



STANDARD OPERATING PROTOCOL for Implementation of **CHRONIC KIDNEY DISEASES** Component under **NP-NCD**



***This SOP is part of Medical Officers' Manual for prevention and management of Chronic Kidney Diseases issued by MoHFW, GoI-2022**



TABLE OF CONTENTS

Title	Page No
Introduction	1
Magnitude of Chronic Kidney Disease (CKD): Global and Indian Perspective	
Integration with Continuum of Care for CKD Patients	
About the SOP: Purpose and Intended Users	
Chronic Kidney Disease	2
Definition	
Acute Kidney Injury (AKI) and Acute Kidney Disease (AKD)	
Chronic Kidney Disease (CKD)	
Causes, Risk Factors of CKD and Risk Multiplier for Other NCDs	2-3
CKD Progression and Contributing Factors	3-4
Compensatory Mechanisms and CKD Complications	4
Factors Causing CKD Progression and Treatment Measures	5
Diagnosis of CKD and Its Pitfalls	
CKD Staging	6
Albuminuria Measurement	
Proteinuria Measurement	
Principles of Management of CKD	7
Lifestyle Management	
Management of Intra-renal Factors	8
Conservative Management	
Role of Medical Officer in Prevention and Management of CKD	9
Early Detection of CKD	
CKD-EPI Creatinine Equation (eGFR Calculation)	
Reducing the Risk of CKD Progression	10
Treatment and Monitoring of Hypertension	10-11
Treatment and Monitoring of Diabetes	11
Detecting Risk Factors of Other/Concomitant NCDs	
Early Detection and Follow-up of CKD-related Complications	12
Referral to Physician/Nephrologist	12-13
Counselling and Preparation for Renal Replacement Therapy (RRT)	14
Role of Community Health Officer (CHO)	15
Role of ASHA/ANM at Community Level and Sub-centre/HWC Level	16

1. INTRODUCTION

Magnitude of Chronic Kidney Diseases (CKD): Global and Indian perspective

CKD constitutes to a major part of the NCDs burden and is a public health problem globally. CKD represents an especially large burden in low- and middle-income countries, which are least equipped to deal with its consequences. With a global prevalence of 13.5%, it is estimated that approximately 500 million people suffer from CKD, of which 80% live in low middle income countries. According to ICMR report on “India: Health of the Nation’s States” (2017), CKD is 9th frequent cause of death in India.

Integration with focus on continuum of care for CKD patients

For early detection, management, appropriate referral and continuum of care, the care for CKD patients under the NHM is to be streamlined with Ayushman Bharat including Comprehensive Primary Health Care, and Pradhan Mantri National Dialysis Programme (PMNDP). As the treatment and rehabilitation for CKD patients are costly option, hence focus is to create awareness in the community for effective prevention and early detection, referrals and treatment.

About the SOP: What and for whom?

This SOP is primarily to be used by the Medical Officers for prevention, early detection and management of CKD patients reporting at Primary Health Center/ Ayushman Arogya Mandir (AAM) level. The SOP also briefly mention the roles and responsibilities of the supporting staff, i.e CHOs, MPWs and ASHAs worker in prevention and early detection of the CKD patients.

2. CHRONIC KIDNEY DISEASE

A. Definition

“Kidney disease” is manifested by evidence of urinary abnormality (Proteinuria and Hematuria) and/or radiological abnormality and/or decrease in kidney function as assessed by increase in serum creatinine (corresponding to decrease in Glomerular Filtration Rate, GFR). Kidney diseases are broadly divided into Acute Kidney Injury (AKI) and Chronic Kidney Disease (CKD).

Acute Kidney Injury (AKI) and Acute Kidney Disease (AKD)

AKI, earlier called as Acute Renal Failure (ARF), is defined as an abrupt (within hours) decrease in kidney function, which encompasses both injury (structural damage) and impairment (loss of function). Patients of AKI, who does not recover within one month, are then labeled as acute kidney disease (AKD) till the end of 3 months, after which if disease persist, it is called CKD.

AKI is diagnosed by:

- An absolute increase in S.Cr., at least 0.3 mg/dl within 48 hours, or
- By a 50% increase in S.Cr., from baseline within 7 days, or
- A urine volume of less than 0.5 ml/kg/h for at least 6 hours

Chronic kidney disease

CKD is defined as evidence of kidney disease with/without decrease in GFR <60 ml/min/1.73 m², persistent for more than 3 months in absence of reversible factors. Evidence of kidney disease is primarily defined by increase in urine protein beyond 30 mg/day.

B. Causes, Risk factors of CKD and Risk multiplier for other NCDs

Causes and Risk Factors of CKD: CKD is not a single disease. It is a syndrome which has many causes. The common causes of CKD are as below:

- Diabetes mellitus-Commonest cause responsible for 35-40% CKD patients
- Hypertension- 2nd common cause responsible for ~15% CKD patients
- Glomerulonephritis- ~ 15% cases of CKD
- Tubulo-interstitial diseases including renal stone and Vesico-Urethral Reflux VUR (~15% CKD cases)
- Cystic diseases of kidney- (~5% CKD patients)
- CKD of undetermined cause- (~10% CKD cases)
- Other miscellaneous causes- (AKI, CVD, Obesity, etc.)

The need of the hour is to target the risk factors of CKD and strive for aggressive risk factor reduction, as this would not only aid in decreasing the burden of CKD and concurrently other NCDs, but it will also reduce the multiplier impact of CKD on other NCDs.

C. CKD progression and its factors

Once correctly diagnosed, CKD cannot be cured by any treatment. It is a progressive kidney disease and invariably progresses to End Stage Kidney Disease (ESKD) irrespective of the cause of initial injury. Retardation progression of CKD and delaying the need for dialysis and/or renal replacement therapy (RRT) is one of the main purposes of conservative management of CKD.

Progression of CKD can occur in a linear and predictable pace or in a non-linear, rapid pace. Majority of the risk factor are potentially modifiable. Progression of CKD is mediated by multiple factors:

I. Progression of initial disease causing CKD

- **Hypertension:** It accelerates glomerulosclerosis and other injurious cascades. Recommended target BP in CKD patients is <130/80 mmHg. A systolic BP of <120 mmHg is suggested if tolerated by the patient.
- **Hyperglycemia:** A tight glycemic control has been demonstrated to prevent, minimize and retard microvascular and macrovascular complications of diabetes including diabetic nephropathy.
- **Proteinuria:** It augments renal injury by multiple mechanisms.

II. Intermittent acute factors causing AKI on pre-existing CKD:

In a patient of CKD, any factor which can potentially cause AKI, usually results in progression of pre-existing CKD. Therefore, all such factors should be prevented and if they develop, then should be promptly treated.

- a. Volume depletion
- b. Hypotension
- c. Systemic infection
- d. Urinary tract infection
- e. Nephrotoxin drugs
- f. Urinary tract obstruction
- g. Hypercalcemia
- h. Contrast nephropathy

III. Compensatory mechanism and complications of CKD

- Protein Restriction: Current guidelines suggest consideration of dietary protein restriction to <1.0 g/kg/day for patients with Stage 3 CKD, and <0.8 g/kg/day for patients with Stage 4-5 CKD.
- Secondary hyperparathyroidism: Failing kidneys lead to phosphate retention, decrease in active vitamin-D3 and secondary hyperparathyroidism to compensate divalent abnormalities. Secondary hyperparathyroidism increases the CKD progression.
- Acidosis: Metabolic acidosis is a complication of CKD, particularly when glomerular filtration rate falls to <30 ml/min.
- Smoking: It induces oxidative stress, causes endothelial dysfunction, enhances micro-inflammation, and favors a pro-thrombotic state. Rapid worsening of glomerulosclerosis and tubular atrophy has been demonstrated with smoking.
- Obesity: It worsens CKD through direct (i.e., inflammation, and alternations of glomerular hemodynamics) and indirect (i.e., increased risk of diabetes, hypertension) mechanisms.
- Obstructive Sleep Apnoea (OSA): It is more prevalent among CKD patients & can cause and perpetuate kidney injury.
- Hyperlipidemia: Dyslipidemia contributes for the high cardiovascular morbidity and mortality in CKD and possibly for progression of CKD.

Table: Factors causing progression of CKD and treatment measures

CKD Progression Factors	Management
Hypertension	BP control Target BP: <130/80 mmHg
Hyperglycaemia	Target HbA1C <7
Proteinuria	RAAS inhibitors
Acidosis	Oral bicarbonate supplementation
Nephrotoxic agents	To be avoided
Obesity	Weight reduction
Obstructive sleep apnoea	Weight reduction, CPAP if needed
Smoking	Cessation of smoking
Periodontitis	Antimicrobials
Other infections	Appropriate antibiotics
Protein consumption	Restriction of protein

D. Diagnosis of CKD and its pitfalls

For diagnosis of CKD, both in hospital setting as well as in community, urine albuminuria and GFR measurements both are crucial and practical parameter. Measurement of GFR is cumbersome process and impractical in community setting, GFR is ‘estimated’ by various formulas using S. Cr. value, so called estimated GFR (eGFR).

CKD is staged into five stages based on GFR. Following table gives various stages of CKD. In addition to stage, if patient is on dialysis then “D” has to be added and if patient had transplant then “T” has to be added. For example, stage 3 CKD with transplant, needs to be written as Stage-3T.

Table: Stages of CKD

Stage	Description	GFR ml/mt/1.73m2
1	Evidence of Kidney disease with normal or ↑ GFR	> 90
2	Mild ↓ in GFR	60-89
3a	Mild to Moderate ↓ GFR	45-59
3b	Moderate to severe ↓ GFR	30-44
4	Severe ↓ GFR	15-29
5	Kidney failure	< 15 or on Dialysis

Albuminuria Measurement

By itself, eGFR is not sufficient for identifying stage 1 and stage 2 CKD, because in those patients the GFR may in fact be normal to near normal. Following are various other markers of kidney disease, though from a public health perspective in community setting, albuminuria is the only point of care marker which can be done for making diagnosis of CKD.

- Albuminuria (albumin excretion >30 mg/24 hours or albumin creatinine ratio >30 mg/g)
- Urine sediment abnormalities
- Electrolyte and other abnormalities due to tubular disorders
- Histologic abnormalities
- Structural abnormalities detected by imaging

Finally, for labelling a patient of kidney disease as “chronic”, the same tests need to be repeated after 3 months to qualify it as “chronic kidney disease”.

Proteinuria Measurement

The commonest semiquantitative method available to screen is the standard urine dipstick primarily detects albumin and is relatively insensitive to non-albumin proteins. The dipstick is very specific but not sensitive to low levels of albumin excretion. The lower limit of detection is a urine albumin concentration of approximately 10 to 20 mg/dL. Microalbuminuria will usually not be identified by this method.

Approximately corresponding value of UPCR with dipstick test is as below:

- Trace: UPCR <30 mg/g
- 1+: UPCR 30-300 mg/g

- Trace: UPCR <30 mg/g
- 1+: UPCR 30-300 mg/g
- 2+: UPCR >300 mg/g
- 3+: UPCR 300-3500 mg/g
- 4+: UPCR >3500 mg/g

For further details please refer to Medical Officers' Manual for Prevention and Management of Chronic Kidney Diseases issued by MoHFW, GoI-2022.

E. Principles of Management of CKD

CKD is usually a relentlessly progressive disease. There are 4 basic aims of management of CKD:

1. Retarding progression of CKD to delay the need of RRT
2. Keep the patient symptom free so that he/she can lead near normal life
3. Prevent and treat complications
4. Best prepare patient for most suitable RRT for him

Step 1: Lifestyle management for patients with CKD

- **Smoking cessation**
- **Weight reduction:** Obese and overweight people should be encouraged to reduce their BMI. Maintenance of healthy body weight of 18.5-22.9 kg/m²; waist circumference <90 cm for men, and < 80 cm for women, is recommended to reduce blood pressure in those with hypertension.
- **Dietary protein control:** A protein-controlled diet (0.8 g/kg/d) is recommended for adults with CKD. Protein < 0.80 g/kg/day should be carefully monitored for clinical and biochemical markers of nutritional deficiencies and malnutrition.
- **Alcohol intake:** Alcohol consumption should be discouraged to control hypertension.
- **Exercise:** A total of 30 minutes, 5 times a week exercise may be a helpful measure for protection from cardiovascular problems. Higher intensity exercises should be avoided.

- **Dietary salt intake:** A dietary sodium intake of < 100 mmol/day (~ 5 g of table salt) is recommended to control hypertension. Patients with T1D may not require reduction in salt intake. Normal salt should be decreased rather than using other alternate salt preparations.

Step 2: Intra-renal factors associated with progression of CKD and its management

Interventions to slow the progression of CKD to ESKD are cost-efficient approaches. It synergizes for the management of diabetes, hypertension, and vascular disease.

Step 3: Conservative management of clinically relevant factors

- **Hypertension:** ACEi and ARB retard CKD's progression through hemodynamic and non-hemodynamic ways by preventing fibrosis. CKD patients also require multiple classes of antihypertensive.
- **Diabetes Mellitus:** Besides RAS blockers, the addition of SGLT2i, further slows the progression of DKD by reducing intraglomerular hypertension and hyperfiltration injuries. For further details refer to Medical Officer's Manual for Prevention and Management of Chronic Kidney Diseases.

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3. ROLE OF MEDICAL OFFICER IN PREVENTION AND MANAGEMENT OF CKD

Medical officer at PHC is expected to have the following roles and responsibilities in prevention and management of CKD:

- Early Detection of CKD
- Reduce the risk of progression
- Detecting the risk factors of other/Concomitant NCDs
- Early detection, follow-up and management of CKD associated complications.
- Referral for consultation at higher center
- Counseling for Renal Replacement Therapy (RRT) for ESKD

A. Early Detection of CKD

- Opportunistic screening of all individuals >30 years at higher risk for CKD
 - Diabetes mellitus
 - High blood pressure
 - Family history of CKD
 - Age >60 years
 - History of acute kidney injury (AKI)
- Order:
 - Urine Routine (albumin, glucose) by Dipstick
 - Serum Creatinine (calculate eGFR where available)
- Confirm CKD and classify the stage as per national guidelines.
- Register diagnosed patients for regular follow-up.

2021 CKD-EPI Creatinine equation

Expressed as a single equation

$$eGFR = 142 \times \min(Scr/\kappa, 1)^\alpha \times \max(Scr/\kappa, 1)^{-1.200} \times 0.9938^{Age} \times 1.012$$

(if female)

Abbreviation/Units

$$eGFR \text{ (estimated glomerular filtration rate)} = \text{mL/min/1.73 M}^2$$

Scr (standardized serum creatinine) = mg/dL; divide by 88.4 for creatinine in $\mu\text{mol/L}$

$k = 0.7$ (females) or 0.9 (males)

$\alpha = -0.241$ (females) or -0.302 (males)

min = indicates the minimum of Scr/k or 1

max = indicates the maximum of Scr/k or 1

age = years

B. Reduce the risk of progression

Role of primary care physician in retarding the progression is as follows:

- I. Monitor and follow-up of patient in relation to treatment planned at higher centre
 - Treatment of primary disease, causing CKD
 - Treatment in relation to factors causing CKD progression like proteinuria, hypertension, hyperparathyroidism, hyperlipidaemia etc.
- II. Prevent and manage acute factors responsible for CKD progression
 - Any systemic infection
 - Fluid loss and dehydration
 - Avoiding nephrotoxic drugs (refer Chapter-1)

Treatment and monitoring of hypertension

Blood Pressure Target in CKD:

Degree of albuminuria	BP Target (mm/Hg)
<300 mg/day	140/90
300 mg/day or more (dipstick method)	130/80

Choice of Anti-hypertensive drug:

- The choice of antihypertensive therapy in CKD should be considered based on the level of proteinuria.

- ACE inhibitor or angiotensin II receptor blocker (ARB) as first-line therapy in patients with proteinuric CKD (i.e., albumin excretion greater than 300 mg/day by dipstick).
- Before starting on ACE-I/ARB therapy, S. Cr. and Potassium should be done. Significantly high creatinine (> 3.0 mg/dl) and high K (> 5.0 meq/L) may make patient unfit for these drugs.
- S. creatinine and serum K should be repeated after 1-2 weeks of starting ACE-I/ARB therapy and after every time dose is increased.

Note: If serum creatinine rises $> 30\%$ or serum K rises > 5.5 meq/L, these drugs should be stopped and other drugs should be used.

Treatment and monitoring of diabetes

- Tight control of blood sugar in diabetic will delay the development and progression of the CKD.
- HbA1c between 6.5 to 7 should be target of good control.
- The targets need to be relaxed in the advanced stage of CKD (Stage-4 and 5), individuals at high CVD risk and older individuals. ($\text{HbA1c} \geq 7$).

C. Detecting the risk factors of other/concomitant NCDs

Role of primary care physician in this regard is as follows:

- Population based and opportunistic screening of all individuals > 30 years for DM & HT
- Counseling for life-style modification
 - Weight control
 - Avoid smoking
 - Balanced healthy diet (Low salt and low cholesterol diet)
 - Regular exercise, at least 45 minutes, five days in a week. In case of heart disease, before starting exercise, consultation with expert is needed
- Monitoring the treatment planned by higher centre for hyperlipidemia, cardiovascular disease etc.

D. Early detection and follow-up of management of CKD associated complications

With decline in GFR, there is disruption of these functions, which need to be investigated and managed. Role of primary care physician in this regard is as follows:

- Monitoring of diet* with an aim to control:
 - Body fluid
 - High Blood pressure
 - Blood sugar
 - Hyperlipidemia
 - Hyperkalemia
 - Hyperphosphatemia
- Adjust doses of drugs as per eGFR
- Screening and managing anemia due to other than erythropoietin deficiency like nutritional and blood loss*

For further details please refer to Medical Officers' Manual for Prevention and Management of Chronic Kidney Diseases issued by MoHFW, GoI-2022.

E. Referral to physician/nephrologist for consultation

Patients of CKD can best be treated by a team of primary care physician and nephrologists. In many situation, treatment can be started by primary care physician. In other situations, it requires expertise of nephrologists. Although once treatment has been started by nephrologists, patient can be followed by primary care physician. Thus, it is important for primary care physician to know that in which setting, patient is to be referred to nephrologists. Primary care physician should broadly refer following patients to nephrologists/physician for consultation:

- Patient of CKD, who need kidney biopsy for making original kidney disease
- Patients of CKD with intrinsic renal disease for planning continuation of specific therapy like patients with:

- Primary glomerular diseases
- Connective tissue disorders with kidney involvement
- Polycystic kidney disease
- Obstructive uropathy
- All patients of CKD stage-3 onward at the time of diagnosis for planning long-term treatment
- All CKD with complications like:
 - Systemic infection
 - Cardiovascular disease
- CKD with uncontrolled hypertension
- CKD with uncontrolled diabetes
- CKD who are expected to initiate following therapies:
 - Erythropoietin stimulating agents
 - Vitamin-D
 - Calcimimetic drugs
 - ACE-I and ARB
 - IV Iron therapy
- CKD patient scheduled for surgery
- CKD patient planning for pregnancy
- CKD patient require consultation and preparation for RRT.

Following is the heat map suggesting when a patient of CKD should be managed by primary care physician and when patient should be referred to nephrologist as per stage of eGFR and stage of albuminuria:

Figure-7

				Persistent albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30–300 mg/g 3–30 mg/mmol	>300 mg/g >30 mg/mmol
GFR categories (ml/min/ 1.73 m ²) Description and range	G1	Normal or high	≥90		Monitor	Refer*
	G2	Mildly decreased	60–89		Monitor	Refer*
	G3a	Mildly to moderately decreased	45–59	Monitor	Monitor	Refer
	G3b	Moderately to severely decreased	30–44	Monitor	Monitor	Refer
	G4	Severely decreased	15–29	Refer*	Refer*	Refer
	G5	Kidney failure	<15	Refer	Refer	Refer

F. Counselling and preparation for RRT for ESKD

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- Role of primary care physician in this aspect is as follows:
- Patients should be subjected to initial counseling for RRT once they are in stage-4 CKD.
- Update the list of the CKD patients in the need of RRT.
- Mapping of the District hospital registered for providing the RRT under the PMNDP.
- Develop referral linkages with the nephrologists and RRT under the PMNDP.
- Vaccination of CKD patients for Hepatitis B vaccine and other vaccinations as soon as diagnosis of CKD is made. CKD patients should be explained to prevent blood borne infection by avoiding high-risk behavior.
- Patients should be advised to preserve both fore-arm veins for arterio-venous fistula for possible future hemodialysis.

4. ROLE OF COMMUNITY HEALTH OFFICER (CHO) RELATED TO CKD FACTORS

- Population based screening for common NCDs including Hypertension and Diabetes mellitus.
- Assessment of patients diagnosed with hypertension and/or diabetes for risk of developing CKD, followed by appropriate referral to higher facilities. CHO can use the same checklist as suggested in the CKD guidelines for inclusion in CBAC form.
- Ensuring routine urine examination and serum creatinine of patients diagnosed with hypertension and diabetes and presenting with other risk factors.
- Counselling regarding lifestyle modification, including diet related advice, weight control, tobacco consumption.
- Ensuring treatment adherence of patients with hypertension and diabetes.
- Ensuring continuation of treatment of patients diagnosed with CKD and monitoring for complications.
- Followup visits by primary healthcare team led by CHO to CKD patients, wherever required.
- Ensuring continuation of dialysis treatment (hemodialysis or peritoneal dialysis) for those identified with the requirement for same. CHO may facilitate peritoneal dialysis treatment at home through home visits.

5. ROLE OF ASHA/ANM AT COMMUNITY LEVEL AND SUBCENTRE/HWC LEVEL: SCREENING

While filling the CBAC (Community Based assessment Checklist) form, ASHA collects information on few common risk factors of NCD that exaggerate the risk for CKD as well, i.e., obesity (by measuring waist circumference), age >60 years. Few other risk factors for CKD may also be asked as a part of CKD screening. Personal H/o:

- Diabetes
- Hypertension
- Known of kidney stones
- Recurrent UTIs
- Swelling on legs and face
- Known of low Hb with chronic anemia other than pregnant and lactating female.
- Known family Kidney disease.
- Known Cardiovascular event
- Known kidney disease
- Past History of Acute Kidney Disease

All individuals with any risk factor for CKD may be referred to PHC for routine urine examination and serum creatinine and screening for other NCDs (DM, HT and three common cancers as mentioned in MO module)



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