2. Guidelines for Investigation of Chronic Kidney Disease

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2.1 Introduction

The Need for Sri Lankan Guidelines on Chronic Kidney Disease

Chronic kidney disease [CKD] is a major public health problem throughout the world. In Sri Lanka, kidney failure is becoming increasingly common, especially in the north-central and central provinces.

Applicability
These guidelines are intended to apply to adults [aged>18y] of all ages.
2.2 Classification and Identification of Patients with Chronic Kidney Disease

This classification is based on estimated GFR, and recognizes five stages of kidney disease, as follows:

- **Stage 1**: Normal GFR; GFR > 90 mL/min/1.73 m² with *other evidence of chronic kidney damage.

- **Stage 2**: Mild impairment; GFR 60-89 mL/min/1.73 m² with *other evidence of chronic kidney damage.

- **Stage 3**: Moderate impairment; GFR 30-59 mL/min/1.73 m².

- **Stage 4**: Severe impairment; GFR 15-29 mL/min/1.73 m².

- **Stage 5**: Established renal failure (ERF); GFR < 15 mL/min/1.73 m² or on dialysis.

*The “other evidence of chronic kidney damage” may be one of the following:

- Persistent microalbuminuria
- Persistent proteinuria
- Persistent haematuria (after exclusion of other causes, e.g. urological disease)
- Structural abnormalities of the kidneys demonstrated on ultrasound scanning or other radiological tests, e.g. polycystic kidney disease, reflux nephropathy
- Biopsy-proven chronic glomerulonephritis (most of these patients will have microalbuminuria or proteinuria, and/or haematuria)

Patients found to have a GFR of 60-89 mL/min/1.73 m² without one of these markers should **not be considered to have CKD** and should not be subjected to further investigations unless there are additional reasons to do so.
2.3 Measurement of excretory kidney function

2.3.1 Method for measurement of excretory kidney function [Grade Y]

Creatinine clearance is being used as an estimate of GFR. However, they are not equivalent: as kidney function declines, creatinine clearance becomes significantly higher than GFR due to preserved tubular secretion of creatinine, and may be twice the GFR when GFR is severely reduced.

Estimation of GFR from 24 h urinary creatinine clearance has been shown to be less reliable than the use of a formula-based estimation: this is primarily due to the difficulty of ensuring an accurately timed and complete 24 h urine collection.

2.3.2 Estimating GFR using creatinine – based formulae (Grade x)

More than 25 such formulae have been published. In adults, the most widely validated of these have been the Cockroft and Gault and Modification of Diet in Renal Disease [4-v MDRD] equations.

Overall evidence supports the use of the 4-v MDRD formula as an improved estimate of GFR in people with moderate/advanced CKD. Neither formula performs well in people with normal and mildly reduced kidney function.

According to 4-variable Modification of Diet in Renal Disease [4-vMDRD] equation:

\[
GFR \text{ (mL/min/1.73 m}^2\text{)} = 186 \times \left[\frac{\text{serum creatinine (µmol/L)/88.4}}{1.154}\right]^{-0.203} \times 0.742 \text{ if female.}
\]

When estimated GFR exceeds 90 mL/min/1.73 m², it should be reported as >90 mL/min/1.73 m².

- Laboratories should communicate to their users (possibly using the laboratory report) the following information:
  
  a) that GFR estimates between 60 and 89 mL/min/1.73 m² do not indicate CKD, unless there is other laboratory /clinical evidence of disease
  
  b) that the estimated GFR should be multiplied by 0.742 for female patients.

Laboratories should provide comparable creatinine results, ideally by the use of identical methodology. This should be audited by internal quality control procedures across the network and satisfactory performance in a national quality assessment scheme.
Renal/pathology networks should agree a common approach to the estimation of GFR.

Until these recommendations are implemented, use of the prediction tables (Appendix 1) will allow estimation of GFR from age, gender, serum creatinine. These tables give a “best case estimate” of GFR, using the lowest age and creatinine value in each cell for the calculation.

As an alternative, software systems used could be amended to include one of these formulae and generate an estimate of GFR upon receipt of a creatinine result. However, unless this formula was used automatically every time a creatinine result was entered, this strategy would be less likely to ensure widespread use of estimated GFR.

2.3.3 When to consider creatinine clearance measurement instead of estimated GFR [Grade x]

- Patients with unusual body habitus or diet; for example, a person with substantial muscle wasting may have a lower GFR than suggested by the GFR estimate, even at GFR levels of less than 60ml per minute per 1.73 m²
- Patients with rapidly changing kidney function; in these patients changes in GFR estimates lag behind changes in measured creatinine clearance.

2.3.4 Cystatin C [Grade Z]

Cystatin C, a nonglycosylated basic protein with a low molecular mass that is freely filtered by the glomerulus, is currently under investigation as a replacement for serum creatinine in estimating the GFR.

**Indications for measurement of serum creatinine concentration**

Serum creatinine concentration should be measured, allowing calculation of estimated GFR, at initial assessment and then at least annually in all adult patients with:

- previously diagnosed CKD, including
  - polycystic kidney disease
  - reflux nephropathy
  - biopsy-proven chronic glomerulonephritis
  - persistent proteinuria
  - urologically unexplained persistent haematuria
- Patients with GFR estimates of 60ml per minute per 1.73 m² or greater.
- More accurate estimates may be necessary to evaluate people for kidney donation, administer drugs with marked toxic effects and that are excreted by the kidneys[eg: high-dose methotrexate] or determine a person's eligibility for research protocols.
Conditions associated with a high risk of obstructive nephropathy, including

- known or suspected bladder outflow obstruction
- neurogenic bladder caused by spina bifida or spinal cord injury (N.B. calculated GFR may overestimate true GFR in these patients because of decreased muscle mass)
- urinary diversion surgery
- urinary stone disease due to primary hyperoxaluria, cystinuria, Dent’s disease, infections (with struvite stones), anatomical abnormalities, or a stone episode rate of > 1/y

Conditions known to be associated with a high risk of silent development of CKD, including

- hypertension
- diabetes mellitus
- heart failure
- atherosclerotic coronary, cerebral, or peripheral vascular disease

Conditions requiring long-term treatment with potentially nephrotoxic drugs, including

- ACEIs and ARBs
- NSAIDs
- Lithium carbonate
- Mesalazine and other 5-aminosalicylic acid drugs
- Calcineurin inhibitors (Cyclosporin, Tacrolimus)

Multisystem diseases that may involve the kidney, including

- systemic lupus erythematosus (SLE)
- vasculitis
- myeloma
- rheumatoid arthritis

A first degree relative with stage 5 CKD

Frequency of measurement of serum creatinine concentration

Kidney function should be measured at least annually in the risk groups outlined above. (ARF must be excluded in all patients with newly detected abnormal kidney function.)
Minimum frequency of measurement of kidney function according to estimated GFR:

- **Stage 1**  
  GFR >90  
  annual

- **Stage 2**  
  GFR 60-89  
  annual

- **Stage 3 (known to be stable)**  
  GFR 30-59  
  annual

- **Stage 3 (newly diagnosed or progressive)**  
  GFR 30-59  
  6-monthly

- **Stage 4 (known to be stable)**  
  GFR 15-29  
  6-monthly

- **Stage 4 (newly diagnosed or progressive)**  
  GFR 15-29  
  3-monthly

- **Stage 5**  
  GFR < 15  
  3-monthly

Stable kidney function defined as change of GFR of < 2 ml/min/1.73 m² over 6 months or more progressive kidney damage defined as change of GFR of > 2ml/min/1.73 m² over 6 months or more

Kidney function should also be checked during intercurrent illness and peri-operatively in all patients with stage 2-5 CKD.

Interpretation of newly diagnosed GFR <60 ml/min/1.73 m²

Because ARF requires emergency treatment, all patients with newly detected abnormal kidney function should be assumed to have ARF until proven otherwise, although the majority will turn out to have CKD.

In patients with newly diagnosed stage 3, 4 or 5 CKD, clinicians should obtain all previous measurements of serum creatinine and estimate GFR from them using the MDRD formula (or tables in Appendix 1) to assess the rate of progression to date.

A blood test showing a GFR <60 ml/min/1.73m² in a patient who is not known to have established CKD with abnormal GFR should prompt:

- Review of medication, particularly recent additions (e.g. diuretics, non-steroidal anti-inflammatory drugs (NSAIDs), any drug capable of causing interstitial nephritis)

- Clinical examination for bladder enlargement

- Urinalysis: haematuria and proteinuria suggest the possibility of glomerulonephritis, which may be rapidly progressive
• Clinical assessment, looking for underlying conditions such as sepsis, heart failure, hypovolaemia

• Repeat measurement of serum creatinine concentration within a maximum of 5 days.

2.4 Recognition of Acute Renal Failure (ARF)

Formula-based estimated GFR should be interpreted with caution in ARF, because the formulae rely on a stable serum creatinine concentration. ARF is a clinical syndrome characterised by a rapid decline in excretory function occurring over a period of hours or days. ARF should be suspected if there is a >1.5-fold rise in serum creatinine concentration, or a fall in estimated GFR of >25%, or oliguria (defined as urine output <0.5 ml/kg/h), in the context of an acute illness. If baseline serum creatinine concentration or GFR is not known, it should be assumed that baseline GFR was 75 ml/min/1.73 m².

2.5 Recognition of acute on chronic kidney disease

A fall in estimated GFR of >25% since the last measurement of kidney function in a patient with CKD should prompt a repeat measurement of kidney function, assessment as for ARF (see preceding section) and referral if the deterioration is confirmed.

2.6 Detection of proteinuria [Grade Y]

2.6.1 Methods for detection and quantitation of proteinuria

A positive dipstick test (1+ or greater) should result in a urine sample (preferably early morning) being sent to the laboratory for confirmation by measurement of the total protein:creatinine ratio or albumin:creatinine ratio (depending on local practice).

Simultaneously, a midstream sample should be sent for culture to exclude urinary tract infection (UTI).

Urine protein:creatinine ratios >45 mg/mmol [>397 mg/g creatinine] or albumin:creatinine ratios of >30 mg/mmol [>265 mg/g creatinine] should be considered as positive tests for proteinuria. Positive tests for proteinuria should be followed by tests to exclude postural proteinuria, by analysis of an early morning urine sample, unless this has already been done.
Patients with two or more positive tests for proteinuria, preferably spaced by 1 to 2 weeks, should be diagnosed as having persistent proteinuria.

**Indications for testing for proteinuria**

As part of the initial assessment of patients with:

- Newly discovered GFR < 60 ml/min/1.73 m²
- Newly discovered haematuria
- Newly diagnosed hypertension
- Unexplained oedema
- Suspected heart failure
- Suspected multisystem disease, e.g. SLE, systemic vasculitis
- Diabetes mellitus

As part of the annual monitoring of patients with

- Biopsy-proven glomerulonephritis
- Reflux nephropathy
- Asymptomatic microscopic haematuria
- Asymptomatic proteinuria

Monitoring for proteinuria is also required for patients receiving treatment with gold and penicillamine.

Recommendations for frequency of monitoring are given in the British National Formulary: for penicillamine, before starting treatment and then every 1-2 weeks for the first 2 months, monthly thereafter, and in the week after any dose increase.

For intramuscular gold, before each intramuscular injection. For oral gold, monthly.

We do not recommend screening of any other groups for proteinuria.

### 2.7 Detection of “microalbuminuria”[Grade Y]

#### 2.7.1 Method for detection of microalbuminuria

Urine albumin should be measured using an immunoassay in an early morning (preferred) or random mid-stream urine sample and expressed as an albumin:creatinine ratio. An albumin:creatinine ratio >2.5 mg/mmol (>22mg/g creatinine) in a male or >3.5 mg/mmol (>30mg/g creatinine) in a female is consistent with microalbuminuria.
Patients demonstrating albumin:creatinine ratios above, or equal to, this cut-off should have urine samples sent to the laboratory on two further occasions (ideally within one to three months) for albumin estimation. Patients demonstrating persistently elevated albumin:creatinine ratios in one or both of these further samples have microalbuminuria.

The diagnosis of microalbuminuria cannot be made in the presence of an acute metabolic crisis. As far as is practicable, the best possible metabolic control of diabetes should be achieved before investigating patients for microalbuminuria. Patients should not be screened during intercurrent illness.

There is no need to exclude urinary tract infection before diagnosing microalbuminuria unless the patient has symptoms of urinary tract infection at the time the urine sample is taken. It is important to consider other causes of increased albumin excretion, especially in the case of type 1 diabetes present for <5 years. In addition to the above caveats, these can include non-diabetic renal disease, menstrual contamination, vaginal discharge, uncontrolled hypertension, heart failure, intercurrent illness and strenuous exercise.

### 2.7.2 Indications for testing for microalbuminuria

Patients with diabetes mellitus who have persistent proteinuria (as defined above) do not require testing for microalbuminuria.

All other patients with diabetes mellitus should undergo, as a minimum, annual testing for microalbuminuria. There is currently no proven role for screening for microalbuminuria in patients who do not have diabetes.

### 2.8 Detection of haematuria [Grade X]

#### 2.8.1 Method for detection of haematuria

Dipstick urinalysis is the test of choice for confirmation of macroscopic haematuria and for detection of microscopic haematuria. Infection, trauma, and menstruation should be excluded before confirmation of haematuria. There is no need in routine clinical practice for confirmation of haematuria by microscopy of a midstream urine sample.

#### 2.8.2 Indications for testing for haematuria

Dipstick urinalysis for blood is indicated as part of the initial assessment of patients with

- Newly detected GFR < 60 ml/min/1.73 m²
- Newly discovered proteinuria
- Suspected multisystem disease with possible renal involvement
• A rise in serum creatinine concentration of >= 20% or fall of GFR of >15% during the first 2 months after initiation of ACEI or ARB treatment.

• Unexplained hypokalaemia with hypertension.

“Screening” of unselected populations for haematuria is not recommended.

2.9 Renal osteodystrophy:
assessment/management in CKD

Antiresorptive treatment (e.g. with bisphosphonates) for suspected or proven reduced bone mineral density should not be commenced in patients with CKD until treatable disorders of calcium, phosphate, PTH and serum 25-hydroxyvitamin D metabolism have been sought and treated.

No measurements of calcium, phosphate, or PTH are required in stage 1 or 2 CKD unless the patient has suspected or proven reduced bone mineral density.

In stage 3 CKD, serum corrected calcium and phosphate should be measured every 12 months. Abnormal values should be confirmed on a repeat fasting sample taken without a tourniquet. Patients with confirmed abnormalities of serum corrected calcium or phosphate should be referred to a nephrologist.

In stage 3 CKD, plasma or serum PTH should be checked when the diagnosis of CKD stage 3 is first made.

If the PTH is < 70 ng/L, no further checking is required unless the patient progresses to stage 4 CKD.

If the PTH is > 70 ng/L, serum 25-hydroxyvitamin D should be checked. If the serum 25-hydroxyvitamin D is low (<80 nmol/L, 30 µg/L), therapy should be commenced with ergocalciferol or colecalciferol 800 units/day in a preparation that contains calcium carbonate or calcium lactate but not calcium phosphate; or colecalciferol 10,000 units monthly by intramuscular injection. PTH should then be rechecked after 3 months of replacement therapy. There is no need to repeat the measurement of serum 25-hydroxyvitamin D unless non-adherence or malabsorption is suspected. Vitamin D therapy should be continued long-term unless the clinical situation changes.

If the PTH is > 70 ng/L despite a normal serum 25-hydroxyvitamin D or treatment with ergocalciferol or colecalciferol, the patient should be referred to a nephrologist for specialist advice on management of hyperparathyroidism.

To convert PTH (ng/L) to SI units (pmol/L) multiply by 0.11

2.10 Laboratory investigations

2.10.1 Urea and Creatinine

They are waste products excreted exclusively by kidney. However the GFR has to decrease by about 40 – 60% [GFR of 30 – 60/min] for urea and creatinine to rise.
Sample collection

- Serum creatinine:
  4 – 5ml of blood in a clean dry plain bottle. 
  Separate serum from cells as early as possible 
  Avoid haemolysed samples 
  Avoid Cephalosporin antibiotics

- Blood urea:
  3 – 4ml of blood in a clean dry plain bottle.

2.10.2 Serum electrolytes

Serum Sodium

Sodium balance is maintained until the GFR falls to very low levels [5ml/min ] and is reflected by an increase in renal fractional excretion of sodium [FE Na]

\[ \text{FE Na} \% = \frac{\text{UNa} \times \text{Scr} \times 100}{\text{SNa} \times \text{Ucr}} \]

UNa = urinary Na  
SNa = Serum Na  
Scr = Serum creatinine  
Ucr = urinary creatinine

In normal subjects the FENa% is<1%, during progressive CKD it will increase up to a maximum of 20%.  
Artefactual and clinically non significant hyponatraemia; Blood taken from a drip arm [5% dextrose drip]

Hyperglycaemia patient, diabetes mellitus or i/v infusion of glucose causing dilutional hyponatraemia in the ECF.

Hyperlipidaemia or increase in globulins [myeloma, macroglobulinaemia] lower Na due to decrease in plasma water.

Serum Potassium

K balance is maintained until the GFR falls below about 20ml/min.[serum creatinine 300-350µmol/L]

Specimen Collection for serum electrolytes:

- 3-4ml of blood is collected to clean, dry plain bottle. 
- Blood should not be collected from a drip arm.  
- Avoid muscle activity [clenching the fist ] when collecting blood samples for electrolytes. Blood specimens should not be chilled before separation of the serum.

Factitious hyperkalaemia is common due to-
- Haemolysis 
- Specimen more than 6hrs old 
- Specimen contaminated with K-EDTA
2.10.3 Serum Ca and Phosphate

In chronic renal failure there is a tendency towards a negative calcium balance and hypocalcaemia.

**Specimen collection and storage**

**Serum Calcium**

Serum is the preferred specimen although heparinized plasma is acceptable. 3-4 ml of blood without applying the tourniquet into acid washed bottles. Fasting specimen is preferred.

Serum should be promptly separated from the cells. Haemolyzed samples are unacceptable.

Centrifuged samples are stored at room temperature for up to 8hrs, at 4°C for one day and frozen for up to 1 year.

**Serum Phosphate**

Phosphate balance is maintained until the GFR falls below 10-20ml/min [s. creatinine of 300-400µmol/L].

- Blood; 3-4 ml blood, fresh blood sample.
- Preferably fasting
- Haemolyzed samples unacceptable.
- Serum should be promptly separated from the cells.

A true serum K of 6.5 mmol/L is a cause for concern and cardiac arrest can occur in patients at a K value of 8.5mmol/l. True serum K seldom rises above 9mmol/L.

2.10.4 Acid base

**Hydrogen ions and plasma bicarbonate**

Normal excretion of H ions and bicarbonate are maintained until the GFR falls to below 30ml/min [creat. 300µmol/L] with a further decrease in GFR H ions retained and bicarbonate progressively falls to a level of 12 – 15mmol/L.

**Specimen collection of blood gas analysis**

Whole blood is the preferred specimen. Specimen is collected anaerobically with lyophilized heparin anticoagulant in sterile syringe with capacities of 4-5ml.

Adequate anticoagulant [0.05mg heparin/ml blood]

**Anion Gap**

As the GFR decreases anions such as sulphate, phosphate etc. will be retained in the blood and along with the positive hydrogen balance will result in a high anion gap metabolic acidosis

\[
A \text{ gap [mEq/L]} = [\text{Na mEq/L} + \text{K mEq/L}] - [\text{Cl m Eq/L} + \text{HCO}_3 \text{. mEq/L}]
\]

2.10.5 Urinary Sediment

An important evaluation is urine analysis particularly the search for red blood cells, cellular debris and casts [ haem, granular] if any one of these is present.
the diagnosis is most likely to be acute tubular necrosis. In the normal subject and in uncomplicated pre-renal uraemia these substances are usually absent from the urine.

2.10.6 Urinary microalbumin

Urine albumin excretion is increased by physiological factors [Eg; exercise, posture]

The method of urine collection should be standardized.

Samples should not be collected after exertion, in the presence of urinary tract infections, during acute illness, immediately after surgery or after an acute fluid load.

*The following urine samples are accepted for the microalbumin measurement*

⇒ 24-hr urine collection.
⇒ Overnight [8-12hrs] collection
⇒ 1-2hr collection [in labor clinic]
⇒ First morning sample for simultaneous measurement of albumin and creatinine

The timed specimens are the most sensitive, but the albumin :creatinine ratio is practical and convenient for the patient.

2.10.7 PTH assays

Clotted blood samples sent for PTH assay need to be separated rapidly and kept on ice. PTH can be done in plasma, blood samples anticoagulated with EDTA.

2.10.8 Creatinine clearance

24hr urine specimen and a blood sample for creatinine [4ml of blood taken during the 24hr period of urine collection.]

Avoid cephalosporin antibiotics.

24hr collection of urine: Empty bladder completely and discard the urine, note the time, from that time onwards collect the sample into a beaker and transfer into a bottle [2.5L] with preservative until 24hrs completed.

Preservative – 10ml of 6mol/L per 24hr excretion.

2.10.9 Specimen collection for ionized calcium

Specimens for ionized calcium must be transported in ice-water and analyzed within 30 minutes of collection to minimize pH change due to CO2 loss and glycolysis.
2.11 Investigations in Categories Graded in Different Levels

Grade X – very basic
Grade Y – desirable
Grade Z - optional

Grade X
Blood urea
Creatinine
Serum electrolytes
Urinary sediment
Serum calcium
Serum phosphate
Acid base
Anion gap
Creatinine clearance
Estimated GFR by equations or
By using tables

Grade Y
Urinary microalbumin
Urinary protein: creatinine ratio
Urinary alb:creatinine ratio

Grade Z
PTH assays
25 – hydroxyvitamin D
Cystatin C

2.12 Abbreviations

ACEI Angiotensin Converting Enzyme Inhibitor
AER Albumin Excretion Rate
ARB Angiotensin Receptor Blocker
ARF Acute Renal Failure
BMD Bone Mineral Density
BSA Body Surface Area
CHD Coronary Heart Disease
CKD Chronic Kidney Disease
CT Computed Tomography
CVD Cardiovascular Disease
EDTA Ethylenediaminetetraacetic acid
ERF Established Renal Failure
ESA Erythropoiesis Stimulating Agent
GFR Glomerular Filtration Rate
HOT Hypertension Optimal Treatment
K/DOQI Kidney Disease Outcomes Quality Initiative
LVH Left Ventricular Hypertrophy
MDRD Modification of Diet in Renal Disease
MR Magnetic Resonance
NHS National Health Service
NICE National Institute for Clinical Excellence
NSAID Non-Steroidal Anti-Inflammatory Drug
PTH Parathyroid Hormone
RAS Renin Angiotensin System
RRT Renal Replacement Therapy
SLE Systemic Lupus Erythematosus
UTI Urinary Tract Infection
2.13 References


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Appendix 1. Prediction of GFR from age and serum creatinine

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Reference values for Sri Lankan men and women are the same as for white men and women given in the chart.