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Research Article

Cindynics applied to Nephrology, A Framework to Standardize Early Detection and Management of Kidney Diseases in Sub-Saharan Africa.

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Abstract

Background: *Dialysis is not funded in the Cameroonian private sector where the prevalence of chronic kidney disease is unknown. Early detection and management of kidney disease must be optimal in sub-Saharan private hospitals where dialysis is not affordable. Lack of routine estimation of the glomerular filtration rate and the variability of serum creatinine reference values between laboratories are major barriers to early detection and treatment for kidney diseases. This must change. We aimed to explore the potential of cindynics, "the science of danger" as a framework to study and prevent kidney disease in sub-Saharan Africa.*

Methods: *We conducted a retrospective study from January 1 2019 to December 31 2021, examining the distribution of reported serum creatinine values in one laboratory, which uses a standardized colorimetric-kinetic Jaffe method and CKD-EPI (2009) equation to estimate the glomerular filtration rate. Reference serum creatinine values were between 0.9 and 1.3 mg/dl for the entire test population.*

Findings: *7028 measurements were analyzed. The mean and median serum creatinine values were 1.2 mg/dl (SD 1.1) and 1.10 mg/dl (range 0.21 - 34 mg/dl) respectively. eGFR ranged from 1 to 238.6 ml/min per 1.73m2 with a mean value of 70.2 ml/min per 1.73m2. Serum creatinine was significantly different between females and males (p <0,005) above 18 years but not below (p=0,5). Mean eGFR was slightly higher in females above 18 years: 72.6 ml/min per 1.73m2 (SD 26,6) vs 68.3 ml/min per 1.73m2 (SD 28,8) in males. In the subgroup with normal ranges of serum creatinine, normal eGFRs (above 90 ml/min per 1.73m2) were present 8.6% in females and 43.7% in males. In this same subgroup, eGFRs below 60 ml/min per 1.73m2 were present 13.4% in females vs 0.1% in males.*

Interpretation and Conclusion*: Chronic kidney disease, because of no immediate and apparent consequences, was here considered as "the danger". Most of the participants particularly females, had both normal serum creatinine values according to the laboratory and abnormal eGFRs. No unique serum creatinine reference values should be performed in the entire test population. "Reference values" are the 4th cindynics dimension. Applied to nephrology by physicians and health policy makers, cindynics is a comprehensive and personalized method implemented to standardize creatinine with low variability across laboratories, to estimate the glomerular filtration rate routinely in all the Cameroonian settings and then contribute more epidemiological data in Central sub-Saharan Africa.*

Key words: *cindynics, kidney disease prevention, bionephrology, serum creatinine reference values, eGFR, CARE (cartographie rénale in French).*

Introduction

Kidney Disease Improving Global Outcomes (KDIGO) guidelines underline that early detection and management of kidney diseases are crucial in resource-limited countries where kidney replacement therapy (KRT, dialysis and transplantation) is not affordable or available [1]. Over 2 million people die each year due to limited access to KRT, predominantly in low- resource settings [2]. In 2030, up to 14.5 million people may need KRT, but only 5.4 million will likely have access to it worldwide. Chronic Kidney Disease (CKD) in sub-Saharan Africa (SSA) is a major public health issue with human, social, economic and political challenges. CKD is defined as abnormalities of kidney structure or function present more than three months, with implications for health. The CKD classification is based on an eGFR using the 2012 KDIGO clinical practice guidelines as follows [3]. Six categories were defined: CKD stages 1-2 (eGFR ≥ 60 ml/min per 1.73m2 and urine ACR > 30 mg/g or 3 mg/mmol); CKD stage 3 (eGFR 30-59 ml/min per 1.73 m2); CKD stage 4 (eGFR 15-29 ml/min per 1.73 m2), CKD stage 5 (eGFR < 15 ml/min per 1.73 m2) and ESKD including those needing KRT. Robust data on the burden of CKD in SSA is lacking, but it is anticipated to be high [4-7]. A systematic review conducted by Stanifer et al [5] found a sub-Saharan African global CKD prevalence of 13.9%. In the Global Burden Disease Chronic Kidney Disease (GBD CKD) Collaboration [8], CKD was defined by level of eGFR, urine ACR or KRT, without chronicity criteria. In the GBD Study, Cameroon was classified in Western sub-Saharan Africa, not in Central sub-Saharan Africa as it is in the UN subregions. The percentage change in age-standardized rates of CKD prevalence between 1990 and 2017 were 2% (-2.9 to 6.7%) in Cameroon; 0% (-3.6 to 3.7%) in Central and 4.3% (0.3 to 8.7%) in Western sub-Saharan Africa. The double burden of CKD traditional and infectious risk factors [9-11] is well described but additional unknown causes and late referral to nephrologists exacerbate the issues. Identifying CKD in high-risk groups is crucial: hypertension, diabetes mellitus, cardiovascular diseases, autoimmune or multisystem disorders, age > 65 years, HIV, urological disorders, chronic users of nephrotoxic medications, high-risk ethnic groups, family history of CKD and acute kidney injury (AKI). CKD also increases cardiovascular risk [12]. Despite this, kidney disease is rarely prioritized by policy makers and multiple challenges remain in terms of understanding the incidence and prevalence, as well as optimizing diagnosis and treatment in SSA. In addition, SSA is the region of the world with the lowest number of nephrologists (0.6 pmp) [13]. A new approach is therefore required to better understand and address the burden of kidney diseases in SSA, which includes among the private sector. Concerningly, in Douala as in other Cameroonian cities, serum creatinine standards differ among different laboratories conducting the test. Reporting of estimated GFR (eGFR) based on a standardized creatinine is not routinely practiced. Albuminuria was not routinely performed by physicians in the high risk

populations to screen for kidney disease. These differences in eGFR reporting contribute to the lack of reliable epidemiological information on kidney health, a major proximal barrier to understanding and managing the burden of kidney disease in SSA. Furthermore, important variability has been observed with serum creatinine reference values between these laboratories. Very wide "normal" reference values for serum creatinine likely contribute to the fact that non-nephrologists do not act earlier in cases of kidney dysfunction or damage. A first step therefore would be to implement standardization of serum creatinine measurement, to reduce the variability of results across laboratories and to improve the reliability of data on CKD incidence and prevalence [14-17].

A further major limitation of any program of early detection and kidney disease management is the observation that a single creatinine or urine measurement overestimates CKD prevalence by 25 to 50% [18-20]. Many CKD prevalence studies were cross-sectional and did not repeat serum creatinine and urine tests over 3 months, which reduces reliability of the data. In a Cameroonian hypertensive population, Kaze et al [21] used a 3-month confirmation; eGFRs were below 60 ml/min per 1.73m2 at the first measurement in the half of the group. Using eGFR by the MDRD equation, the prevalences of CKD stage 3, 4, and 5 were 28.3%, 2.1%, and 2.1% ; 27.7%, 3.0%, and 1.8% with the CKD-EPI equation at the second measurement. Recent studies have shown that creatinine-based eGFR equations overestimate well preserved kidney function (CKD stages G1-G2) but underestimate declining kidney function (CKD stages G3-G5) [22]. Equations used to estimate kidney function from serum creatinine have limited regional validation in SSA however, which adds a further limitation to regional studies. The size of the CKD burden in Cameroon is largely unknown. Better epidemiological data from Cameroon would support advocacy for policies to prevent CKD and call for earlier diagnosis and active and personalized management of kidney disease in the future [23-25]. As a first step to begin to understand the CKD burden in Cameroon, we assessed the variability of serum creatinine reference values between laboratories, the frequency of reporting of eGFR; explored the distribution of measured creatinines falling within and out- side of the "normal" values. We then analyzed the current status quo of CKD testing in Cameroon using the Cindynics framework of danger. Cindynics is a French industrial concept to study risks and protect populations by recommending rules of prevention. Cindynics framework is based on five dimensions: models, data, guidelines, reference values and objectives.

Methods

To assess variability in reporting of values and reference levels, normal serum creatinine ranges from ten laboratories were recorded: 7 in private and 3 in public sectors; 6 from Douala, 2 from Yaounde, 1 from Buea

and 1 from Limbe (Fig.1 and 2). In a next step, a descriptive analysis of creatinine tests was performed in the single private laboratory which was the only laboratory reporting eGFR using the CKD-EPI (2009) equation. We examined the distribution of the reported serum creatinine values recorded in mg/dl, from January 1 2019 to December 31 2021. Anonymized demographic data was included of participants who met all the following criteria: complete recordings of age, gender, serum creatinine measurements and eGFRs. The study was approved by the Ethical Committee of the University of Douala.

Cindynics, an industrial concept put forward by Georges-Yves Kerven in 1987, combines the sciences studying natural risks (forest fires, floods, avalanches, earthquakes…), industrial risks (polluting or dangerous installations) and technological risks (new materials or chemicals) in order to define rules of prevention [26]. It is named "the science of danger" based on a 3-step methodology: 1- identify the risk with effects that are not always immediate or apparent; 2- use a multidisciplinary approach to analyze risk taking into account for its complexity and human, social, economic and political consequences; 3- recommend rules of prevention to protect the populations.

Five cindynics dimensions have been defined to better describe "the bigger space of danger": models or representations, data or observations, guidelines or recommendations, reference values or standards and objectives or goals (Fig. 6A and 6B). In Medicine, cindynics approach was been previously described for Malaria prevention in Cameroon [27]. Marquis et al were convinced that, from an environmental health point of view, improving the well-being of the population and the health system requires, on the one hand: - a better assessment of the impacts of the multifaceted use of water on water-borne diseases, and on the other hand: - the implementation of a strategy to control these impacts and risks, which integrates the socio- economic and cultural context. They aimed to take stock of knowledge on malaria risk and management strategies in the Logone rice-growing valley, with a view to highlighting the need to initiate and develop a more integrated geographical approach to health, which could be extended to the entire kingdom of living organisms and to other disciplines such as epidemiology, ecology and sociology, among others. By comparison, CKD most often asymptomatic, was "the danger or the risk" to explore because of effects not immediate or apparent; human, social, economic and political issues. Cindynics could be applied to nephrology and integrated into a multidisciplinary approach, the bionephrology in order to implement new African models to better identify kidney disease and prevent CKD through a strong collaboration with local clinical pathologist.

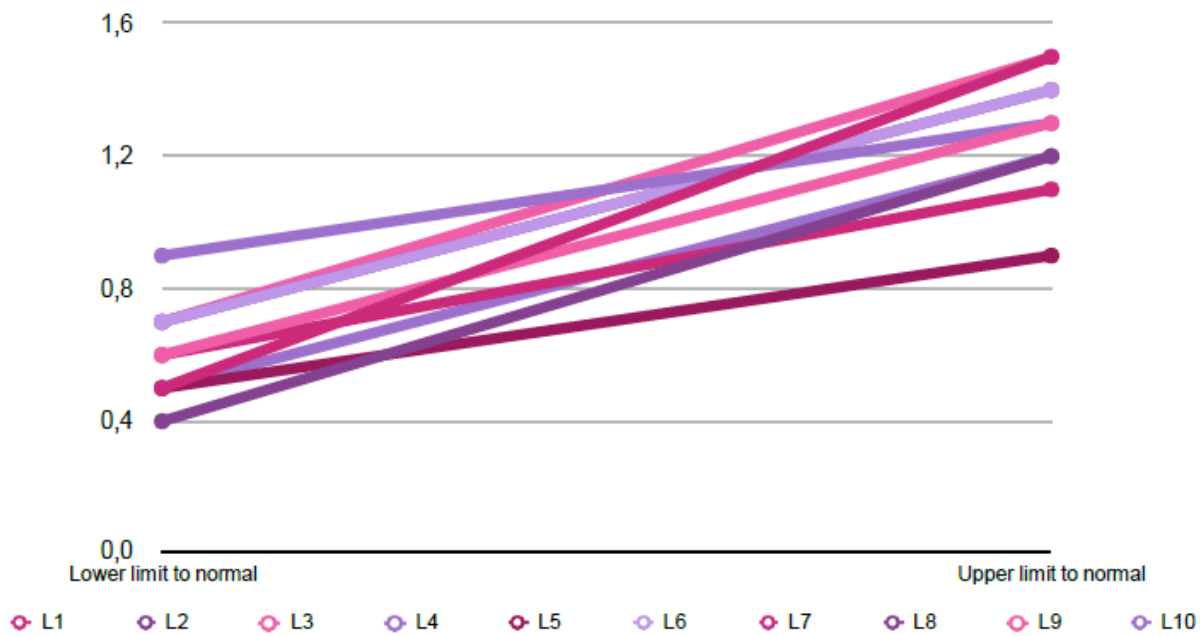
Statistical analysis

Descriptive and inferential statistics were performed using Excel. Medians and interquartile ranges (IQR) were calculated for continuous variables before and after stratification based on gender. Comparison of medians or mean ranks between males and females was done using the Mann-Whitney U test. Classification of eGFR was reported as proportions. A p-value less than 0.05 was considered statistically significant.

Findings

The current metro area population of Douala was 4 million. 3 nephrologists were working exclusively in the private sector, with no funding for dialysis. Across the 10 laboratories included in this study, the lower limits of "normal" serum creatinine ranged 0.4 to 0.9 mg/dl and the upper limits ranged from 0.9 to 1.5 mg/dl (Fig.1). Estimated glomerular filtration rate (eGFR) was routinely reported in three laboratories; all were private (Fig.2). One used Cockroft and Gault, MDRD equations; an other MDRD formula and the last one CKD-EPI (creatinine) 2009 equation.

In the single laboratory using CKD-EPI equation, more detailed analysis was conducted. The standards (normal ranges) were 0.9 to 1.3 mg/dl, using a standardized colorimetric- kinetic Jaffe method (ROCHE, SA).



DMMC: Daniel Muna Memorial Clinic, a private hospital in Douala city. L: laboratory: 1 to 10.

Figure 1: Serum creatinine reference values for 10 clinical laboratories where DMMC's out-patients used to perform their blood tests: 6 at Douala, 2 at Yaounde, 1 at Buea and 1 at Limbe. Serum creatinine values in mg/dl. The 4th cindynics dimension (reference values, see below).

Figure 2 : Is Glomerular filtaration rate routinely estimated in laboratories ? The reality on the ground is the 1st cindynics dimension (models or observations).

Over the 3-year study period, 8982 serum creatinine measurements (SCM) were performed. Forty-four values were removed because of missing demographic data and 1910 were not recorded electronically. 7028 values were available for analysis. The number of tests per individual ranged 1 to 11 in females who represented 43.5% of the entire group; 1 to 17 in males. The characteristics of the population are shown below (Table 1), with a mean age of 50 years (SD 15.53). 74.5% of the entire population had a single creatinine measurement.

Table 1: Descriptive characteristics of the entire test population.

	Females	Males	Total
In years,			
Median age	46.95 (0,09-100,15)	52.35 (0,04 - 101,74)	50.13 (0,04 - 101,74)
Mean age (SD)	48.04 (16.21)	51.65 (14.78)	50.06 (15.53)
N/% (Number/percentage) by age			
< 18 years	85 (3.8)	105 (4.1)	190 (4)
18-29 years	197 (8.8)	105 (4.1)	302 (6.3)
30-39 years	530 (23.6)	413 (16.4)	943 (19.7)
40-49 years	564 (25.1)	656 (26)	1220 (25.5)
50-59 years	443 (19.7)	694 (27.5)	1137 (24)
60-69 years	239 (10.6)	387 (15.4)	626 (13.1)
> 70 years	189 (8.4)	163 (6.5)	352 (7.4)
Total	2247 (100)	2523 (100)	4770 (100)

The mean SCM was 1.2 mg/dl (SD 1.1) in the entire test population, 1 mg/dl in females (SD 0.9) and 1.4 mg/dl in males (SD 1.2). The Median SCM were 1.1 mg/dl, 0.9 mg/dl (0.3 - 34 mg/dl) and 1.2 mg/dl (0.3 - 25.3 mg/dl) respectively. The figures 3 and 4 show the serum creatinine distributions by age and gender. Creatinine concentrations were significantly different between females and males (p <0,005) above 18 years but not below (p=0,5).

eGFRs ranged from 1 to 238.6 ml/min per 1.73m2 with a mean value of 70.2 ml/min per 1.73m2 (SD 28) in the entire test population; 1 to 199.7 ml/min per 1.73m2 in females with a mean value of 72.6 ml/min per 1.73m2 (SD 26,6). In males, the mean eGFR was 68.3 (SD 28,8). Data on eGFRs classified by age and stage are shown in figure 5 and table 2; 18% were below 60 ml/min per 1.73m2.

In the subgroup with normal ranges of serum creatinine according to the laboratory, eGFRs were below 60 ml/min per 1.73m2 for 13.4% in females, 0.1% in males. eGFRs were above 90 ml/min per 1.73m2 for 8.6% in females vs 43.7% in males (Table 3).

Figure 3 : Serum creatinine distribution in the entire test population below 60 years. (Normal ranges 0.9 - 1.3 mg/dl according to the laboratory)

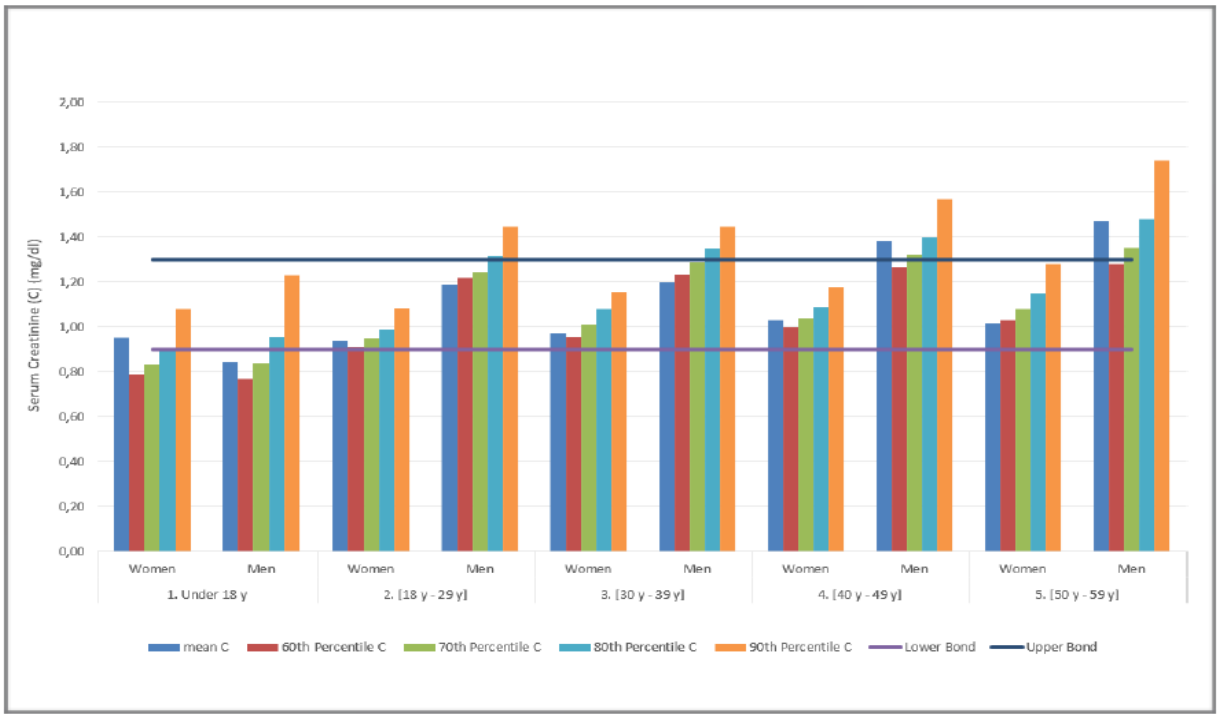


Figure 4 : Serum creatinine distribution in the entire test population above 60 years. (Normal ranges 0.9 - 1.3 mg/dl according to the laboratory)

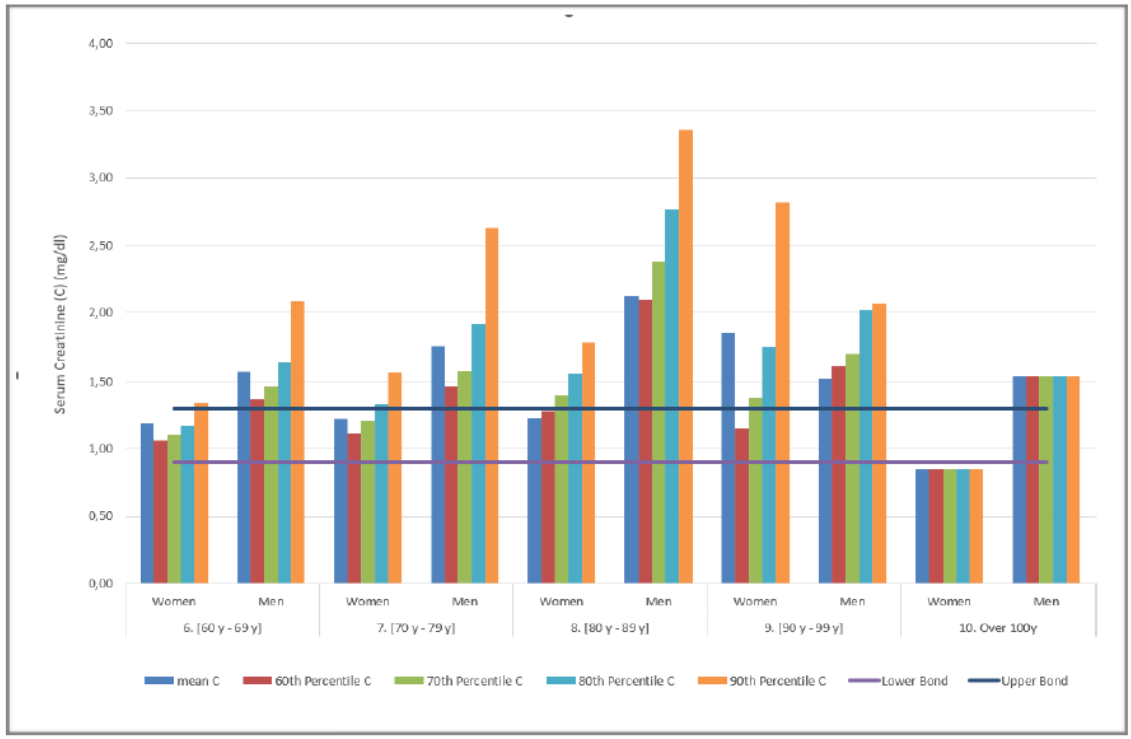


Figure 5: Mean estimated glomerular filtration rate distributions in the entire population by age and gender.

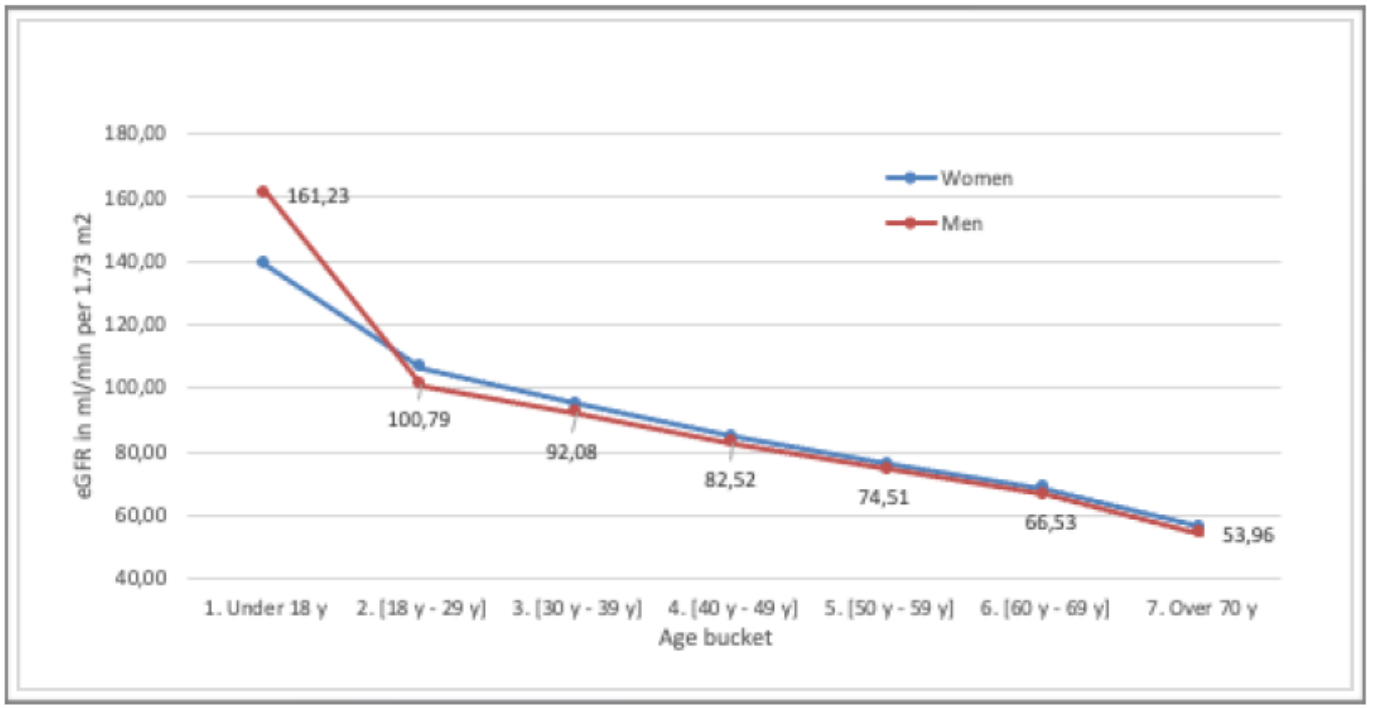


Table 2: eGFRs according to CKD-EPI (2009) equation classified by stage and gender, in ml/min per 1.73m2.

eGFR	Females (N/%)	Males (N/%)	Total (N/%)
< 15	18 (0.6)	81 (2)	99 (1.4)
15 - 29	39 (1.2)	106 (2.7)	145 (2)
30 - 59	414 (13.4)	618 (15.7)	1032 (14.6)
60 - 89	1516 (49)	1922 (49)	3438 (49)
> 90	1108 (35.8)	1206 (30.6)	2314 (33)
Total	3095 (100)	3933 (100)	7028 (100)

Table 3: eGFR according to CKD-EPI (2009) equation in ml/min per 1.73m2, in the subgroup with serum creatinine concentrations in the normal ranges of the laboratory (0.9 to 1.3 mg/dl).

eGFR	Females (N/%)	Males (N/%)	Total (N/%)
Minimal	41.7	59.5	41.7
Maximal	114.2	150.9	150.9
Mean (SD)	73.7 (11.95)	89 (14.11)	82.4 (15.26)
< 15	0	0	0
15 - 29	0	0	0
30 - 59	230 (13,4)	2 (0.1)	232 (5.8)
60 - 89	1139 (78)	1272 (56.2)	2611 (65,6)
> 90	147 (8,6)	988 (43.7)	1135 (28.5)
Total	1716 (100)	2262 (100)	3978 (100)

Interpretation

This study highlights the need for standardization of creatinine reporting across laboratories in Cameroon, as means to better assess kidney function and detect kidney disease, at a point where intervention may meaningfully delay its progression to kidney failure and to build a reliable registry for CKD in Cameroon.

Figure 6 A : Cindynics applied to nephrology, the 3-step methodology.

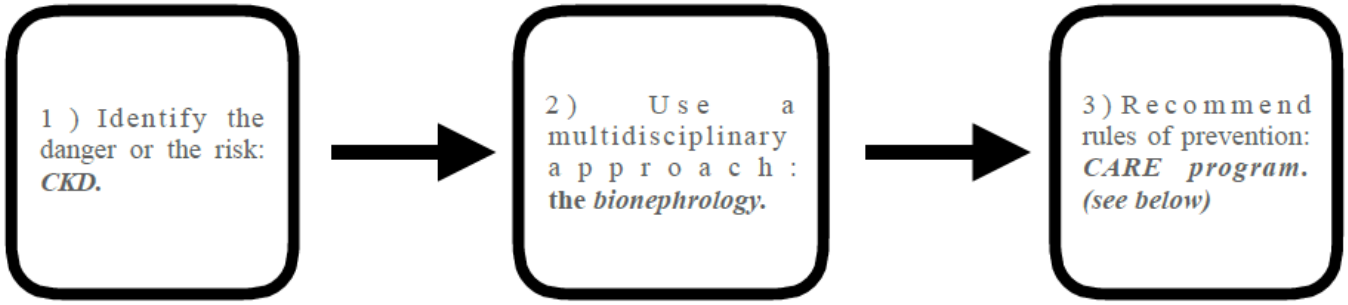
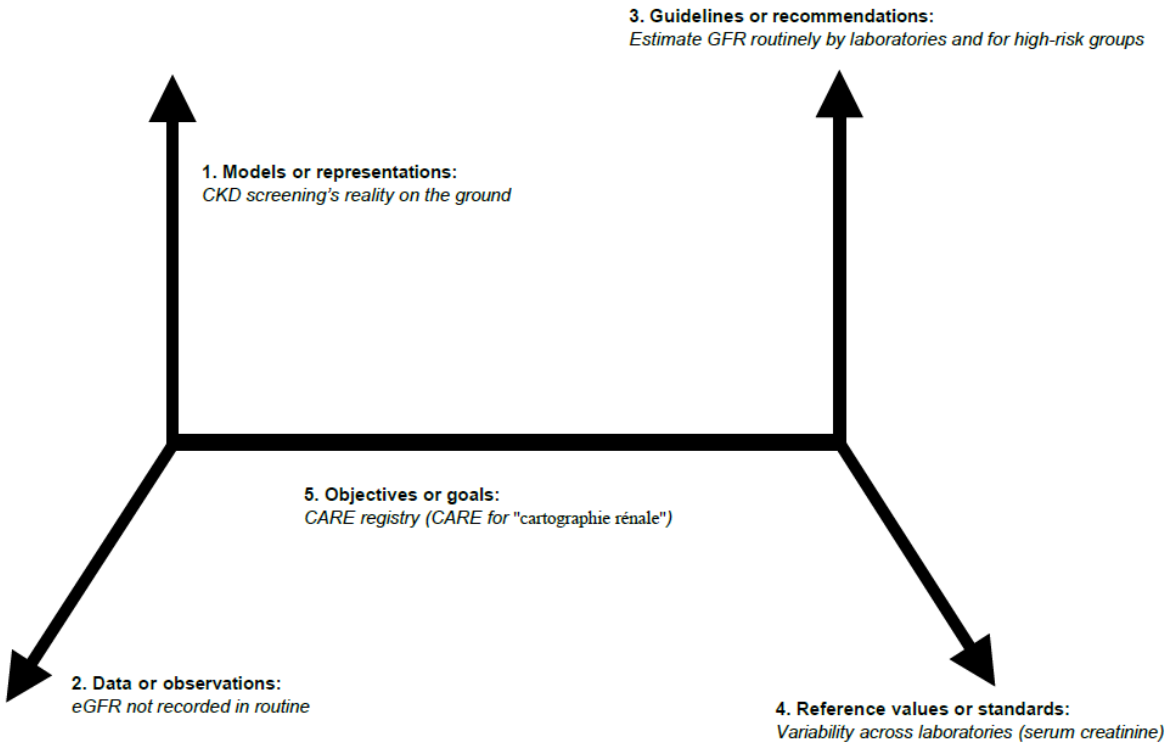


Figure 6 B: "The bigger space of CKD (the danger)"and its five dimensions.



The five cindynics dimensions

1- Models or representations (the first cindynics dimension).

In the private sector, there is no regular post-graduate education on kidney health. The number of nephrologists is low and there are no local guidelines for AKI/CKD screening among general or at-risk populations. AKI, a major risk factor of CKD remains undocumented. Untreated, it can lead to CKD progression and ultimately end-stage kidney disease (ESKD). Furthermore, the physicians commonly asked a nephrology advice only when the serum creatinine concentration is above the upper limits reported by the laboratory, regardless of the eGFR. In daily practice, most laboratories give few details on the creatinine standardization.

7 of 10 laboratories included in this study do not estimate the GFR. These points are "the models", the reality on the ground and contribute to the late referral to nephrologists of patients with AKI or CKD.

2- Data or observations (the second cindynics dimension).

In this study, 74.5% of the subjects had a single creatinine analysis. Improving CKD awareness and screening by physicians and laboratories would help to build a better follow-up and ensure repeat testing where appropriate. As expected, we found a significant difference in the creatinine distribution between females and

males above 18 years. eGFRs were slightly higher in females. Men tend to have a greater body surface area, which is the main predictor of kidney size. Females were also younger than males: 36.2% vs 24.6% below 40 years, 38.7% vs 49.4% above 50 years. Ageing kidney is known to be a determinant risk factor for AKI/CKD. Therefore, different groups may require different reference values. In children, the values would be determined by child age, height, size with the Schwartz (creatinine) formula.

3- Guidelines or recommendations (the third cindynics dimension).

Because mild and moderate kidney injury is poorly inferred from serum creatinine alone, the National Kidney Disease Education Program (NKDEP) strongly encourages clinical laboratories to routinely estimate GFR [28,29], based on a standardized serum creatinine using an enzymatic method or an isotope dilution mass spectrometry (IDMS)-traceable creatinine assay. Equations should differ with populations, based on a strong and true evaluation of GFR and serum creatinine measurements. 56.6% of the serum creatinine measurements were here under the upper limit of 1.3 mg/dl but only 33% corresponded to a normal eGFR (above 90 ml/min per 1.73m2). Appropriate classification and re-testing would ensure individuals not to be misclassified in CKD or non-CKD depending on whether the renal function was under or overestimated by a single creatinine value. According to the KDIGO guidelines (in high income settings), screening for kidney disease is only recommend/cost effective in high risk individuals. Further studies are necessary to define specific high risk groups in the local context, starting with age. Reporting of the eGFR with the serum creatinine is a simple and effective way laboratories can help healthcare providers detect CKD among general or high risk populations. The data required for the calculation, e.g. using the CKD Epi 2021 formula must therefore be collected at the time of blood draw.

4- Reference values (the fourth cindynics dimension).

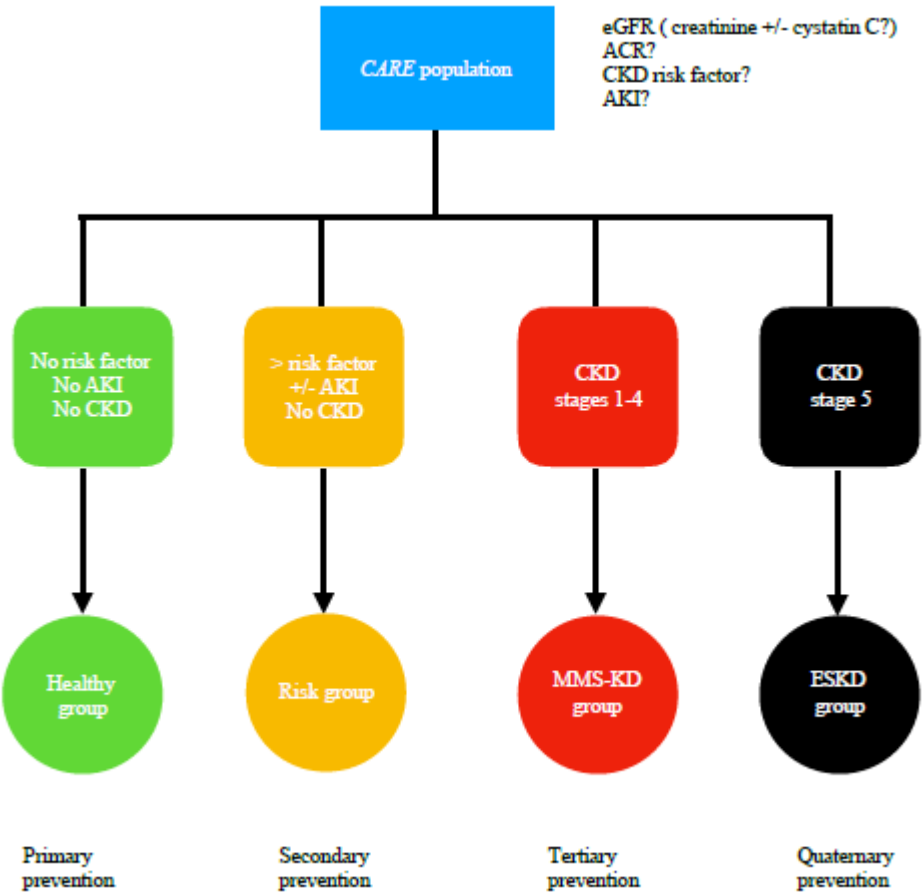
Variability of serum creatinine standards was very large between the ten laboratories selected. Because CKD-EPI (2009 creatinine) equation but not MDRD or Cockroft and Gault equa- tions, was validated in healthy black Africans, we elected to further analyze data from the single laboratory reporting this in this study. In the subgroup with normal serum creatinine values (ranges 0.9 - 1.3 mg/dl), normal eGFR were observed 8.6% in females and 43.7% in males. Females in particularly were at high-risk of potentially undetected AKI/CKD. Standardized creatinine was here systematic but we showed that standards should differ by gender.

5- Objectives or goals (the fifth cindynics dimension).

Expanding research to include the private sector is a means to increase knowledge about incidence and prevalence of the spectrum of kidney disease and to raise awareness about the importance of screening and prevention. Based on national guidelines and the reality on the ground experienced by sub-Saharan physicians, cindynics applied to nephrology would improve relevance for the local context.

To prospectively report more robust epidemiological information, a local database has been developed, CARE (cartographie rénale in French) with the approval of the Ethical Commit- tee of the University of Douala. The standardization of serum creatinine in all the laboratories of the city, with a limited variability in their reference values combined with e-GFR are crucial steps in order to build this local registry. CARE promises to improve data collection, data analysis and data reporting with individuals classified into four groups: healthy if no low eGFR, no albuminuria, no risk factor, no AKI; risk if no low eGFR; no albuminuria and one or more risk factor as AKI; MMS-KD (mild, moderate, severe kidney disease) in CKD stages 1-4; ESKD in CKD stage 5. Based on public and private kidney disease registries, AKI/CKD screening and prevention guidelines should be better defined by the Public Health Ministry in collaboration with the Cameroonian Societies of Nephrology and Biology. To promote research and CKD prevention in the Cameroonian private sector, data must be reported using a standardized method and nephrologists should reach out to healthcare providers to advocate for monitoring of kidney function where appropriate. Cameroonian private hospitals have to invest first in kidney disease prevention then in hemodialysis. Collaboration with the public sector where dialysis is funded, is essential to define an optimal healthcare pathway for patients with AKI/CKD especially given the lack of national health insurance; human, financial and technical resources in low-income settings. Health policy makers would in the future, define rules of prevention to better protect the populations against CKD. A national program of prevention will contribute to reduce AKI/CKD healthcare costs by decreasing AKI/CKD incidences and prevalences; will facilitate access to dialysis and kidney transplantation for the individuals in ESKD[30-34].

Figure 7: CARE registry: a model to apply the four strategies of prevention depending on the specific group: healthy, risk, MMS-KD (mild, moderate, severe Kidney disease), ESKD (end-stage kidney disease). CKD: chronic kidney disease; AKI acute kidney injury; KRT: kidney replacement therapy.



Healthy, risk, MMS-KD, ESKD populations will require a specific follow-up (Fig.7). Primary prevention will be applied in healthy individuals to avoid AKI/CKD or any risk factor. Secondary prevention will aim to detect and stop earlier kidney disease in the risk group, including AKI. In the MMS-KD group, tertiary prevention will be provided to control CKD and delay the progression to the ESKD, using nephroprotective agents and other specific means. For the ESKD group, quaternary prevention will avoid premature deaths through optimal KRT (dialysis, kidney transplantation) or conservative treatment.

Overall, this study has significant strengths and some limitations. To our knowledge this is the first study to evaluate the utilization of private laboratories for kidney function testing. More than 21% of the values were missing as they were not electronically recorded and therefore the data reported here may not reflect the true spectrum of measured serum creatinines.

However the intra-individual assessment for creatinine value vs eGFR is valid and reflects current important weakness in the laboratory system. We did not aim to address CKD prevalence and therefore, we can't comment on an age-standardized CKD prevalence, given the unknown indication of kidney testing in each individual and the lack of reported urine tests. It was not possible to assess why the serum creatinine standards differed from a laboratory to another one, an issue that has been resolved in many settings abroad (another reality on the ground). It is clear that further studies are required to address data on variability in normal ranges between Cameroonian laboratories using standardized creatinine and eGFR, to determine the best serum creatinine reference values by age and gender, or alternative measures e.g. cystatin C.

Disclosure statement

All the authors declared no competing interests.

Acknowledgments

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Conclusion

Improved awareness, research and prevention supported by health policies in the private sector are tools to detect and manage kidney diseases earlier in sub-Saharan Africa and to better understand the burden of the kidney diseases. Cindynics is a combination of scientific and non-scientific methods linked to the reality on the ground. Applying international guidelines is important but local complex realities determine the way these should be effectively implemented in low-income settings. Determining true serum creatinine reference values in healthy individuals is essential to improve laboratory diagnosis of kidney disease with reliable estimation of eGFR. Chronic kidney disease is most often asymptomatic with effects that are not always immediate or apparent. The concept of cindynics in health is a means to develop active and targeted prevention policies and to standardize local, national and international strategies, such that kidney diseases are prioritized by the health systems in sub-Saharan Africa. With more populations protected, CKD prevalence and healthcare costs will significantly reduce. Cindynics applied in nephrology is a strong approach to prevent CKD (the danger) and contribute to a responsible and sustainable kidney replacement therapy.

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