scan	−£367.12	9.993255191	9.97490	£199,497.99	0.00000	£0.00	14	0.0%	0.0%
2	RF + i-STAT		−£281.87	9.993255167	9.97916	£199,583.23	0.00426	£85.24	4	0.0%	0.0%
3	RF + ABL800 FLEX		−£289.72	9.993255171	9.97877	£199,575.39	0.00387	£77.40	9	0.0%	0.0%
4	RF + StatSensor		−£281.70	9.993255154	9.97917	£199,583.40	0.00427	£85.42	3	0.0%	0.0%
5	RF + Lab		−£307.94	9.993255191	9.97786	£199,557.17	0.00296	£59.18	13	0.0%	0.0%
6	RF + i-STAT + lab		−£279.70	9.993255167	9.97927	£199,585.40	0.00437	£87.42	1	79.3%	79.3%
7	RF + ABL800 FLEX + lab		−£288.24	9.993255171	9.97884	£199,576.87	0.00394	£78.88	8	0.0%	0.0%
8	RF + StatSensor + lab		−£280.01	9.993255154	9.97925	£199,585.09	0.00436	£87.10	2	20.7%	20.7%
9	i-STAT		−£290.20	9.993255167	9.97875	£199,574.90	0.00385	£76.91	10	0.0%	0.0%
10	ABL800 FLEX		−£294.83	9.993255171	9.97851	£199,570.27	0.00361	£72.28	12	0.0%	0.0%
11	StatSensor		−£287.82	9.993255154	9.97886	£199,577.29	0.00396	£79.30	7	0.0%	0.0%
12	i-STAT+ lab		−£283.93	9.993255167	9.97906	£199,581.17	0.00416	£83.19	6	0.0%	0.0%
13	ABL800 FLEX+ lab		−£290.55	9.993255171	9.97873	£199,574.55	0.00383	£76.57	11	0.0%	0.0%
14	StatSensor + lab		−£282.95	9.993255154	9.97911	£199,582.15	0.00421	£84.17	5	0.1%	0.1%

[a] According to any test in the testing sequence; [b] According to last test in the testing sequence; [c] At £20,000 per QALY.

Abbreviations: INHB, incremental net health benefit; INMB, incremental net monetary benefit; NB, net benefit; NHB, net health benefit; INMB, net monetary benefit; RF, risk factor screening; lab, laboratory testing; QALY, quality-adjusted life year.

Table 10 Base-case cost-effectiveness deterministic results – full incremental analysis

	Identification	Management	Total costs	Total QALYs	Incremental costs	Incremental QALYs	ICER (per QALY gained)
6	RF + i-STAT + lab	Test negative [a] – contrast-enhanced CT scan Test positive [b] – intravenous hydration and contrast-enhanced CT scan	£275.84	9.99137100231	–	–	–
8	RF + StatSensor + lab		£276.15	9.99137099733	−£0.31	−0.000000005	Dominated
4	RF + StatSensor		£277.84	9.99137099733	−£1.99	−0.000000005	Dominated
2	RF+ i-STAT		£278.02	9.99137100231	−£2.17	0.00000000000	Dominated
14	StatSensor+ lab		£279.09	9.99137099733	−£3.25	−0.000000005	Dominated
12	i-STAT+ lab		£280.08	9.99137100231	−£4.23	0.00000000000	Dominated
11	StatSensor		£283.96	9.99137099733	−£8.12	−0.00000000499	Dominated
7	RF+ABL800 FLEX+lab		£284.39	9.99137100330	−£8.55	0.00000000099	Extendedly dominated
3	RF+ABL800 FLEX		£285.87	9.99137100330	−£10.03	0.00000000099	Dominated
9	i-STAT		£286.35	9.99137100231	£10.51	0.00000000000	Dominated
13	ABL800 FLEX+ lab		£286.70	9.99137100330	£10.86	0.00000000099	Dominated
10	ABL800 FLEX		£290.99	9.99137100330	£15.14	0.00000000099	Dominated
5	RF + lab		£304.06	9.99137101011	£28.22	0.00000000779	£3,620,669,780
1	Lab		£363.26	9.99137101011	£87.42	0.00000000779	Dominated

[a] According to any test in the testing sequence; [b] According to last test in the testing sequence.

Abbreviations: RF, risk factor screening; lab, laboratory testing; QALY, quality-adjusted life year; ICER, incremental cost-effectiveness ratio.

3.29 The strategy with the highest incremental net benefit was strategy 6 (risk factor screening plus i-STAT plus laboratory testing). In the probabilistic sensitivity analysis, this strategy had the highest probability of being the most cost effective (79.3% for maximum acceptable ICERs of £20,000 and £30,000 per QALY gained). It was also the least costly of all strategies compared, but gave fewer QALYs than most other strategies. The corresponding strategy with StatSensor, strategy 8, only had a marginally smaller average incremental net benefit (£87.11 compared with £87.42 for strategy 6). In the probabilistic sensitivity analysis, the probability of this strategy being the most cost effective at maximum acceptable ICERs of £20,000 and £30,000 per QALY gained was 20.7%. Although ABL800 FLEX has the best diagnostic accuracy, strategies including testing with ABL800 FLEX have consistently lower net benefit than corresponding strategies with i-STAT and StatSensor because of the higher costs of testing with this device.

3.30 The fully incremental ICER analysis showed that most strategies were dominated or extendedly dominated by strategy 6. Strategy 5 (risk factor screening plus laboratory testing) had an ICER of £3.61 billion per QALY gained compared with strategy 6.

Analysis of alternative scenarios

3.31 Several scenario analyses were explored; results from most of the analyses were robust to changes in the assumptions. Some analyses caused strategy 8 (risk factor screening plus StatSensor plus laboratory testing) to become more cost effective than strategy 6 (risk factor screening plus i-STAT plus laboratory testing). This was generally because of changes to the assumptions about the diagnostic accuracy and the costs of the POC creatinine tests. The scenario analysis in which there were no delays to CT scanning from laboratory testing with or without intravenous hydration resulted in strategy 5 (risk factor screening plus laboratory testing) and strategy 1 (laboratory testing) being more cost effective than strategies involving POC creatinine devices.

3.32 The base-case analysis was also replicated, adding 2 new strategies:

- a 'no testing' strategy when all patients had a contrast-enhanced CT scan without testing for risk of PC-AKI
- a 'no testing' strategy combined with a greater reduction in risk of PC-AKI from intravenous hydration.

Both these strategies were associated with higher net benefit than other strategies included in the base-case analysis. That is, the no testing strategies were both less effective and cheaper than all other strategies.

3.33 An additional scenario analysis was done to consider the effect on the results if there was a higher risk of PC-AKI than in the base case; the risk from contrast agent was increased and the protective effect of intravenous hydration was increased to give an absolute risk difference with and without hydration of 10.3%. The results of this analysis were consistent with the base case.

4 Committee discussion

Current practice

The safety of contrast agents has improved over time, but they may increase the risk of acute kidney injury in some people

4.1 Historically contrast agents were much more toxic than those used in current practice, with side effects including kidney damage. Clinical experts noted that the risk of developing acute kidney injury (AKI) from contrast agents currently used in the NHS is thought to be very low, especially in people with an estimated glomerular filtration rate (eGFR) of 30 ml/min/1.73 m^2 and above. However, they noted that there is some concern about the risk of post-contrast AKI (PC-AKI) for people with an eGFR of less than 30 ml/min/1.73 m^2, especially if they have other risk factors for kidney disease. Although end-stage renal disease after PC-AKI is extremely rare, transient rises in creatinine (decreases in eGFR) can

have clinical effects and increase mortality, especially if there are repeated rises. Patient experts noted that when a contrast-enhanced CT scan does lead to substantial kidney damage, the effect on a person's quality of life can be considerable. The committee concluded that the risk of PC-AKI is very low for most people, but there may be a higher risk if eGFR is less than 30 ml/min/1.73 m^2.

NHS clinical practice varies on whether an eGFR result is needed for everyone having a contrast-enhanced CT scan

4.2 NICE's guideline on acute kidney injury recommends that the risk of AKI should be assessed before offering iodinated contrast agents to adults for emergency or non-emergency imaging, and that increased risk is associated with an eGFR less than 40 ml/min/1.73 m^2. However, the Royal Australian and New Zealand College of Radiologists guideline on iodinated contrast media, which has been endorsed by the Royal College of Radiologists, recommends that an eGFR is only needed before offering iodinated contrast agents if there are risk factors for AKI. The committee noted that these 2 approaches have resulted in variation in clinical practice in the NHS. Some trusts need a recent eGFR result from all patients before doing a contrast-enhanced CT scan. Other trusts will do a contrast-enhanced CT scan without a recent eGFR result if there is a low risk of AKI. The definition of 'recent' may vary between 3 and 12 months in practice.

Clinical effectiveness

The diagnostic accuracy of the point-of-care creatinine devices is acceptable, but there is uncertainty, particularly for StatSensor

4.3 The evidence showed that the 3 devices with diagnostic accuracy data (ABL800 FLEX, i-STAT and StatSensor) perform reasonably well in classifying eGFR into the correct categories. The committee noted that measuring creatinine using the POC creatinine devices is not as accurate as laboratory measurement. Therefore, there would be some false

positive results (incorrectly categorised as eGFR below 30 ml/min/1.73 m^2; people would have intravenous hydration unnecessarily) and false negative results (incorrectly categorised as an eGFR of 30 ml/min/1.73 m^2 and above; people would miss out on intravenous hydration). However, the number of these would be small. A clinical expert explained that the tests are more accurate at high levels of creatinine (low eGFR values), which is when clinical decision making is the most critical. StatSensor appeared to be less accurate than the other 2 devices, but the committee noted that the 95% credible intervals for sensitivity for the different devices overlapped. This means that the sensitivity of StatSensor could be as good as the other devices. The committee acknowledged that the laboratory reference standard used to calculate diagnostic accuracy for the POC creatinine devices was assumed to be 100% accurate, which is probably not the case. It also noted that the studies would have been done under controlled conditions and that the devices may not perform as well in clinical practice. The committee concluded that there was some uncertainty about whether ABL800 FLEX, i-STAT and StatSensor can correctly categorise eGFR, but in general, the accuracy of the devices was acceptable.

Further research in people with an eGFR of less than 30 ml/min/1.73 m^2 would be helpful

4.4 The diagnostic accuracy studies included very few people with an eGFR less than 30 ml/min/1.73 m^2. The committee noted that although this could affect the confidence placed on sensitivity calculations, it does reflect clinical practice because most people present for an outpatient CT scan with an eGFR of 30 ml/min/1.73 m^2 and above. The committee concluded that further research in a population with eGFR less than 30 ml/min/1.73 m^2 would be beneficial (see section 5.1).

There is no evidence on rates of cancelled CT scans, PC-AKI and patient experience

4.5 The value of the POC creatinine devices is that they prevent the cancellation and rebooking of CT scans, reduce PC-AKI and improve the experience for patients attending for a CT scan by allowing same day assessment and decisions. The committee noted that there was no evidence on these outcomes and encouraged further research incorporating them (see section 5.3).

Cost effectiveness

The structure, inputs and assumptions used in the model are appropriate

4.6 The model only included people who present for an outpatient CT scan without a recent (within 3 months) eGFR result; it did not assess strategies for increasing the number of people who present for their CT scan with a recent eGFR result. The committee considered that the structure, inputs and assumptions used in the model were appropriate. It noted that the external assessment group (EAG) was unable to include the effect of delaying a planned CT scan on clinical outcomes relating to the underlying condition during a wait for a rescheduled scan. This was because there are many different reasons for having a CT scan and the effect of them all could not be quantified. The committee also noted that costs for training and laboratory governance of the POC creatinine devices were not included. But it concluded that this was acceptable for decision making.

The strategy of 'no testing' is not an appropriate comparator for the model

4.7 The testing strategy in which people presenting for a CT scan without a recent eGFR had no further testing and had a contrast-enhanced scan without intravenous hydration resulted in the highest net benefit. The committee considered however, that no testing for anybody, regardless of whether risk factors were present, and giving contrast agent to all without intravenous hydration was not an appropriate comparator in the model.

This was because it is not in line with national and international guidelines (see section 4.2).

The different testing strategies result in similar QALYs

4.8 The differences in quality-adjusted life years (QALYs) between the different testing strategies assessed were extremely small. The strategy in which all people presenting for a CT scan without a recent eGFR would have a laboratory test was associated with more QALYs than the strategies involving a POC creatinine device. The EAG explained that this was because the number of false negative test results (that is, when true eGFR is less than 30 ml/min/1.73 m^2 but the test suggests an eGFR of 30 ml/min/1.73 m^2 and above) is higher for strategies including POC creatinine devices than for the laboratory test (which is assumed to have 100% sensitivity). However, the QALY gain from appropriately managing treatment for people who have an eGFR of less than 30 ml/min/1.73 m^2 is very small. The committee concluded that overall the clinical effectiveness is very similar across the different strategies. But it noted that the effect on quality of life for the small number of people who do develop kidney damage after a contrast-enhanced scan can be considerable (see section 4.1).

The ABL800 FLEX has a higher cost per test than the i-STAT and StatSensor

4.9 In the model, the POC creatinine devices were assumed to be used only for measuring creatinine and calculating eGFR, but the committee noted that some of the devices have multiple uses. For example, the ABL800 FLEX can measure 18 analytes, but test costs were not apportioned to other uses. Therefore, the cost per test for ABL800 FLEX was higher than for the i-STAT and StatSensor. This led to strategies including ABL800 FLEX having lower net benefit than strategies involving i-STAT or StatSensor. The committee noted that depending on the setting of the radiology department, an ABL800 FLEX could also be used by different departments, which would reduce the cost per test because the throughput would be higher.

The opportunity cost of cancelling CT scans is a key factor influencing model results

4.10 In the model, if a scan was cancelled and rebooked because of a positive POC creatinine test result or the need for a laboratory test, then a cost of £87.92 (equal to the cost of an unenhanced scan) was included. The committee noted that this assumes that the cancelled CT scan appointment cannot be filled. Clinical experts explained that in radiology departments that do both acute (emergency and inpatients) and elective (outpatient) CT scans these cancelled appointments would be filled by other patients waiting for CT scans. However, if the radiology department only does elective CT scans, for example a mobile clinic, then the cancelled appointment is unlikely to be filled and the cost assigned to a cancelled scan is appropriate. The committee also considered that using an unenhanced CT reference cost as a proxy for the rebooked CT scan could overestimate the opportunity cost because the cost of cancellation would already be accounted for in the fully absorbed reference cost. The committee noted that a scenario analysis of the model was run in which no CT scans were cancelled because of a laboratory test. The results of this analysis showed that strategies of laboratory testing for all or risk factor screening followed by laboratory testing were the most cost effective. However, in the scenario in which 25% of CT scans were cancelled because of a laboratory test, laboratory testing for all returned to being the least cost-effective strategy. The committee acknowledged that cancelled CT scans are not only an opportunity cost for the NHS, but would not be good for patients, who would have to return to the hospital for a rebooked CT scan. The committee concluded that there was uncertainty in the opportunity cost associated with cancelling CT scans and therefore in the optimal strategy.

Risk factor screening is an appropriate first step for people presenting for a CT scan without a recent eGFR result

4.11 Strategies in which risk factor screening was done first followed by a POC creatinine test for people who were identified as having at least 1 risk factor were more cost effective than strategies in which POC creatinine testing was done for all people presenting for a CT scan without an eGFR. The committee noted that including risk factor screening as a first step reduced the number of POC creatinine tests that would be done, which reduced the overall cost of testing. In the model, risk factor screening was assumed to be done with a generic risk factor questionnaire that had 100% sensitivity and 65.2% specificity. The committee agreed that risk factor screening should identify people at higher risk of AKI. But it noted that defined questionnaires had not been assessed, although risk factors are clearly stated in national and international guidelines. The committee concluded that risk factor screening is likely to be an appropriate first step for people presenting for a CT scan without an eGFR, but that further research should be done to develop a suitable risk tool or validate an existing risk tool for use in the NHS (see section 5.2).

Test strategies that include laboratory confirmation of a positive result from a POC device would not be good for patients

4.12 The strategies with the highest net benefit in the model were those that combined risk factor screening, a POC creatinine test for all people identified as having at least 1 risk factor, and a final confirmatory laboratory test for people who have a positive test result from a POC device. A confirmatory laboratory test would result in the CT scan being cancelled and rebooked. In practice this often means that the referral for CT would be cancelled, resulting in another referral having to be made for the patient. A patient expert explained that cancelling a CT scan would not be good for patients because it would take time to go for a blood test, wait for another referral and return to the hospital for the rebooked CT scan. This may also be associated with travel expenses, time off work, and

anxiety about the scan and the underlying clinical condition, most of which were not captured in the model. The committee noted that people with a true eGFR of 30 ml/min/1.73 m^2 and above who are identified as having an eGFR of less than 30 ml/min/1.73 m^2 using a POC creatinine device (false positive) would have intravenous hydration unnecessarily, which is associated with additional cost, but not with a QALY loss. It therefore concluded that although a strategy with a confirmatory laboratory test is slightly cheaper, it should not be considered further because of the negative experience for patients of cancelling the CT scan, going for a blood test and returning for the rescheduled CT scan.

POC creatinine devices could have a greater benefit for some people

4.13 Men, people over the age of 60, and those of African-Caribbean, African or South Asian family origin are at higher risk of kidney disease than others. The committee noted that people of these family origins are not often included in research studies, but the availability of POC creatinine devices could have a greater benefit for them than for the rest of the population.

POC creatinine devices are likely to be a cost-effective use of NHS resources and improve patient experience in some situations

4.14 The committee concluded that using POC creatinine devices to guide the use of contrast in outpatient CT scans is likely to be cost effective and improve patient experience if current protocols need all outpatients to have a recent eGFR result before a contrast-enhanced CT scan can be done (see section 4.2). The committee agreed that the most appropriate testing strategy was to use a risk factor screening questionnaire and then a POC creatinine device to test people with 1 or more risk factors (see section 4.11), without laboratory confirmation of positive test results (eGFR less than 30 ml/min/1.73 m^2; see section 4.12). The committee acknowledged that POC creatinine devices are less accurate than laboratory creatinine testing. Therefore, patients who arrive at a CT scan appointment with a recent eGFR result are most likely to have appropriate

management of their condition. But the committee noted that these patients were not included in the economic model. It further acknowledged that POC creatinine test results should not be used to make decisions about care other than the decision to give contrast agent because of their lower accuracy than laboratory creatinine measurement.

5 Recommendations for further research

5.1 The committee recommended further research on the incidence and effect of post-contrast acute kidney injury (PC-AKI) in people with eGFR less than 30 ml/min/1.73 m^2.

5.2 The committee recommended that a suitable risk factor screening tool for identifying risk of PC-AKI for use across the NHS in people presenting for an outpatient CT scan with contrast agent is developed or an existing tool is validated.

5.3 The committee recommended studies to collect data on the rates of cancelled CT scans, whether cancelled appointments are filled and the effect on patients' experience before and after the introduction of POC creatinine devices to radiology departments.

6 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

In addition NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be considered by the NICE Medical Technologies Evaluation Programme research facilitation team for the developing specific research study protocols as appropriate. NICE will also incorporate the research recommendations in section 5 into its guidance research recommendations database and highlight these recommendations to public research bodies.

7 Review

NICE reviews the evidence 3 years after publication to ensure that any relevant new evidence is identified. However, NICE may review and update the guidance at any time if significant new evidence becomes available.

Mark Kroese

Chair, diagnostics advisory committee

June 2019

8 Diagnostics advisory committee members and NICE project team

Committee members

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

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

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.

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

Specialist committee members

Dr Jane Belfield

Consultant radiologist, Royal Liverpool University Hospital

Dr Anne Dawnay

Consultant biochemist, Barts Health

Dr Mark Devonald

Consultant nephrologist, Nottingham University Hospitals NHS Trust

Mr Guy Hill

Lay specialist committee member

Ms Emily Lam

Lay specialist committee member

Dr Andrew Lewington

Consultant renal physician/honorary clinical associate professor, Leeds Teaching Hospital Trust

Prof Beverly Snaith

Clinical professor of radiography, University of Bradford/Mid Yorkshire Hospitals

Ms Annette Thomas

Consultant clinical scientist and director of WEQAS, Cardiff and Vale University Health Board

NICE project team

Each diagnostics assessment is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Frances Nixon

Topic lead

Rebecca Albrow

Technical adviser

Donna Barnes

Project manager

ISBN: