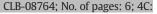
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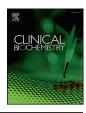
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# Call for the use of a common equation for glomerular filtration rate estimation in East and South-East Asia

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### ABSTRACT

**Background:** Estimated glomerular filtration rate (eGFR) is currently calculated using various equations and 19 serum creatinine (Scr) value measured by different assays. Differences among these eGFRs deserve further study. 20

**Methods:** Volunteers from eight Asian regions (n = 3283; age 20–65 years, 1454 men, 1829 women) were 21 recruited. The Chronic Kidney Disease Epidemiology Collaboration equation (EPI), Modification of Diet in Renal 22 Disease Study equation (MDRD) for Japanese (MDRD<sub>Jap</sub>) and MDRD for Chinese (MDRD<sub>Chi</sub>) were selected. Jaffe 23 and enzymatic assays were used to measure Scr. Six eGFRs were obtained for each volunteer: EPI equation using 24 Scr value of enzymatic assay (EPI/E) and Jaffe assay (EPI/J); MDRD<sub>Jap</sub> equation using Scr value of the two assays 25 (MDRD<sub>Jap</sub>/E, MDRD<sub>Lap</sub>/J); and MDRD<sub>Chi</sub> equation using Scr value of the two assays (MDRD<sub>Chi</sub>/E, MDRD<sub>Chi</sub>/J). 26

**Results:** Neither Scr nor eGFR showed significant regional difference. We compared eGFR calculated using the 27 same equation but with different assays. The medians (2.5%, 97.5%) of eGFR difference were 2.0 (-7, 14) mL/min/ 28 1.73 m<sup>2</sup> for EPI, 3.0 (-12.0, 18.0) mL/min/1.73 m<sup>2</sup> for MDRD<sub>Jap</sub>, and 5.0 (-18, 30) mL/min/1.73 m<sup>2</sup> for MDRD<sub>Chi</sub>. 29 We also compared eGFR calculated using different equations but with the same assay. The medians (2.5%, 97.5%) of 30 eGFR difference were 11 (-6, 56) mL/min/1.73 m<sup>2</sup> between MDRD<sub>Chi</sub>/E and EPI/E; 26 (9, 35) mL/min/1.73 m<sup>2</sup> between EPI/E and MDRD<sub>Jap</sub>/E; and 39 (22, 65) mL/min/1.73 m<sup>2</sup> between MDRD<sub>Chi</sub>/E and MDRD<sub>Jap</sub>/E; respectively. 32

**Conclusions:** eGFR difference caused by using different equations is much larger than that caused by using 33 different Scr assays. A common equation for GFR estimation is encouraged for use in Asians.

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### **39** 38

### 40 Introduction

In general, a glomerular filtration rate (GFR) that is lower than 41 60 mL/min/1.73 m<sup>2</sup> or a urine albumin to creatinine ratio that is higher 4243 than 30 mg/g is considered to be an indicator of chronic kidney disease (CKD) [1]. Early diagnosis and treatment of CKD can prevent or slow 44 progression of the disease, which could reduce the incidences of end-45stage kidney and cardiovascular diseases [2,3]. When such benefit is ac-4647 cepted by the clinical community, physicians are more likely to send a patient to a specialist if they identify such a sign on laboratory reports. 48 It is suspected that the automated laboratory reporting of estimated 49 50GFR (eGFR) is associated with a significant increase in the rate of referral of patients to nephrologists [4]. At present, many equations to estimate 51 GFR have been developed, but they were established on the basis of 5253various populations and various serum creatinine (Scr) measurement 54assays, and referred to various "gold standards" for GFR measurement.

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A fundamental aspect related to GFR estimation deserves thorough in- 55 vestigation: that is, to what extend do the equation and Scr measure- 56 ment assay affect values of eGFR. 57

A multicenter study titled "The Asian Project for Collaborative Deri-58 vation of Reference Intervals" was conducted in East and South-East 59 Asia from 2009 to 2010, aiming at collaborative derivation of reference intervals. The initial report of the study [5] showed that no regional difference was found in Scr level in East and South-East Asians. The present paper reports our follow-up work on this previous study [5]. The objectives of this study were to investigate differences of eGFR among various equation-assay combinations and to study the feasibility of using a common equation in Asian populations. Our hypothesis of using a com-66 mon equation among all Asians is motivated by the accepted under-57 standing that the Modification of Diet in Renal Disease Study equation (MDRD) is suitable to be used in all Caucasians.

In this paper, because Japanese accounted for 46% and Chinese 70 accounted for 28% of all volunteers, we selected 3 equations that contain 71 ethnic considerations: the first is the MDRD equation for Japanese 72 (MDRD<sub>Jap</sub>) [6], which is recommended for use in Japanese by the 73 Japan Society of Nephrology; the second is the MDRD equation for 74 Chinese (MDRD<sub>Chi</sub>), which had been used to investigate the prevalence 75 of CKD in China [7]; and the third is the two-level Chronic Kidney 76

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Disease Epidemiology Collaboration equation (EPI) [8], which has been
proved not to require additional ethnic factors and which can be used
directly in Asians [9,10]. These three equations all use Scr in their calculation. Two common types of assays were used to measure Scr: the Jaffe
assay and enzymatic assay.

# 82 Materials and methods

## 83 Participant enrollment, sample collection and measurement

This study further explored the data of an existing database created in a comprehensive survey among many cities in eight Asian regions. Participant recruitment, sample collection, specimen transportation, the assay's performance validation and target analyte measurement of the survey were described in a previous report [5].

The study was approved by the Ethical Committee of Yamaguchi University Graduate School of Medical Sciences in December 2008. All the volunteers were duly informed of the medical treatment and procedures associated with this study, and all gave their written consent to participate in this research.

## 94 Performance of serum creatinine assays

Scr was measured by UniCell DxC 800 analyzer (Beckman-Coulter, 95 USA) using a kinetic Jaffe assay. The enzymatic assay was performed 96 on a Hitachi 917 analyzer, P module, and the reagent was provided by 97 Shino, Japan. All measurement procedures followed the manufacturer's 98 99 specifications. The accuracy of the two assays was validated by measuring a certified reference material (JCCRM521-10, serum matrix; see 100 the Supplementary material for its certification). The biases of the 101 102Jaffe assay and enzymatic assay were  $-2.7 \,\mu mol/L$  and  $-2.7 \,\mu mol/L$ , respectively, when the Scr level is 78.7  $\mu$ mol/L, and  $-5.3 \mu$ mol/L and 103104  $-3.5 \,\mu mol/L$ , respectively, when the Scr level is 194.5  $\mu mol/L$ . The within-run coefficient of variation was 2.41% for the Jaffe assay and 1051.41% for the enzymatic assay, and the day-to-day coefficient of varia-106 tion was 2.97% for the Jaffe assay and 1.58% for the enzymatic assay dur-107 ing the study period. 108

# 109 Estimation of glomerular filtration rate

Three equations, the EPI, MDRD<sub>Jap</sub> and MDRD<sub>Chi</sub>, were used. When EPI is used to calculate eGFR, the following equations are used for males and females.

113 For males:

115 Scr 
$$\leq 0.9$$
 : eGFR = 141 × (Scr/0.9)<sup>-0.411</sup> × 0.993<sup>Ag</sup>

116

 $Scr{>}0.9:eGFR = 141 \times (Scr/0.9)^{-1.209} \times 0.993^{Age}$ 

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For females:

Scr 
$$\leq$$
 0.7 : eGFR = 144 × (Scr/0.7)<sup>-0.329</sup> × 0.993<sup>Age</sup>

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$$Scr>0.7: eGFR = 144 \times (Scr/0.7)^{-1.209} \times 0.993^{Age}$$

123

124

126

When the  $MDRD_{Jap}$  is used to calculate eGFR, the following equation is used for males and females.

$$eGFR = 194 \times (Scr)^{-1.094} \times (Age)^{-0.287} [if female, \times 0.739]$$

When the MDRD<sub>Chi</sub> is used to calculate eGFR, the following equation 127 is used for males and females.

129 
$$\text{eGFR} = 175 \times (\text{Scr})^{-1.234} \times (\text{Age})^{-0.179}$$
 [if female,  $\times 0.79$ ]

For each volunteer, the following six eGFRs were obtained: EPI using the Scr value of the enzymatic assay (EPI/E) and Jaffe assay (EPI/J); 130 MDRD<sub>Jap</sub> using the Scr value of the enzymatic assay (MDRD<sub>Jap</sub>/E) and 131 Jaffe assay (MDRD<sub>Jap</sub>/J); and MDRD<sub>Chi</sub> using the Scr value of the enzymatic assay (MDRD<sub>Chi</sub>/E) and Jaffe assay (MDRD<sub>Chi</sub>/J). 133

### Statistical analysis

The same statistical methods as reported in the previous study [5] 135 were used. The magnitudes of variation due to sex, age and region 136 were analyzed by three-level nested ANOVA. In brief, the magnitude 137 of variation due to each factor (sex, age and region) was expressed as 138 standard deviations (SD) including between-region SD (SD<sub>region</sub>), 139 between-sex SD (SD<sub>sex</sub>) and between-age SD (SD<sub>age</sub>). The relative 140 magnitude of each factor to that of the residual SD representing a net 141 between-individual SD (SD<sub>net-btw-indiv</sub>) was computed as the SD ratio 142 (SDR) by the following formula: 143

$$\label{eq:SDR} SDR_{factor} = SD_{factor}/SD_{net\text{-}btw\text{-}indiv}.$$

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The SDR of each factor indicates its degree of influence on the target analyte. An SDR of  $\geq$  0.3 was regarded as high, an SDR between 0.26 and 146 0.29 was considered moderate, and an SDR of  $\leq$  0.25 was considered 147 low. 148

The Harris and Boyd algorithm [11] was used to determine whether 149 regional groups could be merged. Distribution of eGFR was analyzed 150 based on nonparametric descriptive statistics, by use of a general- 151 purpose statistical software, Statflex Version 6.0 (Artech Co., Osaka, 152 Japan).

Sex difference was significant for the Scr value because the SDR for 156 Scr was approximately 1.83. However, the sex difference was relatively 157 subdued for the eGFR value because the SDR for eGFR was approximately 158 0.32. 159

Age difference was significant for eGFR because the SDRs for eGFR 160 were 1.24 for males and 1.42 for females. In contrast, age difference 161 showed no significant effect for the Scr value because the SDRs for Scr 162 were only 0.08 for males and 0.00 for females. 163

Both Scr and eGFR showed no noticeable regional differences by 164 three-level nested ANOVA. The SDR<sub>region</sub> for Scr and eGFR was all 165 below 0.25 and was considered not significant (Table 1). 166

#### Scr distribution (by enzymatic assay) in eight Asian regions

The Scr value at each percentile in the eight Asian regions studied 168 was shown in Table 2. The Scr value was obtained from the enzymatic 169 assay. The Harris–Boyd method was applied, and an az value greater 170 than 3.0 was deemed to represent a significant difference. Taking 171 Japan as the comparison region, the az values, which ranged from 0.0 172 to 2.5, suggested no significant regional differences among the eight 173 regions. 174

SD <sub>ratio</sub> of Scr and eGFR (EPI/E) by nested ANOVA.						t1.1 <b>Q2</b> .2
	SDR <sub>sex</sub>	SDR <sub>age</sub>		SDR <sub>region</sub>		t1.3
		Male	Female	Male	Female	t1.4
Scr	1.83	0.08	0.00	0.24	0.22	t1.5
eGFR by EPI/E	0.32	1.24	1.42	0.00	0.00	t1.6

Standard deviation ratio (SDR) of each factor indicates the degree of influence on the<br/>target analyte. SDR ≥0.3 was regarded as high, SDR between 0.26 and 0.29 was considered<br/>moderate, and SDR ≤0.25 was considered low [5].t1.7

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