NICE National Institute for Health and Care Excellence

DIAGNOSTICS ASSESSMENT PROGRAMME

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

Diagnostics Consultation Document – Comments

Diagnostics Advisory Committee date: 20 August 2019

THEME: Care pathway

Comment number	Name and organisation	Section number	Comment	NICE response
1	The Society and College of Radiographers		*Using the devices can also avoid cancelling and rebooking CT scans, which is important for patients* – The Society and College of Radiographers suggest checking the required information about eGFR has been provided by the referrer can also avoid cancelling and rebooking CT scans. It is a requirement under IR(ME)R 2017 Regulation 10(5) that the referrer must supply the practitioner with sufficient medical data (such as previous diagnostic information or medical records) relevant to the exposure requested by the referrer to enable the practitioner to decide whether there is sufficient net benefit as required by regulation 11 (1)(b).	Thank you for your comment which the committee considered. The committee agreed that optimal care is for the referrer to provide a recent eGFR measurement. This is described in a new paragraph in the diagnostics guidance (section 4.15).
2	The Society and College of Radiographers	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.* The Society and College of Radiographers believes this supports the opportunity for referrers to supply an eGFR and that it is likely to remain valid whilst the patient waits for their booked appointment.	Thank you for your comment which the committee considered. The committee agreed that optimal care is for the referrer to provide a recent eGFR measurement. This is described in a new paragraph in the diagnostics guidance (section 4.15).

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3	The Society and College of Radiographers	2.2	*Sometimes, to avoid the risk of kidney injury, people might have unenhanced imaging, which is less accurate than contrast-enhanced imaging.* The Society and College of Radiographers would like to highlight that this should not be considered an alternative unless **specifically justified for an individual** on the basis that the benefit of not having the contrast and achieving a diagnostic outcome from non-enhanced CT images outweighs the risk of a repeat exposure and the risk of causing a PC-AKI.	Thank you for your comment which the committee considered. The committee agreed that a risk of PC-AKI should not prevent diagnostic images being taken that can inform treatment decisions. This is described in a new paragraph in the diagnostics guidance (section 4.15). The sentence about unenhanced imaging has also been taken out of the diagnostics guidance.
4	The Society and College of Radiographers	3.12	*For example, the proportion of people offered scans with or without contrast, or offered a reduced dose of contrast*. The Society and College of Radiographers finds this result concerning. Contrast volume should be optimised for diagnostic quality and be specific to the individual patient, taking into account weight/age and the clinical question. The practice of giving a reduced dose of contrast due to an increased risk of PC-AKI (in isolation of these factors) might not be justified.	Thank you for your comment which the committee considered. The committee agreed that a risk of PC-AKI should not prevent diagnostic images being taken that can inform treatment decisions. This is described in a new paragraph in the diagnostics guidance (section 4.15).

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THEME: Risk factor screening

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5	The Society and College of Radiographers	4.11	The Society and College of Radiographers supports the proposal for risk factor screening as an appropriate first step for people presenting for a CT scan without a recent eGFR result. The Society and College of Radiographers supports the recommendation to undertake further research to develop a suitable risk tool or validate an existing risk tool for use in the NHS. The Society and College of Radiographers advises that both strategies should be done in conjunction with raising awareness amongst referrers of their legal responsibility to supply the practitioner with sufficient relevant clinical information.	Thank you for your comment which the committee considered.

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THEME: Test accuracy

Comment number	Name and organisation	Section number	Comment	NICE response
6	The Society and College of Radiographers	1.4	*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 m2 may be identified if they had laboratory testing*. The Society and College of Radiographers is concerned about the number of people who have an eGFR less than 30 and are at risk of AKI not being identified by POC testing.	Thank you for your comment which the committee considered. The economic model formally accounts for the impact on costs and health outcomes of individuals who are misclassified as false negatives by the POC creatinine devices (i.e. people who have an eGFR lower than 30 ml/min/1.73 m^2, and are at risk of AKI but test results show an eGFR measurement equal to or greater than 30 ml/min/1.73 m^2). The number of people incorrectly categorised would be small, especially for low eGFR values because the tests are more accurate at high levels of creatinine (section 4.3 of the diagnostics guidance). The committee considered that optimal care is for the referrer to provide a recent eGFR measurement, and this has been added to the diagnostics guidance in section 4.15.
7	NHS Professional	1.1	I am not sure I agree with the recommendation to use the Nova StatSensor to assess kidney function prior to contrast CT. One of the specialist committee members' publications (Snaith et al. 2018) states that use of the StatSensor resulted in four out of 13 high risk cases being missed. There are also several publications demonstrating a poor correlation between laboratory methods and	Thank you for your comment which the committee considered. The committee notes in section 4.3 of the diagnostics guidance that StatSensor appears to be less accurate than the other devices, but that the 95% credible intervals for sensitivity for the different devices overlapped. This means that the sensitivity

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			the StatSensor - this is not necessarily bias, but a large scatter about the identity. It would therefore be difficult to take this error into account when interpreting results from this device.	of StatSensor could be as good as the other devices. The committee decided that no changes were needed to the diagnostics guidance.

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THEME: Costs and resource use

Comment number	Name and organisation	Section number	Comment	NICE response
8	The Society and College of Radiographers		• *cancelled CT scan appointments cannot be offered to other people.* The Society and College of Radiographers challenge this statement. Many services make use and some rely on booked patients not attending to be able to fit in urgent in patients or other out patients who attend on the wrong day. It rarely means there is a wasted slot. We note the later comments (section 4.10) and agree with the comments of the committee.	Thank you for your comment which the committee considered. A set of scenario analyses are presented in the diagnostics assessment report where the proportion of cancelled slots was varied. The committee's consideration of this are described in section 4.10 of the diagnostics guidance.
9	The Society and College of Radiographers	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.* SCoR notes there are no costs considered for training radiographic staff to use the POC devices and to maintain competence or for time to undertake the test and interpret and record the result. Has any work been undertaken to consider the impact of moving the task of testing from the referrer to the scanning environment?	Thank you for your comment which the committee considered. The committee considered the costs associated with training/implementation and test governance further at the second committee meeting. This is described further in section 4.6 of the diagnostics guidance.

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			The Society and College of Radiographers notes the later (section 4.6) comments of the committee: *The committee also noted that costs for training and laboratory governance of the POC creatinine device were not included. But it concluded that this was acceptable for decision making.*	
10	The Society and College of Radiographers	3.27	Base case assumptions do not appear to account for the mitigation of costs from "lost slots" being used to scan other people. Has the cost or a re-booked appointment to the patient been accounted for? Arrangements for travel, loss of working time, childcare etc? The Society and College of Radiographers would argue that in patient centred care this is a high priority.	Thank you for your comment which the committee considered. A set of scenario analyses are presented in the diagnostics assessment report where the proportion of cancelled slots was varied. The committee's consideration of this are described in section 4.10 of the diagnostics guidance. The perspective taken in the analysis was that of the NICE reference case (NHS and personal social services). Therefore, costs incurred by patients were not accounted for in the analysis. However, the impact on patients and carers was considered by the committee and this is described in section 4.12 of the diagnostics guidance.

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THEME: POC creatinine devices

Comment number	Name and organisation	Section number	Comment	NICE response
11	Abbott	Section 1.1	It says that the device should calculate the eGFR, but then says i-STAT. To be correct it should really say i-STAT Alinity as the 300 does not calculate eGFR.	Thank you for your comment which the committee considered. This has been changed in the diagnostics guidance.
12	Abbott	Table 1	The table entry on Alinity says it only calculates eGFR using MDRD, where in fact Alinity can calculate both MDRD and CKD-EPI.	Thank you for your comment which the committee considered. Table 1 in the diagnostics guidance has been changed.
13	Abbott	4.1.2	Table states Nova as using CKD-EPI for one of their eGFR calculation methods. Can this be confirmed as being correct?	Thank you for your comment which the committee considered. This information has been checked with the company. Table 1 in the diagnostics guidance has been changed.
14	Siemens Healthcare Ltd		Is there any potential to include the previously untested instruments in a clinical trial. We would like to put epoc forward for a clinical trial.	Thank you for your comment which the committee considered.
15	Institute of Biomedical Science	1.3 & 3	BHR Pharmaceuticals are currently marketing the Pointcare M3 point of care device (essentially a Piccalo copy). The creatinine assay forms part of a number different chemistry rotas requiring 100uL of serum and takes between 9 and 15 minutes. Although an enzymatic assay is use it has been shown to be imprecise and inaccurate when compared against the WEQAS reference mean and so should be added to the “Not recommend” list	Thank you for your comment which the committee considered. This technology was not included in the scope of the assessment; therefore, evidence was not reviewed, and the technology cannot be included in the diagnostics guidance.

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16	Institute of Biomedical Science	1.3 & 3	BHR Pharmaceuticals are currently marketing the Skyla point of care device (essentially a Piccalo copy). Satisfactory performance has not yet been independently established and so this system should also be added to the “Not recommend” list	Thank you for your comment which the committee considered. This technology was not included in the scope of the assessment; therefore, evidence was not reviewed, and the technology cannot be included in the diagnostics guidance.

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THEME: Editorial

Comment number	Name and organisation	Section number	Comment	NICE response
17	Abbott	1.3	Suggest to align the wording to bullet 1.1.: " Point-of-care devices for the measurement of Creatinine (ABL90 FLEX PLUS, Dri-chem NX500, epoc Blood Analysis System, and Piccolo Xpress) are not recommended…"	Thank you for your comment which the committee considered. The wording of bullets 1.1 and 1.3 has been changed in the diagnostics guidance.
18	Abbott		Clarification required around why the committee made this recommendation: Please could you clarify the connection between Creatinine and eGFR: "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" – and the eGFR needs to be determined from the creatinine result.	Thank you for your comment which the committee considered. This has been changed in the diagnostics guidance.

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THEME: General

Comment number	Name and organisation	Section number	Comment	NICE response
19	The Society and College of Radiographers	5	The Society and College of Radiographers welcomes all the recommendations for further research.	Thank you for your comment which the committee considered.
20	Royal College of Radiologists		We see no issues with this document and have no additional comments.	Thank you for your comment which the committee considered.