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RESEARCH ARTICLE

Economic Evaluation of Point-of-Care Creatinine Testing Compared with Conventional Laboratory-Based Testing for Early Detection of Chronic Kidney Disease in India: A Decision-Analytic Model

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ABSTRACT

Background: Chronic kidney disease (CKD) affects an estimated 128 million adults in India, yet early detection remains hampered by reliance on centralised laboratory infrastructure with turnaround times of 24–48 hours. Point-of-care (POC) creatinine/estimated glomerular filtration rate (eGFR) testing offers a rapid, decentralised alternative. However, robust economic evidence comparing POC testing with conventional laboratory methods in the Indian context is lacking.

Methods: A decision-analytic model (decision tree) was constructed to compare the cost-effectiveness of POC creatinine/eGFR testing (NOVA MAX system) with conventional laboratory-based testing from a societal perspective over a one-month time horizon, capturing the full diagnostic episode and its immediate clinical consequences. The model incorporated direct medical costs (test, consumables, staff, equipment, confirmatory investigations) and indirect costs (patient travel and productivity loss). Clinical accuracy parameters sensitivity (0.43–0.44) and specificity (0.97–0.98) were derived from a systematic review and meta-analysis. Health outcomes (QALYs) were derived by applying published EQ-5D utility weights to each diagnostic outcome category (TP, TN, FP, FN) over the model time horizon. India's willingness-to-pay (WTP) threshold of ₹2,31,784 per QALY was applied. One-way (OWSA) and probabilistic sensitivity analyses (PSA) with Monte Carlo simulation were performed.

Results: In the base-case analysis, mean costs per patient were ₹317 (POCT) and ₹419 (laboratory testing), yielding an incremental cost of −₹102 in favour of POCT. Incremental QALYs were −0.135, placing the ICER at ₹1,276 in the south-west quadrant of the cost-effectiveness plane, indicating POCT is cost-saving. The cost-effectiveness acceptability curve demonstrated that POCT had a 90–92% probability of being cost-effective across all WTP thresholds examined. Tornado plot analyses identified POCT true-positive probability as the dominant driver of model uncertainty.

Conclusion: POC creatinine testing is a cost-saving and operationally superior strategy compared with conventional laboratory testing for early CKD detection in India. Despite marginally lower QALYs attributable to moderate sensitivity, the substantial cost advantages and suitability for decentralised settings make POCT a pragmatic, scalable complement to laboratory assays, particularly aligned with India's National Programme for Prevention and Control of Non-communicable Diseases (NPCDCS).

Keywords: chronic kidney disease; point-of-care testing; creatinine; cost-effectiveness analysis; India; eGFR; decision tree model; low- and middle-income countries

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INTRODUCTION

Chronic kidney disease (CKD) represents one of the foremost global public health challenges of the twenty-first century, affecting approximately 850 million individuals worldwide and ranking among the ten leading causes of death.[1] According to the Global Burden of Disease (GBD 2023) study, CKD accounts for nearly four million deaths annually and is projected to become the fifth leading cause of mortality by 2040.[2] The burden falls disproportionately on low- and middle-income countries (LMICs), where limited healthcare infrastructure,

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delayed diagnosis, and restricted access to specialist renal care amplify both morbidity and mortality[3]

In India specifically, CKD affects an estimated 128 million adults, representing one of the world's largest national disease burdens.[4] Approximately 17% of Indian adults exhibit some degree of renal dysfunction, with uncontrolled diabetes mellitus and hypertension identified as the principal drivers.[5] The insidious, asymptomatic progression of CKD frequently results in late-stage presentation, by which point costly interventions such as renal replacement therapy or transplantation become unavoidable, imposing profound financial strain on both health systems and households.

Early detection through serum creatinine measurement and calculated estimated glomerular filtration rate (eGFR) is universally recognized as the cornerstone of preventing CKD progression.[6] Current clinical guidelines advocate risk-based screening of high-risk populations, particularly those with diabetes, hypertension, or cardiovascular disease. However, conventional laboratory-based creatinine assays, whether enzymatic or Jaffé method, depend on centralized infrastructure, trained technical personnel, and electricity-dependent analyzers. In many Indian districts and primary-care facilities, this translates into reporting delays of 24–48 hours, impeding timely clinical decision-making and increasing downstream costs through repeat visits and delayed treatment initiation.[7]

Point-of-care (POC) diagnostics—portable, rapid, and operator-friendly devices capable of providing bedside or community results from small capillary or whole blood samples—represent a technologically mature and operationally viable solution. POC creatinine/eGFR devices yield immediate results, enabling same-day clinical decisions in emergency, radiology (pre-contrast assessment), and primary-care outreach settings.[8,9] Integration of validated POC technologies into national screening frameworks could substantially strengthen decentralised and equitable CKD detection.

A recent systematic review and meta-analysis confirmed that POC creatinine/eGFR devices exhibit moderate sensitivity (0.43–0.44) and high specificity (0.97–0.98) relative to laboratory reference assays, establishing their reliability as first-line screening tools capable of effectively ruling out CKD.[10] Despite growing clinical adoption, robust economic evaluations comparing POC and conventional laboratory testing in the Indian context remain scarce. Given that 77% of total diagnostic costs in India constitute direct out-of-pocket medical expenses, a shift toward POC testing could meaningfully alleviate financial burden on both providers and patients.

This study therefore aims to conduct a cost-effectiveness analysis (CEA) from a societal perspective, comparing POC creatinine/eGFR testing with conventional laboratory-based methods for early CKD detection in India, incorporating both direct medical and indirect productivity costs to inform health-policy and procurement decisions.

METHODS

Study Design

A deterministic decision tree model was developed to compare the cost-effectiveness of POC creatinine/eGFR testing with conventional laboratory-based creatinine testing for early CKD detection. The model structure simulates diagnostic pathways for individuals undergoing renal function assessment in clinical or community screening settings, capturing both costs and health outcomes associated with each testing strategy. The analysis adhered to the CHEERS 2022 reporting checklist for economic evaluations.

Study Population and Setting

The study population comprised adults aged ≥18 years undergoing renal function assessment for suspected or risk-based CKD screening in hospital, diagnostic, or community healthcare settings across India. The target population encompasses individuals with comorbidities including diabetes mellitus, hypertension, cardiovascular disease, or exposure to nephrotoxic agent groups for whom routine creatinine/eGFR monitoring is clinically indicated. The analysis is undertaken from a societal perspective, incorporating both health-system and patient-level costs.

Intervention and Comparator

The intervention arm comprised POC creatinine/eGFR testing performed using the NOVA MAX portable analyzer, a handheld device capable of providing immediate results at the patient's bedside using whole blood or capillary samples without centralized laboratory infrastructure. This device is particularly suited for application in radiology departments (pre-contrast nephropathy screening), emergency settings, and primary care outreach.

The comparator arm represented conventional laboratory-based creatinine testing, in which venous blood samples are analyzed using enzymatic or Jaffé methods in centralized diagnostic laboratories—the current reference standard for renal function evaluation. While analytically superior, laboratory testing is associated with turnaround times of 24–48 hours, dependence on skilled technical personnel, and greater indirect costs arising from delayed diagnosis and repeat patient visits.

Model Structure

The decision tree commenced with a hypothetical cohort of individuals requiring renal function assessment. Each individual entered one of two diagnostic strategies: POC testing or laboratory testing, forming the initial branches. Within each strategy, the model stratified by true disease prevalence (CKD present or absent), and within each stratum, the test could yield a correct or incorrect classification, producing four terminal outcomes: true positive (TP), false negative (FN), true negative (TN), and false positive (FP).

For each terminal node, the model assigned (i) direct medical costs including per-test expenditure, consumables,

Table 1: Model input parameters, values, distributions, and sources

Parameter	*Value / Range*	*Distribution (PSA)*	*Source*
CKD prevalence in screened population	0.35 (0.25–0.45)	Beta	Talukdar et al., 2025
POCT sensitivity	0.435 (0.43–0.44)	Beta	Systematic review & meta-analysis
POCT specificity	0.975 (0.97–0.98)	Beta	Systematic review & meta-analysis
Lab sensitivity (reference)	0.95 (0.90–0.99)	Beta	Van Stralen et al., 2009
Lab specificity (reference)	0.98 (0.95–0.99)	Beta	Van Stralen et al., 2009
Cost of POCT (per test)	₹250 (₹200–₹350)	Gamma	Market survey; Chandrasekar et al., 2025
Cost of laboratory test (per test)	₹350 (₹280–₹450)	Gamma	Published tariff schedules
Cost of confirmatory testing (FP/FN)	₹500 (₹350–₹700)	Gamma	Assumption; expert elicitation
Patient travel cost (POCT)	₹30 (₹10–₹60)	Gamma	National Family Health Survey estimates
Patient travel cost (Lab)	₹80 (₹50–₹120)	Gamma	National Family Health Survey estimates
Productivity loss: POCT (per episode)	₹37 (₹20–₹60)	Gamma	Minimum wage × time lost
Productivity loss: Lab (per episode)	₹89 (₹60–₹130)	Gamma	Minimum wage × time lost (2 visits)
Utility: CKD correctly detected (TP)	0.72 (0.65–0.80)	Beta	Sullivan et al. EQ-5D dataset
Utility: CKD undetected (FN)	0.60 (0.52–0.68)	Beta	Sullivan et al. EQ-5D dataset
Utility: True negative (TN)	0.85 (0.80–0.90)	Beta	Sullivan et al. EQ-5D dataset
Utility: False positive (FP)	0.78 (0.70–0.85)	Beta	Sullivan et al. EQ-5D dataset
Time horizon	1 month	—	Assumption (diagnostic episode)
Discount rate	Not applied (< 1 year)	—	ICER India guidelines
WTP threshold	₹2,31,784 per QALY	—	India GDP-based threshold

FN = false negative; FP = false positive; INR = Indian Rupee; POCT = point-of-care testing; PSA = probabilistic sensitivity analysis; QALY = quality-adjusted life year; TN = true negative; TP = true positive; WTP = willingness-to-pay

staff time, calibration costs, and confirmatory investigations where required; (ii) indirect costs including patient travel and productivity losses from waiting time or repeat visits; and (iii) health outcomes expressed as QALYs, with correctly identified cases (TP + TN) contributing to earlier treatment initiation and prevention of disease progression, and misclassified cases (FP + FN) incurring downstream costs from unnecessary follow-up or delayed therapy. The model applied a one-month time horizon, capturing the diagnostic episode and its immediate consequences. All values were expressed in 2024 Indian Rupees (INR).

Table 2: Base-case cost-effectiveness results: POCT versus laboratory testing

Parameter	*POC Testing (POCT)*	*Laboratory Testing*
Mean cost per patient	₹317	₹419
QALYs	21.5068	21.5846
Net Monetary Benefit (NMB)	₹4,997,124.98	₹50,02,472.68
Incremental Cost	₹−102	—
Incremental QALYs	−0.135	—
ICER	₹1,276	—
Incremental NMB	₹−31,061	—

ICER = Incremental Cost-Effectiveness Ratio; NMB = Net Monetary Benefit; QALYs = Quality-Adjusted Life Years.

A one-month time horizon was applied to capture the complete diagnostic episode and its immediate downstream consequences. This choice is methodologically appropriate because: (i) the primary decision being modelled is which diagnostic test to deploy at a single clinical encounter, rather than the long-term management of CKD; (ii) the differential costs and outcomes between POCT and laboratory testing are realised within days of testing; and (iii) longer-horizon modelling of CKD progression would require assumptions about treatment adherence and disease trajectory that extend well beyond the available evidence base for this diagnostic comparison. Nonetheless, we acknowledge that a full disease-lifetime model would capture important downstream benefits of earlier CKD detection, and this is highlighted as a priority for future research.

Clinical Parameters

Clinical accuracy parameters—sensitivity and specificity—were derived from a pooled systematic review and meta-analysis of published studies evaluating POC creatinine/eGFR devices against laboratory reference assays. Pooled sensitivity of 0.43–0.44 and specificity of 0.97–0.98 were applied to the POCT arm. These estimates reflect the moderate ability of POC devices to detect CKD (consequent on the inherent analytical

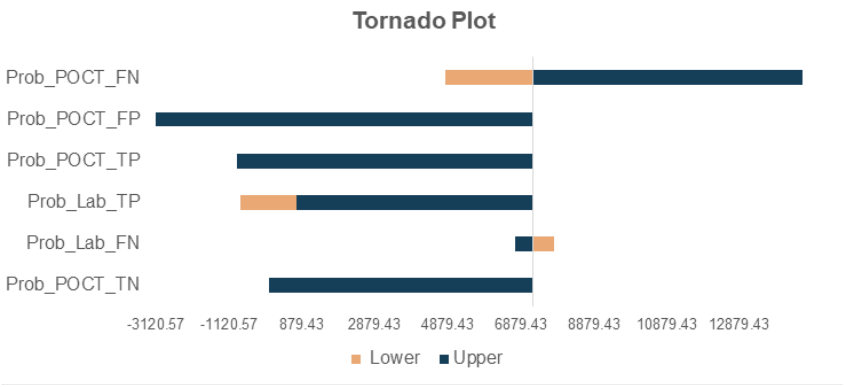

Figure 1: Tornado plot

variability of whole-blood measurements at low eGFR levels) alongside their strong capacity to rule out CKD, minimising false positives and unnecessary downstream investigation. Laboratory testing was assigned a sensitivity of 0.95 and specificity of 0.98 based on published validation studies.

Cost Parameters

All costs were expressed in 2024 INR and standardised to current price levels to ensure comparability. Direct costs comprised per-test consumables and reagent costs, staff time, equipment use and calibration, and the cost of confirmatory investigations for equivocal results. Indirect costs captured patient travel expenses and productivity loss arising from waiting time and repeat visits—components particularly material in the Indian context, where out-of-pocket expenditure constitutes the dominant mode of health financing. Full parameter values with ranges and distributions are presented in Table 1.

QALY Derivation

Quality-adjusted life years (QALYs) were calculated by applying published EQ-5D health-state utility weights to the proportion of time spent in each diagnostic outcome category over the one-month model horizon. Utility values were sourced from a validated preference-based dataset and differentiated by diagnostic classification: true positive (TP, utility 0.72)—representing CKD correctly identified and appropriately managed; false negative (FN, utility 0.60) representing missed CKD with consequent delayed treatment; true negative (TN, utility 0.85) representing a correctly reassured non-CKD patient; and false positive (FP, utility 0.78) representing an unwarranted diagnosis with associated patient anxiety and unnecessary follow-up. QALYs per patient were computed as: QALY = Σ (probability of outcome× utility weight × time in health state). The difference in QALYs between strategies reflects differences in diagnostic accuracy rather than treatment efficacy, consistent with the modelling objective

Outcome Measures

The primary economic outcome was the incremental cost-effectiveness ratio (ICER), calculated as the difference in mean cost between POCT and laboratory testing divided by the difference in effectiveness (QALYs gained). The secondary outcome was Net Monetary Benefit (NMB), expressed as (ΔEffect × WTP) − ΔCost, where India's cost-effectiveness threshold of ₹2,31,784 per QALY was applied as the WTP. Diagnostic outcomes including TP, FN, TN, and FP rates, as well as clinical outcomes (diagnostic turnaround time, early CKD detection rate) were reported as supporting measures.

Sensitivity Analyses

One-way sensitivity analysis (OWSA) was performed to assess the impact of individual parameter variation on model outcomes, identifying key drivers of uncertainty. Parameters were varied across plausible ranges derived from published literature. Results were displayed using a tornado diagram, ranking parameters by the magnitude of their influence on the ICER.

Probabilistic sensitivity analysis (PSA) was conducted using a Monte Carlo simulation of 10,000 iterations, simultaneously varying all parameters across their assigned distributions to quantify overall decision uncertainty. PSA outputs were used to generate a cost-effectiveness acceptability curve (CEAC), illustrating the probability that POCT is cost-effective across a range of WTP thresholds, and an ICER scatter plot on the cost-effectiveness plane. Parameter distributions are summarised in Table 1.

RESULTS

Base-Case Analysis

In the base-case analysis, POC testing (POCT) using the NOVA MAX system was associated with a lower mean cost per patient compared with conventional laboratory-based creatinine testing. The mean cost per patient was ₹317 for POCT versus ₹419 for laboratory testing, yielding an incremental cost of −₹102 in favour of POCT. In terms of health outcomes, POCT yielded 21.5068 QALYs compared with 21.5846 for laboratory testing, resulting in an incremental QALY of −0.135. The base-case results are summarised in Table 2.

The ICER of ₹1,276 is positioned in the south-west quadrant of the cost-effectiveness plane, indicating that POCT is simultaneously less costly and marginally less effective than laboratory testing. At India's WTP threshold of ₹2,31,784 per

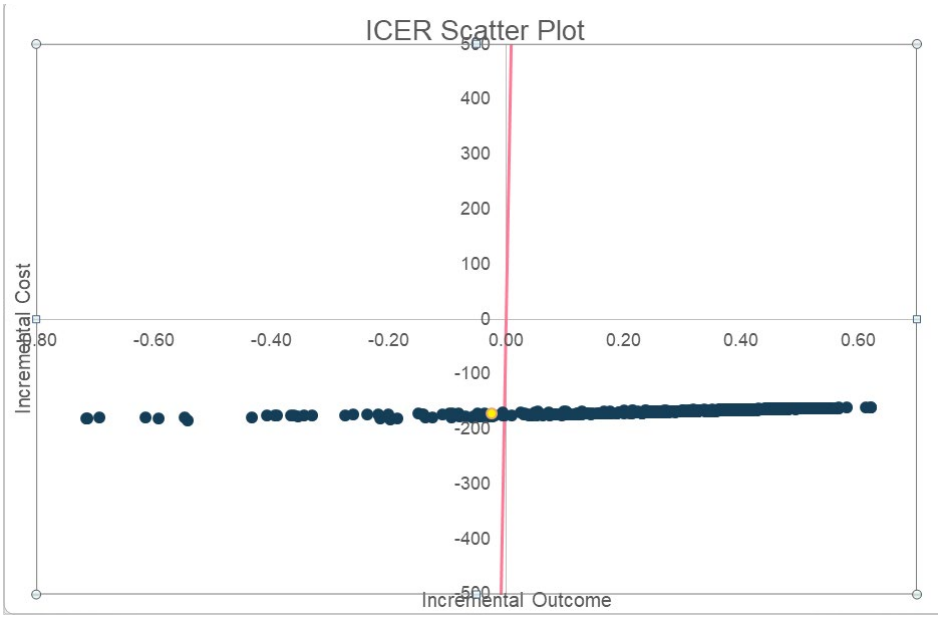

Figure 2: ICER Plot representing the 1000 Monte Carlo iterations

QALY, POCT is classified as a cost-saving strategy, as the cost savings per patient substantially outweigh the modest QALY decrement. The incremental NMB was −₹31,061, reflecting that at the prevailing WTP threshold, laboratory testing confers marginally greater net monetary benefit attributable to its higher QALY yield.

One-Way Sensitivity Analysis (OWSA)

The tornado diagram revealed that variation in the probability of true positive results for POCT produced the widest range of influence on incremental outcomes, identifying POCT diagnostic sensitivity as the primary driver of model uncertainty. Changes in the false-negative probability for POCT also produced meaningful shifts in the ICER, while variation in false-positive and true-negative probabilities exerted more moderate effects. Parameters associated with laboratory testing, including true-positive and false-negative probabilities, exhibited a narrower range of influence, confirming that comparative economic results between POCT and standard care are predominantly driven by assumptions regarding POCT diagnostic accuracy rather than uncertainty in laboratory test performance.

Probabilistic Sensitivity Analysis and Cost-Effectiveness Acceptability Curve

The ICER scatter plot from the PSA demonstrated that the

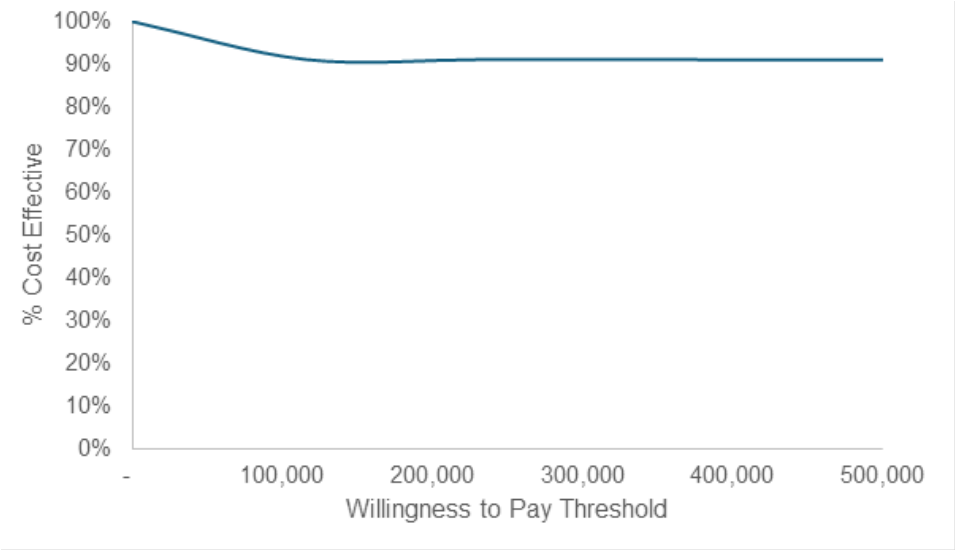

Figure 3: Cost-effectiveness acceptability curve

majority of Monte Carlo simulations were concentrated in the south-west quadrant of the cost-effectiveness plane, consistent with the base-case finding that POCT is cost-saving across most plausible parameter combinations. The cost-effectiveness acceptability curve (CEAC) indicated that POCT had a high probability of being economically favourable at lower WTP thresholds, reflecting the predominance of cost savings across probabilistic simulations. As the WTP threshold increased, the probability of POCT being cost-effective declined modestly and stabilised at approximately 90–92%, indicating increasing, though manageable, sensitivity to uncertainty in health outcomes. Across the full range of thresholds examined (up to ₹500,000 per QALY), POCT remained an economically plausible option under uncertainty.

DISCUSSION

This study demonstrates that POC creatinine/eGFR testing is a cost-saving diagnostic strategy compared with conventional laboratory-based testing for early CKD detection in India, assessed from a societal perspective. The economic advantage of POCT was driven principally by reduced reliance on centralised laboratory services, elimination of sample transport and processing delays, and shorter diagnostic turnaround times. These operational efficiencies translated into a ₹102 reduction in per-patient costs—an economically meaningful difference in a health system where out-of-pocket expenditure constitutes the dominant financing mechanism.

The moderate reduction in QALYs associated with POCT (−0.135) is mechanistically attributable to its pooled sensitivity of 0.43–0.44, which may result in under-detection of early or mild renal impairment—a limitation noted in prior clinical validation studies, including Inoue et al. (2017) and Nataatmadja et al. (2020), both of which reported marginal discrepancies in POC readings at lower eGFR levels.[11] Nevertheless, the high specificity (0.97–0.98) ensures that false positives remain minimal, substantially avoiding unnecessary confirmatory testing and associated costs.

The current findings align with a growing body of international evidence supporting the economic value of POC diagnostics. Florkowski et al. (2017) demonstrated that bedside biochemical testing significantly reduces waiting times and repeat visits, generating savings across both direct medical and productivity cost categories.[12] Similarly, Heidt et al. (2020) established that POC testing in resource-limited settings enhances diagnostic access and reduces long-term healthcare expenditures through early community-level disease detection.[8] In the specific context of CKD, Gama et al. (2024) reported that community-based implementation of POC kidney testing improved early CKD detection and continuity of care while reducing the burden on tertiary facilities.9 Snaith et al. (2018) and Dally et al. (2023) further demonstrated that POC creatinine testing prior to contrast-enhanced radiological procedures substantially reduces workflow bottlenecks and is cost-effective in preventing delays in imaging.[13,14] These operational advantages are particularly germane to India, where logistical barriers and high out-of-pocket expenditure impede timely CKD diagnosis.

From a health system perspective, the preventive economic value of early CKD detection extends beyond the diagnostic episode modelled here. POC testing facilitates early risk stratification, potentially averting downstream complications and the catastrophic costs of late-stage renal replacement therapy. Economic analyses by Mbata et al. (2024) and Currin et al. (2022) reaffirmed that decentralised diagnostic approaches are among the most cost-effective strategies for chronic disease management in LMICs.[15,16] The present analysis, with its one-month time horizon, conservatively captures only the immediate diagnostic consequences; a longer-horizon analysis incorporating disease progression and averted dialysis costs would likely yield even more favourable ICER estimates for POCT.

The CEAC findings are particularly instructive for policy decision-making. With POCT maintaining a 90–92% probability of cost-effectiveness across all WTP thresholds examined, the evidence base robustly supports POCT as an economically defensible choice even under substantial parameter uncertainty. The predominant driver of residual uncertainty in POCT sensitivity points to a clear research priority: improving POC device accuracy at lower eGFR ranges or developing hybrid diagnostic algorithms in which POC screening is followed by selective confirmatory laboratory testing for borderline results. This approach would preserve cost savings while offsetting any loss in diagnostic accuracy.

The study has several limitations. First, cost data capturing the full spectrum of diagnostic service delivery, including consumable logistics, equipment depreciation, and maintenance, were incompletely available, constraining granular scenario analyses across public versus private facilities or urban versus rural settings. Second, clinical accuracy parameters were derived from pooled literature estimates rather than local, multicenter validation studies, which may limit applicability in diverse Indian settings with heterogeneous population characteristics and operational workflows. Third, the model did not explicitly account for downstream health outcomes beyond the immediate diagnostic episode, including long-term CKD progression trajectories or cost offsets from reduced dialysis initiation. Finally, limited adoption of POC testing in public-sector programmes and the absence of standardized procurement and calibration protocols may restrict real-world generalizability and underestimate implementation variability.

Despite these limitations, the study's strengths include the use of a transparent decision-tree framework linking clinical accuracy and economic outcomes, the inclusion of productivity loss as an indirect cost component, standardization of all cost inputs to 2024 INR, and comprehensive uncertainty characterization through both deterministic and probabilistic analyses. These features enhance the relevance of the analysis for Indian health-policy and procurement decision-makers.

CONCLUSION

This economic evaluation demonstrates that POC creatinine testing is a cost-saving and practically superior alternative to conventional laboratory testing for early CKD detection in India. While marginally less effective in terms of QALYs due to moderate sensitivity, the substantial reductions in diagnostic costs, patient waiting time, and system inefficiencies alongside high specificity minimizing false-positive burdens underpin its value as a complementary first-line diagnostic tool, particularly in resource-limited and decentralized healthcare settings.

POC creatinine testing is well positioned to strengthen early CKD detection, align with the objectives of India's National Programme for Prevention and Control of Non-communicable Diseases (NPCDCS), and contribute to equitable renal health coverage at scale. With appropriate policy support, quality assurance frameworks, standardized calibration protocols, and targeted healthcare worker training, POC creatinine testing holds significant potential to transform the diagnostic landscape, optimize healthcare resource utilization, and enhance patient care outcomes across the Indian healthcare continuum.

Future research should prioritize multicenter economic evaluations capturing cost variations across settings with differing resource capacities and disease burdens, budget impact analyses for large-scale POC deployment, and operational research focused on digital data linkage and quality assurance for POC devices in routine care.

Future Research Directions

Several important research priorities emerge from this evaluation. First, multicentre economic evaluations across diverse Indian healthcare settings—encompassing urban tertiary hospitals, district-level public facilities, and rural primary care outreach—are needed to capture cost heterogeneity and contextualise findings for procurement and policy decisions. Studies should include both public and private sector perspectives and assess budget impact at state and national programme levels.

Second, India-specific prospective validation studies are required to generate local clinical accuracy estimates for POCT devices across the full spectrum of CKD stages and in demographically diverse populations. Such studies should assess whether device performance varies by comorbidity burden, patient age, or setting-specific factors such as sample handling conditions.

Third, longer-horizon decision models incorporating disease progression are essential to quantify the full economic value of early CKD detection through POCT. These models should capture downstream outcomes including delayed dialysis initiation, averted transplantation, reduction in hospitalisations for CKD complications, and survival gains attributable to timely nephroprotective therapy.

Fourth, operational research should investigate the real-world implementation of hybrid POCT-laboratory diagnostic pathways, examining clinician adoption, workflow integration, turnaround time impacts, and patient experience. Digital health integration—linking POC results to electronic health records and CKD registries—should be explored as a mechanism to improve longitudinal data capture and quality assurance.

Fifth, India-specific EQ-5D population preference studies for CKD health states would substantially improve the precision of QALY estimates in future models, replacing the current reliance on transferability-adjusted international data. Finally, budget impact analyses from the perspective of government health insurance programmes (e.g., Ayushman Bharat PM-JAY) would directly inform national procurement policy and reimbursement decision-making for POC diagnostics.

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This study did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

DATA AVAILABILITY

All model parameters and data used in this analysis are available from the corresponding author upon reasonable request.

ETHICS APPROVAL

This study is a decision-analytic modelling study using published aggregate data and does not require ethics approval.

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