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Effect of variability in creatinine measurement and estimated glomerular filtration rate on study eligibility and interpretation of large-scale data

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For decades, clinicians have assessed renal function using serum or plasm concentrations of the endogenously produced creatinine, which is incorporated into equations designed to estimate the glomerular filtration rate (GFR). With a number of different methods to measure creatinine, calibration of creatinine in most clinical laboratories has not traditionally been standardized to a common gold standard, and it may result in interlaboratory estimated GFR (eGFR) variability with greater effect at lower creatinine values due to the inverse relationship between creatinine and eGFR. Several substances including bilirubin, glucose, ketones, proteins and some medications may interfere with creatinine assays. The standardization with isotope dilution mass spectrometry (IDMS) has been an important achievement for creatinine assay harmonization by addressing excessive bias that would be due to nonstandardized calibration. However, significant interlaboratory variability in creatinine measurement still remains, due to residual bias and poor precision. Such effect would be greatest when creatinine is not significantly elevated and when individuals' serum contains interfering substances. Any measurement error in creatinine may translate into error in estimating GFR. Consequently, this would not only result in misclassification of the renal function of individuals but also in error estimating the population prevalence of chronic kidney disease (CKD) in epidemiologic studies. Furthermore, if estimating GFR using heterogeneous values obtained from different creatinine assays in large-scale cohort studies, great caution is needed when interpreting the results. Another problem with estimating GFR is that most equations to estimate GFR were not as good in regions outside North America, Europe, and Australia, presumably reflecting differences in creatinine generation due to racial, ethnic, and regional variations in muscle mass and diet that are not captured by the race coefficients. The variability in serum creatinine determination in each laboratory and application of different GFR estimating equations could have significant clinical implications and also substantial potential to affect clinical research studies. The effect of measurement uncertainty in GFR estimation owing to assay bias, imprecision and nonspecificity needs to be recognized when interpreting clinical data. Improvement in application of standardized GFR estimates using standardized creatinine in clinical research as well as clinical practice will lead to better understanding of levels close to measured GFR in representative populations and each patient.