

2. Guidelines for Investigation of Chronic Kidney Disease

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INDEX

CONTENT	PAGE NUMBER
2.1 Introduction	22
2.2 Identification of patients with chronic kidney disease	23
2.3 Measurement of excretory kidney function	25
2.4 Recognition of acute renal failure	33
2.5 Recognition of acute on chronic kidney disease	34
2.6 Detection of proteinuria	34
2.7 Detection of microalbuminuria	36
2.8 Detection of haematuria	38
2.9 Renal osteodystrophy: assessment / management in chronic kidney disease	39
2.10 Laboratory Investigations	40
2.11 Investigations in categories graded in different levels	47
2.12 Abbreviations	48
2.13 References	49
2.14 Appendix	50

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/1.73m² 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, eg. 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 Cockcroft 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:

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

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.

- 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.

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

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 lupuserythematosus (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.)

- 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 >30mg/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

- Diabetes mellitus (patients with diabetes mellitus should also have annual testing for albumin:creatinine ratio if the dipstick urinalysis for protein is negative)

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 [$>22\text{mg/g creatinine}$] in a male or >3.5 mg/mmol [$>30\text{mg/g creatinine}$] 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 $\geq 20\%$ 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 $\mu\text{g/L}$), 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]

$$FE\ Na\% = \frac{UNa \times SCr}{SNa \times Ucr} \times 100$$

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

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.

2.10.3 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 4⁰c 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.

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 gap [mEq/L] = [Na mEq/L + K mEq/L] – [Cl m Eq/L + Hco₃. 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

White men Creatinine	Age						
	20	30	40	50	60	70	80
70	>90	>90	>90	>90	>90	>90	>90
80	>90	>90	>90	>90	>90	88	86
90	>90	>90	86	82	79	77	75
100	88	81	76	73	70	68	66
110	79	72	68	65	63	61	59
120	71	66	62	59	57	55	54
130	65	60	56	54	52	50	49
140	60	55	52	49	48	46	45
150	55	51	48	46	44	43	42
160	51	47	44	42	41	40	39
170	48	44	41	40	38	37	36
180	45	41	39	37	36	35	34
190	42	39	36	35	34	32	32
200	39	36	34	33	32	31	30
210	37	34	32	31	30	29	28
220	35	33	31	29	28	27	27
230	34	31	29	28	27	26	25
240	32	29	28	27	26	25	24
250	31	28	27	25	24	24	23
260	29	27	25	24	23	23	22
270	28	26	24	23	22	22	21
280	27	25	23	22	21	21	20
290	25	24	22	21	21	20	19
300	25	23	21	21	20	19	19
310	24	22	21	20	19	18	18
320	23	21	20	19	18	18	17
330	22	20	19	18	18	17	17
340	21	20	19	18	17	17	16
350	21	19	18	17	17	16	16
360	20	18	17	17	16	16	15
370	19	18	17	16	16	15	15
380	19	17	16	16	15	15	14
390	18	17	16	15	15	14	14
400	18	16	15	15	14	14	13
410	17	16	15	14	14	13	13
420	17	15	15	14	13	13	13
430	16	15	14	14	13	13	12
440	16	15	14	13	13	12	12
450	15	14	13	13	12	12	12
460	15	14	13	13	12	12	11
470	15	14	13	12	12	11	11
480	14	13	12	12	11	11	11

White Women	20	30	40	50	60	70	80
Creatinine							
40	>90	>90	>90	>90	>90	>90	>90
50	>90	>90	>90	>90	>90	>90	>90
60	>90	>90	>90	>90	>90	>90	89
70	>90	>90	95	82	79	76	74
80	84	78	73	70	67	65	64
90	74	68	64	61	59	57	56
100	65	60	57	54	52	51	49
110	58	54	51	48	47	45	44
120	53	49	46	44	42	41	40
130	48	44	42	40	39	37	36
140	44	41	38	37	35	34	33
150	41	38	35	34	33	32	31
160	38	35	33	31	30	29	29
170	35	33	31	29	28	27	27
180	33	30	29	27	26	26	25
190	31	29	27	26	25	24	23
200	29	27	25	24	23	23	22
210	28	26	24	23	22	21	21
220	26	24	23	22	21	20	20
230	25	23	22	21	20	19	19
240	24	22	21	20	19	18	18
250	23	21	20	19	18	18	17
260	22	20	19	18	17	17	16
270	21	19	18	17	17	16	16
280	20	18	17	16	16	15	15
290	19	18	17	16	15	15	14
300	18	17	16	15	15	14	14
310	18	16	15	15	14	14	13
320	17	16	15	14	14	13	13
330	16	15	14	14	13	13	12
340	16	15	14	13	13	12	12
350	15	14	13	13	12	12	12
360	15	14	13	12	12	12	11
370	14	13	13	12	12	11	11

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