# Using the ADDIE Framework to Eliminate Race Correction for Kidney Disease Function

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## Introduction

This paper is based on the Assess, Design, Develop, Implementation, and Evaluation (ADDIE) framework. A simple, yet important, laboratory test calculation change to improve outcomes for people of color in a primary care practice will be the focus. In this paper, the author will assess the problem of how most health care institutions measure the estimated glomerular filtration rate (eGFR) today and why this is problematic. She will then provide evidence in an in-depth discussion to support the change in the interpretation of the eGFR. A Use Case to illustrate the issue will be included in the development section. A chart in the implementation section will elaborate on how this new policy will be rolled out and finally, an evaluation of the first six months after the change is implemented will be included.

## Assess

Black Americans have lower life expectancy than other races in the United States (U.S.). In 2017, white life expectancy in total was 78.8 years and for Black Americans it was 75.3 (Arias & Xu, 2019). For males, the gap was wider – 76.4 for whites and 71.9 for Blacks. And for women, life expectancy for white females was 81.2 and for Black females 78.5 (Arias & Xu, 2019). Kidney disease is a leading contributor to morbidity and cause of mortality for Black Americans. The rate of kidney failure is more than three times higher for Black Americans than for Caucasians (National Kidney Foundation, 2016). Black Americans are only 13.2% of the U.S. population but comprise over 35% of patients receiving dialysis. The leading cause of kidney failure in Black Americans is type 2 diabetes and Black Americans are diagnosed with diabetes two times more frequently than those who are white (National Kidney Foundation, 2016).

However, for the past 30 years the most common laboratory test used to diagnose kidney problems and severity of kidney disease has been adjusted upwards for Black Americans, potentially leading to underdiagnosis of kidney disease in Black Americans and delays in care including referral to nephrologists and kidney transplants. In 2009, Levey et al., published data to support including race as a factor when calculating the eGFR with the assumption that Black Americans have more muscle mass and therefore higher creatinine levels. This recommendation was adopted widely in the U.S. although not in Europe or in Africa (M. Hoenig, personal communication, July 17, 2020). Six points are routinely added to the eGFR value for Black Americans giving them higher values than other races, although race is a social construct, not biological.

## Design

The population most at risk for high morbidity and mortality from kidney disease receives artificially elevated values for the most used diagnostic test on which decisions for all stages of treatment are based. Avi-Yonah (2019) noted that over 200 million eGFR tests are ordered annually. Vyas et al., (2020) wrote about multiple race corrections built into our health care system. These "…race-adjusted algorithms guide decisions in ways that may direct more attention or resources to white patients than to members of racial and ethnic minorities" (p. 1). Other algorithms or calculations with race corrections include the Heart Failure Risk Score, Vaginal Birth after Cesarean Score and the STONE score for kidney stones.

Because people of color in the United States typically have worse health outcomes than the white population, race and ethnicity are typically cited as the cause, rather than poverty, racism, lack of housing, etc. In addition, many algorithms equate genetics with race however there is much genetic variation within races (Maglo et al., 2016). Further, none of the algorithms

or calculations take mixed race into account. Notably, with the eGFR, if a patient is mixed race, it is not clear if the higher or lower value should be used (Eneanya et al., 2019).

Levey et al., (2020) continued to argue that using race in the eGFR calculation remains important until further research elucidates a different factor to include in that calculation or a new test is available as a substitute. Many large hospitals and health systems that have dropped the race correction for eGFR began taking height and weight or muscle mass into account along with eGFR results in addition to ordering a cystatin C-based test when additional evidence is needed (Eneanya, 2019; Zoler, 2020). Beth Israel Deaconess Medical Center in Boston, Massachusetts was the first institution to implement this change in 2017 (Zoler, 2020). Since then a handful of other institutions including Mass General Brigham (formerly Partners Health Care), San Francisco General and University of Washington teaching hospitals have dropped the race correction (Kolata, 2020; Zoler, 2020).

The National Kidney Foundation and American Society for Nephrology created a task force to study this issue (M. Hoenig, personal communication, July 17, 2020). There are research projects at the above-mentioned institutions to track outcomes based on the laboratory test revisions. Given the weak data employed by Levey et al., (2009), the rising awareness of how race corrections in algorithms and laboratory values may reduce access to care for people of color in the United States, and the current attention on institutional and structural racism, this author recommends dropping the race-based eGFR value. The Use Case included in the next section will illustrate how using the same eGFR values for all races may improve outcomes related to kidney disease.

## Develop

A Use Case is included in this paper to identify, plan, organize and clarify system requirements to implement this suggested change in a primary care clinic. The Use Case highlights the key actors, system changes needed and required decisions. It is a useful model, often used in Information Technology, to outline steps for system change and prevent steps and processes from being missed that could lead to failure. Conditions for success and failure are included to help guide the process.

**Use Case:** New testing procedure for kidney disease in Black and mixed-race patients

**ID:** New testing procedure for kidney disease in Black and mixed-race patients, Version 1

**Description of Use Case:** Patients who are at risk of severe kidney disease are seen by primary care clinician (MD, NP, PA) and blood tests are drawn and sent to the laboratory. Race corrected values are no longer calculated or entered in to the electronic medical record (EMR) Additional information may be collected and analyzed including age, height/weight, BMI, muscle mass, albumin level and cystatin C may be ordered to confirm eGFR results. Additional lab results discussed with the patient and referrals to nephrology will be made if 3 consecutive monthly eGFR tests are under 60.

**Primary Actors:** Patients and primary care clinicians

**Supporting Actors:** Information system team, phlebotomy team, laboratory team, nephrology practices

**Stakeholders and Interests:** Clinic executive management team (CEO, COO, CFO), board members, insurance companies

**Pre-Conditions:**

1. Agreement by the clinical and laboratory teams to make this change

2. Information Systems team makes the change in the EMR
3. Insurance companies agree to cover additional tests when required to make diagnosis of kidney disease
4. Patient education materials are developed to include the new test results and procedures
5. Nephrology practices agree to accept all patients, no matter what race, based on eGFR results and any additional data/testing done

**Normal Flow of Events:**

1. Patients who are at risk of severe kidney disease are seen by primary care clinician (MD, NP, PA) and referred to phlebotomy team at end of visit
2. Blood draws are completed by phlebotomy team
3. Labs are sent to the laboratory
4. eGFR test is completed, no race-based values are calculated, values are entered into the electronic medical record (EMR) system
5. Results are discussed in person or by phone by the primary care provider and the patient
6. Based on eGFR results, additional information may be collected and analyzed including age, height/weight, BMI, and muscle mass. Other lab values including albumin level and cystatin C may be ordered
7. Additional lab results discussed with the patient and referrals to nephrology will be made if 3 consecutive monthly eGFR tests are under 60
8. Primary care clinicians will continue to follow patients and collaborate with the nephrology team on next steps in treatment

9. If eGFR and other lab results/clinical data do not support referral at this time, patient will continue to be followed closely for progressive kidney disease. If eGFR is > 60 in any subsequent visits, 3-lab test series will be repeated
10. Support – contact the lead clinician with any questions
11. Evaluate – lead clinician on this project will review data quarterly on referrals, patient outcomes, billing issues. An annual review will also be completed. If problems are detected, revise the Normal Flow

**Post Conditions:**

Success-end condition

1. The changes are approved by primary care clinician and laboratory teams and executive management
2. Nephrology practices and insurance companies accept the new changes
3. All steps in the Normal Flow of Events are successfully completed when needed
4. All patients meeting the criteria for referral are referred and accepted into nephrology practices
5. Patients kidney disease is stabilized or mitigated with additional treatments and procedures

Failure-end condition:

1. The laboratory test changes are not approved by primary care clinician or laboratory teams or executive management
2. Nephrology practices or insurance companies refuse to accept patients or cover lab costs
3. Steps in the Normal Flow of Events are ignored or missed and confusion about patient care flow is introduced

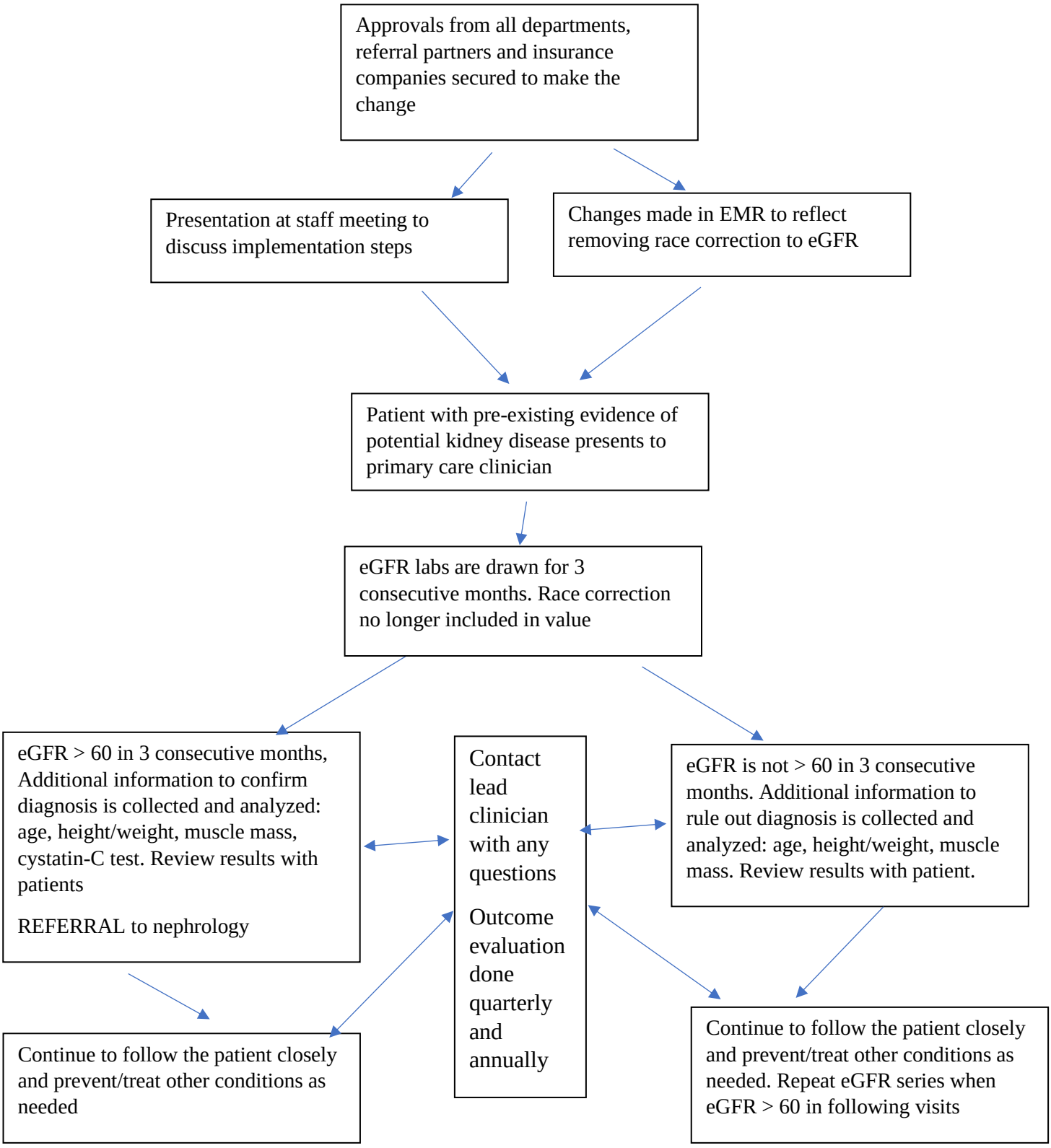
4. Patients of color are refused from nephrology practices which continue to use old eGFR values as referral basis
5. Additional data or laboratory tests are not used to confirm eGFR results and there is potential over-diagnosis of kidney disease
6. Patients of color continue to have poorer kidney disease outcomes

**Trigger:** Patients of color are being seen at primary care practices

The workflow or Normal Flow of Events from above is visually depicted in the next section.

## Implementation

Workflow for new eGFR calculations, values and referrals



## Evaluation

After reviewing two quarters of data, referrals of Black patients to nephrology practices increased 10%. An additional 15 patients began receiving dialysis. This compares to an average of 12 per six months. These are interesting findings on their own, but it will be important to compare data with the next two quarters and beyond. Clinical outcomes will be analyzed after one year of implementation.

Clinicians contacted the lead clinician on this project at least 15 times to clarify which additional data to analyze or tests to order to complement the eGFR values. One preliminary finding is that there may be overdiagnosis of severe kidney disease in patients over 65 years, therefore the additional data from muscle mass, comorbidities, BMI is now required for analysis before referral for that set of patients. The lead clinician added more detail to the workflow chart and developed a 2-page clinical guide with information on when to use the additional data/tests. The guide is based on experience from those health care institutions which implemented this change over the past few years and Eneanya (2019) and Zoler (2020) as discussed in the Design section. The lead clinician is now part of a nationwide working group that meets virtually every month to discuss how the change in eGFR calculation is being implemented and preliminary outcomes.

From a technical standpoint, the IS team successfully made the change in our EMR and no users flagged issues about data entry or access. The laboratory team smoothly transitioned to eliminating the race correction although a few residual increased values were detected. In those instances, the clinician contacted the lab and reviewed the cases and whether any errors were made. Only one insurance company refused to cover the cystatin-C tests and in those instances

the issue was discussed with the patients who either decided to pay for the test themselves or declined to have that test drawn.

Data will continue to be reviewed quarterly and annual reports shared with the clinical and laboratory teams for the next five years. Any new research published on this topic that is relevant will be reviewed and shared with the clinical team.

## Conclusion

Based on the current medical literature and recognizing the racism built into the U.S. health care system, the clinical and laboratory teams and executive management decided to eliminate the race correction when calculating the eGFR. The team followed the ADDIE framework and a Use Case which provided a road map to implement the change and identify any issues. Based on initial feedback, the lead clinician and author developed and enhanced clinical guidance for the primary care clinicians. Initial results show a 10% increase in referrals for Black patients. The clinic is at the forefront of addressing one of the problems that Black patients face and attempting to address it with a relatively simple change that could lead to much improved outcomes for this patient population.

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