'THINK KIDNEYS'

The NHS campaign to improve the care of people at risk of, or with, acute kidney injury
www.thinkkidneys.nhs.uk

Development of 'timeliness in response' appropriateness ratings in relation to AKI Warning Stage Results to primary care

A RAND Appropriateness Method: Round 1 – Context Document

OVERVIEW:

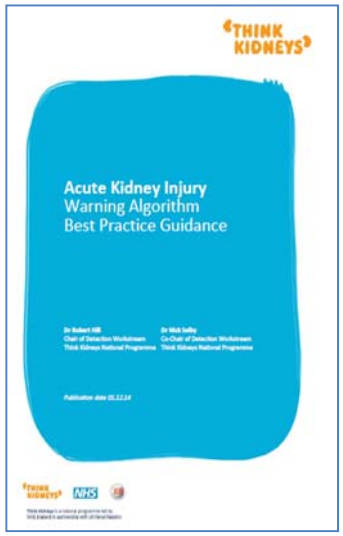
The RAND Appropriateness Method seeks to ensure that Acute Kidney Injury (AKI) warning stage results are considered in a clinical context. That is, AKI is a clinical syndrome, NOT a biochemical diagnosis. Members of Think Kidneys Primary Care working group have developed a range of scenarios in order to help identify necessary steps to be taken by both the Clinical Pathology Service and Primary Care in response to AKI warning stage results. This document provides definitions and rationale for the characteristics (variables) that make up each clinical scenario. These characteristics have been chosen to examine necessary responses to a range of scenarios. The scenarios have been written with a level of precision that reflects day-to-day clinical care and each scenario represents a separate indication. It is not possible to test all possible scenarios that might exist in every day practice. However, if you feel that any of the scenarios should be reformulated or if others should be added, please could you comment in the notes section of the table (the final column).

KEY CHARACTERISTICS OF CATEGORISATIONS

AKI Warning stages	Clinical History	Other Features/ Complications	Next Steps…
• AKI Warning Stage 1 • AKI Warning Stage 2 • AKI Warning Stage 3	• Acute illness • Chronic Heart Failure • Chronic Kidney Disease and/or history of renal transplant • Change in dose of a diuretic and/or ACE Inhibitors/Angiotensin Receptor Blocker (ARB) • Age • End of Life care	• Poor Fluid intake/urine output • Mild Hyperkalaemia • Moderate Hyperkalaemia • Risk of urinary tract obstruction or Intrinsic renal disease	Communication by Clinical Pathology Service (Laboratory Staff): • Send an AKI Warning Stage Result via the data transfer service without comment (non-interruptive communication) • Send an AKI Warning Stage Result via the data transfer service with comment (non-interruptive communication) • Send an AKI Warning Stage Result to an NHS email address that is known to be monitored regularly during working hours (non-interruptive communication) • Send an AKI Warning Stage Result by telephone call to GP/practice/out of hours service provider (interruptive communication) Response by GP/Primary Care team : • Seek immediate admission • Respond to the AKI Warning Stage Result <6 hours • Respond to the AKI Warning Stage Result <24 hours • Respond to the AKI Warning Stage Result <72 hours

AKI Warning Stage Result

AKI Warning Stage Result

Characteristic	Definition, Rationale, References & Links
AKI Warning Stage 1 **AKI Warning Stage 2** **AKI Warning Stage 3**	***Definition:*** ***AKI Warning Stage Result*:** - as defined by the use of the algorithm for detecting Acute Kidney Injury (AKI) based on serum creatinine changes with time. Please refer to the algorithm relating to the NHS England patient safety alert: NHS/PSA/D/2014/010. http://www.england.nhs.uk/ourwork/patientsafety/akiprogramme/aki-algorithm/ Defining AKI: The NHS England algorithm aims to standardise the definition of AKI and is based on the biochemical component of the KDIGO (2012) classification of acute kidney injury[1,2]: http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO%20AKI%20Guideline.pdf https://www.thinkkidneys.nhs.uk/wp-content/uploads/2014/12/AKI-Warning-Algorithm-Best-Practice-Guidance-final-publication-0112141.pdf  **Adults:** AKI stage 1 is a rise of >1.5x baseline level, or of >26ìmol/L within 48h, or a urine output <0.5mL/kg/h for 6-12h AKI stage 2 is a rise of>2x baseline or a urine output <0.5mL/kg/h for ≥12h AKI stage 3 is a rise of>3x baseline or a rise of >1.5 baseline to >354ìmol/L, a urine output <0.3mL/kg/h for ≥24h or anuria for ≥12 h **For age <18 years**, AKI stage 3 is also defined as a rise in serum creatinine to >3 x the upper limit of the age-related reference range. The urine output criteria also differ for age <18 years: stage 1 is <0.5mL/kg/h for >8h; stage 2 is <0.5mL/kg/h for more than 16h; stage 3 is

AKI Alert

Generation of an alert for AKI is best regarded as a two-step process. The first stage is the detection of creatinine changes consistent with AKI. This will be delivered by the NHS England detection algorithm running in the laboratory information management system (LIMS). This algorithm automatically identifies potential cases of acute kidney injury from laboratory data in real time and produces a test result (i.e. AKI stage 1, 2 or 3). The test result is named 'AKI warning stage'. A text comment can be appended to the AKI warning stage result. There is no standard or agreed wording and this can be configured locally. An example for adults (age >18 years) is included in the Acute Kidney Injury warning best practice document[2] as follows:

Rise in creatinine may indicate Acute Kidney Injury stage x (1, 2 or 3). Please review urgently.

1. AKI stage 1 is a rise of >1.5x baseline level, or of >26ìmol/L within 48h, or a urine output <0.5mL/kg/h for 6-12h

2. AKI stage 2 is a rise of>2x baseline or a urine output <0.5mL/kg/h for ≥12h

3. AKI stage 3 is a rise of>3x baseline or a rise of >1.5 baseline to >354µmol/L, a urine output <0.3mL/kg/h for ≥24h or anuria for ≥12 h

Clinical comment: Consider drugs that may be harmful to kidneys, obstruction, hydration and infection

The second stage of the process is the communication of the AKI result to clinicians – the alerting phase of the process. As a minimum, positive AKI warning stage results (with or without a comment) will be sent from the laboratory system to General Practice Clinical Systems via the Data Transfer Service (DTS) where they may be viewed by clinicians.

The DTS is a reliable proven system and GP practices have robust systems in place to access this information and distribute it to appropriate people in the practice for action. The DTS system works well for routine results. It is worth noting that for a number of reasons including clinician absence and local arrangements to ensure that when multiple tests are requested, results are all reported at the same time, this system may not be sufficiently responsive if rapid communication and actioning of a result(s) is required In addition, the DTS is unlikely to be used for communicating results to GP out-of-hours services.

Alternative methods of non-interruptive communication may involve fax or e-mail. Of note, NHS net mail stopped the NHS net fax service on 31st March 2015. Hence the future of fax communication is now severely limited and fax communication is being replaced by secure NHS net e-mail. NHS mail is available for use by any organisation commissioned to deliver NHS Healthcare or related activity including GP practices and GP out of hours providers. It works all day and night running across duplicated secure data centres – in a similar way to other major, global organizations for whom the security and safety of information is mission critical. An e-mail alert sent to a secure, monitored NHS mail account may facilitate non-interruptive communication of a result that needs to be viewed and acted upon that day or night. In addition, providing that a robust system of acknowledging receipt of the e-mail is in place, e-mail may allow laboratories to ascertain whether the alert has been received and allow an electronic audit trail of events. The development of such systems are, however, still in their infancy.

Critical result

A critical result is defined as a result that may signify a pathophysiological state that may be life-threatening or of immediate clinical significance and that requires urgent action. These results usually require interruptive communication – usually via a telephone call between the laboratory and the GP provider. The circumstances and setting of the clinical team receiving the communication needs to be taken into account when defining critical results including the time delay that would normally occur if the decision to not communicate a result by telephone was made.

The active communication of critical results is part of the overall responsibility for patient care of a clinical pathology service. Local arrangements must be in place to cover patient pathways defining critical results and providing clear lines of communication and fail safe systems. For pathology, having a system in place to communicate such test results is an explicit requirement of ISO 15189:2012[3]. It may also be worth noting that a key performance indicator for UK laboratories is that critical laboratory results should be phoned/actively communicated by the laboratory within 2 hours of the result being available to the laboratory including out of hours[5]. The communication of critical results is resource intensive both on the laboratory service having to make the calls and the clinical teams having to receive and take action.

Guidance for the out-of hours reporting of laboratory results requiring urgent clinical action to primary care is available[4]. Of note this guidance currently defines absolute creatinine values of over 400 umol/L for adults and over 200 umol/L for children 16 years as critical results.

Note: Increasingly, patients are able to access their pathology tests results directly. While this is mostly occurring via primary care portals currently, it is likely that in the future pathology providers will communicate results directly to patients and this may include the communication of critical or unexpected results. This is not within the remit of the RAND process.

Rationale:

1. To develop consensus based guidance on the timeliness of response to an AKI Warning Stage Result in primary care. This requires consideration of the appropriate laboratory response
2. Need to recognise that AKI is a clinical syndrome, and not just a biochemical diagnosis, requiring an understanding of the clinical context. As stated in KDIGO guidelines (2012), 'while the definitions and classification system discussed in chapter 2.1 provide a framework for the clinical diagnosis of AKI, they should not be interpreted to replace or to exclude clinical judgment. While the vast majority of cases will fit both AKI diagnostic criteria as well as clinical judgment, AKI is still a clinical syndrome—not all cases of AKI will fit within the proposed definition and not all cases fitting the definition should be diagnosed as AKI.'
3. As highlighted by KDIGO guidelines (2012), it is advisable to tailor management to AKI stage and 'manage patients with AKI according to the stage and cause,' according to 'their susceptibilities and exposures.'[1]

The prevention, detection and management of Acute Kidney Injury (AKI) is a national priority.[6,7] AKI is a clinical syndrome characterised by rapid reduction in kidney function.[1] There are many causes for AKI (pre-renal, renal, and post-renal) but it is most commonly associated with episodes of acute illness, such as sepsis.[1,6] AKI is more common in older people, prescribed multiple medicines and living with multiple long-term conditions. Patients with pre-existing reduced kidney function (chronic kidney disease (CKD)), or underlying cognitive decline are particularly at risk.[1]

AKI occurs in approximately 1 in 5 unplanned hospital admissions, with almost two thirds of patients having developed it in community settings.[8] It is associated with longer lengths of stay and increased requirement for renal replacement therapy. It is also associated with poorer health outcomes including increased risk of progression of CKD and increased mortality both in the short and long-term.[1]

	At least some AKI is preventable and treatable. NHS England's National 'Think Kidneys' Programme aims to reduce avoidable harm associated with AKI.[7] To date, a key focus has been the implementation of a Level 3 Patient Safety Alert within all NHS Acute Trusts and Foundation Trusts to standardise the early identification of AKI. Specific actions relating to this directive include the integration of the NHSE Detection Algorithm into Laboratory Information Management Systems (LIMS) and to ensure AKI test results are sent to hospital patient management systems as well as a data message for transmission to a central point (UK Renal Registry).[7] This patient safety directive came into effect from the 9th of March, 2015. The next phase of AKI alerting will involve direct communication with primary care with a plan to cease suppressing the test results generated by the Detection Algorithm in the 2016. Education and guidance to primary care physicians will be required to ensure appropriate response to an AKI Warning Stage result. From a recent NHS England AKI stakeholder event, and also from Programme Board members' activities in AHSN and Patient Safety Collaborative work, selected localities are implementing primary care AKI alerts along with locally agreed guidance on initial management in primary care. In order to support the development and implementation of guidance for primary care in how to respond to AKI Warning Stage Results, key steps to be taken include conducting a consensus process with engagement from AKI specialists, Clinical Biochemists and general practitioners followed by a pilot phase to tailor its use in routine practice.

References:

1. Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury working group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. *Kidney Int Suppl* 2012; 2:1-138. http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO%20AKI%20Guideline.pdf:

2. Acute Kidney Injury Warning Alert Best Practice document. Think Kidneys 2014.

3. ISO 15189:2012 Medical Laboratories – requirements for quality and competence

4. Out of hours reporting of laboratory results requiring urgent clinical action to primary care. Advice to pathologists and those that work in laboratory medicine. Royal College of Pathologists (2010). https://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/G/g025_outofhoursreporting_nov10.pdf

5. Key performance indicators in pathology. Recommendations from the Royal College of Pathologists (2013). http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/K/key_performance_indicators_in_pathology_3_2.pdf

6. NICE. Acute Kidney Injury. 2013. National Institute for Health and Care Excleence. 10-12-2013. Available from http://www.nice.org.uk/guidance/cg169/resources/guidance-acute-kidney-injury-pdf

7. NHS England. Think Kidneys National AKI programme. 2015 Available from: http://www.england.nhs.uk/ourwork/patientsafety/akiprogramme/

8. Selby NM, Crowley L, Fluck RJ et al. Use of Electronic Results Reporting to Diagnose and Monitor AKI in Hospitalized Patients. *Clin J Am Soc Nephrol* 2012; 7(4):533-540.

Clinical History

Clinical History

Characteristic	Definition, Rationale, References & Links
Acute Illness	**Acute illness** – Consider evidence from history or examination that the patient is experiencing an episode of acute illness as defined by Jones et al, 2010.[1] For the purposes of the RAND process, please take into account the following boundaries: Kidney function blood tests were taken in the context of a patient presenting with an episode of acute illness but which was deemed not to require immediate admission at the point of initial assessment. Examples for consideration include patients who have had blood tests in the context of an episode of acute illness such as diarrhoea or vomiting caused by gastroenteritis, urinary tract infection, or respiratory infection/ exacerbation of COPD. Please do not consider patients who at initial assessment required immediate admission (E.g. Evidence of 'red flag sepsis'). At the other end of the spectrum, for the purposes of the RAND process, please do not consider patients with a single episode of diarrhoea or vomiting. *'Defining acute illness' Jones et al, 2010* 'Acute illnesses are those that are of short duration. They may be minor or they may be serious. Minor acute illnesses include some of the commonest problems presented in general practice, such as upper respiratory tract infections or skin rashes. Major acute illnesses may present as an acute exacerbation of an underlying chronic illness, such as a myocardial infarction or diabetic coma, or the sudden onset of a previously undiagnosed condition, such as epilepsy or stroke or an acute emotional or psychological problem. Symptoms of rapid onset can pose a diagnostic puzzle…but they can be significant in determining whether the underlying problem is acute, in the sense of being self-limiting, or not. We have therefore included the problem of triaging acute presentation into minor and serious problems. Acute is also often encountered in a lay sense as meaning 'serious', but we believe that this usage is also encompassed in our coverage of acute illnesses and acute presentations. For our contribution to the inquiry, we have classified acute illness as: • acute minor illness (self-limiting) • acute major illness (self-limiting or requiring treatment) • acute presentation of existing major illness (acute exacerbation) • acute presentation of new chronic illness.' http://www.kingsfund.org.uk/sites/files/kf/field/field_document/managing-acute-illness-gp-inquiry-research-paper-mar11.pdf[1]

	Rationale: 1. 'Up to two-thirds of primary care contacts are for acute problems' and 'the assessment of acutely and potentially seriously ill patients in community settings is a core skill of general practice, and has major implications for medical education and vocational training schemes, which need to equip GPs to deal better with major illness.'[1] 2. The majority of episodes of AKI involve pre-renal aetiology.[2] 3. NICE AKI Clinical Guidelines (cg169), 2013, recommend 'identifying acute kidney injury in patients with acute illness,' if patients have any of the following are likely or present: • Chronic kidney disease (eGFR<60 ml/min/1.73 m2) • heart failure • liver disease • diabetes • past history of acute kidney injury • oliguria (urine output less than 0.5 ml/kg/hour) • neurological or cognitive impairment or disability, which may mean limited access to fluids because of reliance on a carer • hypovolaemia • use of drugs with nephrotoxic potential (such as non-steroidal anti-inflammatory drugs [NSAIDs], aminoglycosides, angiotensin-converting enzyme [ACE] inhibitors, • angiotensin II receptor antagonists [ARBs] and diuretics) within the past week, especially if hypovolaemic • use of iodinated contrast agents within the past week • symptoms or history of urinary tract obstruction, or conditions that may lead to obstruction • sepsis • deteriorating early warning scores

	References: 1. Jones R, White P, Armstrong D, Ashworth M, Peters M. Managing acute illness. London, The King's Fund, 2010. http://www.kingsfund.org.uk/sites/files/kf/field/field_document/managing-acute-illness-gp-inquiry-research-paper-mar11.pdf[1] 2. Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury working group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. *Kidney Int Suppl* 2012; 2:1-138. 3. NICE CG169: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. http://www.nice.org.uk/guidance/cg169

Characteristic	Definition, Rationale, References & Links
Chronic Heart Failure	***Definition:*** **Chronic Heart Failure –** For the purposes of the RAND process, chronic heart failure encompasses any patient who has a diagnosis as defined in NICE Guidance (cg108), 2010.[1] https://www.nice.org.uk/guidance/cg108/resources/guidance-chronic-heart-failure-pdf: 'Heart failure is a complex clinical syndrome of symptoms and signs that suggest the efficiency of the heart as a pump is impaired. It is caused by structural or functional abnormalities of the heart. Some patients have heart failure due to left ventricular systolic dysfunction (LVSD) which is associated with a reduced left ventricular ejection fraction. Others have heart failure with a preserved ejection fraction (HFPEF). Most of the evidence on treatment is for heart failure due to LVSD. The most common cause of heart failure in the UK is coronary artery disease, and many patients have had a myocardial infarction in the past.' ***Rationale:*** ***1.*** As highlighted in NICE Clinical Guideline for Acute Kidney Injury (cg160), 2013, patients with a diagnosis of heart failure are at increased risk of acute kidney injury during episodes of acute illness.[2] ***2.*** Patients with heart failure represent a population with increased morbidity and mortality, and account for 5% of all emergency medical admissions to hospital.[1] ***3.*** Patients with chronic heart failure require increased monitoring of their renal function. Pharmacological treatment of chronic heart failure can include use of angiotensin-converting enzyme (ACE) inhibitors, angiotensin 2 receptor antagonists (ARB) aldosterone antagonists and diuretics all of which have a renal effect. NICE guidance (cg108), 2010, emphasises that all patients with chronic heart failure require monitoring. This monitoring should include: a clinical assessment of functional capacity, fluid status, cardiac rhythm (minimum of examining the pulse), cognitive status and nutritional status; a review of medication, including need for changes and possible side effects on serum urea, electrolytes, creatinine and eGFR. Patients with heart failure require monitoring (including renal function), the frequency of which depends on the clinical status and stability. The monitoring interval should be short (days to 2 weeks):[1] In terms of monitoring:

	• It is advised that serum urea, creatinine, electrolytes and eGFR should be measured at initiation of an ACE inhibitor and after each dose increment.[1] • In patients with heart failure due to left ventricular systolic dysfunction who are taking aldosterone antagonists, closely monitor potassium and creatinine levels, and eGFR. Seek specialist advice if the patient develops hyperkalaemia or renal function deteriorates.[1] • Monitor serum urea, electrolytes, creatinine and eGFR for signs of renal impairment or hyperkalaemia in patients with heart failure who are taking an ARB.[1] ***References:*** 1. NICE CG108: Management of chronic heart failure in adults in primary and secondary care https://www.nice.org.uk/guidance/cg108/resources/guidance-chronic-heart-failure-pdf 2. NICE CG169: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. http://www.nice.org.uk/guidance/cg169

Characteristic	Definition, Rationale, References & Links
Chronic Kidney Disease stage 4 of 5, or history of renal transplant	***Definition:*** **Chronic Kidney Disease or history of renal transplant**- For the purposes of the RAND process, clinical scenarios will be presented that include patients who have a diagnosis of stage 4 or 5 chronic kidney disease (CKD) or a past history of having had a renal transplant, as defined by NICE Clinical Guideline (cg182), 2014. https://www.nice.org.uk/guidance/cg182 ***Rationale:*** **1.** Patients with existing CKD are at increased risk of AKI [2] and it is advised that measuring serum creatinine should be carried out in adult patients who have CKD and present with an episode of acute illness.[1,2] **2.** CKD is the most consistently reported condition associated with acute kidney injury.[3] **3.** Ensure that acute kidney injury is considered when an adult, child or young person presents with an illness with no clear acute component and has chronic kidney disease, especially stage 3B, 4 or 5.[2] **4.** NICE guidance recommends discussing the management of acute kidney injury with a nephrologist or paediatric nephrologist as soon as possible and within 24 hours of detection in patients chronic kidney disease stage 4 or 5 or patients who have had a renal transplant.[2] **5.** Patients with a history of renal transplant are at increased risk of AKI.[2] 6. NICE CKD guidance (CG182) states that in people with a new finding of reduced GFR, repeat the GFR within 2 weeks to exclude causes of acute deterioration of GFR – for example, acute kidney injury or starting renin–angiotensin system antagonist therapy.[1] 7. NICE CKD guidance (CG182) states that 'to improve concordance, inform people who are prescribed renin–angiotensin system antagonists about the importance of: achieving the optimal tolerated dose of renin–angiotensin system antagonists and monitoring eGFR and serum potassium in achieving this safely. In people with CKD, measure serum potassium concentrations

	and estimate the GFR before starting renin–angiotensin system antagonists. Repeat these measurements between 1 and 2 weeks after starting renin–angiotensin system antagonists and after each dose increase. (also see other RAND characteristics).[1] ***References:*** 1. NICE CG182. Chronic kidney disease early identification and management of chronic kidney disease in adults in primary and secondary care, 2014 https://www.nice.org.uk/guidance/cg182 2. NICE CG169: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. http://www.nice.org.uk/guidance/cg169 3. Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury working group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. *Kidney Int Suppl* 2012; 2:1-138. http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO%20AKI%20Guideline.pdf:

Characteristic	Definition, Rationale, References & Links
Change in dose of a diuretic and/or ACE Inhibitors/Angiotensin Receptor Blocker (ARB)	***Definition:*** **Change in dose of a diuretic and/or ACE Inhibitors/Angiotensin Receptor Blocker** – Evidence that the patient has had a recent change in dose/introduction of a diuretic and/or an ACE Inhibitor/ARB, which may have contributed to a significant rise in serum creatinine. ***Rationale:*** Linking to other 'chronic heart failure'[1] and 'chronic kidney disease'[2] characteristics, NICE Clinical Guidelines advise: 1. It is advised that serum urea, creatinine, electrolytes and eGFR should be measured at initiation of an ACE inhibitor and after each dose increment.[1] 2. NICE CKD guidance (CG182) states that 'to improve concordance, inform people who are prescribed renin–angiotensin system antagonists about the importance of: achieving the optimal tolerated dose of renin–angiotensin system antagonists and monitoring eGFR and serum potassium in achieving this safely. In people with CKD, measure serum potassium concentrations and estimate the GFR before starting renin–angiotensin system antagonists. Repeat these measurements between 1 and 2 weeks after starting renin–angiotensin system antagonists and after each dose increase. (also see other RAND characteristics).[1]NICE CKD (CG182) Clinical Guidelines state the following: • 'Following the introduction or dose increase of renin–angiotensin system antagonists, do not modify the dose if either the GFR decrease from pretreatment baseline is less than 25% or the serum creatinine increase from baseline is less than 30%.'[2] • 'If there is a decrease in eGFR or increase in serum creatinine after starting or increasing the dose of renin–angiotensin system antagonists, but it is less than 25% (eGFR) or 30% (serum creatinine) of baseline, repeat the test in 1–2 weeks. Do not modify the renin–angiotensin system antagonist dose if the change in eGFR is less than 25% or the change in serum creatinine is less than 30%.'[2]

	• 'If the eGFR change is 25% or more, or the change in serum creatinine is 30% or more: investigate other causes of a deterioration in renal function, such as volume depletion or concurrent medication (for example, NSAIDs) if no other cause for the deterioration in renal function is found, stop the renin–angiotensin system antagonist or reduce the dose to a previously tolerated lower dose, and add an alternative antihypertensive medication if required.'[2] ***References:*** NICE CG108: Management of chronic heart failure in adults in primary and secondary care https://www.nice.org.uk/guidance/cg108/resources/guidance-chronic-heart-failure-pdf NICE CG182. Chronic kidney disease early identification and management of chronic kidney disease in adults in primary and secondary care, 2014 https://www.nice.org.uk/guidance/cg182

Characteristic	Definition, Rationale, References & Links
Age: • **Adult** • **Child or Young Person**	***Definition:*** **Adult v Child or Young person** – For the purposes of the RAND process, please refer to NICE guidelines regarding the definition of adults, children and young people. NICE AKI CG169 guidelines considers the patient's age in the management of acute kidney injury. NICE use the term 'adults' is used to describe people who are aged 18 years or older, and 'children' those who are aged 11 years or younger (excluding neonates less than 1 month old). 'Young people' describes those who are aged 12 to 17 years. https://www.nice.org.uk/guidance/cg169 ***Rationale:*** 1. NICE guidance distinguishes care for adult and paediatric populations and primary care response needs to consider different types of response according to age ***References:*** 1. NICE CG169: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. http://www.nice.org.uk/guidance/cg169

Characteristic	Definition, Rationale, References & Links
End of Life care	**End of Life Care** - Clinical evidence that the patient is approaching end of life and is requiring end of life care – for the purposed of RAND process, please refer to the NICE quality standard for end of life care[1]: https://www.nice.org.uk/guidance/QS13/chapter/List-of-statements **Information for adults who use NHS end of life care services and their families and carers** The NICE quality standard for end of life care sets out how a high-quality end of life care service should be organised so that the best care can be offered to people using NHS services in England. End of life care is the care provided by the NHS in England for people who are likely to die within the next 12 months (including people with incurable and life-threatening conditions and those who die unexpectedly) and their families and carers. **NICE quality standard for end of life care** The quality standard for end of life care is made up of 16 statements that describe high-quality care. These statements are about the best care you should receive and are summarised below. 1. People approaching the end of their life are identified at the right time to receive care and support to meet their needs and preferences. 2. People approaching the end of life and their families and carers are communicated with and offered information in a sensitive way, at a time when it is helpful and with respect for their needs and preferences. 3. People approaching the end of life are offered full assessments to ensure they are getting the best care and support for their circumstances. During these assessments, they have the opportunity to discuss their needs (for example, physical, psychological, social, spiritual and cultural needs) and preferences. This includes the opportunity to develop and review a care plan detailing their preferences for current and future support and treatment. 4. People approaching the end of life receive treatment and care to manage their physical and psychological needs, which may be at any time of day and night.

	5. People approaching the end of life are offered social, practical and emotional support tailored to their needs and at the right time to help them feel supported, retain their independence and do things they enjoy for as long as possible. 6. People approaching the end of life are offered spiritual and/or religious support appropriate to their needs and preferences. 7. Families and carers of people approaching the end of life have their own needs fully assessed as appropriate for their changing needs and preferences, and are offered support to help them cope. 8. People approaching the end of life receive care whenever they need it (day or night) that is consistent, smoothly coordinated and delivered by staff who are aware of their medical condition, care plan and preferences. 9. People approaching the end of life who experience a crisis at any time of day or night receive prompt, safe and effective urgent care that takes into account their needs and preferences. 10. People approaching the end of life are offered specialist palliative care if their usual care team is unable to relieve their symptoms adequately. It is offered at the right time for them and is appropriate to their needs and preferences at any time of day or night. 11. People in the last days of life are identified and receive care according to their care plan, which takes into account their needs and preferences, and ensures they can have rapid access to all the support they need, including equipment (such as a pressure-relieving mattress) and medication. 12. The body of a person who has died is cared for in a culturally sensitive and dignified manner. 13. Carers and family members of people who have died receive verification and certification of the death as soon as possible. 14. People closely affected by a death are communicated with in a sensitive way and offered bereavement, emotional and spiritual support appropriate to their needs and preferences. This may include information about practical arrangements and local support services, supportive conversations with staff, and in some cases referral for counselling or more specialist support. 15. People approaching the end of life and their families and carers are cared for and supported by staff with the knowledge, skills and attitudes needed to provide high-quality care. 16. People approaching the end of life and their families and carers receive high-quality care and support because there is enough staff with the right skills to meet their needs.

	Rationale: 1. Need to determine appropriate response to an AKI Warning Stage Results in circumstances when generated for patients approaching end of life (e.g. kidney function checked during an assessment for hypercalcaemia). ***References:*** 1. NICE Quality Standards End of Life Care Pathway 2011 – Quality Standards https://www.nice.org.uk/guidance/qs13/chapter/Quality-statement-1-Identification#/definitions

Other Features/ Complications

Other Features/ Complications

Characteristic	Definition, Rationale, References & Links
Poor Oral Intake/ urine output	***Definition:*** **Poor Fluid intake/urine output** – Recognising that assessment of fluid balance differs between primary care and secondary care, for the purposes of the RAND process, please consider the definition poor oral intake and urine output based on an evaluation in primary care according to a history of poor oral intake and urine output and/or clinical examination (including pulse, blood pressure (BP), jugular venous pressure, capillary refilling, recent change in weight and postural change in pulse and BP). http://www.rcpe.ac.uk/sites/default/files/files/Final_statement_0.pdf ***Rationale:*** 1. All acutely ill patients in primary care will require assessment of their volume status…Evaluation of volume status should be based on history, cumulative fluid balance and clinical examination…[1] 2. Pre-renal causes common and management in community includes ensure maintenance of fluid intake. Patient who are particularly at risk of developing acute kidney injury (and worsening clinical state) in the community, include those who have neurological or cognitive impairment or disability, which may mean limited access to fluids because of reliance on a carer.[2] 3. This variable is a driver to ensure carer status considered as part of care. 4. As highlighted in KDIGO guidelines (2012), Dehydration' deemed a common cause of AKI, and there is need for assessment of patient's volume status.[3]

	References: **1.** Feehally J, Gilmore I, Barasi S et al. RCPE UK consensus conference statement: Management of acute kidney injury: the role of fluids, e-alerts and biomarkers. *J R Coll Physicians Edinb* 2013; 43(1):37-38. http://www.rcpe.ac.uk/sites/default/files/files/Final_statement_0.pdf **2.** NICE AKI Quality Standards 2014 http://pathways.nice.org.uk/pathways/acute-kidney-injury#path=view%3A/pathways/acute-kidney-injury/risk-assessment-and-prevention-of-acute-kidney-injury.xml&content=view-quality-statement%3Aquality-statements-raising-awareness-in-people-at-risk 3. Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury working group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. *Kidney Int Suppl* 2012; 2:1-138. http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO%20AKI%20Guideline.pdf:

Characteristic	Definition, Rationale, References & Links
	Definitions: Please refer to the Renal Association Guidelines for definitions of Hyperkalaemia. For the purposes of the RAND process, clinical scenarios have been chosen that consider response to AKI Warning Stage Results in the presence of hyperkalaemia. Severe hyperkalaemia (≥ 6.5 mmol/l) is not considered, as guidance recommends that all patients with severe hyperkalaemia (irrespective of kidney function) are referred to secondary care for immediate assessment and treatment. http://www.renal.org/guidelines/joint-guidelines/treatment-of-acute-hyperkalaemia-in-adults#sthash.T3aoglXt.f4WXgntA.dpbs
Mild Hyperkalaemia	**Mild Hyperkalaemia** – as defined by the Renal Association Guidelines for Hyperkalaemia 2014 as a potassium level between 5.5 and 5.9 mmol/l. http://www.renal.org/guidelines/joint-guidelines/treatment-of-acute-hyperkalaemia-in-adults#sthash.T3aoglXt.f4WXgntA.dpbs
Moderate Hyperkalaemia	**Moderate Hyperkalaemia** – as defined by the Renal Association Guidelines for Hyperkalaemia 2014 as a potassium level between 6.0 and 6.4 mmol/l. http://www.renal.org/guidelines/joint-guidelines/treatment-of-acute-hyperkalaemia-in-adults#sthash.T3aoglXt.f4WXgntA.dpbs

	Rationale: 1. All patients with mild or moderate hyperkalaemia have a review of their medication and diet and regular monitoring of serum potassium; the urgency and frequency of monitoring will depend on individual circumstances.[1] 2. Hyperkalaemia is a complicating factor that needs consideration when assessing and managing patients with suspected AKI. ***References:*** 1. Renal Association Guidelines for Hyperkalaemia 2014 http://www.renal.org/guidelines/joint-guidelines/treatment-of-acute-hyperkalaemia-in-adults#sthash.T3aoglXt.f4WXgntA.dpbs

Characteristic	Definition, Rationale, References & Links
Risk of urinary tract obstruction or Intrinsic renal disease	***Definitions:*** For purposes of the RAND process, please consider evidence suggestive of urinary tract obstruction or intrinsic renal disease as causes of AKI that require referral to secondary care to either urology (urinary tract obstruction) or nephrology (intrinsic renal disease). Please consider the next steps necessary in terms of timeliness of response for the scenarios when either of these features is present. **Risk of urinary tract obstruction or Intrinsic renal disease** – For the purposes of the RAND process, risk of urinary tract obstruction is based on history and examination in primary care. Consider urinary tract obstruction when history or examination suggests the patient may have renal stones, pyonephrosis, blocked catheter, pelvic mass, enlarged prostate, carcinoma, retroperitoneal fibrosis, or neurogenic bladder. **Risk of urinary tract obstruction or Intrinsic renal disease** – For purposes of the RAND process, consider intrinsic renal disease based on history or examination including evidence of proteinuria and haematuria on urinalysis without evidence of urinary tract infection and/or systemic symptoms: arthralgia, arthritis, mononeuritis multiplex, rash, uveitis, epistaxis or haemoptysis. ***Rationale:*** 1. Local and national guidance emphasise the importance of thinking about the cause of AKI and if clinical assessment points to evidence of urinary tract obstruction or intrinsic renal disease, then the patient needs specialist referral (urology or nephrology).[1,2, 3, 4] 2. NICE guidance refers to discuss of management of AKI with a nephrologist asap and within 48 hours of detection when then is possible tubulointerstitial nephritis, glomerulonephritis (indicated by haematuria/proteuniria), systemic vasculitis, or myeloma (NICE CKS)[3] 3. NICE guidance (CG169) recommends perform urine dipstick testing for blood, protein, leucocytes, nitrites and glucose in all patients as soon as AKI is suspected or detected. Think about acute nephritis and referral to nephrology when an adults, child or

	young person with no obvious cause of AKI has urine dipstick results showing haematuria and proteinuria, without urinary tract infection or trauma due to catheterisation.[2] 4. KDIGO recommends that all patients with AKI should have a renal tract ultrasound within 24 hours if renal tract obstruction is suspected.[4] 5. NICE AKI Guidance (CG169) states that 'when pyonpehrosis (infected and obstructed kidney(s) is suspected in adults, children and young people with AKI, offer immediate ultrasound of the urinary tract (to be performed within 6 hours of assessment).'[2] 6. NICE guidance (CKS) recommends to arrange urgent admission or same day referral (depending on clinical judgement) for people with a risk of urinary tract obstruction (for example known prostate or bladder disease, abdominal or pelvic cancer; known previous hydronephrosis; recurrent UTI; or other conditions consistent with possible obstruction, for example anuria, single functioning kidney, neurogenic bladder).[3] 7. Important that guidance documents to act as a driver to consider renal and post-renal causes of AKI and therefore need consideration in RAND process.

References:

1. Derby Hospitals Guidance

   https://www.derbyhospitals.nhs.uk/easysiteweb/getresource.axd?assetid=277344&type=0&servicetype=1

2. NICE CG169: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy. http://www.nice.org.uk/guidance/cg169

3. NICE CKS AKI

   http://cks.nice.org.uk/acute-kidney-injury

4. Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury working group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. *Kidney Int Suppl* 2012; 2:1-138.

   http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO%20AKI%20Guideline.pdf:

Next Steps…

Next Steps…

Characteristic	Definition, Rationale and References
Communication by Clinical Pathology Service (Laboratory Staff): • Send an AKI Warning Stage Result via the data transfer service without comment (non-interruptive communication) • Send an AKI Warning Stage Result via the data transfer service with comment (non-interruptive communication) • Send an AKI Warning Stage Result to an NHS email address that is known to be monitored regularly during working hours (non-interruptive communication) • Send an AKI Warning Stage Result by telephone call to GP/practice/out of hours service provider (interruptive communication)	Please also refer to AKI Warning Stage Result section. The choices presented relate to the second stage of the process is the communication of the AKI result to clinicians – the alerting phase of the process. As stated above, as a minimum, positive AKI warning stage results (with or without a comment) will be sent from the laboratory system to General Practice Clinical Systems via the Data Transfer Service (DTS) where they may be viewed by clinicians. The DTS is a reliable proven system and practices have robust systems in place to access this information and distribute it to appropriate people in the practice for action. The DTS system works well for routine results. It is worth noting that this system may not be sufficiently responsive if rapid communication and actioning of results is required and is unlikely to be used for communicating results to GP out-of-hours services. Alternative methods of non-interruptive communication may involve fax or e-mail. Of note, NHS net mail stopped the NHS net fax service on 31st March 2015. Hence the future of fax communication is now severely limited and fax communication is being replaced by secure NHS net e-mail. All practices should have a generic NHS mail account. Provided that this is checked regularly throughout the day, e-mail communication may facilitate non-interruptive alerting of the practice to a result(s) that need to be viewed and acted upon that day and, providing that a robust systems of acknowledging the alert is in place, email may facilitate an electronic audit trail of events. **Critical result** A critical result is defined as a result that may signify a pathophysiological state that may be life-threatening or of immediate clinical significance and that requires urgent action. These results usually require interruptive communication to clinicians.

	The active communication of critical results is part of the overall responsibility for patient care of a clinical pathology service. Local arrangements must be in place to cover patient pathways defining critical results and providing clear lines of communication and fail safe systems. For pathology, having a system in place to communicate such test results is an explicit requirement of ISO 15189:2012. It may also be worth noting that a key performance indicator for UK laboratories is that laboratory results should be phoned/actively communicated by the laboratory within 2 hours of the result being available to the laboratory including out of hours. ***References:*** Acute Kidney Injury Warning Alert Best Practice document. Think Kidneys 2014. ISO 15189:2012 Medical Laboratories – requirements for quality and competence Out of hours reporting of laboratory results requiring urgent clinical action to primary care. Advice to pathologists and those that work in laboratory medicine. Royal College of Pathologists (2010). https://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/G/g025_outofhoursreporting_nov10.pdf Key performance indicators in pathology. Recommendations from the Royal College of Pathologists (2013). http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/K/key_performance_indicators_in_pathology_3_2.pdf

Characteristic	Definition, Rationale and References
Response by GP/Primary Care team: • Seek immediate admission • Respond to the AKI Warning Stage Result <6 hours • Respond to the AKI Warning Stage Result <24 hours • Respond to the AKI Warning Stage Result <72 hours	The 'next step' choices relate to the timeliness of response to AKI Warning Stage Results by primary care. The choices for rating are based on the need to consider timeliness of response by both in hours and out of hours services. Based on the presenting AKI stage, clinical history including complications, it is suggested that general practitioners (responsible primary care team) will need to make one of four decisions. **RATINGS SYSTEM**: As stated in the Instructions document, the scoring system is based on a nine-point scale with 1 indicating `extremely inappropriate next step` and 9 indicating `extremely appropriate next step: **Scores 1 to 3**: Inappropriate next step (i.e. no benefit, possible harms). **Scores 4 to 6**: Uncertainty about next step (i.e. when harms and benefits are judged as approximately equal, or when the best available evidence does not support a judgement either way). **Scores 7 to 9**: Appropriate next step (i.e. benefits were judged to outweigh harms). Round 1 seeks to gain clarity on 'necessary' processes of care under ideal conditions. At this time we would ask that **no consideration** is given to the costs to the health service in determining appropriateness.