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February 15, 2023

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Re: U.S. Preventive Services Task Force Draft Research Plan on Chronic Kidney Disease Screening

Dear Drs. Mangione, Nicholson, and Barry:

The American Kidney Fund appreciates the opportunity to comment on the U.S. Preventive Services Task Force's (USPSTF) draft research plan on chronic kidney disease (CKD) screening.

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

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AKF commends the USPSTF for developing this draft research plan and opening it up for public comment. As we noted in our August 2022 letter to the USPSTF, our support for CKD screening recommendation stems from concerns about the growing number of people who experience kidney failure and need dialysis or transplantation, and the stark health disparities associated with kidney disease. We broadly support the USPSTF's draft research plan, particularly the proposed approach to assessing health equity and variation in evidence across populations. We also offer the following comments on other components of the plan.

Definitions

It would be useful if the USPSTF clarified the definition of screening that is being used in the evidence review, and if there is a specific standard of screening in the inclusion criteria. There are variations in the types of screenings used in evaluating kidney function, including eGFR (estimated glomerular filtration rate) blood test, serum creatinine blood test, blood urea nitrogen (BUN) test, and the different types of urine analysis, including microalbumin and the albumin-to-creatinine ratio (UACR). Additionally, there are variations in the frequency of these tests that may need to be considered when assessing the evidence. Given these factors, a clearer definition of screening in the research plan would be beneficial in understanding the conclusion of an eventual recommendation.

Similarly, it would be useful if the USPSTF clarified the definition of harms that is being used in the evidence review. Understanding the types of potential harmful outcomes that are being assessed in the evidence review would clarify the factors that inform a recommendation on CKD screening.

Another term that would benefit from a clearer definition is quality of life, which is listed as an outcome that would be included as part of the evidence review for key questions 1, 4 and 7. Quality of life can be defined and measured in different ways, and patients may have perspectives on it that may not be fully considered by clinicians and researchers. It would be helpful for the USPSTF to provide a clear definition of quality of life that it intends to use for its evidence review, and whether it is a heterogenous definition and includes factors such as a patient's emotional, mental, and financial health.

Populations

The USPSTF's proposed research approach would include adults aged 18 or older in its evidence review. However, there are subpopulation segments for those under the age of 18 that may be worthy of inclusion in the evidence review, such as teens and adolescents who are Black, have genetic factors, or have obesity. We recommend the USPSTF consider including studies that examine these subpopulations in its evidence review.

The proposed research approach divides populations into two categories: asymptomatic patients without known CKD and not selected on the basis of presence of diabetes mellitus or hypertension, with or without recognized risk factors for CKD; and patients with screen-detected CKD or non-screen-detected CKD stages 1–3, including adults with diabetes mellitus or hypertension. We caution that just because a patient may have been identified as having CKD stage 1-3 at one point, it does not necessarily mean they are actively receiving care, so they could functionally be in the same group as

those who are asymptomatic or not screened. The USPSTF may want to take this into consideration as it evaluates studies in its evidence review and may want to consider further refinements to the population category in its proposed research approach.

Outcomes

AKF agrees with the listed outcomes in the proposed research approach that would be included in the USPSTF's evidence review. We recommend the USPSTF consider including additional patient-centered outcomes in its evidence review, such as referral time to nephrology, referral time to transplant, effects on a patient's employment, patient costs, and quality of dialysis start (e.g., fistula placement, home dialysis initiation).

We also recommend the USPSTF consider including broader health care system outcomes in its evidence review, such as financial impact to the health care system, both potential cost savings and increased expenditures. Additionally, the USPSTF should consider whether to include in its evidence a review of the potential impact of increased CKD screening on the system of care. For example, the USPSTF could consider for inclusion, if it were to find such a study, an estimate of how many patients a specialist can adequately provide care to and how many nephrologists are available to handle an influx of patients with newly identified CKD.

Availability of Studies

We want to note that there are few longitudinal studies or comprehensive reviews looking at outcomes of patients who were screened and not screened for CKD, which would impact the assessment of key questions 1 and 2 and result in publication searches that are not fruitful. We support the USPSTF in conducting a thorough search and review of available studies, but we raise this point to note that it may affect the evaluation of benefits and harms of increased screening for CKD.

Thank you for the opportunity to provide comments on this draft research plan. If you have questions about our comments, please contact Holly Bode, Vice President of Government Affairs at hbode@kidneyfund.org.

Sincerely,

LaVarne A. Burton
President and CEO