

PATIENTS PILOT PROJECT APPLICATION

PATient-centered Involvement in Evaluating the effectiveNess of TreatmentS

Application Title:

Patient-centered approach to developing a plan to achieve blood pressure control while on medication for hypertension (high blood pressure)

Principal Investigator: Catherine E. Cooke, PharmD, BCPS, Research Associate Professor in the Department of Pharmacy Practice & Science at the University of Maryland School of Pharmacy

Principal Investigator Qualifications: Please limit to no more than 3 sentences

Dr. Cooke has contributed to quantifying the burden of medication non-adherence and describing associated patient, prescriber, medication and pharmacy benefit factors. Her past clinical experience in co-managing chronic disease with prescribers in private practices provides insight into applying patient-centered outcomes research (PCOR) to a longer term approach to managing chronic disease. She is developing additional research skills to conduct PCOR through formal coursework and collaborations with faculty in the Department of Pharmaceutical Health and Services Research (PHSR) engaged in PCOR.

Co-investigator(s):

Susan dosReis, BSP Pharm, PhD, Associate Professor in the Department of *Pharmaceutical Health Services Research* at the University of Maryland School of Pharmacy

Sharon-Taylor Johnson, Management Associate, Division of Curriculum, Assessment and Accountability at the Maryland State Department of Education

Co-investigator(s) Qualifications: Please limit to no more than 3 sentences.

Dr. dosReis is a pharmacist and health services researcher with a PhD in pharmacoepidemiology earned from the University of Maryland Graduate School. Dr. dosReis has extensive research experience and is the recipient of a 2013 PCORI grant, "Methods for Prioritizing Surrogate Desired Health Outcomes for Patients" (3-year, \$937,520). Several of her publications highlight her experience with qualitative research methods and engaging patients and care-givers in PCOR.

Mrs. Taylor Johnson has had hypertension for over 10 years. She has worked with her primary care provider and a clinical pharmacist to help manage her hypertension. In addition to her experience with the healthcare system, she also has experience with preparing written documents and reading technical jargon related to her field of work.

Relevance and Future Goals: Using no more than three sentences, describe the relevance of this pilot project to the PATIENTS infrastructure building and/or training activities. In this section, include information on your methods but be succinct and use plain language that can be understood by a general, lay audience.

This pilot study will contribute to the PATIENTS program by identifying a new patient partner, Mrs. Sharon Taylor-Johnson, and her community (New Union Baptist Church in Sandtowne area of Baltimore) and contributing to the evidence development hypertension, which is one of the five disease areas of focus identified by PATIENTS partners.

The results of this pilot study, which will interview patients and healthcare professionals, will address the first 3 steps (1. Topic Solicitation 2. Prioritization and 3. Framing the Question) in the “10-step process for Continuous Patient Engagement in Comparative Effectiveness Research.”¹

[REDACTED]

Estimated Budget: Using the space below, please detail proposed expenses.

Item	Amount	Brief Justification
Patient Partner	\$ [REDACTED] (\$ [REDACTED]/day x 5 days)	Mrs. Sharon-Taylor Johnson will be the Patient Partner and participate in developing questions for the focus group interview (FGI), facilitating the FGI, reviewing the themes identified, developing research questions and reviewing results of patient rankings.
Research assistant/project coordinator (PharmD or PHSR Graduate student)	\$ [REDACTED] (\$ [REDACTED]/hr x 50)	Participating in FGI (i.e., note taking and non-verbal notations) and transcription of FGI and key informant interviews, manage patient communications, organize FGI (e.g., space, refreshments, participants, gift cards) and key informant interviews (e.g., schedule, honoraria).
Patient focus group - gift card in appreciation for participation	\$ [REDACTED] (\$ [REDACTED] x 6)	We will provide a \$100 Walmart gift card in appreciation for participation in our patient FGI.
Key informant interviews	\$ [REDACTED] (\$ [REDACTED] x 3)	We will provide a \$100 Walmart gift card for each key informant interview.
NVivo Qualitative Analysis Software	\$ [REDACTED] (\$ [REDACTED] training + \$ [REDACTED] for individual, 12-month license)*	NVivo software supports qualitative research and will be used to assist with organizing, analyzing and finding insights in data from the interviews.
Total	\$5,000	

*<http://www.qsrinternational.com/Products/NVivo/Starter/Education/New/NVivo11StarterStuLic12Mon>

¹ JAMA 2012; 307(15): 1587-8.

Specific Aims: *Using the space below, please insert your specific aims page. This section should include information on the proposed study methods and partnering organization.*

Only 50% of individuals achieve blood pressure control, despite pharmacologic treatment, and in the past decade, a growing number of deaths attributable to hypertension has occurred.² There is an urgent need to consider new approaches to improve blood pressure control. A substantial amount of literature describes the provider and patient factors associated with suboptimal blood pressure control. Patient education about the benefits of achieving goal blood pressure and prescriber education to encourage once-daily antihypertensives that have few side effects and low out-of-pocket costs have improved both hypertension treatment and control rates. While these studies have been important contributions, there are several gaps in patient-centered care to optimize blood pressure control. Prior research has focused primarily on shared-decision making for the initial treatment of hypertension, but in two-thirds of patients, the initial medication regimen does not achieve the intended blood pressure. There is no evidence to guide shared-decision making for second-line treatment or augmentation therapy. Moreover, previous studies have not engaged patients as a way to elicit their needs, concerns, and priorities for achieving goal blood pressure. **This pilot study proposes to better understand patients' experience with how their hypertension has been treated in order to develop patient-centered outcomes research to improve control rates.**

Specific Aims

Aim 1. *To elicit patients' experiences with the treatment of their hypertension.*

A focus group interview with 6 individuals who have hypertension will be conducted to obtain a rich description of their treatment experiences. We will use the University of Maryland PATIENTS (Patient-Centered Involvement in Evaluating the Effectiveness of Treatments) Program and our patient partner's community to identify patients to participate in focus group interviews. The focus group interview will be recorded and transcribed verbatim, and NVivo software will be used for the coding analysis. Our patient partner, Mrs. Sharon Taylor-Johnson will participate in all aspects of the project, from designing the focus group questions, recruiting participants, conducting the focus groups, and assisting with the data interpretation. She has already contributed to a list of potential topics for the focus group discussion, including Can you describe what events led to you first being told you had high blood pressure?; Can you tell us about the things you did or are doing now to manage your blood pressure? Probes will be used to gain greater depth of the blood pressure management tactics in order to elicit individual perspectives on first-line and second-line medication treatment for blood pressure.

Aim 2. *To understand healthcare providers' approach to managing hypertension after the initial medication regimen has not achieved goal blood pressure*

Three key informant interviews will be conducted to elicit healthcare providers' perspective on their approach to managing hypertension after the initial medication regimen has not achieved goal blood pressure in a patient. The key informant interviews will target one primary care physician, one cardiologist and one ambulatory care pharmacist, since they represent the range of specialty providers that manage the care of individuals with hypertension. For the primary care physician, we will interview Dr. Bill Hammerash, for the cardiologist, Dr. Michael Miller and for the ambulatory care pharmacist, Dr. Charmaine Rochester. Key informant interviews will be conducted in person, using a semi-structured field guide, recorded and transcribed verbatim. NVivo software will be used to code and analyze the transcripts. The patient partner, Mrs. Sharon Taylor-Johnson, will participate in developing the questions for the key informant interviews and reviewing the insights.

² <http://blog.heart.org/high-blood-pressure-causing-deaths-despite-drop-heart-disease-stroke-deaths/>. Accessed 1 November 2015.

Aim 3. *To develop a patient-centered research question related to the management of hypertension.*

Drs. Cooke and dosReis and Mrs. Sharon Taylor-Johnson will review the data gathered from Aims 1 and 2 to identify potential research questions. The research team **will conduct discussion groups with the patient participants from the focus group interviews (Aim 1) to discuss the potential research questions and to elicit their assistance in formulating the question(s) that is(are) most important and meaningful to them and would help others make the best treatment decisions given their own personal situation.**

Dissemination of Results

A summary of the information obtained during each specific aim will be reported back to all of the participants in written format. A follow-up call to each participant will offer an opportunity to respond to the information received. In addition, the information learned will be posted to the PATIENTS website³ and included in the PATIENTS newsletter⁴.

³ Web address for PATIENTS website, <http://patients.umaryland.edu/>

⁴ Web address for the archive of PATIENTS newsletters, <http://patients.umaryland.edu/about/news.html>