

December 23, 2020

Alex H. Krist, MD, MPH Chairperson, U.S. Preventive Services Task Force One Capitol Square, 6th Floor 830 East Main Street Richmond, Virginia 23219

Karina W. Davidson, PhD, M.A.Sc. Vice-Chairperson, U.S. Preventive Services Task Force North Shore University Hospital 350 Community Drive Manhasset, New York 11030

Carol M. Mangione, MD, M.S.P.H Vice-Chairperson, U.S. Preventive Services Task Force Internal Medicine, Suite 420 200 UCLA Medical Plaza Suite 420 Los Angeles, California 90095

Dear Drs. Krist, Davidson, and Mangione,

The Coalition for Kidney Health is writing today to thank the United States Preventive Services Task Force (USPSTF) for the opportunity to nominate chronic kidney disease (CKD) for evaluation for a future recommendation. USPSTF last issued a CKD screening recommendation in 2012. Since that time, CKD progression has become increasingly modifiable. In fact, there are at least two and potentially three drug classes of treatment options for CKD that did not exist in 2012. These new advances in slowing CKD progression add weight to the benefits of CKD screening in asymptomatic high-risk patients. Furthermore, as the nation reinvigorates the conversation about health disparities, we note that African Americans are more likely to have diabetes, the leading cause of CKD, and more likely to suffer its consequences including kidney failure and death.¹ CKD screening has never been more important and, at the intersection of novel science and public health need, the benefits outweigh any theoretical harms of screening these asymptomatic patients at high risk of CKD.

We have provided documentation supporting our nomination via the USPSTF "New Topic" form. The bibliography follows at the conclusion of this letter. In the following sections, we outline the context in which we hope USPSTF will evaluate the supporting documentation we have submitted.

¹ https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18

The absence of a current CKD screening recommendation exacerbates the lack of attention paid to the growing kidney disease public health crisis and contributes to the low rates of CKD diagnosis in the primary care setting. In addition, the lack of recommendations for kidney disease screening is misaligned with the Administration's Advancing American Kidney Health initiative. Rather than general population or mass screening, current evidence supports case finding using testing of individuals at risk for CKD, including individuals with diabetes, hypertension, cardiovascular disease, family history of kidney disease, and individuals with a history of acute kidney injury (AKI), as recommended by clinical practice guidelines from the American Diabetes Association, the Kidney Diseases Improving Global Outcomes and the Kidney Disease Outcomes Quality Initiative.

The Coalition for Kidney Health is a multi-stakeholder group of partners working to transform the landscape of CKD management by generating awareness of CKD, increasing screening of at-risk patients, and driving forward high-quality, coordinated care focused on delaying CKD progression. CKD is a public health emergency. An estimated 37 million Americans have CKD and the vast majority are unaware.² CKD patients are at extremely high risk of cardiovascular disease (CVD) and are much more likely to die of CVD than they are to progress kidney failure.³ CKD is the ninth leading cause of death in the United States, causing more deaths than common cancers such as breast cancer. CKD is more common in the elderly and among non-Hispanic Black populations, coinciding with some of the communities most vulnerable to COVID-19. Preliminary Medicare claims and observational data show the COVID-19 pandemic has only worsened the existing disparities among CKD populations and that COVID-19 associated acute kidney injury can cause or exacerbate CKD.

Despite being preventable and treatable, CKD is too often not intensively managed until a patient has progressed to kidney failure. Our coalition is committed to addressing gaps in care to improve population health and the lives of CKD patients, however all improvement in the continuum of care for CKD rest on CKD screening to identify patients and improve upon missed opportunities for early intervention and management. Since the USPSTF issued its CKD screening recommendation in 2012, CKD has become increasingly modifiable and screening high risk individuals for CKD has become even more important. For example, in addition to the use of blockers of the renin-angiotensin system, the drug class of sodiumglucose co-transporter-2 (SGLT-2) inhibitors show efficacy in slowing CKD progression and reducing risk of cardiovascular disease and heart failure in patients with Type-2 Diabetes Mellitus (T2DM) and CKD, as well as in patients with CKD without diabetes. Finerenone, currently under review by the Food and Drug Administration, is a potential first-in-class CKD treatment that has demonstrated positive renal and cardiovascular outcomes in a Phase III study. In addition, there are several interventions that have no effect on CKD progression, but reduce risk of CVD, including statin-based therapies and the glucagon-like peptide receptor agonists (GLP-1 RA) drug class for T2DM. Observational studies have shown multidisciplinary care that may include a dietitian, pharmacist and nephrologist is also associated with improved outcomes for T2DM with CKD.

.

² https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

³ https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease#:~:text=CKD%20often%20occurs%20in%20the,diabetes%20and%20self%2Dreported%20CVD.

Additionally, presence of CKD may alter decisions for preventive care. The recently published American College of Cardiology and American Heart Association (ACC/AHA) guideline for the diagnosis and treatment of hypertension identifies kidney disease as an important risk factor for cardiovascular disease and recommends a blood pressure level less than 130/80 mmHg for individuals with kidney disease. Similarly, the recent guidelines for the management of lipids for the prevention of cardiovascular disease recommend a moderate dose statin medication for adults with non-dialysis dependent kidney disease who are age 50 years and older. Recent analysis of the National Health and Nutrition Examination Survey and data from the Department of Veterans Affairs show that statin use is low among adults with kidney disease in the absence of diabetes mellitus. Because kidney disease is a risk factor for cardiovascular disease, it is imperative that this disease be identified so appropriate therapies not only for kidney disease but also for cardiovascular disease prevention, be implemented. Kidney disease does not have symptoms usually and unless patients are screened, they may never be diagnosed and treated.

We believe that the opportunity to improve outcomes for CKD patients warrants a CKD screening recommendation for patients at high risk of CKD. We believe that CKD screening is relevant to clinical practice, can be implemented by a primary care clinician and has an enormous public health burden. In addition, the body of evidence supporting screening in high-risk populations has grown. This new evidence, as well as the opportunity to intervene early in high-risk patients and provide better outcomes, weights the scales in favor of CKD screening for patients at high risk.

Our coalition supports improvements in CKD screening via multiple avenues. We supported the adoption of the measure, Kidney Health Evaluation for Patients with Diabetes, into the National Committee for Quality Assurance (NCQA) HEDIS measure set, which will improve guideline-concordant annual testing of urine albumin-creatinine ratio (uACR) and estimated glomerular filtration rate (eGFR) in adult patients with diabetes, as recommended by the National Kidney Foundation and the American Diabetes Association (ADA). We expect the measure will be adopted by the Centers for Medicare and Medicaid Services (CMS) for use in its clinician and plan-level quality reporting programs. In addition, many of our members are supporters of and partners with the Administration in the implementation of the Advancing American Kidney Health initiative. The initiative aims to reduce the risk of kidney failure by 25 percent by 2030. A cornerstone of the goal is a CKD awareness campaign launched as a partnership between the Department of Health and Human Services, the National Kidney Foundation, and the American Society of Nephrology. The purpose of the campaign is to empower patients to know their risks of CKD and speak with their providers about it and to inform clinicians that CKD awareness and screening as critical elements of good patient care. All of these important endorsements reflect a landscape that is primed for improvements in CKD care rooted in CKD screening and early intervention and management.

Once again, we express our thanks to USPSTF for considering our nomination of CKD for evaluation for a screening recommendation. Please contact Miriam Godwin (<u>miriam.godwin@kidney.org</u>) if there is any further information we can provide or if members of the Task Force have guestions or concerns. We are

grateful for the USPSTF's commitment to and leadership in improving public health and the lives of patients.

Sincerely,

The Coalition for Kidney Health

CC:

- Dr. Michael J. Barry, MD
- Dr. Michael Cabana, MD, MA, MPH
- Dr. Aaron B. Caughey, MD, MPP, MPH, PhD
- Dr. Katrina Donahue, MD, MPH
- Dr. Chyke A.Doubeni, MD, MPH
- Dr. John W. Epling, Jr., MD, M.S.Ed.
- Dr. Martha Kubik, PhD, RN
- Dr. Gbenga Ogedegbe, MD, MPH
- Dr. Lori Pbert, PhD
- Dr. Michael Silverstein, MD, MPH
- Dr. Melissa A. Simon, MD, MPH
- Dr. Chien-Wen Tseng, MD, MPH, M.S.E.E.
- Dr. John B. Wong, MD

Appendix 1.

Bibliography

- Bakris, G. L., Agarwal, R., Anker, S. D., Pitt, B., Ruilope, L. M., Rossing, P., . . . Filippatos, G. (2020). Effect of Finerenone on Chronic Kidney Disease Outcomes in Type 2 Diabetes. *New England Journal of Medicine*, *383*(23), 2219-2229. doi:10.1056/nejmoa2025845
- Bhatt, D. L., Szarek, M., Pitt, B., Cannon, C. P., Leiter, L. A., Mcguire, D. K., . . . Steg, P. G. (2020). Sotagliflozin in Patients with Diabetes and Chronic Kidney Disease. *New England Journal of Medicine*. doi:10.1056/nejmoa2030186
- de Boer, I. H., Caramori, M. L., Chan, J. C., Heerspink, H. J., Hurst, C., Khunti, K., . . . Rossing, P. (2020). KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney International*, *98*(4). doi:10.1016/j.kint.2020.06.019
- Bowe, B., Xie, Y., Li, T., Mokdad, A. H., Xian, H., Yan, Y., . . . Al-Aly, Z. (2018). Changes in the US Burden of Chronic Kidney Disease From 2002 to 2016. *JAMA Network Open, 1*(7). doi:10.1001/jamanetworkopen.2018.4412
- Carroll, J. K., Pulver, G., Dickinson, L. M., Pace, W. D., Vassalotti, J. A., Kimminau, K. S., . . . Fox, C. H. (2018). Effect of 2 Clinical Decision Support Strategies on Chronic Kidney Disease Outcomes in Primary Care. *JAMA Network Open*, *1*(6). doi:10.1001/jamanetworkopen.2018.3377
- Heerspink, H. J., Stefánsson, B. V., Correa-Rotter, R., Chertow, G. M., Greene, T., Hou, F., . . . Wheeler, D. C. (2020). Dapagliflozin in Patients with Chronic Kidney Disease. *New England Journal of Medicine*, *383*(15), 1436-1446. doi:10.1056/nejmoa2024816
- Hoerger, T. J., Simpson, S. A., Yarnoff, B. O., Pavkov, M. E., Burrows, N. R., Saydah, S. H., . . . Zhuo, X. (2015). The Future Burden of CKD in the United States: A Simulation Model for the CDC CKD Initiative. *American Journal of Kidney Diseases*, *65*(3), 403-411. doi:10.1053/j.ajkd.2014.09.023
- Inker, L. A., Astor, B. C., Fox, C. H., Isakova, T., Lash, J. P., Peralta, C. A., . . . Feldman, H. I. (2014). KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD. *American Journal of Kidney Diseases, 63*(5), 713-735. doi:10.1053/j.ajkd.2014.01.416
- KDOQI Clinical Practice Guideline for Diabetes and CKD: 2012 Update. (2012). *American Journal of Kidney Diseases, 60*(5), 850-886. doi:10.1053/j.ajkd.2012.07.005

- KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Diabetes and Chronic Kidney Disease. (2007). *American Journal of Kidney Diseases, 49*(2). doi:10.1053/j.ajkd.2006.12.005
- Narva, A. (2018). Population Health for CKD and Diabetes: Lessons From the Indian Health Service. *American Journal of Kidney Diseases, 71*(3), 407-411. doi:10.1053/j.ajkd.2017.09.017
- Narva, A. S., & Norton, J. M. (2020). Could a Pragmatic Detection Strategy Be the Gateway for Effective Population Health for CKD? *Journal of the American Society of Nephrology, 31*(9), 1921-1922. doi:10.1681/asn.2020070992
- Nichols, G. A., Ustyugova, A., Déruaz-Luyet, A., O'Keeffe-Rosetti, M., & Brodovicz, K. G. (2020). Health Care Costs by Type of Expenditure across eGFR Stages among Patients with and without Diabetes, Cardiovascular Disease, and Heart Failure. *Journal of the American Society of Nephrology, 31*(7), 1594-1601. doi:10.1681/asn.2019121308
- Packer, M., Anker, S. D., Butler, J., Filippatos, G. S., Ferreira, J. P., Pocock, S., . . . Zannad, F. (2020). Effect of Empagliflozin on the Clinical Stability of Patients with Heart Failure and a Reduced Ejection Fraction: The EMPEROR-Reduced Trial. *Circulation*. doi:10.1161/circulationaha.120.051783
- Peralta, C. A., Livaudais-Toman, J., Stebbins, M., Lo, L., Robinson, A., Pathak, S., . . . Karliner, L. S. (2020). Electronic Decision Support for Management of CKD in Primary Care: A Pragmatic Randomized Trial. *American Journal of Kidney Diseases, 76*(5), 636-644. doi:10.1053/j.ajkd.2020.05.013
- Perkovic, V., Jardine, M. J., Neal, B., Bompoint, S., Heerspink, H. J., Charytan, D. M., . . . Mahaffey, K. W. (2019). Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy. *New England Journal of Medicine*, *380*(24), 2295-2306. doi:10.1056/nejmoa1811744
- Professional Practice Committee: Standards of Medical Care in Diabetes—2020. (2019). *Diabetes Care,* 43(Supplement 1). doi:10.2337/dc20-sppc
- Saran, R., Robinson, B., Abbott, K. C., Agodoa, L. Y., Bragg-Gresham, J., Balkrishnan, R., . . . Shahinian, V. (2019). US Renal Data System 2018 Annual Data Report: Epidemiology of Kidney Disease in the United States. *American Journal of Kidney Diseases, 73*(3). doi:10.1053/j.ajkd.2019.01.001
- The SPRINT Research Group. (2015). A Randomized Trial of Intensive versus Standard Blood-Pressure Control. *New England Journal of Medicine*, *373*(22), 2103-2116. doi:10.1056/nejmoa1511939

- Tonelli, M., & Dickinson, J. A. (2020). Early Detection of CKD: Implications for Low-Income, Middle-Income, and High-Income Countries. *Journal of the American Society of Nephrology, 31*(9), 1931-1940. doi:10.1681/asn.2020030277
- Vassalotti, J. A., DeVinney, R., Lukasik, S., McNaney, S., Montgomery, E., Voss, C., & Winn, D. (2019). CKD Quality Improvement Intervention With PCMH Integration: Health Plan Results J. *American Journal of Managed Care, 25*(11). doi:https://www.ajmc.com/view/ckd-quality-improvement-intervention-with-pcmh-integration-health-plan-results
- Wanner, C., Inzucchi, S. E., Lachin, J. M., Fitchett, D., Eynatten, M. V., Mattheus, M., . . . Zinman, B. (2016). Empagliflozin and Progression of Kidney Disease in Type 2 Diabetes. *New England Journal of Medicine*, *375*(4), 323–334. doi:10.1056/nejmoa1515920
- Wheeler, D. C., Stefánsson, B. V., Jongs, N., Chertow, G. M., Greene, T., Hou, F. F., . . . Heerspink, H. J. (2021). Effects of dapagliflozin on major adverse kidney and cardiovascular events in patients with diabetic and non-diabetic chronic kidney disease: A prespecified analysis from the DAPA-CKD trial. *The Lancet Diabetes & Endocrinology, 9*(1), 22-31. doi:10.1016/s2213-8587(20)30369-7
- Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., . . . Wright, J. T. (2018). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. *Journal of the American College of Cardiology*, *71*(19). doi:10.1016/j.jacc.2017.11.006