

Acute Kidney Injury Warning Algorithm Best Practice Guidance

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1. Introduction

The installation of the NHS England AKI detection algorithm should be regarded as one part of a trust-wide approach to tackle Acute Kidney Injury (AKI). The installation of the algorithm will primarily be the role of laboratory staff but other elements of the pathway will require a multispecialty approach, including appropriate clinical engagement and senior executive buy in. This Best Practice Guidance is intended to help with the installation, testing and introduction of AKI detection into clinical practice. It is supported by additional materials and initiatives from the NHS England AKI Programme, Think Kidneys.

2. Terminology

Generation of an ‘e-alert’ for AKI is best regarded as a two-step process. The first stage is the detection of creatinine changes consistent with AKI, which will be delivered by the NHS England detection algorithm running in the laboratory information management system (LIMS). This will automatically compare measured creatinine values with a baseline variable on an individual patient basis to determine significant change.

It should be noted that the NHS England patient safety alert (NHS/PSA/D/2014/010) refers to this detection step only. Detection of a rise in creatinine will produce a test result (AKI Warning stage) in the LIMS. The second stage of the process is the communication of AKI results to clinicians - the alerting phase of the process. As a minimum, positive AKI results will be sent to hospitals’ results reporting systems where they can be viewed by clinicians. However, depending on local resources/capabilities, you may choose to institute additional alerting pathways; this part of the process is not mandated in the patient safety alert and should be developed locally (see section 4).



Figure 1. The two step process in generating an e-alert for AKI

It is obvious that AKI can be detected in different health care settings: this includes AKI that occurs and is detected in primary care; AKI that is present and detected on admission to hospital (often referred to as community acquired AKI in studies looking at hospitalised patients); and AKI that occurs during a hospital stay (hospital acquired AKI).

3. Installation and testing

The AKI detection algorithm provided by your LIMS provider should match the specification contained in the NHS England patient safety notice (NHS/PSA/D/2014/010), detailed on their website at www.england.nhs.uk/ourwork/patientsafety/akiprogramme/aki-algorithm/

Please check the specification against that provided by your LIMS provider prior to installation and discuss any discrepancies. After installation, the performance of the algorithm should be verified before introduction into clinical practice. Your LIMS provider should be able to supply you with a test script from NHS England to allow you to do this. The purpose of the test script is not to test all functioning aspects of the AKI warning algorithm but rather to demonstrate that the principal features of the algorithm are working correctly in your local laboratory environment. Successful running of the test script does not absolve LIMS suppliers from the need to thoroughly test all aspects of the operation of the algorithm within all versions of their software; nor is it intended to validate the operation of the AKI warning algorithm outside the LIMS environment. The test script comprises four steps, each of which must be tested, and full instructions of how to do so are included.

4. AKI warning stage test result

The AKI detection algorithm will produce a test result for every creatinine result that is consistent with AKI; the test result is named 'AKI Warning Stage'. This test result will be a numerical field with four possible variables: null, 1, 2 or 3. The null results will not be reported, but results 1, 2, or 3 should be sent to your local results reporting system/patient management system and set to flag as abnormal as for all other biochemical test results.

You should append a text comment to the reported AKI Warning Stage test results. It should be possible to set rules in the LIMS to automatically append the appropriate comment for stage 1, 2 or 3. At present, there is no standard or agreed wording and this can be configured locally. However, an example for adults (age >18 years) is included here:

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 >26 μ mol/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 \geq 12h
3. AKI stage 3 is a rise of >3x baseline or a rise of >1.5 baseline to >354 μ mol/L, a urine output <0.3mL/kg/h for \geq 24h or anuria for \geq 12 h

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

Trusts are expected to identify and keep under review appropriate guidelines regarding acute kidney injury. It is recommended that guidelines on the diagnosis, investigation and treatment of AKI can be found on your organisation's intranet.

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 <0.3mL/kg/h for 24h or anuria for 12h.

The algorithm will also identify creatinine results that are elevated above your local reference range but for which there are no previous creatinine values within the last 12 months to use as baseline comparators. These results should have a comment appended e.g. 'creatinine high. ?AKI ?CKD, consider early repeat'.

You should determine from your LIMS provider how the calculated baseline creatinine value will be handled within the LIMS, and in particular whether this will be stored as a temporary variable. If it is stored as a temporary variable, then this can be added to the AKI report e.g. inclusion in the text comment that accompanies a positive AKI Warning Stage result. It can also be useful to extract the calculated baseline variable for local audit purposes.

5. Communicating AKI warning test result to clinicians ('alerting')

The AKI Warning Stage results will be sent from the LIMS to your local results reporting system or patient management system, as for all other biochemical results. Clinicians will be able to view these when they login to check patients' results. As such, it is good practice to embed methods of results' acknowledgement that include AKI Warning Stage results to make this process more robust.

In addition, there are other methods of alerting clinicians that you may be able to configure locally to maximise impact and visibility of an AKI result:

- Depending on local resources and capabilities, laboratory staff can telephone AKI Warning Stage results to clinicians/clinical areas just as they would a high potassium. Due to the volume of work, this may not be practical for all AKI Warning Stage results and may only be possible for stage 2 and 3 or stage 3 only. At what AKI warning stage and within what timeframe this should occur should be determined by local governance/risk assessment and within the Trust's overall AKI response; any resourcing issues may need to be discussed with commissioners. One example would be to telephone AKI stage 3 results immediately and AKI stage 2 results within 24 hours.
- Development of additional alerting systems that are triggered by a positive AKI Warning Stage test result will depend on your local resources and capabilities. There are many examples of different methods to do this, including those within patient management systems, via dedicated messaging platforms and through electronic 'track and trigger' patient observation systems.

Examples of good practice will be held and updated on the NHS England website at <http://www.england.nhs.uk/?s=alerting+systems&searchhttp://www.england.nhs.uk/>

- PAS (Patient Administration System) link. There are examples of good practice from around the country in which positive AKI Warning Stage results generate an automatic AKI notification within a hospital's PAS Electronic Patient Record. These notifications are temporary and are removed at

the end of the hospital stay, which then allows re-notification if the patient sustains AKI during a subsequent hospital admission. There are several uses for this including real time surveillance of AKI across the hospital, and linkage to other systems such as electronic whiteboards that can then list patients in each clinical location who have had an AKI Warning Stage result.

6. Excluding results from certain locations

Whilst the AKI Warning Stage is intended to apply to all creatinine results from across the hospital, there are certain clinical areas that should be excluded. This can be done by suppressing the transfer of AKI Warning Stage results from the LIMS when samples are sent from certain clinical locations. These include:

- Renal units – to prevent chronic dialysis patients from being mis-classified as AKI. This will not prevent dialysis patients admitted to other locations from generating false positive alerts. Depending on local capabilities, other solutions to identifying dialysis patients may come from excluding patients with dialysis clinic codes, or who have specific blood test orders (if your local hospital has blood test orders that are used specifically by dialysis patients e.g. peritoneal equilibrium testing, urea kinetic modelling).
- Neonatal units – neonates are excluded from the AKI detection algorithm due to the specific nature of interpreting creatinine values in this setting.
- Primary care locations – at present the NHS England Patient Safety Alert is explicit in advising the exclusion of primary care locations from AKI Warning Stage results, although future rollout of alerts to primary care is planned. This decision has been made because levels of AKI awareness amongst primary care health care workers is highly variable, and the potential harm associated with early introduction (e.g. increase in unnecessary hospital admissions, clinician disengagement) outweighs potential benefits, bearing in mind that creatinine results will still be communicated in the standard way, including the telephoning of high creatinine results in line with RCPATH guidelines.

During the transition period between secondary care introduction of the detection algorithm and its release to primary care, there will be a period in which AKI test results may be generated for creatinine tests requested from primary care when these AKI results are not directly visible to the requesting clinician. This has been deemed as acceptable by the NHS England AKI Programme Board, bearing in mind the balance of risks as described above. However, local governance procedures in trusts retain the prerogative to review this and to decide whether to additionally telephone suppressed results for more severe AKI (for example stage 2 or 3 results that do not fulfil RCPATH creatinine criteria) during the transition period. This would be a modification of current practice in which current guidelines recommend telephoning creatinine results that are $>400\mu\text{mol/L}$ in adults ($>200\mu\text{mol/L}$ if age <16 years) for the first time. Some laboratories may have already started sending AKI results to primary care – please note that this recommendation doesn't mean that existing practices should be halted when they are working well.

Where trusts are sending AKI warning stage test results to secondary care but not to primary care, they should be aware that test results may be visible to primary care e.g. in discharge letters. Some trusts also offer 'look up' facilities on their Hospital Information System that GPs can access.

Consequently communications with GPs should be in two stages:

- 2014-2015: Inform GPs about the new AKI warning stage test, how it is being used in secondary care and advance warning that it will be reported to GPs from April 2016. It may be advisable to state that there is no plan for secondary care to discharge untreated or partially treated AKI patients to primary care (this concern has been expressed repeatedly by GPs during the consultation phase of the programme). This communication could be sent out via the lab or trust primary care newsletter or via the usual communication channels for informing primary care test requesters about new tests. During this communication phase, AKI warning stage results arising from requests in primary care should be suppressed to avoid confusion. It may be the case in some Trusts that AKI warnings are already being sent to primary care from the hospital LIMS. It is not advisable to suppress AKI warning stage results in these circumstances. However, it is very important to communicate effectively with primary care users where switching on the new AKI detection algorithm alters the number of AKI cases detected or where the reporting format is significantly different.
- 2016 and thereafter : AKI warning test results should no longer be suppressed. Information about the test and guidance on action will have been delivered to GPs before turning on the appropriate PMIP feed. The guidance should be agreed with nephrologists or the appropriate acute physicians in secondary care. Where possible guidance should accompany the test result rather than referring to sources of information that requires access to other applications – see Section 4. However, hyperlinking may be appropriate if all primary care systems for viewing results support this functionality.

7. Multiple patient records

NHS pathology laboratories are affected to differing extents by the problem of individual patients having multiple patient records. This has relevance as failure to reconcile multiple patient records limits the availability of previous creatinine measurements to use when calculating the baseline value. Having multiple records for individual patients is not considered good practice for many reasons beyond the scope of AKI detection, and you should ensure that you have assessed the extent of this locally and put measures in place to address this. Use of the NHS number, as the identifier, may be a practical solution if available.

8. Time and date issues

Time periods for calculating baseline are measured in both hours (initial 48hour period) and days. It is possible that your local arrangements for recording sample times may impact this and you should be aware of how the algorithm is performing in your local environment (e.g. sample collection time versus laboratory received time). In addition, you should check that when no sample time is recorded the algorithm still functions and that a default time value (e.g. midnight) is not automatically entered that affects the results. The NHS England test script will help with this.

9. Reducing false positive alerts

Any automated AKI detection algorithm based on serum creatinine changes will generate false positive and false negative results; it is for this reason that the result must be interpreted within the clinical context of the individual patient. You may wish to audit this; you may also wish to develop exception reports that screen for such situations. Some examples may be:

- Falsely low creatinine measurements (e.g. creatinine taken from drip arm) used as baseline within 7 days
- Dialysis patients with blood samples sent from locations other than renal department
- The effect of previous AKI episodes on the diagnosis of new AKI episodes
- Action that occurs when a null creatinine result is generated. If NA or any other null field indicator is generated from the analyser, some LIMS store these results as '0' and if so these data points may affect calculation of baseline value. These results need to be excluded.
- Increases of serum creatinine over 48 hours of more than 26 μ mol/L (but less than 50% above baseline) in stable chronic kidney disease (CKD). The within individual variation of serum creatinine is unknown in patients with this condition but the reference change value may exceed 26 μ mol/L

10. Setting up links with UK Renal Registry

One of the requirements stipulated in the NHS England patient safety notice was to set up processes to allow AKI Warning Stage data to be extracted and sent to the UK Renal Registry to facilitate benchmarking and quality improvement. Setting up these links is outside the scope of this Best Practice Guidance, and advice regarding this aspect of the process will be available separately.

11. Actions to support the introduction of electronic detection

Prior to the launch of AKI warning test results into clinical practice, it is considered good practice to have local plans for publicity and education to raise awareness and understanding among clinicians. The impact of the introduction of AKI detection may also be enhanced by combining its introduction with other hospital wide interventions aimed at improving care for patients with AKI. These may include ongoing education programmes, the introduction of AKI guidelines (which you may choose to link to the AKI warning stage test result script), AKI care bundles and delineation of local referral and network frameworks.

Clinician engagement in the development of the alerting step of the process may be valuable. A full description of these interventions is beyond the scope of this good practice guideline, but further information and examples of good practice in these areas can be found on the NHS England website <http://www.england.nhs.uk/ourwork/patientsafety/akiprogramme/aki-algorithm/>

12. Recommendation to use enzymatic creatinine

Enzymatic creatinine assays are less susceptible to interference than Jaffe-based assays and are recommended in both the CKD and AKI NICE guidelines

- <http://www.nice.org.uk/guidance/cg182>
- <http://www.nice.org.uk/guidance/CG169>

For financial reasons, many laboratories use enzymatic assays for selected patients only, e.g. children, those with high bilirubin. The AKI warning may be set up for both Jaffe and enzymatic assays, but where both are in use the warning algorithm should be assay-specific.

13. Point of care analysers

These all use enzymatic assays and if results are displayed in the electronic patient record they should clearly be shown as POCT results. The precision of these assays is worse than for laboratory assays, they are most widely used to screen for CKD prior to high-risk procedures, and we are not aware of data regarding their reliability for AKI detection.

14. Ongoing quality control, Laboratory Quality Assurance

The day-to-day imprecision for creatinine across all analysers within a laboratory or network should be less than 5%. All laboratories should be part of an external EQA scheme that will periodically distribute samples designed to test for AKI detection.

Prior to going live, laboratories should audit the results flagged with an AKI warning (kept blind from the requester) by manual evaluation of the patients' creatinine results to determine the proportion of false positives. This will help detect if there are specific locations that may need to be excluded if they generate high false positive rates.

15. Advice to measure the impact

A key component of the NHS England AKI programme is to incorporate the measurement of effect alongside the introduction of improvement strategies to assess efficacy and generate an evidence base as well as quality improvement. If you are in the position of introducing AKI detection for the first time, you may wish to consider this approach, utilising the tools and approaches developed by NHS England in partnership with the UK Renal Registry. If you already have an algorithm in place, then there may be a transition period when you continue to run your current algorithm whilst installing and running the NHS England algorithm. You may then wish to run both simultaneously and compare results, an approach that may inform future iterations of the AKI detection algorithm.

16. Evidence generation, sharing learning, algorithm review – a national approach to this

It is envisaged and well understood that the introduction of a national AKI detection algorithm is the start of an evolutionary process. The Think Kidneys programme wishes to publicise and share examples of good practice, to encourage measurement of effect, to promote evidence generation and to have methods of receiving and responding to feedback. One of the purposes of these processes will be to feed into a group that is scheduled to meet to regularly review the performance of the algorithm in clinical practice. This will determine if future modifications are necessary, and if so, feed into a structured process by which updates occur in a step-wise fashion and involve LIMS providers. We have therefore set up the following resources, and others will follow:-

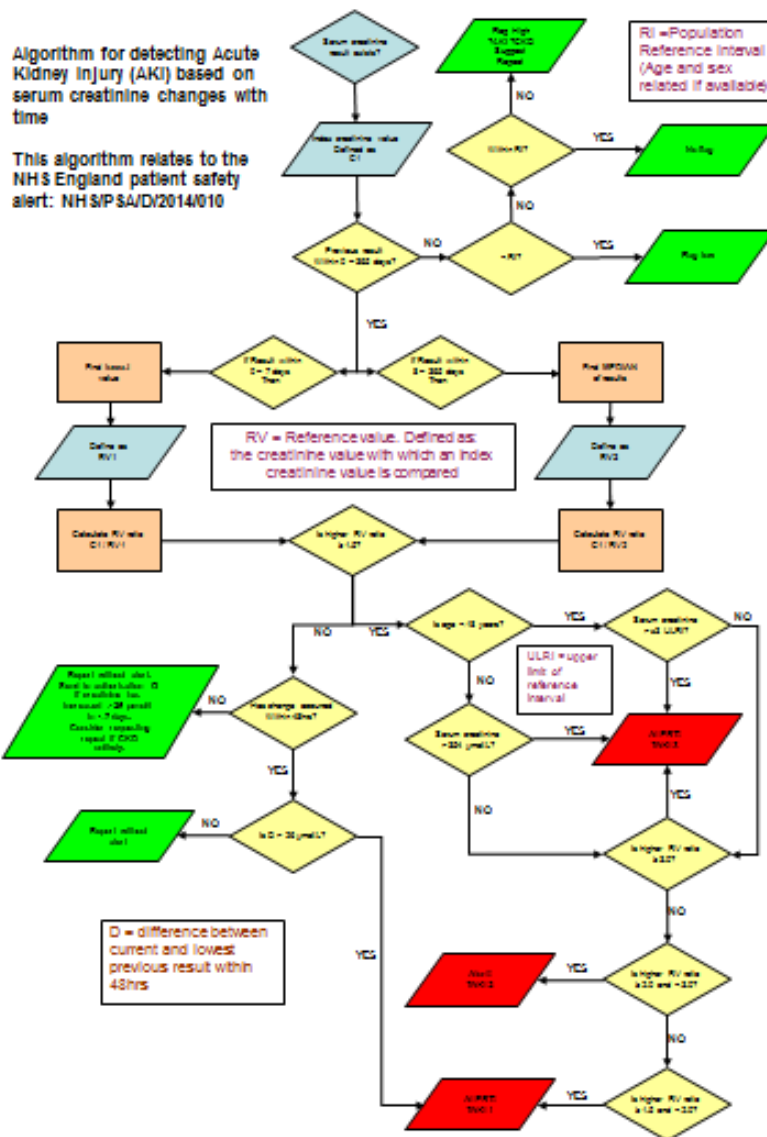
- Website www.thinkkidneys.nhs.uk
- JISMAIL discussion group <https://www.jiscmail.ac.uk/cgi-bin/webadmin?A0=ACB%2dAKI%2dALGORITHM&t=&X=BFE4248C17A8B4772E>

If you would like to contact us, please do so at thinkkidneys@renalregistry.nhs.uk

Appendix A – AKI Warning Algorithm

The algorithm below can also be viewed at the following link

<http://www.england.nhs.uk/ourwork/patientsafety/akiprogramme/aki-algorithm/>



Appendix B – AKI Master Patient Index Dataset

AKI Data Specification for reporting to UK Renal Registry

Version 2.0

1st December 2014

The NHS England AKI National Programme requires that a report of data is produced and transmitted electronically to the UK Renal Registry for patients with an AKI Warning Grade Result.

We are aware that some LIMS may have difficulty in extracting elements of the required data so we are asking for two files – a file of AKI Warning Grade data which we expect every system to be able to supply and an additional file with the creatinine results data for these patients. Laboratories with modern LIMS systems should be able to supply both of these files by the March 2015 deadline; more legacy systems may have to work towards being able to submit the second file.

Please note, the need to submit RV1 and RV2 data (as used by the AKI algorithm to calculate the AKI Warning Grade Result) has been dropped.

Sites should send one submission per month containing the data for the previous full calendar month (1-31st) based on Date Processed. The files should be submitted to the Registry before the end of the following month.

If there are problems with extracting a full month of data from a particular system then possible solutions such as more frequent, smaller submissions can be discussed with the UKRR.

Laboratory ODS codes can be found at <http://systems.hscic.gov.uk/data/ods/datadownloads/misc> - if your site is not present or your details are not correct please contact HSCIC.

If a site is only able to supply local patient identifiers but not NHS Numbers or sufficient demographics allow the number to be traced you should expect that we will contact you periodically to request an extract from your PAS to supply this information.

Files should be submitted as ASCII CSV files. Fields should be supplied in the order given in the specification. No header row should be submitted. Any fields in the specifications which do not exist in the source data should be present but blank. No Line Feeds / Carriage Return characters should be present in any field.

String – ASCII String

Number – an Integer

Date – DD/MM/YYYY

Datetime – DD/MM/YYYY HH:MM:SS

We appreciate that there will be some variation in the format of data produced by the LIMS and will try to accommodate this as part of the import logic.

Any “quirks” of your LIMS output that could affect the interpretation of the data should be described in an e-mail to George.Swinnerton@renalregistry.nhs.uk that includes the ODS lab code of the submitting system. Please do not include any Patient Identifiable Data in your initial e-mail.

Filename:

Format: LABCODE_YYYYMMDD_YYYYMMDD.csv

(where the 1st date is the start of the period and the 2nd the end inclusive)

Example: 69120_20140301_20140331.csv

Criteria:

One row should be included in the file for every alert that is generated within the period of the report. It is possible that there will be more than one row per patient in the files.

Data Item	Data Format	Notes
NHS Number	String	
Local Patient Identifier	String	If NHS Number not available
Forename	String	
Surname	String	
Sex	M/F/U	
DOB	Date	
Address 1	String	
Address 2	String	
Address 3 (Town)	String	
Address 4 (County)	String	
Post Code	String	
Lab Code	String	ODS Code of Processing Lab
Specimen Number	String	
Source of Request	String	ODS Code if possible or text
Inpatient / Outpatient Care Indicator Field	IP/OP	
Alert Datetime	Datetime	Date used in the AKI Algorithm
AKI Warning Stage Test Result	1/2/3	
Serum Creatinine Result (umol/l)	Decimal	The result associated with the alert
eGFR by MDRD Result	Decimal	The result associated with the alert
eGFR by CKD EPI Result	Decimal	If being used in place of eGFR by MDRD

Filename:

Format: LABCODE_YYYYMMDD_YYYYMMDD.csv

(where the 1st date is the start of the period and the 2nd the end inclusive)

Example: 69120_20140301_20140331.csv

Criteria:

Serum Creatinine results should be included in this table where:

An AKI Alert has been recorded for the patient within the report period and the test result (based on processing date) occurred less than 15 months prior to the date the alert was generated.

Or

The test result (based on processing date) occurred within the report period and the patient has had an AKI alert generated 15 months or less prior to the processing date of the test.

Each result should only appear once in the file even if it meets multiple criteria for inclusion.

Data Item	Data Format	Notes
NHS Number	String	
Local Patient Identifier	String	If NHS Number not available
Lab Code	String	ODS Code of Processing Lab
Specimen Number	String	
Source of Request	String	ODS code if available or text
Inpatient/ Outpatient Care Indicator Field	IP/OP	
Collection Date	Datetime	If known
Processing Date	Datetime	
Serum Creatinine Result (umol/l)	Decimal	
eGFR by MDRD Result	Decimal	The result associated with the alert
eGFR by CKD EPI Result	Decimal	If being used in place of eGFR by MDRD

E-mail

The files should be compressed as a Zip file if possible and sent from an NHS.Net e-mail account to nbn-tr.AKIRegistry@nhs.net

If you do not have an NHS.Net e-mail account you will need to encrypt the files with PGP before sending them. Our public PGP key can be found at https://www.renalreg.org/wp-content/uploads/2014/10/Renal-Registry_public-key.asc

DTS

The files can be sent to our DTS mailbox - 8hq50pm.