Availability and Affordability of Kidney Health Laboratory Tests around the Globe

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Keywords

Chronic kidney disease · Diagnostics · Access · Affordability · Global health · Laboratory testing

Abstract

Background: Kidney disease is a major global public health problem, and laboratory testing of kidney health measures is essential for diagnosis and monitoring. The availability and affordability of kidney health laboratory tests across countries has not been systematically described. **Methods:** The International Society of Nephrology (ISN), in partnership with leaders of a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference, surveyed a representative subset of ISN-Global Kidney Health Atlas (ISN-GKHA) respondents from April to June 2020. We assessed the association between country gross national income (GNI) per capita and laboratory testing availability and affordability. **Results:** Of 33 regional expert nephrologists invited, 24

(73%) responded, representing all 10 ISN regions around the world. Availability of kidney health laboratory tests was as follows: serum Cr (100%), serum cystatin C (67%), urine albumin (96%), urine Cr (100%), and dipstick urinalysis (100%). Median (IQR) reimbursement values in international dollars were as follows: serum Cr Int\$ 6.61 (3.42–8.84), serum cystatin C Int\$ 31.51 (17.36–46.25), urine albumin Int\$ 10.22 (5.90–15.42), urine Cr Int\$ 7.50 (1.66–8.84), and dipstick urinalysis Int\$ 6.26 (2.56–8.40). Reimbursement values did not differ significantly by World Bank income group or by GNI per capita. **Conclusion:** There was widespread availability of kidney health laboratory tests and substantial variation in reimbursement values. To achieve meaningful progress across nations in mitigating the growth of kidney disease, access to affordable diagnostic technology is essential. Our results are highly relevant to policymakers and researchers as countries increasingly consider national strategies for kidney disease detection and management.

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Introduction

Chronic kidney disease (CKD) affects nearly 700 million persons globally, and its contribution to worldwide disability and death is rising [1]. Population health strategies that slow the progression of kidney disease are particularly crucial for low- and middle-income countries (LMIC), which face a high burden of CKD and have lower access to dialysis services: only 5% of low-income countries have access to dialysis [2]. Yet, only one-third of countries surveyed in the International Society of Nephrology's Global Kidney Health Atlas (ISN-GKHA) had specific CKD care policies, and fewer than half had national strategies for noncommunicable diseases [2]. Accordingly, there have been renewed calls for early CKD detection and intervention on the global scale [3, 4].

Early diagnosis and management of CKD requires available and affordable laboratory testing of kidney health measures [5]. Based upon current guidelines, testing for estimated glomerular filtration rate and albuminuria is necessary to effectively diagnose and stage CKD. Cost is a critical factor, with reimbursement values of kidney health laboratory tests being a key determinant of affordability [6, 7]. Because the availability of and reimbursements for the full range of CKD laboratory tests have not been systematically described on an international scale, the International Society of Nephrology (ISN) surveyed a sample of its members worldwide.

Methods

The ISN conducted a global survey to assess international kidney health laboratory testing availability and affordability. A representative subset of ISN-GKHA respondents was chosen as regional expert nephrologists for this survey. In partnership with leaders of a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference [4], the ISN constructed a 21-item survey consisting of (1) respondent demographics (position, country, city, and ISN region), (2) laboratory test availability (yes/no), and (3) laboratory reimbursement values in the public or government healthcare system. Test availability and reimbursement values were assessed for serum Cr, serum cystatin C, urine albumin, urine Cr, and dipstick urinalysis.

The survey was conducted online from April 20 to June 4, 2020, via an e-mail invitation to ISN regional expert nephrologists. Respondents self-reported reimbursement values in their native currency, and values were converted to 2019 international dollars based on purchasing power parity exchange rates (Table 1) [8]. International dollar is a hypothetical unit of currency that would buy in a given country a comparable amount of goods and services that a US dollar would buy in the USA. Additionally, we converted kidney test reimbursement values to US dollars on July 12, 2020, using Google currency converter and a user-generated Stata

module (see online suppl. Table 1; for all online suppl. material, see www.karger.com/doi/10.1159/000511848) [9]. Gross national income (GNI) per capita from 2019 was obtained from World Bank estimates [10], and countries were classified into World Bank income groups based on their GNI per capita as low-income (USD 1,035 or less), lower-middle-income (USD 1,036–4,045), upper-middle-income (USD 4,046–12,535), or high-income economies (USD 12,536 or more) [11]. We additionally validated a subset of the reimbursement values using publicly available online sources.

We first described the availability of the 5 kidney health laboratory tests overall and stratified by World Bank income group. We compared the availability of testing across income groups using Fisher's exact test. We then reported the median and interquartile range (IQR) of the nonmissing reimbursement values in international and US dollars, overall and stratified by World Bank income group (Table 2; online suppl. Table 2). We also reported the median (IQR) values for combinations of tests, including the following: (1) serum Cr plus urine albumin-to-Cr ratio (ACR); (2) the "triple marker" panel of serum Cr, serum cystatin C, and urine ACR; and (3) serum Cr plus dipstick urinalysis. Using simple linear regression, we evaluated the association between country GNI per capita and kidney testing reimbursement values and whether the national income group was associated with kidney testing reimbursement values. Data analyses were performed using Stata/IC, version 15.1 (StataCorp), and R statistical software.

Results

Of the 33 regional expert nephrologists invited to the survey, a total of 24 responded (response rate 73%). All 10 ISN regions around the world were represented among the respondents (Table 1), with 6 (25%) from lower-middle-income countries, 9 (37.5%) upper-middle-income countries, and 9 (37.5%) high-income (Table 2) countries. Results showed that serum Cr testing was available among 100% of countries; testing availability was 67% for serum cystatin C, 96% for urine albumin, 100% for urine Cr, and 100% for dipstick urinalysis (Table 2). Availability of any of the 5 kidney health laboratory measures did not statistically differ by country income group in our sample (Table 2).

There was substantial variation in kidney health laboratory reimbursement values (Table 1; Fig. 1). The overall median (IQR) values in international dollars were as follows: serum Cr Int\$ 6.61 (3.42–8.84), serum cystatin C Int\$ 31.51 (17.36–46.25), urine albumin Int\$ 10.22 (5.90–15.42), urine Cr Int\$ 7.50 (1.66–8.84), and dipstick urinalysis Int\$ 6.26 (2.56–8.40) (Table 2). The median (IQR) reimbursement was a total of Int\$ 22.10 (14.63–30.35) for serum Cr plus urine ACR testing; Int\$ 47.37 (39.95–91.21) for the "triple marker" panel of serum Cr, serum cystatin C, and urine ACR; and Int\$ 12.61 (4.90–16.81) for serum Cr plus dipstick urinalysis testing. Reimburse-

Table 1. Survey-reported reimbursement values in international dollars for kidney health laboratory tests around the globe

Country	ISN region	Serum Cr	Serum cystatin C	Urine albumin	Urine Cr	Urinalysis (dipstick)
Argentina	Latin America	160 ARS (Int\$ 7.62)	NA	120 ARS (Int\$ 5.72)	160 ARS (Int\$ 7.62)	150 ARS (Int\$ 7.15)
Australia	Oceania and South East Asia	12.73 AUD (Int\$ 8.84)	25 AUD (Int\$ 17.36)	13.27 AUD (Int\$ 9.22)	12.73 AUD (Int\$ 8.84)	11.59 AUD (Int\$ 8.05)
Canada ¹	North America and the Caribbean	12 CAD (Int\$ 4.20)	NA	12 CAD (Int\$ 10.08)	1.60 CAD (Int\$ 1.34)	8 CAD (Int\$ 6.72)
Canada ²	North America and the Caribbean	5 CAD (Int\$ 10.08)	NA	22 CAD (Int\$ 18.49)	5 CAD (Int\$ 4.20)	10 CAD (Int\$ 8.40)
China	North and East Asia	7 CNY (Int\$ 1.66)	U	50 CNY (Int\$ 11.85)	7 CNY (Int\$ 1.66)	1 CNY (Int\$ 0.24)
Czech Republic	Eastern and Central Europe	19 CZK (Int\$ 1.53)	315 CZK (Int\$ 25.32)	144 CZK (Int\$ 11.58)	19 CZK (Int\$ 1.53)	42 CZK (Int\$ 3.38)
France	Western Europe	2.50 EUR (Int\$ 3.42)	23 EUR (Int\$ 31.51)	5 EUR (Int\$ 6.85)	2.40 EUR (Int\$ 3.29)	0.1 EUR (Int\$ 0.14)
Georgia	NIS and Russia	8 GEL (Int\$ 9.30)	NA	NA	8 GEL (Int\$ 9.30)	10 GEL (Int\$ 11.63)
India ³	South Asia	80 INR (Int\$ 3.77)	NA	100 INR (Int\$ 4.71)	80 INR (Int\$ 3.77)	25 INR (Int\$ 1.18)
India ⁴	South Asia	100 INR (Int\$ 4.71)	1,200 INR (Int\$ 56.58)	300 INR (Int\$ 14.14)	250 INR (Int\$ 11.79)	200 INR (Int\$ 9.43)
Iran	Middle East	100,000 IRR (Int\$ 7.66)	U	200,000 IRR (Int\$ 15.31)	U	U
Japan	North and East Asia	110 JPY (Int\$ 1.08)	1,210 JPY (Int\$ 11.92)	1,050 JPY (Int\$ 10.35)	110 JPY (Int\$ 1.08)	260 JPY (Int\$ 2.56)
Kazakhstan	NIS and Russia	1,000 KZT (Int\$ 7.37)	NA	1,000 KZT (Int\$ 7.37)	1,000 KZT (Int\$ 7.37)	700 KZT (Int\$ 5.16)
Lebanon	Middle East	6,000–10,000 LBP (Int\$ 7.84–13.06)	100,000 LBP (Int\$ 130.61)	40,000 LBP (Int\$ 52.25)	6,000 LBP (Int\$ 7.84)	10,000 LBP (Int\$ 13.06)
Mexico	Latin America	30–300 MXN (Int\$ 3.22–32.22)	60–600 MXN (Int\$ 6.44–64.45)	60–600 MXN (Int\$ 6.44–64.45)	60–600 MXN (Int\$ 6.44–64.45)	30–300 MXN (Int\$ 3.22–32.22)
Nigeria	Africa	600 NGN (Int\$ 4.43)	20,000 NGN (Int\$ 147.60)	7,700 NGN (Int\$ 56.83)	1,100 NGN (Int\$ 8.12)	800 NGN (Int\$ 5.90)
Pakistan	South Asia	250 PKR (Int\$ 6.97)	800 PKR (Int\$ 22.29)	200 PKR (Int\$ 5.57)	450 PKR (Int\$ 12.54)	300 PKR (Int\$ 8.36)
Philippines	Oceania and South East Asia	260 PHP (Int\$ 13.36)	900 PHP (Int\$ 46.25)	300 PHP (Int\$ 15.42)	315 PHP (Int\$ 16.19)	220 PHP (Int\$ 11.31)
Russia	NIS and Russia	170 RUB (Int\$ 6.61)	970 RUB (Int\$ 37.74)	410 RUB (Int\$ 15.95)	200 RUB (Int\$ 7.78)	U
Senegal	Africa	2,000 CFA (Int\$ 8.34)	NA	2,000 CFA (Int\$ 8.34)	2,000 CFA (Int\$ 8.34)	1,500 CFA (Int\$ 6.26)
Singapore	Oceania and South East Asia	Dependent on means testing, can be up to 75% of total amount				
Spain	Western Europe	0.052 EUR (Int\$ 0.08)	3.00 EUR (Int\$ 4.76)	0.68 EUR (Int\$ 1.08)	0.052 EUR (Int\$ 0.08)	0.80 EUR (Int\$ 1.27)
Turkey	Eastern and Central Europe	1.050 TRY (Int\$ 0.57)	8.075 TRY (Int\$ 4.39)	1.050 TRY (Int\$ 0.57)	1.050 TRY (Int\$ 0.57)	1.050 TRY (Int\$ 0.57)
Uruguay	Latin America	150 UYU (Int\$ 5.90)	NA	150 UYU (Int\$ 5.90)	150 UYU (Int\$ 5.90)	150 UYU (Int\$ 5.90)

Reimbursements are shown in local currency (international dollars). NA, laboratory test not available in the survey country; U, reimbursement value for laboratory test unknown/not reported by the survey respondent. ¹ Regina, Canada. ² Edmonton, Canada. ³ New Delhi, India. ⁴ Hyderabad, India, from Dr. Lal PathLabs, a private sector laboratory.

Table 2. Availability and median (IQR) reimbursement values in international dollars for kidney health laboratory tests around the globe, by World Bank income group and overall

World Bank income group	Availability/ reimbursement	Serum Cr	Serum cystatin C	Urine albumin	Urine Cr	Urinalysis (dipstick)
Lower-middle income (<i>N</i> = 6)	Availability	100%	67%	100%	100%	100%
	Reimbursement	Int\$ 5.84 (4.43–8.34)	Int\$ 51.41 (34.27–102.09)	Int\$ 11.24 (5.57–15.42)	Int\$ 10.06 (8.12–12.54)	Int\$ 7.31 (5.90–9.43)
Upper-middle income (<i>N</i> = 9)	Availability	100%	67%	89%	100%	100%
	Reimbursement	Int\$ 7.62 (6.61–9.30)	Int\$ 36.59 (19.92–84.18)	Int\$ 13.58 (6.54–25.70)	Int\$ 7.70 (4.51–8.57)	Int\$ 7.15 (0.57–13.06)
High income (<i>N</i> = 9)	Availability	100%	67%	100%	100%	100%
	Reimbursement	Int\$ 3.81 (1.31–7.37)	Int\$ 17.36 (11.92–25.32)	Int\$ 9.65 (6.38–10.96)	Int\$ 2.41 (1.21–5.05)	Int\$ 4.64 (1.92–7.39)
Overall (<i>N</i> = 24)	Availability	96%	67%	96%	100%	100%
	Reimbursement	Int\$ 6.61 (3.42–8.84)	Int\$ 31.51 (17.36–46.25)	Int\$ 10.22 (5.90–15.42)	Int\$ 7.50 (1.66–8.84)	Int\$ 6.26 (2.56–8.40)

Reimbursement values are survey-reported and in international dollars.

ment values did not differ significantly by country income group or by GNI (online suppl. Table 3). Reimbursements according to publicly available online sources were similar to survey-reported values (online suppl. Table 4).

Discussion

In this global survey of nephrologists conducted to assess the availability of and reimbursements for the full range of laboratory tests necessary for CKD monitoring and management, we found widespread availability of kidney health laboratory tests across middle- and high-income countries. The reported reimbursement values were found to be less costly for serum Cr and dipstick urinalysis testing, compared to urine ACR and cystatin C testing across country income groups. These results complement the previously published findings in the ISN-GKHA on the availability of kidney health testing capacity with no additional specifics on costs [12]. The combination of serum Cr, serum cystatin C, and urine ACR testing (the “triple marker”) is likely affordable in high-income settings. The combination of serum Cr and dipstick urinalysis had the lowest costs, but it may not be the most cost-effective, as urinalysis is substantially less sensitive than urine ACR for detection and monitoring of

albuminuria, particularly in patients with diabetes [13–15].

As policymakers around the world increasingly consider national strategies for noncommunicable diseases and CKD specifically, our results are highly relevant for estimating the affordability of the testing component of a CKD detection and management program. Because the countries we surveyed utilize a diverse and expansive range of healthcare financing mechanisms, we decided to obtain reimbursement values from public payors, which were most suitable for comparisons across countries. Importantly, these reported “costs” are reimbursements, which are more akin to prices, and do not represent the actual costs of performing the tests to laboratories, clinics, or hospitals. These reimbursement values are often decided arbitrarily, instead of after a formal health technology assessment. We believe that the variability in our results reveals potential opportunities for reducing the per capita costs for kidney testing. For example, more widespread availability and an increased volume of ACR and cystatin C testing could allow laboratories to operate the test at a lower reimbursement [16]. Additionally, making tests such as cystatin C available as an “in-house” rather than a “send-out” test may increase ordering volume and decrease costs [17].

Our findings are also useful for researchers, as kidney laboratory testing costs are an important input in cost-

Fig. 1. Reimbursement values in international dollars for kidney health laboratory tests around the globe. Canada and India are depicted as averages of the 2 survey responses from each country.

effectiveness analyses of CKD screening and management programs. Previous cost-effectiveness studies have focused primarily on high-income countries in a few geographic locations [18–20]; our data may allow future cost-effectiveness analyses to be applied across more diverse settings.

Interestingly, we did not find an association between country income and kidney laboratory testing costs although our results may not have been powered to detect small differences. There remains concern that in some LMICs, kidney health laboratory testing may be disproportionately expensive from the standpoint of purchasing power parity, which may limit the affordability of CKD testing in LMIC settings. If laboratory testing costs are transferred to patients via out-of-pocket payments, this financial burden would further threaten access to kidney

health testing and treatments [21]. Notably, only half of countries provide public funding for nondialysis CKD care [2], so broad-based efforts are clearly needed from governments and international societies to support CKD early detection and management programs. Undertaking health technology assessment would systematically assess the clinical and societal value of laboratory testing for early CKD detection and management, incorporating the perspectives of diverse stakeholders including public and private payors, patients, healthcare providers, and industry [22].

Our survey focused on laboratory testing for the initial detection and diagnosis of CKD. Future studies could examine the availability and affordability of advanced testing for the diagnostic workup of CKD, including serologic markers, imaging studies, and pathology services,

which may vary by country income level and correlate with the availability of other advanced therapies, such as kidney replacement therapy. Limitations of our findings include the lack of low-income countries in the survey and the survey report design of our ascertainment of reimbursement values, which could result in inaccuracies. In the previously completed ISN-GKHA survey, only one-third of low-income countries reported ability to measure serum Cr, and none were able to access estimated glomerular filtration rate or measure proteinuria quantitatively, with most relying on qualitative measurements using urinalyses [12]. Survey responses may reflect testing availability in the particular city or locale of the respondent and not across the country as a whole. For example, we included 2 survey respondents each from Canada and India who reported different reimbursement values, reflecting within-country heterogeneity. Furthermore, the tests surveyed were restricted to those usually conducted in central laboratories. We did not explore the use of portable point-of-care testing that might be more commonly available and affordable in some settings.

In summary, we found that kidney health laboratory testing is commonly available across middle- and high-income nations and mostly affordable particularly in high-income settings. Further work is needed to evaluate the affordability and cost-effectiveness of different CKD early detection and intervention strategies across a range of health systems and geographies globally. To achieve any meaningful progress across nations in mitigating the growth of CKD, access to basic diagnostic technology is essential. Professional organizations like the ISN shall partner with key stakeholders such as the World Health Organization, the World Bank, governments, and industry to enhance access to basic tools required for diagnosis and monitoring of CKD across countries.

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Statement of Ethics

This study was done for quality improvement purposes, and Institutional Review Board approval was not required or obtained.

Conflict of Interest Statement

Sri Lekha Tummalapalli has received consultancy fees from Bayer AG. Michael Shlipak is a consultant for Cricket Health and Intercept Pharmaceuticals and stockholder in Tai Diagnostics. David Johnson has received consultancy fees, research grants, speaker's honoraria and travel sponsorships from Baxter Healthcare and Fresenius Medical Care, consultancy fees from Astra Zeneca and AWAK, speaker's honoraria and travel sponsorships from ONO, and travel sponsorships from Amgen. He is a current recipient of an Australian National Health and Medical Research Council Practitioner Fellowship. Vivekanand Jha has received research grants and consultancy fees from Baxter Healthcare, GSK, Biocon, Aztra Zeneca, Zydus Cadilla, and Nephroo Plus. He has a policy of all payments going to the organization.

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Author Contributions

Research idea and study design: S.L.T., M.G.S., and A.K.B.; data acquisition: S.D., A.L., and A.K.B.; data analysis/interpretation: S.L.T., M.G.S., and A.K.B.; statistical analysis: S.L.T.; supervision or mentorship: M.G.S., V.J., C.M., A.L., D.W.J., and A.K.B. Each author contributed important intellectual content during manuscript drafting or revision, accepts personal accountability for the author's own contributions, and agrees to ensure that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved.

Availability of Data and Material

The data underlying this article will be shared on reasonable request to the corresponding author.

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