

Screening Guidelines

Chronic Kidney Disease

Sri Lanka

2017



Epidemiology Unit
Ministry of Health



Screening Guidelines

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Sri Lanka**

These guidelines were developed based on the best available evidence at the time of writing. It is expected to be used in screening for Chronic Kidney Disease. The guidelines will be reviewed when new evidences become available

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Message from the Director General of Health Services

Surveillance of Chronic Kidney Disease carried out by the Epidemiology Unit is a “challenging yet successful endeavour”. As a result of the surveillance programme, the Ministry of Health possesses statistics on patients with the Chronic Kidney Disease.

The active surveillance by means of screening asymptomatic people living in the high risk areas for Chronic Kidney Disease of Uncertain aetiology has enabled detection of more cases compared to previous years.

I appreciate the deliberations made by the Epidemiology Unit to revise the screening guidelines keeping abreast with the current evidence based practices. I believe that the screening guidelines will be extensively used by the health care workers in the field in indemnifying suspected cases.

I congratulate the Epidemiology Unit and the panel of experts for accomplishing the task of revising the screening guidelines

Dr. P. G. Mahipala
Director General of Health Services

Message from the Chief Epidemiologist

Screening of inhabitants in high risk areas where Chronic Kidney Disease of Uncertain aetiology is an integral part of the surveillance programme conducted by the Epidemiology Unit. First screening guidelines for community screening was set in 2014 in order to streamline and standardize the ongoing screening programmes.

Based on scientific evidence, experts have suggested some changes to the previously set guidelines. Considering evolving science and feasibility at the ground level, revisions were made.

I sincerely feel that the revised guidelines will serve as a comprehensive guide for those engaged in the screening programme.

I take this opportunity extent my gratitude to those who have contributed their expertise without hesitation.

Dr. Paba Palihawadana
Chief Epidemiologist

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Introduction

During the recent past, high prevalence of Chronic Kidney Disease was observed in some geographic areas of Sri Lanka. Especially the North Central Province (NCP) was noted as an endemic area for CKD. Some areas outside the NCP, but geographically adjacent, were later on detected to have similarly high prevalence of CKD.

Unfortunately, a fair proportion of CKD cases were not attributable to known aetiological factors. This scenario has led to coining a term “Chronic Kidney Disease of Uncertain aetiology” (CKDu). The unknown aetiology has hampered implementation of effective preventive measures over the years.

At present, scientific data are available on the high endemicity of CKD in these areas. The World Health Organization (WHO) report on “Kidney Disease of Uncertain Aetiology (CKDu) in Sri Lanka” says that the age standardized prevalence of CKDu among females in the age group of 15 to 70 years of age is 16.9% and that of males in the same age category is 12.9%.

In January 2014, the Standing Cabinet Appointed Officials’ Committee for the Mitigation of CKDu in the North Central Province has recommended to establish a criterion for diagnosing CKDu patients and to plan a systematic Screening Programme for early diagnosis. It has further recommended mapping the cases of CKD/CKDu considering the Grama Niladhari (GN) divisions as the base for mapping.

The Screening Programme for CKD/CKDu is intended to detect asymptomatic individuals in the early stages of CKD. The screening programme will serve as a comprehensive and active epidemiological surveillance with provisions for mapping and analyzing attributes and possible aetiologies.

Surveillance on Chronic Kidney Disease in Sri Lanka

The Epidemiology Unit of the Ministry of Health, Sri Lanka has established surveillance on chronic kidney disease since October 2013. Thirty hospitals were declared as sentinel sites initially with further expansion now the total number is 50. The rationale of selecting the hospitals as sentinel sites was the available statistics on the disease burden and the media reports and public concerns of the presence of the disease in geographic locations. Based on the hospital statistics and the statistics at the renal research unit, the Polonnaruwa and Anuradhapura districts and geographically adjacent areas namely, Dehiattakandiya, Girandurukotte, Welioya, Polpithigama, Padavi Sripura, Wilgamuwa and Vavuniya South Divisional Secretariat divisions were proclaimed as high risk areas. The hospitals catering to the populations in the proclaimed areas were selected as sentinel sites. Another set of hospitals were selected on the basis of patients referral mechanisms, resource availability including availability of specialists' services, having renal clinics. In Addition, some institutions were selected considering the potentials of having the disease, anecdotal reports on the presence of disease and public concerns on the presence of the disease. As surveillance continues, the list of sentinel sites could be evolved based on the evidence generated.

- | | |
|-----------------------------|----------------------------|
| 1. DH Padawiya | 26. DH Kahatagasdigiliya |
| 2. DH Madawachchiya | 27. DH Thanamalwila |
| 3. BH Kabithigollawa | 28. DH Buttala |
| 4. BH Thambuththegama | 29. GH Mannar |
| 5. DH Kakirawa | 30. DH Sampathnuwara |
| 6. BH Madirigiriya | 31. NHSL |
| 7. DH Hingurakgoda | 32. NINDT |
| 8. DH Elahara | 33. TH Karapitiya |
| 9. DH Welikanda | 34. GH Sri Jayewardenepura |
| 10. DH Aralaganwila | 35. TH Kalubowila |
| 11. DH Nikawawa | 36. DH Rambewa |
| 12. DH PadawiSripura | 37. DH Polpithigama |
| 13. DH Giradurukotte | 38. BH Nikaweratiya |
| 14. BH Mahiyangana | 39. BH Dambulla |
| 15. DH Galenbidunuwawa | 40. DH Gomarankadawala |
| 16. TH Anuradapura | 41. DH Badulla |
| 17. GH Polonnaruwa | 42. BH Wellawaya |
| 18. TH Kandy | 43. BH Cheddikulam |
| 19. GH Vavuniya | 44. BH Mallavi |
| 20. BH Dehiattakandiya | 45. DH Mamaduwa |
| 21. TH Jaffna | 46. BH Tissamaharama |
| 22. GH Mullaithivu | 47. BH Tangalle |
| 23. GH Killinochchi | 48. DGH Hambantota |
| 24. TH Kurunagala | 49. DH Bakamuna |
| 25. DH Hettipola, Wilgamuwa | |

Objectives of the Screening Programme

- Detect asymptomatic individuals in the preclinical stages of the chronic kidney disease
- Assess the disease burden of CKD/CKDu in the entire country giving priority to CKDu endemic areas
- Refer those found positive in the screening to the curative care system for further medical evaluation, and if found to have the disease, for clinical care.
- Study the factors associated with the chronic Kidney Disease with uncertain aetiology

Methodology

Screening Method – Selective Screening

The programme will aim at screening “high risk group” defined by age limits giving priorities to endemic areas. Chemical assays will be carried out on urine and blood to detect CKD/CKDu.

High risk geographic areas

Following a series of consultative meetings, the panel of experts decided upon the under-mentioned areas as “high risk” considering the present pattern of geographic distribution of cases.

No	Province	District	DS Division
01	North Central	Anuradhapura	All
02	North Central	Polonnaruwa	All
03	North Western	Kurunegala	Polpithigama & Giribawa
04	Eastern	Ampara	Dehiattakandiya
05	Eastern	Trincomalee	Padavi Sripura
06	Uva	Badulla	Mahiyanganaya & Rideemaliyadda
07	North	Mullaitivu	Welioya
08	North	Vavuniya	Vavuniya & Vavuniya South
09	Central	Matale	Wilgamuwa

Primary Target Group

In endemic areas, those who are above the age of twenty years are eligible to be screened. In non-endemic arrears,

those who are above the age of thirty will be considered eligible for screening.

Exclusion Criteria

Those who are suffering from acute illness, pregnant women and women during menstruation are not eligible for screening. Suitable measures need to be assured to screen them once they recover from contraindications.

Screening Settings – Community Settings

Screening will be carried out in community settings on pre determined dates with prior notification given to the target population. Screening will be carried out at **Field Screening Clinics** conducted in places easily accessible to the catchment population, preferably at the Gramodaya Health Centres, Central Dispensaries, Hospitals, and Offices of the Public Health Inspectors, Offices of Medical Officers of Health or any other facility depending on the programmatic feasibility.

Screening Tool

The screening tool is a package consisting of a combination of tests, testing for Serum Creatinine with calculating estimated glomerular filtration rate (eGFR), measuring urine albumin creatinine ratio (UACR) on an early morning urine sample and measuring blood pressure.

Administration of Screening Tool

The tool is expected to be administered in the community setting, in a **field screening clinic**. The **data sheet** needs to be filled with legible letters and all fields must be filled.

Collecting and Dispatching of Blood Samples

- The responsibility of venipuncture and proper labelling of samples of blood is vested upon the Public Health Nursing Sister and Nursing Officer.
- Venipuncture should follow the routine procedure practised in hospital settings.
- Either plain tubes or Serum Separating Tubes (Serum separating tubes are preferred) should be used for collecting blood. 3 ml of blood is required.
- If plain tubes are used, the separated serum needs to be transferred to a secondary tube taking precautions to label properly.
- The secondary tubes or the Serum Separating Tubes (SST) should be stored in cool boxes with ice packs in a temperature ranging from 10 to 15°C.
- The properly stored samples should reach the laboratory within a maximum of six hours.

Collecting and Dispatching Urine Samples

- Urine sample of 30 ml, preferably from the first or second void needs to be collected in a screw capped container.
- Overnight rest with a good sleep needs to be ensured before collecting the sample.
- Practice of proper labelling needs to be adhered to.

- Samples should be stored in Igloo type cool boxes in the temperature range of 2 to 8°C as soon as they reach the field screening clinic.
- Urine samples should not be stored with blood/serum samples. Urine sample should not be frozen/ kept at below 0°C.

Testing for serum Creatinine and calculating eGFR

The testing should be done as soon as the samples reach the testing laboratory, necessarily not exceeding 24 hours from the time of sample collection.

Jaffe Kinetic Method should be used in testing for serum Creatinine in an appropriated fully automated analyzer to ensure the validity of the test. CKD-EPI formula is suggested to be used to calculate eGFR. Patient's age and sex are required for the calculation.

Quality Assurance of laboratory tests

▪ Internal Quality Assurance

Every testing laboratory should strictly follow the quality control guidelines prescribed here.

- ✓ At the beginning of the day, internal quality control should be performed at two levels. Further, level – I & II quality control should be performed on completion of every hundred tests.

- ✓ The equipment shall be calibrated with traceability established calibrators on instructions from the manufacturer. In an event of quality failure, the equipments should be calibrated immediately.
- ✓ Proper maintenance of the equipment according to manufacturer's instructions is mandatory.

- **External Quality Assurance**
 - ✓ The Chemical Pathology Department of the Medical Research Institute (MRI) of Sri Lanka will serve as the national reference laboratory for external quality control of the screening programme.
 - ✓ The MRI would
 - monitor the internal quality assurance serum creatinine, urine albumin and urine creatinine assays
 - distribute quality assurance serum and urine samples on a regular basis to selected labs
 - harmonize serum creatinine results between labs selected for CKD screening
 - achieve traceability of creatinine assay to IDMS traceable creatinine assay
 - Supervise on a distant basis calculation of eGFR in laboratories where chemical pathologists are not available
 - monitor urine albumin creatinine ratio similarly
 - training of MLTs in those hospitals for internal and external quality assurance
 - quality inspection visits
 - ✓ Carry out monthly, inter-laboratory evaluation with standard samples.

Cutoff Values for Blood Pressure and Laboratory Investigations

- **Blood Pressure**

140 mmhg and 90 mmhg would be stipulated as upper limit of normal for systolic and diastolic blood pressure respectively. Either of the readings above these levels would be taken as high blood pressure.

- **Serum Creatinine**

Sex specific reference ranges given for creatinine assay by the manufacturer would be taken as the reference limits for serum creatinine. Any value above the upper reference limit would be considered as positive screening test for CKD. Estimated glomerular filtration rate (eGFR) below 60ml/1.73m²/min is taken as positive for screening for CKD.

- **Urine Albumin Creatinine Ratio (UACR)**

30 mg/g of creatinine would be considered as the upper normal normal for UACR. Values above this level would be considered as positive in screening for CKD.

Interpretation of Results

If a person gets any one of the screening tests positive (serum creatinine, eGFR or UACR) **he or she** would be considered as **positive** for screening test, **irrespective of** their blood pressure reading levels.

Referral Procedure for Persons with Abnormal Test Results

Persons who are negative for both investigations and for blood pressure measurements will be considered as **negative** for screening and reviewed in three years time in a similar screening programme.

Persons who report **only** elevated blood pressure would be referred to nearby curative care facilities for follow up with regard to elevated blood pressure. This category is also considered as **negative** for the screening programme.

Persons who are considered as **positive** (having either elevated S. Creatinine or low eGFR or elevated UACR irrespective of blood pressure levels) for screening should be channelled to curative care facilities for further evaluation by means of history, clinical examination, biochemical investigations and radiological, histological assessments (protocols need to be developed). Persons who are found positive at secondary evaluation would be referred to the Nephrologists' clinics as specified in clinical management guidelines.

Responsibilities

Provisions of technical guidance and database management for the screening programme are vested with the Epidemiology Unit of the Ministry of Health. Implementation of the screening programme comes under the purview of provincial health authorities. In the North Central Province, the Renal Research Unit will take part in the planning and implementation of the screening programme.

In the districts where Medical Officers/ CKD prevention have been appointed, the MO/CKD holds the responsibility of implementation of the screening programme. In other districts where there is no appointed MO/CKD, the Regional Epidemiologist is responsible for the implementation of the screening programme. The Medical Officer of Health is held responsible for conducting screening clinics in the area according to an approved advanced programme. The heads of curative care institutions in the areas are expected to support the screening programme specially with respect to human resource mobilization. The RE or MO/CKD should liaise with the MOH and heads of curative care institutions in planning and implementation of the screening programme.

Field Screening Clinics

The screening clinics should be planned in such a way that once a round of screening clinic is over, the entire Medical Officer of Health area should be covered. When identifying the places, accessibility of the catchment population should be considered a priority requirement. The MO/CKD or RE should work together to identify the sites to conduct Field Screen Clinics.

The clinics should commence by 8.00 am and continue till the target is covered. The clinics can be planned on any day including weekends considering the ground realities of resource mobilization. Every fortnight, a screening clinic should be conducted in the office of the MOH (Central Screening Clinic) to cater for those who missed the area field clinic.

The date, time and venue of the screening clinic should be informed to the population to be screened by any means.

All individuals screened at the clinic should be registered in the field screening clinic and a Clinic Registration Card should be issued. All particulars should be entered in legible letters.

At the time of Screening, a session on health education should be conducted according to the guidelines set by the Health Education Bureau.

Human Resources

The team should consist of the following categories of health staff,

- Medical Officers
- Public Health Nursing officer or Nursing Sisters or Nursing officer
- Public Health Midwife of the respective area
- Public Health Inspector of the respective area
- Medical Laboratory Technologists
- Other necessary supportive staff.

Implementation Plan

At the outset of the programme, an implementation plan for each district should be drafted covering the entire high risk area. The Provincial and Regional Directors of Health Services, Regional Epidemiologists, Medical Officers (CKD Prevention), Medical Officer – in – Charge of the Renal Research Unit of the NCP (in case of Anuradhapura and Polonnaruwa Districts only) and heads of curative care institutions should take part in the planning process. The areas with high disease burden should be covered in the initial stages of the programme.

Following factors need to be considered in planning the programme.

- Spatial distribution of cases
- Availability of logistics
- Availability of human resources
- Capacities of laboratories to handle samples
- Routine health care delivery in the field

The plan should include

- The number of clinic sessions per district with a breakdown at MOH division level for each quarter
- Locations of field screening clinics
- Tentative date of each clinic
- Locations and tentative dates of central screening clinics
- The number of individuals to be covered in each clinic session
- Human resource mobilization plan for each clinic

The tentative district programme should be submitted to the Deputy Director General of Health Services (Public Health Services) I and the Chief Epidemiologist.

Monitoring and Evaluation

The programme would be continuously monitored and evaluated quarterly at district, provincial and national level.

The Regional Directors and the Provincial Directors should continuously monitor the implementation of the screening programme in the respective districts and provinces. At district level, monthly evaluation needs to be conducted

before the 10th of the subsequent month and the evaluation report should be submitted to the office of the PDHS and the Chief Epidemiologist.

Quarterly review would be conducted at the Epidemiology Unit with the participation of PDHSS, RDHSS, REE, and MOO/CKD at the end of each quarter.

District level Indicator and targets

- Total number screened during the month

- Proportion of Screening Clinics conducted

$$\frac{\text{Number of clinics conducted}}{\text{Number planned for the same period}} \times 100 = \text{target } 100\%$$

- Percent coverage of screening at field clinics

$$\frac{\text{Number screened at field clinic}}{\text{Number planned}} \times 100 = \text{target } 100\%$$

- Percent positive

$$\frac{\text{Number positive}}{\text{Number screened}} \times 100 = \text{target } 100\%$$

- Number screened at the central clinic

- Percent screened at central clinic

$$\frac{\text{Number screened}}{\text{Number planned for the same period}} \times 100 = \text{target } 100\%$$

In addition, at district reviews, attention must be paid to any failures in conducting the total planned number of clinics for

each month. In-depth fact finding analysis needs to be done as to the cause for failing to conduct the planned number of clinics. Remedial actions need to be identified to prevent further failures of similar nature.

Further, analysis needs to be done to investigate into any other reasons for the gap between the target and the reported percent coverage of screening.

National level Indicators

- Total number screened
- Percent coverage
- Percent positive

National level indicators will be analyzed at quarterly reviews. In addition, the programmatic issues will be looked into.

Data Analysis and dissemination of information

Data will be compiled and analyzed at the Epidemiology Unit together with the statistics generated by the Sentinel Surveillance and information will be published in the Quarterly Epidemiological Bulletin.