

Acute kidney injury: prevention, detection and management - Assessing risk factors for acute kidney injury in adults having iodine-based contrast media

**Consultation on draft guideline - Stakeholder comments table
05/08/2024 – 19/08/2024**

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Association of Laboratory Medicine	Guideline	General	General	We agree with the revised comments with reference to eGFR in this draft Guideline	Thank you for your support.
Association of Nephrology Nurses UK	Guideline	004	008	Could this recommendation include documentation of discussion and decision making in medical notes?	Thank you for your comment. The guideline has cross referred to the NICE guidelines on Shared decision making . This includes generic recommendations on recording discussions in care plans or medical notes and sharing this with the person.
Association of Nephrology Nurses UK	Guideline	004	011	Could this recommendation include a definition of emergency? (e.g. treatment change based on scan results) and be clear that this applies to inpatient care settings as well as the emergency department/ critical care.	Thank you for your comment. The committee agreed that it is difficult to provide a definition of what would be considered an emergency as this would be variable. A clinician would need to carry out an assessment of an individual and use their clinical judgement on a case-by case basis. The heading for this section of the recommendations states it applies to the emergency department or inpatient settings.
Association of	Guideline	General	General	Should/ could this recommendation include some guidance on the need for critical care/ renal team involvement in decision making regarding scanning.	Thank you for your comment. The committee agreed there was no need for the renal team involvement at this point in

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Nephrology Nurses UK				<p>Current practice in acute hospitals is that if patients have an AKI and require scanning that radiology refuse to carry out the scan unless intensive care or nephrology agree that this is ok, and to offer acute renal replacement therapy should renal function deteriorate. This often delays scanning whilst medical/ surgical teams get reviews carried out.</p> <p>Could there be a recommendation that recognises the risk that people may need renal support, and the appropriateness of this should be considered prior to scanning- but critical care/ renal referrals should not be required by radiology, the referring teams should acknowledge risk and take appropriate action as required (including referral to critical care/ renal if necessary).</p> <p>This is especially important for patients who are not appropriate for short or long term renal replacement therapy where involvement from these teams would not be required- but where scanning might change outcomes (e.g. would be appropriate for MRCP/ stent- but not for major surgery).</p>	<p>the pathway. If a patient is unwell then there may need to be a discussion with the appropriate team, that may mean the renal team or another team such as haematology depending on the reason the person is unwell. Any decision would need to be made on a case-by-case basis. The committee also noted that that in practical terms this may not be feasible owing to staffing levels particularly if it is not necessary for all cases.</p>
Institute of Biomedical Science	Guideline	005	004	Concerned that a six-month old eGFR does not reflect current renal health	Thank you for your comment. The committee agreed an eGFR from the last 6 months in a stable well person would be acceptable to base decisions on the use of iodine-based contrast. If the person presented as acutely unwell or has had periods of illness since the last eGFR this should prompt consideration of another eGFR test being carried out. The recommendation recommended asking

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					<p>screening questions has been amended to include taking symptoms of acute illness into account.</p> <p>The committee also agreed that if the test is available it should not be ignored, it may be that a clinician decides to order an additional test to be sure.</p>
MCT Lifesciences Limited	Evidence Review A	General	General	<p>The REMEDIAL II (Renal Insufficiency After Contrast Media Administration II) study was a randomized, multicenter trial aimed at evaluating the effectiveness of the RenalGuard System in preventing contrast-induced acute kidney injury (CI-AKI) in high-risk patients undergoing angiography. The study compared the RenalGuard System, which includes controlled hydration with saline plus N-acetylcysteine (NAC) and furosemide, to a standard hydration protocol using sodium bicarbonate and NAC.</p> <p>Key Findings:</p> <ul style="list-style-type: none"> - Incidence of CI-AKI: The incidence of CI-AKI was significantly lower in the RenalGuard group (11%) compared to the control group (20.5%). This result represents a 53% relative risk reduction for CI-AKI in the RenalGuard group. - Renal Function Biomarkers: The increase in serum cystatin C, a marker for kidney function, was also significantly less in the RenalGuard group at both 24 and 48 hours post-procedure. 	<p>Thank you for your comment. Preventing contrast induced acute kidney injury in at risk adults was not within the scope of this update. However, it is recognised that other sections of the guideline may require updating so this has been passed to the NICE surveillance team for consideration when future updates are planned.</p>

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				<p>- Need for Dialysis: Fewer patients in the RenalGuard group required in-hospital dialysis (0.7% vs. 4.1% in the control group).</p> <p>- Fluid Management: The RenalGuard System allowed for highly accurate, temporally matched fluid replacement, which helped achieve a high urine output while minimizing the risks associated with hypovolemia or overhydration.</p> <p>Conclusion: The study concluded that the RenalGuard System is more effective than standard hydration with sodium bicarbonate and NAC in preventing CI-AKI in high-risk patients. It supports the strategy of using controlled forced diuresis to reduce the toxic effects of contrast media during procedures. The findings suggest that the RenalGuard System can significantly reduce the incidence and severity of CI-AKI, which is a critical complication in patients with compromised kidney function undergoing contrast media exposure.</p> <p>Source: https://pubmed.ncbi.nlm.nih.gov/21844075/</p>	
MCT Lifesciences Limited	Evidence Review B	General	General	The REMEDIAL III study was designed to evaluate the effectiveness of the RenalGuard System in reducing contrast-induced acute kidney injury (CI-AKI) in high-risk patients. The study compared two tailored hydration strategies: a urine flow rate (UFR)-guided approach using the RenalGuard System and a left ventricular end-diastolic pressure (LVEDP)-guided hydration method.	Thank you for your comment. Preventing contrast induced acute kidney injury in at risk adults was not within the scope of this update. However, it is recognised that other sections of the guideline may require updating so this has been passed to the

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				<p>The results demonstrated that the UFR-guided strategy was significantly more effective in reducing the incidence of CI-AKI and acute pulmonary edema compared to the LVEDP-guided method. Specifically, CI-AKI occurred in 5.7% of patients in the UFR group versus 10.3% in the LVEDP group. Additionally, the incidence of major adverse events, such as the need for dialysis or sustained kidney damage, was lower in the UFR group (7.1% vs. 12% in the LVEDP group) one month after treatment.</p> <p>Overall, the study supported the use of UFR-guided hydration with the RenalGuard System as a superior method for preventing CI-AKI and related complications in high-risk patients undergoing interventional procedures.</p> <p>Source: https://pubmed.ncbi.nlm.nih.gov/31282129/</p>	<p>NICE surveillance team for consideration when future updates are planned.</p>
MCT Lifesciences Limited	Evidence Review C	General	General	<p>The MYTHOS (Induced Diuresis With Matched Hydration Compared to Standard Hydration for Contrast Induced Nephropathy Prevention) trial aimed to assess the effectiveness of furosemide-induced diuresis with matched hydration in preventing contrast-induced nephropathy (CIN) in patients with chronic kidney disease (CKD) undergoing coronary procedures.</p> <p>Key Findings:</p> <ul style="list-style-type: none"> - CIN Incidence: The incidence of CIN was significantly lower in the group receiving furosemide with matched hydration (FMH) at 4.6%, 	<p>Thank you for your comment. Preventing contrast induced acute kidney injury in at risk adults was not within the scope of this update. However, it is recognised that other sections of the guideline may require updating so this has been passed to the NICE surveillance team for consideration when future updates are planned.</p>

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				<p>compared to 18% in the control group that received standard hydration. This represents a substantial reduction in CIN risk in the FMH group.</p> <p>- Safety and Efficacy: The study found that the FMH protocol was safe, with no significant therapy-related complications observed. The matched hydration system effectively maintained intravascular volume, preventing both fluid overload and dehydration, which are common concerns with diuresis.</p> <p>- In-Hospital Outcomes: The FMH group also showed a trend towards fewer in-hospital clinical complications (8% vs. 18% in the control group), although this difference was at the threshold of statistical significance (p = 0.052).</p> <p>Conclusion: The study concluded that using furosemide to induce diuresis, combined with matched hydration using the RenalGuard system, is an effective and safe strategy to reduce the risk of CIN in high-risk patients undergoing coronary interventions. This approach could be particularly beneficial in urgent procedures, such as those involving non-ST-segment elevation myocardial infarction (NSTEMI) patients.</p> <p>These findings suggest that this method could be a valuable addition to clinical practice for protecting kidney function during procedures that involve contrast media.</p> <p>Source: https://pubmed.ncbi.nlm.nih.gov/22230154/</p>	

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MCT Lifesciences Limited	Evidence Review D	General	General	<p>The AKIGUARD (Acute Kidney Injury GUARding Device) trial was a study designed to evaluate the effectiveness of high-volume forced diuresis with matched hydration in preventing contrast-induced acute kidney injury (CIAKI) in patients with chronic kidney disease undergoing coronary angiography or percutaneous coronary intervention (PCI). The study compared this method with a control group receiving standard prophylaxis, which included sodium bicarbonate, isotonic saline, N-acetylcysteine, and vitamin C (BS-NAC).</p> <p>Key Findings:</p> <ul style="list-style-type: none"> - The incidence of CIAKI was significantly lower in the matched hydration group (MHG) at 7%, compared to 25% in the control group. - At one-year follow-up, the MHG had fewer major adverse cardiac and cerebrovascular events (MACCE) (7% vs. 32%) and lower rates of readmission to cardiology or nephrology departments (8% vs. 25%) compared to the control group. - The study demonstrated that matched hydration effectively slowed down chronic kidney disease progression and reduced the need for hospital readmissions. <p>Conclusion:</p>	<p>Thank you for your comment. Preventing contrast induced acute kidney injury in at risk adults was not within the scope of this update. However, it is recognised that other sections of the guideline may require updating so this has been passed to the NICE surveillance team for consideration when future updates are planned.</p>

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				<p>The AKIGUARD trial concluded that the matched hydration strategy was superior to the standard BS-NAC prophylaxis in preventing CIAKI and improving long-term outcomes in high-risk patients undergoing coronary procedures.</p> <p>Source: https://pubmed.ncbi.nlm.nih.gov/26702595/</p>	
MCT Lifesciences Limited	Evidence Review E	General	General	<p>The study conducted by Briguori and colleagues in 2015 focused on evaluating the effectiveness and safety of the RenalGuard system in preventing contrast-induced acute kidney injury (CI-AKI) in high-risk patients. This prospective, observational registry included 400 patients with significant risk factors such as an estimated glomerular filtration rate (eGFR) of ≤ 30 mL/min per 1.73 m^2 and/or a high predicted risk according to the Mehran and Gurm risk scores.</p> <p>Key Findings:</p> <ul style="list-style-type: none"> - Urine Flow Rate (UFR): The study found that achieving a high urine flow rate (UFR) during the intraprocedural phase was crucial for preventing CI-AKI. Specifically, a mean UFR of ≥ 450 mL/h was identified as the optimal threshold for reducing the risk of CI-AKI. - Incidence of CI-AKI: The incidence of CI-AKI was significantly lower in patients who maintained this high UFR during the procedure. Patients who did not achieve the UFR target had a higher risk of developing CI-AKI. 	<p>Thank you for your comment. Preventing contrast induced acute kidney injury in at risk adults was not within the scope of this update. However, it is recognised that other sections of the guideline may require updating so this has been passed to the NICE surveillance team for consideration when future updates are planned.</p>

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				<p>- Safety: The study also addressed concerns about potential side effects such as pulmonary edema and electrolyte imbalances. The RenalGuard system was generally safe, with a low incidence of pulmonary edema (1%) and manageable electrolyte disturbances, primarily hypokalemia, which required potassium replacement in 4% of patients.</p> <p>Conclusion: The study concluded that the RenalGuard system is effective in reaching and maintaining high UFRs, which are crucial for optimal CI-AKI prevention in high-risk patients. The findings suggest that a targeted UFR of ≥ 450 mL/h during the intraprocedural phase should be the goal when using the RenalGuard system to reduce the likelihood of CI-AKI.</p> <p>This study highlights the importance of precise fluid management in patients at risk of CI-AKI and supports the use of the RenalGuard system as a valuable tool in this context.</p> <p>Source: https://pubmed.ncbi.nlm.nih.gov/26920598/</p>	
MCT Lifesciences Limited	Evidence Review F			<p>The PROTECT-TAVI study investigated the use of the RenalGuard system to prevent acute kidney injury (AKI) in patients undergoing Transcatheter Aortic Valve Replacement (TAVR). This study was a single-center, prospective, open-label, randomized trial conducted at the Ferrarotto Hospital in Catania, Italy. The study included 112 patients who were randomized into two groups: one receiving</p>	<p>Thank you for your comment. Preventing contrast induced acute kidney injury in at risk adults was not within the scope of this update. However, it is recognised that other sections of the guideline may require updating so this has been passed to the</p>

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				<p>standard hydration and the other receiving hydration controlled by the RenalGuard system along with furosemide-induced diuresis.</p> <p>Key Findings:</p> <ul style="list-style-type: none"> - The incidence of AKI was significantly lower in the RenalGuard group (5.4%) compared to the control group (25.2%). - The RenalGuard system was particularly effective in reducing mild AKI (stage 1), though only one patient in the control group developed severe AKI (stage 3). - There were no significant differences between the groups regarding other outcomes like mortality, cerebrovascular events, or hospitalization for heart failure. <p>Conclusion:</p> <p>The study concluded that the RenalGuard system is a safe and effective tool for reducing the occurrence of AKI in patients undergoing TAVR. The RenalGuard system's ability to match fluid replacement to urine output allows for high urine flow rates without causing overhydration, making it particularly beneficial for patients at risk of AKI during TAVR.</p> <p>Source: https://pubmed.ncbi.nlm.nih.gov/26386766/</p>	<p>NICE surveillance team for consideration when future updates are planned.</p>
MCT Lifesciences Limited	Evidence Review G	General	General	ESC	Thank you for your comment. Hydration regimen was not within the scope of this update.

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				<p>As an alternative to the pre-and post-hydration regimen, tailored hydration regimens may be considered. Evidence class IIb and level B. Source: https://academic.oup.com/eurheartj/article/35/37/2541/581070</p>	
MCT Lifesciences Limited	Guideline	006	007	<p>1.1.7. The entire draft guideline and the existing guideline do not mention percutaneous coronary interventions (PCI) which uses iodine-based contrast media too. PCI is an intra-arterial procedure and directly affecting the kidneys.</p> <p>Background on Iodine-Based Contrast Media-Induced Acute Kidney Injury</p> <p>Iodine-based Contrast Media-Induced Acute Kidney Injury (CIN-AKI) is a serious complication that can occur after the administration of iodinated contrast media during imaging procedures, particularly CT imaging and catheter-based cardiac interventions like Percutaneous Coronary Interventions (PCI) and Transcatheter Aortic Valve Implantation (TAVI). It is characterized by a sudden decline in renal function, leading to increased morbidity and mortality. Preventing CIN-AKI is crucial, especially for patients with pre-existing chronic kidney disease (CKD), elevated serum creatinine (SCr), reduced estimated glomerular filtration rate (eGFR), advanced age (>75 years), congestive heart failure (CHF), hypotension, cardiogenic shock (with intra-aortic balloon pump [IABP]), anemia, diabetes, high contrast volume (related to procedural complexity or operator skill), or NSAID use. According to the BCIS 2022-2023 Coronary & Structural Audit results, 92,000 PCI cases were performed during this period.</p>	<p>Thank you for your comment. These recommendations are about when to do the blood tests. Other areas in the pathway are dealt with elsewhere in the guideline.</p> <p>Section 1.2 of NG148, which was not updated with this version, covers preventing AKI already. This recommends in 1.2.8 what to do if intra-arterial administration of contrast medium with first-pass renal exposure is being used.</p>

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				<p>Scientific publications indicate that 7% of these patients are at risk of developing CIN-AKI, translating to approximately 6,440 at-risk patients in 2022-2023. If additional comorbidities are present, the risk of CIN-AKI is significantly higher.</p>	
NHS England	General	General	General	<p>Under the Equality Act 2010, organisations have a legal duty to make changes in their approach or provision to ensure that services are as accessible to people with disabilities as they are for everybody else.</p> <p>It is important that autistic people and people with a learning disability are not deprived of iodine-based investigation because of a lack of trainable adjustments.</p> <p>As set out on the NHS pages NHS England</p> <p>» Reasonable adjustments, Reasonable adjustments can be things like:</p> <ul style="list-style-type: none"> ○ making sure there is good access for people who use a wheelchair in GP surgeries and hospitals ○ providing plain English or easy read appointment letters ○ giving someone a priority appointment if they find it difficult waiting in their GP surgery or hospital ○ offering a longer appointment if someone needs more time with a doctor or nurse to make sure they understand the information they are given ○ having a quiet space available for people waiting for their appointment 	<p>Thank you for your comment. The committee agree reasonable adjustments should be made to enable people with disabilities to access iodine-based contrast media scans. The current guideline refers to generic NICE guidance Shared decision making and Patient experience in adult NHS services. A link has also been added to the NICE guideline on Decision making and mental capacity. All of these contain recommendations covering principles of good practice on advance care planning, tailoring healthcare services to the individual, and enabling patients to participate in their care.</p>

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				NHS England has built the Reasonable Adjustment Digital Flag to enable health and care professionals to record, share and view details of a person's disability and the reasonable adjustments that disabled people may need across the NHS, wherever the person is seen or treated. The digital flag will support health and care professionals to deliver high quality care for patients requiring reasonable adjustments and is supported by staff training in using the Digital Flag across health and social care.	
NHS England	Guideline	005	001	In a community setting (in this case primary care), where a patient has a history of kidney disease a previous eGFR should be available but may not be within the previous 6 months as often these are done annually so could mean the test would be 11 months ago. Here this need for a more in date eGFR would increase the burden on phlebotomy and lab testing etc	Thank you for your comment. The committee believe this recommendation will decrease and not increase workload for the following reasons. The recommendation for this update has been changed from the original guideline recommendation advising the use of an eGFR result from the last 6 months (previously, the recommendation only advised using an eGFR result if it was within the last 3 months). The screening questions in the subsequent recommendation on what to do if there is no eGFR result in the last 6 months and the actions on what to do with the answers are aimed at ensuring only those with a suggestion of AKI receive a an eGFR.

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					For people without an eGFR within the last 6 months where AKI is a possibility the committee also agreed that it would be better to have a blood test result before going straight to contrast media where there is a suggestion of AKI.
NHS England	Guideline	005	009	Where an eGFR is not available within the past 6 months the recommendation to ask either the person or a family member is advised. Many patients (and relatives) would not be aware that they have kidney disease and so the need for a blood test is still likely to arise.	Thank you for your comment. This recommendation has been updated to include taking the person's symptoms into account. The subsequent recommendation has also been updated to advise consider an eGFR if the person has acute illness to suggest AKI is likely.
NHS England	Guideline	006	020	Noted that the risk prediction tools were made using a low number of participants from a younger population. In a primary care/community setting the cohort of patients are likely to be 80 years and over and have other comorbidities (some they may be aware of themselves such as diabetes) but kidney disease is not one that features heavily in the patient awareness probably because they don't 'see' the effect of the disease. Many of these patient will also have cognitive declined which may make a reliable understanding of their health and ill health less likely and so the decision will still likely mean a burden on lab testing to obtain a more up to date eGFR	Thank you for your comment. The committee used their experience and expertise to make the recommendations because of the limitations in the evidence population. The committee believe the recommendations will decrease and not increase workload for the following reasons. The recommendation for this update has been changed from the original guideline recommendation advising the use of an eGFR result from the last 6 months (previously, the recommendation only advised using an eGFR result if it was within the last 3 months). The screening questions in the subsequent

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					<p>recommendation on what to do if there is no eGFR result in the last 6 months and the actions on what to do with the answers are aimed at ensuring only those with a suggestion of AKI receive a an eGFR.</p> <p>For people without an eGFR within the last 6 months where AKI is a possibility the committee also agreed that it would be better to have a blood test result before going straight to contrast media where there is a suggestion of AKI.</p>
NHS England	guidelines	8	4	<p>These recommendations may support decision makers to proceed with CT scans without the need for recent eGFR in an acute situation (where the balance of risk is in favour of diagnostics). However, in the elective setting where there is no up to date eGFR (within 6 months) the reliance on the risk assessment questionnaire in patients who are older and frailer and less likely to have an awareness of their own kidney disease should not presume to reduce eGFR testing.</p> <p>Using a previous eGFR from the past 6 months as an acceptable measure would be helpful and reduce cancellation etc as long as the medical records are available to ensure that no AKI had occurred in the intervening time.</p>	<p>Thank you for comment. The recommendations have been updated to take symptoms into account as well as asking the person screening questions.</p> <p>The committee recognise that medical records might not be available. The recommendation to use an eGFR from the last 6 months is aimed at supporting the decision on whether to use iodine based contrast media. It does not preclude a clinician ordering another eGFR if they think it is necessary.</p>
NHS Grampian	Guideline	009	020	The reduction in the number of screening questions, along with the increased period of validity of eGFR, are welcomed. These	Thank you for your comment.

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Acute kidney injury: prevention, detection and management - Assessing risk factors for acute kidney injury in adults having iodine-based contrast media

**Consultation on draft guideline - Stakeholder comments table
05/08/2024 – 19/08/2024**

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				changes have the potential to reduce healthcare resource usage while remaining sufficiently safe for patients.	
The UK Kidney Association	Guideline	004	010	I agree this is an important change to make to prevent delays in urgent studies	Thank you for your comment.
The UK Kidney Association	Guideline	005	001	This is an important distinction and very pragmatic approach	Thank you for your comment.
The UK Kidney Association	Guideline	005	020	The change to having a cut off of eGFR < 30 is acceptable and reflects common practice	Thank you for your comment.
The UK Kidney Association	Guideline	006	001	The proposed research question is valid and timely	Thank you for your support.
The UK Kidney Association	Guideline Questions	General	General	Should the NICE guideline use the term 'contrast-associated acute kidney injury' rather than 'contrast-induced acute kidney injury'? I would propose changing to contrast associated as it is not clear whether contrast itself causes AKI in many cases due to the heterogeneous nature of AKI, particularly in the acutely ill patients	Thank you for your response. We have updated the guideline to use the term 'contrast-associated acute kidney injury'.
The UK Kidney Association	Guideline	General	General	General Point – it will be important to still stress the need to avoid/correct hypovolaemia in any patient receiving contrast but especially in the acutely ill patient	Thank you for your comment. Hypovolaemia has been added as a bullet point to the recommendation on what to do if no eGFR is available in the last 6 months. What to do if hypovolaemia is present is covered by the NICE guideline on Intravenous fluid therapy in adults in hospital .

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The UK Kidney Association	Guideline Questions	General	General	<i>Would it be challenging to implement of any of the draft recommendations?</i> I do not think it would be challenging to implement the draft recommendations. It would standardise and streamline practice	Thank you for your response.
The UK Kidney Association	Guideline Questions	General	General	<i>Would implementation of any of the draft recommendations have significant cost implications?</i> I do not expect this	Thank you for your response.
University Hospital Birmingham NHS Trust	Guideline	005	012	I am concerned that the guideline doesn't advise what the requesting physician should then do if the answer to the question regarding a renal transplant or waiting to see a kidney/urology specialist is yes. I think this is likely to result in patients who have excellent renal transplant function being denied CT imaging or subsequent A and R requests asking if we are happy for the patient to have a scan. Renal transplant patients should all have a prior eGFR within 6 months as they are on immunosuppression which requires renal monitoring.	Thank you for your comment. These recommendations are just covering whether this blood test is needed. The rest of the guideline cover other recommendations in the pathway.
University Hospital Birmingham NHS Trust	Guideline	005	020	Being aware that there is an increased risk of AKI associated with an eGFR <30ml/min doesn't help the requester know whether they should or should not request the scan. I would suggest adding in a comment that states 'this information should be discussed with the patient and provided the patient and the requester have discussed the risk and accept it then proceed to requesting the test'.	Thank you for your comment. The recommendation is to highlight when the associated risk between AKI and eGFR occurs. The committee agreed it is a factor that feeds into the decision on when to

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					scan but eGFR alone should not be a reason to test. This recommendation has been moved to immediately follow the recommendation on discussing the risks and benefits of tests or treatments. This is then followed by recommendations on testing.

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