National Kidney Foundation®

**Proposal for Pfizer & the International Atherosclerosis Society**

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

**2016-2017**

**Request ID: 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 our foci on awareness, prevention (this resource), and treatment (PCSK9). The resource will be assessed by expert review and a post launch survey.

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**Overall Goals and Objectives**

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 our foci on awareness, prevention (this resource) and treatment (PCSK9).

**Needs Assessment**

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 $m^2$).[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.

**Target Audience**

This resource will be available both print and online, in English and Spanish. The target audience is:

- All patients at-risk for high cholesterol and kidney disease;
- All patients diagnosed with high cholesterol and kidney disease;
- Caregivers who manage these patients;
- Providers who manage these patients and who can use this resource when explaining the two conditions.

**Project Design and Methods**

NKF will develop 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 will collaborate with experts to develop the content and handle the writing and the design of the FAQ. It will be 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 to use a variety of outreach mechanisms (as listed above) in the hope to reach as many patients as possible.

**Evaluation Design**

All of our educational pieces are followed by a survey and are evaluated by our external committees for review. An example questionnaire is attached to this 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.

**Detailed Work Plan and Deliverables Schedule**

*Start Date August 1, 2016*

- **August to November, 2016**
  - Planning, content development and design and layout are created
  - Expert review of content

- **November 2016**
  - Coordination with vendors for printed resource and e-resource
  - Set up order

- **December 2016**
  - Sent to printer
  - Quality control review

- **January to February 2017**
  - Mailings and shipping done to targeted groups
  - E-blasts done to targeted group
  - Social media mentions
  - Added to our Kidney.org A-Z guide
  - Given to our staff at the CARES hotline to distribute should patients have questions about cholesterol and kidney disease

- **March 2017**
    - Survey sent out
    - Evaluation conducted

**Contact Details**

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