NICE National Institute for Health and Care Excellence

Point-of-care creatinine tests to assess kidney function before administering intravenous contrast for computed tomography (CT) imaging

Diagnostics Assessment Report (DAR) - Comments

Stakeholder	Comment no.	Page no.	Section no.	Comment	NICE Response
The Society and College of Radiographers (SCoR)	1	1	Title	The title and assessment of 'CT imaging' places a limitation on the study and cost benefit analysis of POC testing. Within radiology, SCoR members report that cross-sectional MRI departments do use POC renal function testing alongside a number of other modalities that could use them (basically all areas that use contrast agents), especially interventional radiology and fluoroscopy. For the full cost benefit of POC testing the whole spectrum of examinations which employ the use of contrast agents within clinical imaging (radiology) departments must be taken into account.	This is relevant to the scope of the assessment rather than to the report. The scope focussed on CT outpatients as this was the population deemed most likely not to have a recent eGFR result.
The Society and College of Radiographers (SCoR)	2	Up to p20	Abstract and section 1	On the whole, a very comprehensive review which we are sure will be welcomed. It does however still leave a questions, What is the justification for only considering the modality of CT scan? Due to the length of the document it is difficult to initially comprehend from the abstract and summary exactly what the purpose, methods, and conclusions are. The full conclusions in section 8 are clearer. At section 1 some confusion is caused by the content and structure of sentences that are contradicted in subsequent paragraphs – a result perhaps because they are taken from a different sub-section of the review.	See response to comment 1 We will re-read section 1 and amend any text which is contradictory.
The Society and College of Radiographers (SCoR)	3	12	Abstract	Renal function testing: checking creatinine or eGFR? A number of POC devices check eGFR – it is not clear to practitioners reading the abstract whether the assessment team investigated eGFR results.	We will add text to clarify that devices which output results as eGFR or creatinine were included.

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Stakeholder	Comment no.	Page no.	Section no.	Comment	NICE Response
The Society and College of Radiographers (SCoR)	4	21	2.1	Good explanation of the issue although the data does appear somewhat dated (CT Scans performed in England for period 2012-13). The level of demand for all clinical imaging examinations, including CT Scans, has increased in the 7 year period since 2012.	We will ask our clinical advisers if they are aware of a more recent reference.
The Society and College of Radiographers (SCoR)	5	14	Plain English summary	Use of screening questionnaire: Agree, for example, a centre may only test if the patient is over 70yrs old, is diabetic, or has any known problems with the kidneys.	N/A
The Society and College of Radiographers (SCoR)	6	17	1.4 Results	Results accuracy: Agree; not at all tests are accurate when compared with laboratory blood results – it simply gives an indication of renal impairment.	N/A
The Society and College of Radiographers (SCoR)	7	23	2.2 Current Service	For example, a centre reports that eGFR threshold for CT is <40ml/min For example, a centre reports that eGFR threshold for MRI is <30 mls/min	N/A
The Society and College of Radiographers (SCoR)	8	23	2.2 Current Service	Agreement with the comment no blood results = no test: SCoR members report that at some centres, regardless of age of patient etc., contrast enhanced CT scan would not be booked in the absence of blood results - an approach which causes delays.	N/A
The Society and College of Radiographers (SCoR)	9	24	2.2	The SCoR agree that POC devices could present a good solution to cancellation of CT scans. SCoR members of one organisation report that POC testing made a significant difference for patients for whom there were no blood results in the previous 3 months. Members report that at an organisation which could not obtain funding for the device and ongoing costs of	N/A N/A

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				consumables there is dismay from referrers at a decision to withhold scan appointments until blood results are available. There is subsequent debate about funding for patients to continue to have blood tests as an alternative to POC - clear guidance would thus be welcomed. The content of 2.2 seems reasonable. SCoR members do report that they would rarely cancel appointments if they don't have egfr results as long as the patient is classified as low risk and had not been ill recently, for example, vomiting and diarrhoea.	N/A
The Society and College of Radiographers (SCoR)	10	186-7	8	SCoR welcome the research priorities outlined. SCoR note that currently there is variation in practice across organisations. Consistency of approach with standardisation for all patients is desirable and regarded to be a significant method of evidence-based quality improvement for imaging patients. Queries are raised around some of the cost benefit comments. For example, NHS CT scanners would not be idle due to a cancelled appointment - demand commonly outstrips supply of appointments - in such cases staff substitute missed appointment slots to instead move appointments forward for those already in departments. In turn this enables staff to utilise any time free at the end of AM / PM sessions to scan patients waiting on wards. Cost benefit must also take into account the whole range of examinations within a clinical imaging department using contrast agents (not just CT). The potential for cost benefit is much wider than envisaged – cross-system	N/A We did not identify published data on the rates of CT scan cancellation in the UK. Discussions with our clinical advisor and the specialist assessment subgroup, suggest that the rates of cancellation will be heterogeneous across NHS trusts, and highly dependent on local level organisational setup of radiology departments and laboratory facilities. In the absence of other evidence, we have made a simplifying assumption that all CT scans will be cancelled if the patient requires a laboratory test or IV hydration. The robustness of results to this

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				working must take into account the fact that POC device usage would not simply be limited to CT scan patients within a clinical imaging department (for example, the POC device would also be used by interventional radiology, MR, fluoroscopy contrast-enhanced imaging).	assumption was then tested in scenario analyses (Scenarios 7.1-7.4, please see table 56, p164) that varied the proportion of cancelled CT scans, including a scenario (7.1) assuming no cancellations. We will revise the wording in the relevant sections and try to clarify this issue in the final version of the HTA report. In regards to the exclusion of other imaging modalities, please see the answer to comment 1.
The Society and College of Radiographers (SCoR)	11		Overall comments following study conclusion	There is variable evidence of contrast induced AKI (or the clinical significance of transient decline in 'healthy patients). The study discusses that this is a matter to consider when justifying the costs associated with POC testing, because it is more expensive that routine laboratory testing. As an alternative, has any assessment been made elsewhere of the effects of processes to streamline/standardise the CT appointment/referral process? For example, POC testing is a reactive solution to the problem. An alternative proactive approach would be to ensure that when a referrer completes an outpatient request card for CT scan the patient also has a blood test if not already performed within a certain timeframe. As the report suggests, the risk of contrast induced nephropathy from modern contrast media is very low. Commonly for patients who have a eGFR of greater than	We have identified one unpublished study on the impact of POC creatinine testing in the context of alternative configurations of the CT appointment/referral process. Since this study has not yet been published, the sections where elements of this study are described have been marked Academic in Confidence (AIC) and will have been censored from the public version of the report. AIC marking is used when data are provided which are not currently in the public domain and that are critical to future planned publications. The AIC marking will be removed when the paper is published or within a reasonable timeframe (1-2 years). Nevertheless, the NICE Appraisal Committee has access to the full version of the report without AIC redaction, and relevant evidence from the

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				30 practitioners will proceed with a pre and post hydration policy, taking into account the greater diagnostic value of a contrast enhanced scan. However, unless the current system is streamlined, POC could still potentially reduce the number of rescheduled appointments or length of duration spent in hospital by an individual. Crucially, the study demonstrates that in the current system POC testing is a quick and straightforward method that has the potential to reduce cost to the healthcare system as a whole together with the stress, worry and anxiety experienced by patients who have their appointments rescheduled or delayed.	unpublished study informs the decision analytic model. Furthermore, while we acknowledge that there might be a range of alternative strategies or approaches which might help improve the efficiency of the current CT pathway, our specific research question was to address the downstream management of patients who currently attend radiology departments for a CT scan without an eGFR measurement. Hence, although the issues around the potential value of POC testing to improve the efficiency of the CT pathway are relevant, we consider that they are beyond the boundaries of our work as defined by the NICE scope.
NHS professional	12	116 onward	6	I wouldn't be surprised if there is challenge over the use RRT as the end outcome as this is a big jump from contrast media administration in this low risk group although I know that the Qalys for this economic analysis are not straight forward.	The RRT outcome refers to the use of temporary haemodialysis (3 months duration) to treat PC-AKI and not permanent RRT (please see section 6.4.6). The risk of RRT in the model cohort is very low (please see section 6.4.5), reflecting the low risk of PC-AKI in the population. While we recognise that risk of RRT in the study population is a source of uncertainty, the study informing this parameter was the only source of evidence in the relevant population and is therefore relevant.
NHS professional	13	184	7	Spelling mistake needs correcting to 'analysis'	We acknowledge the spelling mistake; this will be updated in the final report to HTA.

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Renal Association	14		(comments relate to both DAR and model)	Overall – incredibly complex. Prediction of PC-AKI not straight forward. Concern about model is that all patients with GFR <30 will be denied contrast without IV hydration. This will effect particularly the elderly population.	Future guidance informed by our study pertains only to the use of the diagnostic devices, and not to the downstream management of patients. Thus, no recommendations on whether to IV hydrate patients prior to CT scan will be made. Furthermore, our results suggest that IV hydration has a modest impact on the risk of PC-AKI while having high associated costs. Therefore, our findings do not make any formal recommendations concerning policy decisions that may directly effect the elderly population.
Renal Association	15		(comments relate to both DAR and model)	The published data relating to the incidence of PC-AKI in the outpatient setting in patients who have not had their renal function checked previously is unclear.	This issue is covered in section 4.3.1. We note that the risk of PC-AKI associated with an eGFR <30 mL/min/1.73 m2, is likely to be lower in the outpatient population (than in inpatients) given that inpatients are more likely to have other AKI risk factors (including acute illness and exposure to nephrotoxic treatments).
Renal Association	16		(comments relate to both DAR and model)	Will the denial/delay in CT scanning impact on the time to diagnosis of other conditions and will that therefore impact on the patient's health and quality of life? Such as a delayed cancer diagnosis.	Our analysis does not consider the impact from the delay of the planned CT scan on patient outcomes as a result of any change in their underlying condition while they wait for the rescheduled CT scan (please see section 6.4.5). This simplification was necessary due to the variety of conditions that lead to referral to CT scans in the study population and, therefore, to the variety of potential consequences. Furthermore, we did not identify evidence that would allow characterising the consequences of delay in the relevant population. We

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					acknowledge in our report that this is a potential limitation of the study.
Renal Association	17		(comments relate to both DAR and model)	Would a model where the person booking the scan fills the risk factor questionnaire and then if deemed higher risk at that point requests a lab creatinine, be a more robust scenario? Then the requester could order a more appropriate scan and counsel the patient appropriately.	The pathway described here is similar to strategy 5, where risk factor screening is combined with laboratory testing. The main difference is that the pathway suggested in this comment, allows for different actions to mediate risk dependent on clinical decision. In our base case clinical decision based on the results of screening and testing were limited to whether to IV hydrate or not prior to CT scan. This was a necessary simplification given the limited data available and the challenges of characterising the heterogeneity in the overall population and the underlying reason for imaging and linking this to individualised clinical decision making and associated outcomes. While we acknowledge that this is a potential limitation, we also conducted scenario analyses to explore the impact of alternative actions to mediate risk of PC-AKI (please see section 6.6.2) and found the results to be robust.
Radiometer Ltd	18	16	1.3.1	Could a comment be made that the ABL800 and ABL90 are multi-parameter Blood Gas Analysers. They measure more than Creatinine with each sample	This is covered in Table 1.
Radiometer Ltd	19	19	1.5	Diagnostic accuracy data were not available. We have recently received a paper/poster from Belgium which looks at PC-AKI Could this be taken into consideration?	The data in this poster does not report the type of detailed diagnostic accuracy data which is needed to be included in the review synthesis.

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				A copy is available here https://www.researchgate.net/publication/330839097_Analytical_and_diagnostic_performance_evaluation_of_five_creatinine_POCT_devices_in_the_identification_of_patients_at_risk_for_post-contrast_acute_kidney_injury_PCAKI	
Institute of Biomedical Science	20	NA	NA	What is the definition of recent with regards to the '*most recent serum creatinine/eGFR measurement*'? • one of the references states *'within 3 months'*; Snaith et al 2019 – p.260 & 271 • Cope et al p.101 *'kidney function tests within 3 months'* • within one reference (Harris, Snaith & Clarke; 2016) recent ranges from within 1 month to >6 months	There is no fixed definition – practice varies across the NHS.
The Royal College of Radiologists	21		General	We are happy with the report and believe it is proportionate and appropriate.	N/A