Title: Cholesterol and Kidney Disease: What You Need to Know Patient FAQ

Organization: National Kidney Foundation Inclusive Dates of Project: 2016-2017 Grant Award Number: 24039391

Abstract

The goal of this educational resource is to educate patients on cholesterol and kidney disease in a succinct, easy-to-read format. This project aligns with the RFP goals of helping patients understand this important topic and recent advances in the field. The educational piece is aligned with the National Kidney Foundation's (NKF) strategic 5-year plan that outlines the NKF focus on awareness, prevention (this resource), and treatment (PCSK9). The resource will be assessed by expert review and a post launch survey.

Purpose:

Our overall goal is to educate patients on cholesterol and kidney disease in a succinct, easy-to-read format. This aligns with the RFP goals of helping patients understand this important topic and recent advances in the field. The educational piece is very aligned the NKF's strategic 5-year plan that outlines the NKF focus on awareness, prevention (this resource) and treatment (PCSK9).

Scope:

Despite extensive research and available therapies, cardiovascular disease (CVD) remains a significant public health challenge, and continues to be associated with high morbidity and mortality. An estimated 83 million American adults (>1 in 3) have 1 or more types of CVD.i Along with numerous risk factors such as hypertension and diabetes, dyslipidemia is a major risk factor for CVD. An estimated 32 American million adults have serum total cholesterol levels ≥240 mg/dL.i The relationship between dyslipidemias and CVD is comprehensive.ii,iii An underlying cause of the majority of clinical cardiovascular events is atherosclerosis, a systemic disease process in which fatty deposits, inflammation, cells, and scar tissue build up within the walls of arteries.3 High cholesterol has become known as one of the major controllable risk factors for coronary heart disease, heart attack, and stroke.

In addition to the general population, studies on cardiovascular risk reduction have also examined lipid management in the presence of chronic kidney disease (CKD). CKD affects an estimated 26 million Americans and carries a lifetime risk of 59.1% for moderate CKD (estimated glomerular filtration rate (eGFR) 30-59 mL/min/1.73 m2).iv,v Data has shown a strong association between CKD and CVD.vi,vii,viii,ix,x,xi Dyslipidemia is an important risk factor not only for atherosclerosis, but it is also associated with decreased kidney function.xii Evidence also suggests that the type and severity of atherosclerosis in patients with CKD is different from that in the general population; for example, cardiovascular events associated with atherosclerosis are more often fatal in patients with CKD than in individuals without CKD.xiii Furthermore, microalbuminuria, a marker for kidney disease, has been shown to be a surrogate

marker of early atherosclerosis.xiv,xv Despite these associations, studies have also indicated suboptimal lipid management within the CKD population.

A cross-sectional study by Foster et al examined NHANES data to determine the proportion of individuals with LDL-C levels above treatment targets and above the threshold for lipid-lowering therapy, but also incorporating simulated scenarios based on CKD severity (CKD stages 3-5, and CKD stages 1-5). The addition of these CKD scenarios was considered as CHD risk equivalents.xvi The study showed that 24% of individuals overall did not reach target LDL-C, and 58% of high-risk individuals did not reach target LDL-C. When the CKD 1-5 scenarios were added, 34.6% of individuals overall did not reach target LDL-C, and 55.5% of high-risk individuals did not reach target LDL-C. The study estimated that 55.1 million adults in the US population did not achieve LDL-C goals, and when the risk criteria expanded to CKD stages 1-5, this population expands to 65.2 million adults not achieving goal. Of this population of 65.2 million, 33.9 million and 14.4 million would merit therapy initiation and intensification, respectively.

Overall, these studies show significant gaps in lipid management, particularly in high-risk patients. As a result, many patients may still have high CV risk, despite receiving treatment. These gaps express a need for additional strategies to improve lipid management.

In summary, professionals need to recognize the clinical gaps and barriers to optimal lipid management, how to manage high-risk patients, and become aware of novel therapies that can potentially address various clinical unmet needs. Education on lipid management can provide an opportunity to improve outcomes. Central to the healthcare team is the patient, and their awareness, knowledge, self-management and adherence to treatment are important parts of their care. Patients need to be educated about their condition so they can manage reasonable expectations, while at the same time remain positive and active participants in their care. However, knowledge gaps persist. For example, the majority of patients with CKD are not aware of their CKD diagnosis or the effect of poor control of CV-related risk factors (e.g., dyslipidemia, high blood pressure, and diabetes) on their health.xvii,xviii Hence, education for healthcare providers and patients represents an important opportunity to improve knowledge and awareness.

Methods: Project Design and Methods

NKF developed a list of frequently asked questions (FAQs) or 'questions and answers' about cholesterol and CKD. The patient resource will be designed in a succinct, easy-to-read format by our in-house education & design teams. The content will address various topics, such as: definition, how it is treated and steps patients can take to reduce risks. Sample questions could include: What is cholesterol & how is it connected to my kidneys? What are the risk factors for high cholesterol and kidney disease? How are CKD & cholesterol tested? How are the two conditions treated? How can I reduce my risk?

NKF's staff and medical writers collaborated with experts to develop the content and handle the writing and the design of the FAQ. It was disseminated to 3,000 clinician offices for distribution (with an accompanying introduction letter from the NKF medical

leadership), to the Patient Council (17,500 members), to our Clinician Database (5,600 members divided into MDs, PAs, Nurses, NP, Social Workers) and via our online mechanisms such as kidney.org, A-Z Guide, social media and linked to newsletters, such as 'Pressure Point' dedicated to cardio-renal issues.

Topics on dual diagnosis issues are rarer than individual pieces targeting one disease state. When a patient is diagnosed with two or more conditions, there is much more to handle from not only an emotional standpoint but also with conflicting information on how everything works together. By outlining the basics and helping the patient navigate a dual diagnosis, we believe this FAQ is innovative in its utility and simplicity, both of which are hard to find at times. We plan used a variety of outreach mechanisms (as listed above) in the hope to reach as many patients as possible.

Evaluation Design

All of NKF's educational pieces are followed by a survey and are evaluated by our external committees for review. An example questionnaire was attached to the initial proposal that was sent out to a similar resource in atrial fibrillation and chronic kidney disease resulting in relevant feedback from the target audience. There were both quantitative and qualitative responses, many preferring print resources and translations into Spanish. Additionally, we provide these resources for free to our NKF CARES hotline for patients, many of which have been very well-received. Our evaluation design focuses on these survey results in addition to our overall in-house team and experts post-launch gathering to discuss reception and outcomes.

Results:

NKF educated patients on cholesterol and kidney disease in a succinct, easy-to-read format. Aligned with the RFP goals of helping patients understand this important topic and recent advances in the field. Educated on awareness, prevention (this resource) and treatment. The FAQ was disseminated to 3,000 clinician offices for distribution (with an accompanying introduction letter from the NKF medical leadership), to the Patient Council (17,500 members), to our Clinician Database (5,600 members divided into MDs, PAs, Nurses, NP, Social Workers) and via our online mechanisms such as kidney.org, A-Z Guide, social media and linked to newsletters, such as 'Pressure Point' dedicated to cardio-renal issues (PCSK9). The materials were well received by clinicians and patients.

List of Publications and Products:

ⁱ Go A, Mozaffarian D, Roger V, et al. Heart disease and stroke statistics - 2014 update: a report from the American Heart Association. *Circulation*. 2014;129:e28-e292.

- Perkovic V, Verdon C, Ninomiya T, et al. The relationship between proteinuria and coronary risk: a systematic review and metaanalysis. *PLoS Med.* 2008:5:e207.
- Go A, Chertow G, Fan D, McCulloch C, Hsu C. Chronic kidney disease and the risks of death, cardiovascular events, and hospitalization. *N Engl J Med.* 2004:351:1296-1305.
- ^{ix} Chronic Kidney Disease Prognosis Consortium. Association of estimated glomerular filtration rate and albuminuria with all-cause and cardiovascular mortality in general population cohorts: a collaborative metaanalysis. *Lancet*. 2010;375:2073-2081.
- ^x Das M, Aronow W, McClung J et al. Increased prevalence of coronary artery disease, silent myocardial ischemia, complex ventricular arrhythmias, atrial fibrillation, left ventricular hypertrophy, mitral annular calcium, and aortic valve calcium in patients with chronic renal insufficiency. *Cardiol Rev.* 2006;14:14-17.
- xi Herzog C, Asinger R, Berger A, et al. Cardiovascular disease in chronic kidney disease. A clinical update from Kidney Disease: Improving Global Outcomes (KDIGO). *Kidney Int*. 2011;80:572-586.
- xii National Kidney Foundation. KDOQI clinical practice guidelines for managing dyslipidemias in chronic kidney disease. Am J Kid Dis. 2003;41(suppl 3):S1-S92.
- ^{xiii} Drüeke T, Massy Z. Atherosclerosis in CKD: differences from the general population. *Nat Rev Nephrol.* 2010;6:723–735.
- xiv Stehouwer C, Smulders Y. Microalbuminuria and risk for cardiovascular disease: analysis of potential mechanisms. J Am Soc Nephrol. 2006;17:2106–2111.
- ^{xv} Dasmahapatra P, Srinivasan S, Mokha J, et al. Subclinical atherosclerotic changes related to chronic kidney disease in asymptomatic black and white young adults: the Bogalusa Heart Study. *Ann Epidemiol*. 2011;21:311-317.
- ^{xvi} Foster M, Rawlings A, Marrett E, et al. Potential effects of reclassifying CKD as a coronary heart disease risk equivalent in the US population. *Am J Kidney Dis*. 2014;63:753-760.

Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive Summary of the Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA*. 2001:285:2486-2497.

Stone N, Robinson J, Lichtenstein A, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 201463:2889-2934.

^{iv} Coresh J, Selvin E, Stevens L, et al. Prevalence of chronic kidney disease in the United States. *JAMA*. 2007;298:2038-2047.

^v Grams M, Chow E, Segev D, Coresh J. Lifetime incidence of CKD stages 3-5 in the United States. *Am J Kidney Dis.* 2013;62:245-252.

vi Ninomiya T, Perkovic V, de Galan B, et al. Albuminuria and kidney function independently predict cardiovascular and renal outcomes in diabetes. *J Am Soc Nephrol*. 2009;20:1813-1821.

xvii Plantinga L, Boulware L, Coresh, et al. Patient awareness of chronic kidney disease: trends and predictors. *Arch Intern Med*. 2008;168:2268-2275.

wiii Waterman A, Browne T, Waterman B, et al. Attitudes and behaviors of African Americans regarding early detection of kidney disease. *Am J Kidney Dis*. 2008;51:554-562.