Medica

Title: *Estimated Glomerular Filtration Rate (eGFR)*

This guideline was approved by the Medical Policy Committee.

Scope and Purpose

Medica's goal is to achieve equity and eliminate disparities in kidney care. The purpose of this guideline is to provide evidence-based information for alternative approaches to GFR equations that calculate kidney function without the inclusion of the race coefficient, meet the standards of transparency and shared decision-making, and ensure equity and personalized care for patients with kidney disease. Recognition has been increasing that the use of race and ethnicity when estimating glomerular filtration rate (eGFR) is an imprecise variable that does not meet scientific rigor, provides a biased assessment of kidney function that affect the diagnosis and subsequent treatment of kidney diseases, and may inequitably delay health care.

Medica supports eliminating race correction in the GFR calculation in order to ensure that our health care systems do not perpetuate the very inequities we aim to repair.

Definitions

Blood urea nitrogen: This test measures the amount of urea in your blood. Urea is a waste product made when protein is broken down in your body. Urea is made in the liver and passed out of your body in the urine.

Blood urea nitrogen-to-creatinine ratio: The levels of blood creatinine and blood urea nitrogen (BUN) can be used to find the BUN-to-creatinine ratio. This ratio can help to identify problems, such as dehydration, that may cause abnormal BUN and creatinine levels.

Creatinine Blood Level: The blood creatinine level shows how well your kidneys are working. The amount of creatinine in the blood depends partly on the amount of muscle tissue you have. Men generally have higher creatinine levels than women. A high level may mean that your kidneys are not working, as they should.

Creatinine Clearance: A creatinine clearance test measures how well creatinine is removed from your blood by your kidneys. This test gives better information than a blood creatinine test on how well your kidneys are working. The test is done on both a blood sample and on a sample of urine collected over 24 hours.

Creatinine: A waste product in the blood that results from the normal breakdown of muscle. Healthy kidneys filter creatinine from the blood.

Disparity in healthcare: As defined by NAM, disparity in health care a difference in care that arises through operation of the healthcare system; legal or regulatory climate; or discrimination, biases, stereotyping, and uncertainty; but is not due to clinical appropriateness or patient preference.

Equity in healthcare: The National Kidney Foundation (NKF) define it as care that does not vary in quality on the basis of personal characteristics, such as sex, race/ethnicity, geographic location, or socioeconomic status.

Glomerular filtration: It is the process by which the kidneys filter the blood, removing excess wastes and fluids.

- High creatinine blood levels can be caused by kidney damage or chronic kidney disease, dehydration, shock, cancer, low blood flow to the kidneys, muscle injury and other muscle conditions.
- Low values can mean lower muscle mass caused by a disease, such as muscular dystrophy, or by aging. Low levels can also mean some types of severe liver disease or a diet very low in protein. Pregnancy can also cause low levels.

Glomerular filtration rate (GFR): GFR is a calculation that determines how well the blood is filtered by the kidneys, which is one way to measure remaining kidney function. GFR is also used to find the stage of chronic kidney disease. Glomerular filtration rate is usually calculated using a mathematical formula that compares a person's size, age, sex, and race to serum creatinine levels. The normal GFR for an adult male is 90 to 120 mL per minute. A GFR under 60 mL/min/1.73 m^2 may mean kidney disease—the lower the GFR number, the worse the kidney function. This number is an estimate. It may not be a good measure of kidney health in some people, such as the very young or very old, amputees, or obese people.

Race: A construct of human variability based on perceived differences in biology, physical appearance, and behavior. Race and ethnicity are social and not biological constructs.

Comments

The use of race in measuring eGFR has been a subject of debate. Critics say that use of race in these algorithms is flawed for multiple reasons. The race adjustment overestimates kidney function (which suggest better kidney function) and ignores the substantial diversity within self-identified Black or African American individuals and other racial or ethnic minority groups. The algorithm developers justified these outcomes with evidence of higher average serum creatinine concentrations among black people than among white people. Explanations that have been given for this finding include the notion that black individuals release more creatinine into their blood at baseline, in part because they are reportedly more muscular. Analyses have cast doubt on this claim, but the "race-corrected" eGFR remains the standard. Proponents of the equations have acknowledged that race adjustment "is problematic because unlike age, sex and body weight, race is a social concept, not a biological construct," but warn that ending race adjustment of eGFR might lead to overdiagnosis and overtreatment of black individuals. Conversely, race adjustments that yield higher estimates of kidney function in black individuals might delay their referral for specialist care or transplantation and lead to worse outcomes, while black people already have higher rates of end-stage kidney disease and death due to kidney failure than the overall population.

As long as uncertainty persists about the cause of racial differences in serum creatinine levels, we should favor practices that may alleviate health inequities over those that may exacerbate them. Researchers and clinicians must distinguish between the use of race in descriptive statistics, where it plays a vital role in epidemiologic analyses, and in prescriptive clinical guidelines, where it can exacerbate and propagate inequities.

Background

There are more than 37 million people affected by kidney diseases in the United States. A disproportionate number are of African American, Hispanic, Asian, and Native American descent. African Americans are three times more likely than Non-Hispanic Whites to experience kidney failure. Such disparities go beyond the high prevalence of kidney diseases and extend into differences in treatment modality. Postulated causes include increased prevalence of early stage chronic kidney disease (CKD), higher CKD progression rates, and lower mortality rates (survival advantage) in the earlier stages of CKD in African Americans.

The estimated glomerular filtration rate (eGFR) is one of the primary diagnostic methods that healthcare professionals use for diagnosing and managing kidney disease. eGFR is widely accepted and has standardized the diagnosis and care of all individuals with kidney diseases, it provides reliable and accurate information on kidney function, and helps determine appropriate treatment. Almost all clinical laboratories in the United States now report eGFR with any blood test that contains serum creatinine.

Several eGFR equations have been developed to estimate kidney function from serum creatinine concentration, adjusting for demographic factors including age, sex, race and/or body weight based on correlations with measured GFR across diverse populations.

1. **Cockcroft–Gault**: The original equation (Cockcroft–Gault) was developed in 1976 from a clinical study that included 249 Caucasian men and extrapolated to other groups using epidemiologic and statistical methods. It estimates glomerular filtration rate on the basis of a measurement of serum creatinine.
2. **Modification of Diet in Renal Disease (MDRD):** A couple decades later, after Cockcroft–Gault was developed, published research by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and other investigators showed that serum creatinine concentrations were higher among African American adults who had the same measured GFR (iothalamate clearance) as their White adult counterparts, indicating that determinants of serum creatinine levels, other than GFR, differed between the groups. Although investigators could not explain why that is, they observed that the increase was not always related to kidney disease and attributed the differences to muscle mass, diet and the way the kidneys eliminate creatinine. They also suggested that using

race could make the eGFR more accurate compared to the true most accurate measured GFR. So, in 1999, the Modification of Diet in Renal Disease (MDRD) study equation updated the original Cockcroft–Gault equation with new study data that included African Americans and women and confirmed the racial differences in creatinine levels. That's when race was factored into eGFR to account for those differences.

The MDRD equation reports a higher eGFR (by a factor of 1.210) if the patient is identified as black. This adjustment is similar in magnitude to the correction for sex (0.742 if female).

3. **Kidney Disease Epidemiology Collaboration (CKD-EPI) equation**: The recommended GFR calculation formula by the National Kidney Disease education program is the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. This equation was developed using data pooled from 10 studies and validated against data derived from 16 additional studies, in which the gold standard was direct measurement of GFR using external filtration markers (e.g., iothalamate). The study population included a larger number of black individuals with and without kidney disease who had a wide range of GFRs. The CKD-EPI equation proposes a more modest race correction (by a factor of 1.159) if the patient is identified as black. This correction is larger than the correction for sex (1.018 if female). Although the CKD-EPI equation is more accurate and less biased than the previous equations, precision has not substantially improved. However, data show that, across multiple populations, the use of the CKD-EPI equation results in a lower prevalence estimate of CKD and more accurate risk prediction for adverse outcomes compared with the MDRD study equation. Nevertheless, these higher eGFR values may delay referral to specialist care or listing for kidney transplantation.

GFR – Tests

There are different ways to assess the glomerular filtration rate, and estimating GFR is distinct from directly measuring GFR. The best overall indicator of the glomerular function is direct measurement of GFR.

Direct measurement of GFR is possible by infusing a substance, such as a compound called inulin or certain radioisotopes (e.g., 51 Cr-EDTA, 99 Tc-DTPA), into the blood and seeing how quickly it is cleared by the kidneys. While more accurate, this type of testing is expensive, highly complex, and requires more specialization. For this reason, its ability to serve as a widespread method of assessing kidney function is reduced. They typically only take place for research or transplant purposes.

In the eGFR test, the rate is not measured directly. Instead, it is estimated by measuring another substance in the blood. Most often, creatinine is measured, and then special formulas calculate eGFR based on the level of creatinine in the blood. However, eGFR is not a perfect test, and several factors can affect its accuracy. Most eGFR tests are based on creatinine levels, and test accuracy is affected by multiple factors that can influence creatinine levels and the calculation of eGFR. eGFR calculation is affected by multiple factors including creatinine generation (which is correlated primarily with muscle mass), renal tubular secretion of creatinine (which can be affected by certain medications), and by other individual factors that can influence creatinine levels (e.g., age, sex, diet, pregnancy).

While commonly used, creatinine is not the only substance that can be used to indirectly estimate GFR. For example, some eGFR tests measure cystatin C, which is a protein produced by many types of cells in the body. The advantages of cystatin C over creatinine are that it is not affected by age, muscle bulk (race) or diet, and various reports have indicated that it is a more reliable marker of GFR than creatinine, particularly in early renal impairment. Cystatin C has also been incorporated into eGFR equations, such as the combined creatinine-cystatin KDIGO CKD-EPI equation. This combination serves as a type of initial and confirmatory testing that improves overall accuracy of estimating GFR.

Given the above, in situations where the absolute eGFR value will directly affect clinical decision-making (e.g. medication dose or appropriateness), clinicians should consider using serum cystatin C to estimate GFR (which does not involve the consideration of race), or direct measure of GFR.

How the Test is Performed:

A blood draw for an eGFR test is a routine outpatient procedure. For an at-home test, the blood sample comes from your fingertip. The blood sample is sent to a laboratory where the blood creatinine level is tested. The lab

specialist combines the blood creatinine level with several other factors to estimate GFR. Different formulas are used for adults and children. Currently, the formula includes some or all of the following individual factors:

- Age
- Blood creatinine measurement
- Race and/or ethnicity
- Gender
- Height
- Weight

The creatinine clearance test, which involves a 24-hour urine collection, can also provide an estimate of kidney function.

GFR – Indications

Indications for the assessment of renal function are varied and range from acute emergency to chronic settings.

- To make a diagnosis in individuals with signs or symptoms of kidney disease.
- To screen persons with risk factors for kidney disease:
  - Diabetes
  - Family history of kidney disease
  - Frequent urinary tract infections
  - Cardiovascular disease
  - High blood pressure
  - Urinary blockage
  - Other conditions that increase the risk of kidney disease
- To monitor kidney disease treatment or progression, ensure timely and optimal management, and monitor response to interventions.
- To monitor for side effects of drugs that may include kidney damage or altered kidney function.
- To monitor the function of a transplanted kidney.

GFR – Test Results

GFR estimates and prediction intervals should be interpreted on the basis of patients' clinical status. Patients with better nutritional status, fitness levels, who are very muscular or take medications that decrease creatinine secretion (e.g. trimethoprim-sulfamethoxazole, cimetidine, certain HIV medications), are more likely to have higher GFRs, whereas those with decreased muscle bulk such as elders, frail patients, limb amputation, or muscular dystrophy are more likely to have a lower end of the range.

Trends over time in eGFR and serum creatinine levels also must be interpreted in the context of any changes in clinical status. Clinicians should perform additional tests, such as kidney ultrasonography and albuminuria measurement, if appropriate; evaluate risk factors for kidney disease and its consequences; and consider measuring GFR directly for critical decisions, such as whether to start dialysis or whether a potential kidney donor is a suitable candidate.

Normal Results
According to the National Kidney Foundation, normal results range from 90 to 120 mL/min/1.73 m^2.

- Some individuals, such as the elderly or infants, a GFR between 60 to 89 mL/min/1.73 m^2 may be normal, because GFR decreases with age. Otherwise, mild kidney disease (stage 2).
- Normal value ranges may vary slightly among different laboratories. Some labs use different measurements or test different samples.

Abnormal Results
Levels below 60 mL/min/1.73 m^2 for three or more months are a sign of chronic kidney disease.

- The range of scores below 60 may be used to monitor treatment and disease progression.
- The range between 30 and 59 means moderate decreased kidney function (stage 3A or B) and patient may experience symptoms.
- Levels between 15-29 mL/min/1.73 m^2 means severe decreased kidney function (stage 4).

- A GFR lower than 15 mL/min/1.73 m^2 (stage 5) is a sign of kidney failure. It means an individual has less than 15% kidney function. This stage is the most serious and can be life-threatening. The patient will need dialysis (a machine to filter the blood) or a kidney transplant.

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