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OPPORTUNITY SNAPSHOT

Cardiovascular disease (CVD) refers to all diseases that affect the heart or blood vessels, including conditions such as heart attack, stroke, coronary artery disease, peripheral artery disease, and high blood pressure, or hypertension. The leading cause of death in the United States, CVD is responsible for one in every three deaths. While CVD represents a pervasive health problem across the populations, there are significant racial/ethnic and socioeconomic disparities in CVD prevalence and outcomes. African American men are 30% more likely than their white counterparts to die from heart disease, and both African American men and women are 40% more likely to have high blood pressure, and 10% less likely to have their blood pressure under control.

Hypertension is a leading cause of CVD and affects nearly one in three adults in the U.S. There is clear evidence supporting the effectiveness of hypertension treatments, and even small improvements in blood pressure can significantly reduce cardiovascular events and premature mortality. Therefore, many quality improvement initiatives to address CVD are centered around hypertension management. However, despite effective treatments, more than half of individuals with hypertension do not have adequate control over their condition. Consistent with broader cardiovascular disease, there are well-documented disparities in prevalence, diagnosis, and treatment of hypertension. African American experience higher prevalence of hypertension than Whites and Hispanics (40% vs. 27% and 26%, respectively) and hypertension awareness, treatment, and control rates are lower among Mexican-Americans than among either Whites or African Americans. Among those with uncontrolled hypertension, awareness and treatment rates are greater for African Americans (66% and 50%, respectively) compared with Whites (59% and 44%) and Mexican-Americans (51% and 36%).

More research is needed on strategies to improve hypertension care outcomes among populations likely to experience disparities, including racial and ethnic minorities and low-income and rural populations.

PCORI is working with Million Hearts®, an initiative co-led by the Centers for Medicaid and Medicare Services and Centers for Disease Control and Prevention (CDC), to identify key knowledge gaps that can lead to comparative effectiveness research that will have a direct positive impact on these problems.

PCORI and Million Hearts® have identified four clinical interventions to improve hypertension management that have the potential to deliver high-impact results. A topic brief on each of these interventions is provided below.
Topic 1: Compare the effectiveness and impact of using different methods for tracking data from home blood pressure monitoring

Background and Significance

One proposed method to improve measurement, patient engagement, clinical decision making, and blood pressure control is home blood pressure monitoring (HBPM). HBPM refers to patient self-measurement of blood pressure at home, outside of the healthcare setting, as either a supplement or alternative to measurement in the healthcare setting. Studies have indicated that HBPM may be a better predictor of CVD outcomes than office blood pressure monitoring.

Use of HBPM has increased over the past years. From 2009 to 2010, approximately 21.7% of the entire population used HBPM, and approximately 14.5% monitored their blood pressure monthly or more frequently. Over 40% of persons with hypertension who were aware of, treated for, or had controlled blood pressure engaged in monthly or more frequent HBPM.

While the strength of evidence is considered moderate regarding the use of HBPM alone to improve blood pressure control, there is strong evidence that the use of HBPM with additional support is effective in improving blood pressure outcomes. Supplemental mechanisms for improving measurement, patient engagement, clinical decision making, and control rates include the use of telemedicine/telemonitoring and information and feedback delivered by internet, email, and patient portals. These methods may be superior to in-person classes for providing feedback and may hold particular appeal for rural populations or others with limited access to in-person services. Yet, while evidence suggests that using HBPM and additional support can improve blood pressure outcomes, little is known about types of additional support that are superior or whether HBPM used in conjunction with additional supports is more effective in improving outcomes among racial/ethnic minority or rural populations.

Existing Evidence Base

A few studies have shown that several modes of tracking and reporting HBPM readings can improve hypertension management. HBPM with telemonitoring—wirelessly transmitting data from patients to providers—has recently been shown to effectively reduce blood pressure in patients with uncontrolled hypertension in primary care settings. Use of web-based mobile health (mHealth) technology has increased in popularity and has been considered to be more patient-centered; one study found that this approach resulted in improved outcomes. Another study found that HBPM connectivity to personal health records and tailored web portal access along with a patient navigator was well received by patients and providers and had the potential to minimize factors associated with low literacy and limited technology literacy. Studies combining HBPM and a tailored behavioral phone intervention seem to be particularly effective for improving blood pressure in non-White patients. One study found that, compared with usual care, HBPM along with telecommunication resulted in significant improvements in mean arterial pressure for African Americans.

As studies address various methods for patients to report HBPM readings and receive clinical feedback and instructions based on these readings, it will be of interest to determine the effect that the type of
clinician (e.g., nurse, pharmacist, physician) receiving the information and providing instructions and feedback might have on patient outcomes. For instance, some studies show that pharmacist-led HBPM interventions result in greater blood pressure reduction and higher patient satisfaction.\textsuperscript{16-18} Nurses can also play critical roles in providing support and advice to patients with hypertension based on their HBPM readings, and the use of HBPM along with culturally appropriate and tailored education delivered by nurses has resulted in increased HBPM and improved blood pressure control for African Americans.\textsuperscript{19}

Research Areas of Interest

There is little evidence regarding the effectiveness of HBPM with additional support to improve patient-centered outcomes in populations at risk for disparities (e.g., racial/ethnic, rural, low income). In a number of trials looking at HBPM and technology for physician feedback, minorities were underrepresented.\textsuperscript{8} Additional limitations include the lack of studies addressing similar modes of support across demographic groups and on the long-term sustainability of these modes on blood pressure control.\textsuperscript{8,10} Further, questions remain about the relative effectiveness of telecommunications with various health professionals and using various means for clinician feedback support in improving outcomes related to hypertension. Technologies that allow for communication of HBPM measurements to providers can offer mechanisms to support patient education, allow for timely feedback of results to clinicians, and facilitate patient-clinician communication. Whether this can translate into improved outcomes and reduced disparities for racial/ethnic minorities and rural populations remains to be shown.

PCORI is interested in funding comparative effectiveness research that addresses research gaps around the relative effectiveness of various modes of communication with regard to HBPM that might reduce disparities and improve outcomes related to hypertension. Based on the research gaps mentioned above, PCORI could address the following:

- Comparing the use of clinical interactions around HBPM data via the internet (e.g., Heart 360) to usual care or other modes of communication around HBPM measurements (e.g., telephone) in populations experiencing disparities in blood pressure control rates
- Comparing one or more different formats for information delivery about blood pressure management, such as phone, email, mobile apps, etc.
- Comparing the relative accuracy of automated reporting of blood pressure measures versus patient recording and reporting of HBPM results
- Comparing the relative effectiveness of providing HBPM readings to different types of clinicians (e.g., physician, nurse, pharmacist) with varying methods of responding and making decisions about adjustments to medications or providing other advice (e.g., does it make a difference if the pharmacist is empowered to make medication changes directly versus making recommendation about changes to the physician?)
Topic 2: Compare the effectiveness of different models for supporting patient self-management that help people achieve and maintain control of high blood pressure

Background and Significance

Achieving blood pressure control for hypertensive patients is challenging for a variety of reasons. Community-based studies show that blood pressure goals are achieved less than half of the time even among patients who have been prescribed anti-hypertensive medication. Some of this reflects inadequate treatment (e.g., therapeutically inert among practitioners), but a major contributor is lack of adherence to prescribed medications among individuals with hypertension. Nonadherence is more common among minority patient groups and is an important driver of disparities in outcomes.

Because patients spend relatively little time in formal healthcare settings, building self-management skills is key to improving outcomes, especially among individuals with chronic conditions that require daily self-care. For managing high blood pressure, improving patient self-management skills and attitudes may be particularly important, because it facilitates improved precision and frequency of measurements using HBPM (thus providing better data for decision making) as well as improves adherence to prescribed medications and lifestyle interventions.

Existing Evidence Base

While several studies demonstrate that efforts to improve self-management results in modest to significant reductions in either systolic or diastolic blood pressure, other studies have shown no significant improvements. A wide variety of models have been proposed to improve patient self-management, including patient reminders, health coaching, patient goal setting, and written action plans.

Results have been mixed within each of these types of interventions, perhaps because of heterogeneity in how they have been implemented. For example, patient reminders by mobile messaging have not led to significant improvements in blood pressure control. Yet other studies show that appointment reminders, when used in conjunction with self-monitoring and a system of regular followup and review of care plans in family practices and community-based clinics, can improve blood pressure control rates. Also, patient reminders when used along with team-based approaches, particularly the use of nonphysician team members (pharmacists and nurses), have been associated with improvements in blood pressure control. In various other settings, postal, telephone, and computer reminders have also been associated with improvements in followup and control among patients with hypertension. One study found that a mail intervention and telephone intervention conducted over 6 months in patients with mild to moderate hypertension resulted in increased medication adherence.

In addition to providing data for clinical decision making, HBPM is often used as a tool to encourage patient engagement and to build self-management skills. But there are mixed results on the effects of using HBPM on medication adherence. Among studies using HBPM that have shown significant
improvements in medication adherence, most used complex interventions that also included patient counseling and education as well as timed medication reminders.\textsuperscript{25}

Clinician goal setting with patients and the production of written action plans may also be effective at facilitating patient self-management and can lead to improved blood pressure control. While goal-oriented management has resulted in better blood pressure control, achieving these outcomes in outpatient practice may be challenging.\textsuperscript{26}

**Research Areas of Interest**

There is inconclusive evidence regarding the effectiveness of the wide variety of different strategies for improving patient self-management. A number of heterogeneous methods have been proposed and studied as means of improving adherence to blood pressure medication and lifestyle interventions and hence improvements in blood pressure control. Some of these proposed strategies, such as formal patient goal setting, are very underdeveloped in hypertension care.\textsuperscript{27} Few studies have examined methods for supporting patient self-management by looking at outcomes like long-term blood pressure control; only one study reported marginally significant improvement in adherence 12 months post-intervention.\textsuperscript{22}

More research is needed to understand the effects of different methods, and combinations of methods, for supporting patient self-management, and research should track meaningful outcomes like long-term adherence and blood pressure control rates. Additionally, little research is available on whether specific methods to support patient self-management are more effective in different populations, which might make them effective at reducing disparities and improving outcomes related to hypertension for racial/ethnic minorities and rural populations.

PCORI is interested in funding comparative effectiveness research that addresses research gaps around different methods for supporting patient self-management, especially those that might help reduce disparities in hypertension outcomes. Research gaps that could be addressed include:

- Comparing different interventions that aim to improve medication adherence to determine which are most effective and whether differences in effectiveness exist across subpopulations
- Comparing patient reminders, including types of patient reminders (medication reminders, appointment reminders, lifestyle reminders) and different modes by which reminders can be provided (e.g., mobile phone, mail, email)
- Comparing various methods to provide health coaching to improve self-management knowledge, skills, and attitudes (e.g., in person versus electronic, live chat versus avatar delivered)
- Comparing different methods or combinations of methods for patient goal setting, such as tools for the development of written action plans, with and without team-based care
- Comparing options to reduce patient burdens associated with self-management, such as cost or psychological hurdles.
Topic 3: Compare the effectiveness of different compositions of care teams for managing hypertension

Background and Significance

Team-based care for managing hypertension is defined as a “health systems-level, organizational intervention that incorporates a multidisciplinary team to improve the quality of hypertension care.” Teams comprise the patient, the patient’s primary care practitioner, and other clinicians and professionals, such as nurses, pharmacists, social workers, and community health workers. Each team member is tasked with using his or her skills and training to enhance hypertension care by performing activities such as providing information and following up with patients, helping to manage patient medications, and helping patients adhere to their treatment regimen, such as monitoring blood pressure, taking medications, reducing sodium intake, and exercising.

Team-based care is supported by a robust evidence base, and is endorsed by the CDC and the Community Preventive Services Task Force as an effective model for blood pressure management. Dr. Thomas Frieden, Director of the CDC, declared that adoption of the team-based model across the country would improve blood pressure control for 68 million Americans with high blood pressure. However, despite the great potential for team-based care to reduce heart attacks and strokes, there are critical gaps in research related to the effectiveness of team-based care in improving outcomes among populations at risk of experiencing disparities. In particular, there is lack of evidence around the comparative effectiveness of different compositions of teams, and/or different roles for team members, with regard to impact on hypertension management.

Existing Evidence Base

In May 2012, the Community Preventive Services Task Force announced its endorsement of team-based care for improving blood pressure control based on strong evidence from two systematic reviews of 80 studies from 1980 to 2012. Evidence synthesized from these studies shows that patients who received care from a team of professionals were more likely to have improved blood pressure compared to patients who received care from a single physician. In addition, evidence from these reviews suggests that the benefits of team-based care extend beyond hypertension management—this model was also effective in improving diabetes outcomes and cholesterol control, critical risk factors for cardiovascular disease.

The large majority of studies of team-based care examine the effectiveness of nurses and/or pharmacists as team members. Teams were most effective when members other than physicians were directly involved in managing hypertension medications, either with approval and or/consultation with
the physician or following agreed-upon protocols.28 Notably, adding pharmacists to the team was associated with a “considerably higher” proportion of patients achieving controlled hypertension compared to all other aspects of team-based care studied.28 When nurses or nurses and pharmacists are added to the team, the outcomes are similar to the overall outcome improvements of adding pharmacists alone.28 However, as emphasized in one review of team-based care involving nurses and/ pharmacists, when evaluating the effectiveness of team-based models, it is important to contextualize interventions and consider “dose” and duration of the intervention, in addition to other factors such as setting (e.g., home, clinic, community pharmacy), level of team member autonomy, and rapport between team members.30 As a result, each intervention is unique, making it impossible to determine the relative effectiveness of individual components of team-based care without considering these contextual components.

Only four studies examined the impact of specific other team members such as dieticians or social workers.28 These studies did not include nurses and pharmacists, and outcomes were smaller in magnitude compared to outcomes in studies of adding pharmacists and nurses to teams.28

Research Areas of Interest

The Community Preventive Services Task Force review identified several research gaps highlighting missing information that would help determine the effectiveness of specific aspects of team-based care in reducing disparities. Potential areas for PCORI funding include the following:

- More information is needed about the effectiveness of team-based care for patients from low socioeconomic status groups, and racial and ethnic groups other than Whites and African Americans, and on whether specific aspects of team-based care (e.g., composition, roles, demographics, and training) are of particular importance for these groups.
- Only a few studies have evaluated teams that included members other than primary care providers, nurses, and pharmacists, such as community health workers and dieticians. More evidence is needed on differences in effectiveness when different types of professionals are on the team.
- The role of technology in facilitating team-based care needs to be examined extensively.
- More information is needed about patient-centered outcomes such as satisfaction with care and adherence to healthy behaviors (e.g., increased physical activity, improved diet).
Topic 4: Compare the effectiveness of diuretics

Background and Significance

Hypertension is commonly treated with several classes of medications, including diuretics, beta blockers, calcium channel blockers, angiotensin-converting enzyme (ACE) inhibitors, and angiotensin receptor blockers. Generally, diuretics have been considered first-line agents for treatment of hypertension. The seventh report issued by the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, issued in 2003, recommended that treatment for uncomplicated hypertension begin with diuretics, and when more than one class of drugs is required, treatment should usually include a diuretic. The committee recommended the use of “thiazide-type” diuretics, specifically hydrochlorothiazide or chlorthalidone, but indicated no preference for one over the other. While recent recommendations have not consistently endorsed use of thiazides as first-line agents, they remain a critical component of anti-hypertensive therapy, and 45% of patients with hypertension who are undergoing treatment take a thiazide diuretic. Moreover, thiazide diuretics are widely used among African Americans, for whom they may be particularly effective.

The pharmaceutical preparations for hydrochlorothiazide and chlorthalidone are different, carrying implications for practicality and convenience, and consequently, use of the drugs. In the United States, hydrochlorothiazide is available in two doses in individual tablets, and in 19 combination tablets, whereas chlorthalidone is available in one tablet, in a dose that is excessive for many patients, and in just three combination tablets. Presumably, because of the wider availability and options for dosing of hydrochlorothiazide, prescriptions for it outnumber chlorthalidone prescriptions by more than 20-fold and it is the 10th most commonly prescribed drug in the United States.

Despite the widespread use of hydrochlorothiazide, recent studies indicate that chlorthalidone may be superior in preventing cardiovascular events. Evidence from a recent review of randomized controlled trials with either hydrochlorothiazide or chlorthalidone reinforced this notion, suggesting that millions of Americans are not being treated with the most effective antihypertensive medication. However, the comparative effectiveness of these drugs in preventing cardiovascular events has not been studied in head-to-head randomized controlled trials. There is also limited evidence on the effect of population-drug interaction, or if a characteristic such as ethnicity modifies the effect of a drug, which has implications for addressing different target populations. More evidence generated from head-to-head randomized controlled trials has the potential to inform changes to antihypertensive medication prescription practices, improve hypertension care, and achieve high-impact results, particularly for disparate populations.

Existing Evidence Base

In a recent systematic review, researchers identified nine randomized controlled trials in which either hydrochlorothiazide or chlorthalidone was used in one arm of the study to examine the effectiveness of antihypertensive drugs in preventing cardiovascular events, including heart attack, congestive heart failure, stroke, or coronary heart disease. In this review, compared to hydrochlorothiazide, chlorthalidone reduced cardiovascular events by 21%. 

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One potential threat to the validity of this study is the possibility that the drugs have different effects on different populations resulting from an interaction between the drugs and certain population characteristics (e.g., African American ethnicity). However, overall the researchers conclude that chlorthalidone is more effective than hydrochlorothiazide in preventing cardiovascular events because of one or more of the following effects: chlorthalidone more effectively reduces systolic blood pressure, hydrochlorothiazide is active for a shorter duration of time leaving patients vulnerable during the night, and/or altered effects of chlorthalidone in the presence of other medications.

**Research Areas of Interest**

An area of potential interest to PCORI is the comparative effectiveness of hydrochlorothiazide versus chlorthalidone among populations with diverse racial and ethnic characteristics. Such a study should be large enough to determine the presence and magnitude of population-drug interactions and to detect impacts on health outcomes such as cardiovascular events.

More generally, research is needed to compare alternative first- and second-line antihypertensive drugs using rigorous head-to-head trial designs and comparing clinically meaningful drug combinations (i.e., with commonly prescribed generic drugs or drug combinations in each study arm).
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