# SPECIAL ARTICLE

# Prevalence of Estimated GFR Reporting Among US Clinical Laboratories

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**Background:** Routine laboratory reporting of estimated glomerular filtration rate (eGFR) may help clinicians detect kidney disease. The current national prevalence of eGFR reporting in clinical laboratories is unknown; thus, the extent of the situation of laboratories not routinely reporting eGFR with serum creatinine results is not quantified.

**Design:** Observational analysis.

**Setting:** National Kidney Disease Education Program survey of clinical laboratories conducted in 2006 to 2007 by mail, web, and telephone follow-up.

**Participants:** A national random sample, 6,350 clinical laboratories, drawn from the Federal Clinical Laboratory Improvement Amendments database and stratified by 6 major laboratory types/groupings.

Predictors: Laboratory reports serum creatinine results.

**Outcomes:** Reporting eGFR values with serum creatinine results.

**Measurements:** Percentage of laboratories reporting eGFR along with reporting serum creatinine values, reporting protocol, eGFR formula used, and style of reporting cutoff values.

**Results:** Of laboratories reporting serum creatinine values, 38.4% report eGFR (physician offices, 25.8%; hospitals, 43.6%; independents, 38.9%; community clinics, 47.2%; health fair/insurance/public health, 45.5%; and others, 43.2%). Physician office laboratories have a reporting prevalence lower than other laboratory types (P < 0.001). Of laboratories reporting eGFR, 66.7% do so routinely with all adult serum creatinine determinations; 71.6% use the 4-variable Modification of Diet in Renal Disease Study equation; and 45.3% use the ">60 mL/min/1.73 m<sup>2</sup>" reporting convention. Independent laboratories are least likely to routinely report eGFR (50.6%; P < 0.05) and most likely to report only when specifically requested (45.4%; P < 0.05). High-volume laboratories across all strata are more likely to report eGFR (P < 0.001).

Limitations: Self-reporting by laboratories, federal database did not have names of laboratory directors/ managers (intended respondents), assumed accuracy of federal database for sample purposes.

**Conclusions:** Routine eGFR reporting with serum creatinine values is not yet universal, and laboratories vary in their reporting practices.

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*INDEX WORDS:* Estimated glomerular filtration rate (eGFR); laboratory reporting; serum creatinine; kidney disease.

# Editorial, p. 645

**E** arly detection of chronic kidney disease (CKD) is critical to implementing preventive strategies; however, early detection can be challenging because of the absence of symptoms. Serum creatinine has historically been used as a key measure of kidney function; however, kidney function is poorly inferred from serum creatinine level alone because it is affected by multiple factors related to muscle mass, such as age, sex, race, and body size. Misinterpretation also may be a problem. A case study designed to test physician skills in interpreting serum creatinine results showed a tendency to overestimate kidney function and therefore underestimate kidney disease.<sup>1</sup>

The National Kidney Disease Education Program (NKDEP), an initiative of the National Institutes of Health, recommends the use of estimated glomerular filtration rate (eGFR) instead

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of serum creatinine level alone to assess kidney function in adults older than 18 years. NKDEP and other organizations<sup>2,3</sup> encourage laboratories to estimate GFR by using the Modification of Diet in Renal Disease (MDRD) Study equation<sup>4</sup> and routinely report eGFR with all serum creatinine determinations. This practice has been associated with improved physician recognition of CKD in the primary care setting<sup>5</sup> and in elderly patients.<sup>6</sup>

Laboratory reporting of eGFR appears to have increased during the past several years, possibly because of the inclusion of eGFR in clinical guidelines, an increase in the number of states with reporting mandates, and education efforts of various organizations. In 2003 and 2005, the College of American Pathologists (CAP), through its General Chemistry Survey, determined that 2.7% and 20.0% of respondents reported an eGFR result based on serum or plasma creatinine measurement, respectively.<sup>7</sup> However, the CAP studies included only laboratories that participate in the organization's proficiency testing program. Although these data provide a helpful snapshot of eGFR use and show that it has increased significantly among CAP proficiency testing participants, the CAP studies were not nationally representative of eGFR reporting and associated laboratory practices.

NKDEP designed a representative study to assess the prevalence of eGFR reporting in the United States and its territories and to characterize reporting and related practices. The objective is to determine the extent to which laboratory practices are consistent with recommendations made by NKDEP and other organizations. NKDEP recommends that laboratories<sup>8</sup>: (1) use the 4-variable MDRD Study equation<sup>4</sup> to calculate the result because it is useful for most patients and uses values that are easily accessible; (2) report eGFR with all serum creatinine determinations for adults 18 years and older when appropriate and feasible, primarily for the purpose of flagging CKD for clinicians who may not have been thinking about impaired kidney function; (3) report eGFR values of 60 mL/min/1.73 m<sup>2</sup> or greater simply as " $\geq 60$  mL/min/1.73 m<sup>2</sup>," not as an exact number, because interlaboratory variation among and imprecision of creatinine assays and the estimating equation result in greater inaccuracies for eGFR values at 60 mL/min/1.73 m<sup>2</sup> or

greater<sup>9</sup>; and (4) report serum creatinine to 2 decimal places (for milligrams per deciliter) to reduce rounding errors that may contribute to

imprecision in eGFRs.<sup>10</sup> Other study objectives are to generate data that provide a baseline useful for measuring the rate of adoption of eGFR reporting among US laboratories and gain insights into areas in which NKDEP and others might strategically focus efforts to increase or improve eGFR reporting. Our hypothesis is that laboratories conducting relatively greater volumes of serum creatinine tests are more likely than laboratories with lower volumes to report eGFR.

### METHODS

#### **Study Population and Sampling**

On November 22, 2005, NKDEP obtained the Clinical Laboratory Improvement Amendments (CLIA) database from the Centers for Medicare & Medicaid Services, which includes all laboratories that hold or are seeking 1 of 4 types of certification required to perform laboratory tests on humans in the United States. The file includes laboratory/facility type (eg, community clinic and hospital), testing specialties and subspecialties, related annual test volumes, and other information. Of the nearly 200,000 laboratories in the CLIA database, we identified 20,532 that met the 2 inclusion criteria for this study: (1) possession of (or applying for) a Certificate of Compliance or Accreditation, and (2) a specialty in chemistry with a subspecialty in routine chemistry testing.

These 20,532 laboratories represent the universe of those that could be reporting eGFR and constitute the sample frame for this study. A sample was designed to allow results to be generalized to US-based clinical laboratories. The sample design maximized the precision of the estimated proportion of laboratories reporting eGFR for the national sample, as well as for 6 meaningful laboratory categories. The first 4 categories are those with the largest number of laboratories of 27 unique types of laboratories/facilities identified in the CLIA database. The 4 categories, accounting for 84.6% of all those that met the inclusion criteria, are physician office (7,627), hospital (6,574), independent (which traditionally conduct high test volumes; 2,174), and community clinic (986) laboratories. Samples were drawn from each of these 4 laboratory/facility types. The fifth category includes a small number of individual laboratories (28 in all) representing 3 laboratory types-public health (14), health fair (11), and insurance (3)-that account for 60.5% of the total volume of routine chemistry tests performed nationally. The 28 were combined to form a single group of "highvolume" laboratories that would be examined separately. The sixth or "other" category represents the 3,143 laboratories from the remaining 20 laboratory/facility types. As a result, a total of 6 laboratory-type strata were created for sampling purposes. Table 1 lists brief descriptions of the different types of laboratories.

Stratum (no.)	Description of Type of Laboratories	Why Selected as a Stratum
Physician office (7,627)	Tests performed in physician office setting; results typically shared during visit Practices are often small, but can be large (2 or 3 to 200 providers) May conduct only rapid tests or operate laboratories like those	Highest number of facilities that met inclusion criteria Patient population with CKD risk factors (diabetes and hypertension)
Hospital (6,574)	in hospitals Tests performed include those needed in emergency situations and those done in high enough volume to warrant acquisition of necessary equipment May be segmented by chemistry, pathology, and other specialty divisions	Second-highest number of facilities that met inclusion criteria
Independent (2,174)	Usually proportionate in size to the population it serves; generally used by all inpatients at particular hospital and many outpatients seen by physicians with offices in hospital Send some tests to reference laboratories if demand is low Blood chemistry analyses and urinalyses are some of most frequently requested tests Generally conduct high routine and specialty test volumes;	Third-highest number of facilities that met inclusion criteria
Community clinic (986)	often operate all day/week Private commercial facilities, including 2 largest national providers, Quest Diagnostics and LabCorp; at least 35 other companies exist Also known as reference laboratories; most tests requested from physician offices and hospitals Laboratories that are on site at community clinics Laboratories perform tests on samples drawn from patients on site; some samples sent to reference laboratories for testing	Serve populations disproportionately affected by CKD risk factors
Health fair/insurance/	Patients typically get results during follow-up visits Health fair laboratories are set up as part of a health fair, health	Fourth-highest number of facilities that met inclusion criteria (excluding CLIA "other" category) Exceptionally high mean
public health (28)	assessment, or health risk reduction program; can include lipid testing, measurement of prostate-specific antigen, and comprehensive chemistry panels. Usually operated by a clinical laboratory under special permit and must follow strict procedural and management guidelines Insurance laboratories perform tests required by insurance companies to determine whether to extend coverage or pay a	annual routine chemistry volumes (range, 524,460 to 1,658,704)
	claim Public health laboratories typically function to safeguard communities through monitoring communities for pathogens that spread through food/people/animals, testing to detect and monitor newly emerging infectious diseases, and so on	
Other (3,143)	Mix of remaining laboratory types: ambulatory surgery center, comprehensive outpatient rehabilitation facility, ancillary testing site in health care facility, end-stage renal disease dialysis facility, health maintenance organization, home health agency, hospice, industrial, intermediate-care facility for mentally retarded, mobile laboratory, pharmacy, school/ student health service, skilled nursing facility/nursing facility, other practitioner, tissue band/repositories, blood banks, rural health clinics, federally qualified health centers, ambulance, and other	Catch all for remaining laboratories, including CLIA "other" category

Table 1. Descriptions of Types of Laboratory Facilities

Abbreviations: CKD, chronic kidney disease; CLIA; Clinical Laboratory Improvement Amendments.

### Prevalence of eGFR Reporting

A minimum sample size was calculated for each of the 6 strata using a proportional sampling approach. Based on the 2005 CAP survey, the expected proportion of laboratories reporting eGFR was set to 0.20 and the desired level of precision was set to  $\pm 2.0\%$  with 95% confidence and corrected for each stratum's finite size. Taking into account the design effect of the stratified sample (design effect = 1.24), the overall precision of the weighted national estimate was expected to provide a level of precision of  $\pm 1\%$ . Planning for an 80% response rate, according to Office of Management and Budget requirement, the sample size randomly drawn from each of the sampled strata was 1,599 physician office, 1,557 hospital, 1,125 independent, and 751 community clinic laboratories, all 28 high-volume laboratories (a census of all 3 laboratory types, not a sample), and 1,290 other. The total sample was 6,350 laboratories.

#### Instrument Development and Data Collection

NKDEP developed a 10-item questionnaire (Table 2) for both paper-and-pencil and web administration modes. The questions are based in part on survey questions used by CAP and 2 state departments of health that were known to have asked laboratories about eGFR-reporting practices. The paper-based instrument was pretested by laboratory professionals before implementation, and feedback was used to finetune the wording of questions and response selections. Although NKDEP was most interested in determining an estimate for the prevalence of eGFR reporting, the survey also provided an opportunity to ask questions related to the NKDEP reporting-related recommendations (see introduction). The web version was pretested by communication professionals to ensure that it was easy to use. On October 20, 2006, a cover letter and questionnaire, including a postage-paid return envelope, were mailed to the sample of 6,350 clinical laboratories. Addressed to laboratory directors/ managers, recipients were requested to either complete and return the paper questionnaire or log on to the NKDEP website to access the electronic questionnaire. One week later, a reminder postcard was mailed to the entire sample.

The initial mailing and postcard yielded a response rate of approximately 30.0%. A telephone reminder call was fielded to all nonresponders who had telephone numbers recorded in the sample database. During that telephone contact, if possible, survey data were directly collected by a trained interviewer to maximize response rates. This reminder/computerassisted telephone interview data collection effort was fielded between January 16 and February 13, 2007. A total of 4,013 laboratories responded across all 3 modes (52.7% telephone, 41.2% mail, and 6.1% web). The overall survey response rate was 63.4% (range, 58.2% to 78.6% across laboratory types). Data from all modes were merged and prepared for analysis. The number of laboratories excluded from analyses because of missing data is noted in the relevant data tables.

Item No.	Question	Response Choices
NO.	Question	Response Choices
1	Does your laboratory report serum creatinine values for adults ( $\geq$ 18 y)?	Yes, No, Not sure
2	How does your laboratory report serum creatinine values?	mg/dL, μmol/L
3	To how many decimal places do you report the creatinine result?	None, 1, 2
4	How many serum creatinine tests did your laboratory perform in 2005?	Fill in the blank
5	Does your laboratory EVER report eGFRs with serum creatinine determinations?	Yes, No, Not sure
6	Is your laboratory currently considering reporting eGFR with serum creatinine determinations?	Yes, No, Not sure
7	Under what circumstances does your laboratory report eGFR?	With ALL measured serum or plasma creatinine determinations, Only when specifically requested, Other: please specify
8	Which estimating equation do you use for your reports?	4-variable MDRD Study, 6-variable MDRD Study, Cockcroft-Gault, Not sure, Other: please specify
9	When reporting eGFR, at what point do you assign a "greater than" (>) value?	60 mL/min/1.73 m <sup>2</sup> , 90 mL/min/1.73 m <sup>2</sup> , Never (we always report an exact number), Other: please specify
10	Please indicate the 1 identifier you use for your laboratory when submitting your CMS-116 form (CLIA Application for Certification)	See list of 26 laboratory types at: www.cms.hhs.gov/cmsforms/ downloads/cms116.pdf
11	For paper-based respondents: Enter the 2-letter state or territory abbreviation where your laboratory is located	Fill in the blank

Abbreviations: NKDEP, National Kidney Disease Education Program; eGFR, estimated glomerular filtration rate; MDRD, Modification of Diet in Renal Disease; CMS, Centers for Medicare & Medicaid Services; CLIA, Clinical Laboratory Improvement Amendments.

### Analysis

All analyses were conducted using SAS (version 9.1; SAS Institute, Cary, NC) PROC SURVEYFREQ. This procedure uses sampling weights and the finite population correction (FPC) to estimate the overall percentages, pooled variances, and 95% confidence intervals. The FPC was used in estimating the variance within strata, and the Rao-Scott  $\chi^2$  test<sup>11</sup> was used to test for differences among the strata. P values for comparisons among the first 4 strata were adjusted by using the stepdown Bonferroni method (SAS PROC MULTTEST).12 Note that 22 of 28 possible responded in the public health/ insurance/health fair stratum. Although a small number, confidence intervals are still shown for this group and are expectedly wide for all items. Serum creatinine volume quartiles were developed for each stratum to test the hypothesis that higher volume laboratories are more likely than lower volume laboratories to report eGFR. This study was implemented after receiving clearance from the US Office of Management and Budget (Office of Management and Budget no. 0925-0570).

#### RESULTS

### **Serum Creatinine Reporting**

Of laboratories performing routine chemistry tests for adult patients (survey item 1), 63.8% report a serum creatinine result (Table 3). Serum creatinine reporting is highest in hospital (91.5%) and independent (70.7%) laboratories and lowest in physician office (45.9%) and other (48.4%) laboratories. Differences for the percentage of reporting across strata were significant at a level of P less than 0.001. When reporting serum creatinine in milligrams per deciliter (survey item 2), 90.5% report the value with 1 or no decimal places, whereas the remaining 9.5% report to 2 decimal places (data not shown).

## eGFR Reporting

Of all laboratories that report serum creatinine, 38.4% calculate and report eGFR (survey item 5; Table 3). A statistical difference is seen across laboratory types (P < 0.001), with physician office laboratories, at 25.8%, the least likely to report eGFR compared with hospital, independent, or community clinic laboratories (P <0.001). When the annual volume of serum creatinine tests (survey item 4) is examined by quartile, as listed in Table 4, higher eGFR-reporting prevalence for laboratories at or greater than the median volume compared with less than the median was significant for the overall weighted estimates (P < 0.001) and most significant for physician office, hospital, and independent laboratories (all P < 0.001). In addition, eGFRreporting prevalence varies across categories, even in the laboratories with the highest test volumes (top 5%; P = 0.01).

	Serum	Creatinine Reporting		eGFR Reporting by Laboratories Reporting Serum Creatinine				
Stratum	Yes*	No	Total No.†	Yes	No	Total No.		
Physician office	45.9 (43.1-48.8)	54.1 (51.2-56.9)	1,010	25.8 (22.1-29.6)	74.2 (70.4-77.9)	453		
Hospital	91.5 (90.0-93.1)	8.5 (6.9-10.0)	1,064	43.6 (40.7-46.5)	56.4 (53.5-59.3)	963		
Independent	70.7 (67.8-73.7)	29.3 (26.3-32.2)	649	38.9 (35.1-42.7)	61.1 (57.3-64.9)	455		
Community clinic	50.9 (47.5-54.3)	49.1 (45.7-52.5)	454	47.2 (42.4-51.9)	52.8 (48.1-57.6)	229		
Health fair/insurance/ public health	50.0 (39.5-60.5)	50.0 (39.5-60.5)	22	45.4 (29.2-61.7)	54.5 (38.3-70.8)	11		
Other	48.4 (45.5-51.4)	51.6 (48.6-54.5)	803	43.2 (38.9-47.5)	56.8 (52.5-61.1)	382		
Overall (%)‡	63.8 (62.5-65.1)	36.2 (34.9-37.5)	4,002	38.4 (36.6-40.2)	61.6 (59.8-63.4)	2,493		

Note: Values expressed as percentage (95% confidence interval).

Abbreviation: eGFR, estimated glomerular filtration rate.

\*Does not include 9 laboratories that were not sure and 2 that refused to answer. P < 0.001 for comparison of the percentage reporting creatinine over stratum.

†A total of 2,528 laboratories reported serum creatinine. This table excludes 35 laboratories that did not know or did not answer the question about eGFR. P < 0.001 for comparison of the percentage reporting eGFR over stratum. P < 0.001 for pairwise comparisons of physician office laboratory to hospital, physician office laboratory to independent, and physician office laboratory to clinic; P = 0.2 for hospital to independent, P = 0.3 for hospital to clinic, and P = 0.1 for independent to clinic. Pairwise comparisons are based on comparisons of the first 4 groups using the stepdown Bonferroni method.

‡Weighted percentage.

		Top 5% Volume Laboratories						
Stratum	Quartile 1, % reporting eGFR (95% Cl)	Quartile 2, % reporting eGFR (95% CI)	Quartile 3, % reporting eGFR (95% CI)	Quartile 4, % reporting eGFR (95% CI)	Total No.†	<i>P</i> ‡	Yes, %§ (95% CI)	Total No.
Physician office	22.4 (14.1-30.6)	15.3 (8.1-22.5)	27.6 (18.8-36.4)	43.7 (33.9-53.4)	344	<0.001 <0.001	31.6 (10.1-53.0)	19
Hospital	25.3 (19.6-30.9)	38.1 (31.9-44.4)	52.2 (45.5-59.0)	59.0 (52.9-65.1)	776	<0.001 <0.001	64.1 (49.7-78.5)	39
Independent	24.7 (17.2-32.3)	28.0 (20.3-35.6)	35.4 (26.7-44.1)	65.3 (57.5-73.2)	365	<0.001 <0.001	86.4 (73.3-99.4)	22
Community clinic	31.6 (20.7-42.5)	41.7 (31.4-52.0)	45.2 (34.1-56.4)	60.9 (50.5-71.3)	174	0.06 0.03	66.7 (38.6-94.8)	9
Health fair/insurance/ public health	0.0	33.3 (3.3-63.4)	100	66.7 (36.6-6.7)	10	NA 0.09	0.0	1
Other	20.3 (12.3-28.2)	43.4 (33.8-53.1)	47.3 (37.4-57.2)	53.9 (44.2-63.7)	300	<0.001 0.001	75.0 (54.4-95.6)	16
Overall %	24.1 (20.4-27.7)	31.9 (28.1-35.8)	42.8 (38.5-47.1)	55.6 (51.5-59.7)	1969	<0.001 <0.001	59.7 (51.0-68.5)	106
Stratur	n	Quartile 1	Qu	artile 2	(	Quartile 3	Qua	rtile 4
Physician office		<1,100	1,100	)-3,099	3,1	00-9,999	9 ≥1	0,000
Hospital		<5,500	,	)-18,199		00-49,99		0,000
Independent		<2,400	,	)-7,799	7,800-29,99			0,000
Community clinic		<1,000	,	)-3,599	3,600-12,99			3,000
Health fair/insurance	e/public health	<2,000	,	)-40,699	40,700-199,9		,	
Other		<1,800	1,800	)-7,099	7,1	00-42,99	99 ≥4	6,000

Table 4. eGFR-Reporting Prevalence by Serum Creatinine Test Volume (2005) and by Laboratory Strata

Abbreviations: eGFR, estimated glomerular filtration rate; CI, confidence interval; NA, not applicable.

\*See quartile volume cut-offs and ranges in bottom section of table.

†Volume not available for 524 laboratories.

‡First *P* value for comparison of the 4 groups; second *P* value is for comparison of less than median versus median or greater. Comparisons are made within each stratum and pooled over strata.

P = 0.01 for comparison of percentage yes over stratum (excluding health fair/insurance/public health category). Includes only laboratories with a volume in the top 5% for each stratum.

Weighted percentage.

### Protocol for Reporting eGFR

The majority (66.7%) of eGFR-reporting laboratories do so with all measured serum or plasma creatinine determinations (survey item 7). Alternatively, 25.0% report eGFR only when it is specifically requested, whereas 8.3% report for other reasons (eg, with certain panels or profiles, for patients of a certain age, or for outpatients; Table 5). A comparison across all laboratory types shows a significant difference in the percentage of laboratories that routinely report eGFR with all determinations (P < 0.001). Independent laboratories are least likely (50.6%) to report eGFRs with all determinations and most likely (45.5%) to report eGFRs when specifically requested. These estimates are significantly different from those for physician office (P = 0.04),

hospital (P < 0.001), and community clinic (P < 0.001) laboratories.

### **Estimating Equation and Reporting Convention**

Almost 3 of 4 laboratories (71.6%) use the 4-variable MDRD Study equation (survey item 8), whereas another 14.3% use some other equation (eg, 6-variable MDRD Study equation or Cockcroft-Gault). Some responding laboratories (14.1%) did not know which equation was being used (Table 5). Use of the MDRD Study equation ranged among laboratory types from 58.1% to 76.2% (P < 0.001). An eGFR reporting convention (survey item 9) of ">60 mL/min/1.73 m<sup>2</sup>" when the result is greater than 60 mL/min/1.73 m<sup>2</sup> is used by 45.3% of laboratories; however, 38.7% always report the exact numeric

	Circumstances for Reporting*			Equation Used†				Reporting Convention‡					
Stratum	All	When Requested	Other	Total No.	4-Variable MDRD	Other	Not Sure	Total No.	>60 mL/min/ 1.73 m <sup>2</sup>	>90 mL/min/ 1.73 m <sup>2</sup>	Exact No.	Do Not Know	Total No.
Physician office	65.8 (57.6-74.0)	25.4 (17.9-33.0)	8.8 (3.9-13.7)	114	70.4 (62.6-78.3)	13.9 (7.9-19.9)	15.7 (9.4-21.9)	115	36.2 (27.9-44.4)	5.2 (1.4-9.0)	46.6 (38.0-55.1)	12.1 (6.5-17.7)	116
Hospital	68.8 (64.7-72.9)	21.7 (18.1-25.4)	9.4 (6.8-12.0)	414	76.2 (72.4-79.9)	14.3 (11.2-17.4)	9.5 (6.9-12.1)	420	49.2 (44.8-53.6)	5.3 (3.3-7.2)	37.4 (33.1-41.7)	8.2 (5.7-10.6)	417
Independent	50.6 (44.3-56.8)	45.5 (39.2-51.7)	4.0 (1.5-6.4)	176	72.9 (67.3-78.4)	11.9 (7.8-15.9)	15.3 (10.8-19.7)	177	46.0 (39.8-52.6)	8.0 (4.6-1.3)	35.8 (29.8-41.8)	10.2 (6.4-14.0)	176
Community clinic	79.2 (73.5-85.0)	17.9 (12.4-23.4)	2.8 (0.5-5.2)	106	58.1 (51.1-65.1)	16.2 (11.0-21.4)	25.7 (19.5-31.9)	105	28.3 (21.9-34.7)	9.4 (5.3-13.6)	50.0 (42.9-57.1)	12.3 (7.6-16.9)	106
Health fair/insurance/	. ,	. ,	. ,		. ,	. ,	. ,		. ,	. ,	, ,	. ,	
public health	100.0 (100.0-100.0)	0	0	5	80.0 (54.3-100)	0	20.0 (0.0-45.7)	5	60.0 (28.5-91.5)	0	40.0 (8.6-71.5)	0.0	5
Other	69.1 (62.9-75.3)	21.6 (16.1-27.1)	9.3 (5.4-13.2)	162	58.3 (51.7-64.9)	16.6 (11.6-21.5)	25.1 (19.3-31.0)	163	47.5 (40.8-54.2)	3.1 (0.8-5.4)	31.5 (25.2-37.7)	17.9 (12.8-23.0)	162
Overall %§	66.7 (63.8-69.5)	25.0 (22.5-27.6)	8.3 (6.6-10.0)	977	71.6 (69.0-74.3)	14.3 (12.2-16.4)	14.1 (12.1-16.1)	985	45.3 (42.3-48.3)	5.5 (4.1-6.8)	38.7 (35.7-41.6)	10.5 (8.7-12.3)	982

Table 5. Circumstances for eGFR Reporting, Estimating Equation Used, and Reporting Convention by Laboratory Strata

Note: Values listed as percent (95% confidence interval) unless noted otherwise.

Abbreviations: eGFR, estimated glomerular filtration rate; MDRD, Modification of Diet in Renal Disease.

\*Circumstances for reporting: 992 laboratories answered that they report eGFR. This table excludes 1 laboratory that skipped the question, 8 that answered "do not know," and 6 that supplied answers that did not make sense; P < 0.001 for comparison over stratum. Pairwise comparisons were calculated for reporting eGFR for all tests versus when requested or other for the first 4 strata. P = 0.04 for independent comparison to physician office laboratory, P < 0.001 for independent comparison to community clinic and to hospital. P = 0.5 for physician office laboratory comparison to hospital, P = 0.08 for physician office laboratory comparison to clinic, and P = 0.08 for hospital comparison to clinic.

†Equation used: This table excludes 7 laboratories that skipped the question; P < 0.001 for comparison over stratum.

 $\pm$ Reporting convention: This table excludes 10 laboratories that skipped the question; P = 0.001 for comparison over stratum. Pairwise comparisons were calculated for greater than 60 versus exact for the first 4 strata. P = 0.004 for clinic comparison to hospital, P = 0.02 for clinic comparison to independent, P = 0.09 for physician office laboratory comparison to hospital, P = 0.6 for physician office laboratory comparison to clinic, and P = 0.9 for hospital comparison to independent.

§Weighted percentage.

value. Another 5.5% use ">90 mL/min/1.73 m<sup>2</sup>" when reporting (Table 5). Some (10.5%) respondents did not know the eGFR reporting convention being used. Differences in the reporting convention exist across laboratory types (P < 0.001). Community clinic laboratories are the least likely (28.3%) of all laboratory types to use ">60 mL/min/1.73 m<sup>2</sup>" when reporting.

## **Considering Reporting eGFR**

Of laboratories not reporting eGFR, only 29.3% are currently considering reporting it, whereas 58.8% are not considering doing so. Another 11.9% of respondents reported that they are unsure of their laboratory's consideration of reporting (Table 6). This is significantly different across laboratory types (P < 0.001). Hospital laboratories (38.4%) are more likely to be considering eGFR reporting than other laboratory types, whereas community clinic (16.4%) and physician office laboratories (19.8%) are least likely to be considering reporting reporting eGFR.

### DISCUSSION

eGFR is currently the clinical standard for assessing kidney function; for detecting early CKD, monitoring kidney function, and assessing the effectiveness of treatment plans. NKDEP, along with others in the kidney community, has encouraged widespread adoption of eGFR reporting with all determinations for those 18 years and older to facilitate earlier diagnosis and treatment of CKD. This is especially important in the primary care setting, in which clinicians may routinely rely on serum creatinine alone to assess kidney function or may not be thinking about kidney disease when they order a metabolic panel for a particular patient. A national estimate for the prevalence of eGFR reporting was not available before this research was conducted.

1. The majority of laboratories are not reporting eGFR. Our findings indicate that more than half the serum creatinine-reporting laboratories are not reporting eGFR. We believe this is problematic because it likely represents a tremendous number of missed opportunities to diagnose CKD. This is especially true for clinicians using independent laboratories, which, as a group, conduct exceptionally high routine chemistry test volumes and have the third-highest number of facilities that do routine chemistry testing compared with the 26 other facility types in the CLIA database.

This baseline study yielded findings that fall into

3 areas, as discussed next.

2. Improvements are necessary in laboratories already reporting eGFR. This study shows there is room for improvement in laboratories already reporting eGFR because many of their practices are not consistent with the recommendations outlined. For example, approximately 25.0% of eGFR-reporting laboratories do so only

 Table 6. Considering eGFR Reporting by Laboratory Strata in All Who Report Serum Creatinine and Said No to

 eGFR Reporting

Stratum*	Yes, % (95% CI)	No, % (95% CI)	Not Sure, % (95% CI)	Total No.†						
Physician office	19.8 (15.7-23.8)	68.4 (63.7-73.1)	11.9 (8.6-15.1)	329						
Hospital	38.4 (34.6-42.3)	52.0 (48.1-55.9)	9.6 (7.2-11.9)	523						
Independent	26.9 (22.5-31.3)	55.3 (50.3-60.2)	17.8 (14.0-21.6)	275						
Community clinic	16.4 (11.4-21.4)	70.7(64.5-76.8)	12.9 (8.4-17.5)	116						
Health fair/insurance/public health	16.7 (0.0-36.5)	66.7 (41.6-91.7)	16.7 (0.0-36.5)	6						
Other	28.8 (23.6-34.1)	57.2 (51.5-63.0)	14.0 (9.9-18.0)	215						
Overall %‡	29.3 (27.1-31.5)	58.8 (56.4-61.2)	11.9 (10.3-13.4)	1,464						

Abbreviations: eGFR, estimated glomerular filtration rate; CI, confidence interval.

\*P < 0.001 for comparison over stratum. Pairwise comparisons for yes versus no were calculated for the first 4 strata. P < 0.001 for comparison of physician office laboratory to hospital and hospital to clinic. P = 0.04 for comparison of physician office laboratory to clinic, hospital to independent, and independent to clinic laboratories.

†A total of 1,511 laboratories answered that they did not report eGFR; 47 laboratories that did not answer the question are excluded from this table.

‡Weighted percentage.

when specifically requested; that is, for clinicians already considering the possibility of kidney disease. Another concern is that only about half the independent laboratories report eGFR with all serum creatinine determinations. Again, given volumes of these laboratories, this may represent a significant number of missed opportunities to identify early CKD.

The accuracy of eGFR also is a challenge because less than half the reporting laboratories (45.3%) and only 28.3% of laboratories in community clinics are using the ">60 mL/min/1.73 m<sup>2</sup>" reporting convention. Reporting exact numbers may be problematic if clinicians and patients attempt to track a decrease in kidney function by using eGFR results that are not valid. In addition, this study shows that virtually all eGFR results in the United States are calculated by using serum creatinine determinations reported to 1 or 0 decimal places (survey item 3; data not shown). The NKDEP Laboratory Working Group has called upon in vitro diagnostic companies to improve the precision of creatinine methods and develop instruments that report to 2 decimal places, both of which will improve the accuracy of eGFR determinations.

3. eGFR reporting is more common in laboratories serving higher risk patients and laboratories with relatively high test volumes. Stratum- and volume-level analyses of eGFR reporting yield 2 positive findings. Reporting is higher than the overall mean in hospital- and community clinicbased laboratories, which are facilities that commonly serve populations with high rates of CKD risk factors. In addition, for all laboratory categories, eGFR reporting prevalence is higher for laboratories with volumes greater than versus less than the median. Similarly, although the number of laboratories analyzed is relatively small, it appears that the eGFR-reporting prevalence is relatively high in the highestvolume laboratories overall (59.7%) and especially in laboratories in the independent (86.4%), other (75.0%), and hospital (64.1%) categories.

The study's limitations are those inherent to all research that relies upon "self-reporting," albeit across different modes. We expected respondents to be knowledgeable about their respective laboratory practices and use their records to retrieve information about serum creatinine testing volume in 2005. Instead, we observed that a small percentage of respondents were unsure about the equation and reporting convention used by the laboratory and found that many respondents left the volume item blank. The latter hindered our ability to determine precise prevalence estimates for eGFR reporting by volume, although we observed statistically significant differences in reporting prevalence for hospital and independent laboratories when we compared topversus bottom-half volumes. This limitation of course does not necessarily mean that survey results are inaccurate. Another possible limitation is that laboratories may have been more likely to respond to the survey if they reported serum creatinine than if they did not report serum creatinine.

Use of a previously existing database may present a second limitation because any errors in the CLIA database would have carried through to impact on the sampling design and study results. A third limitation, also associated with the database, was the absence of the names of laboratory directors and managers, our intended respondents. Our study correspondence was addressed to individuals with those or related titles, but it is unclear whether laboratory directors and managers were the individuals who completed the surveys/interviews. Completion of surveys by nonintended respondents may explain the cases in which the laboratory indicated it "did not know" or did not indicate the volume, as mentioned.

Additional research questions that future investigations may address include reasons laboratories are not reporting eGFR, reasons laboratories are not considering reporting eGFR, and the actual percentage of serum creatinine results that are reported with an eGFR by laboratories known to serve high-risk populations.

This baseline study has produced a relatively precise estimate for the prevalence of eGFR reporting and associated practices in US clinical laboratories during the end of 2006/beginning of 2007. Results can be used in future investigations to estimate the rate of adoption of eGFR reporting overall, as well as by laboratories most likely to serve people at highest risk of CKD.

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