Protocol Title: Implementing the Los Angeles Barber-Pharmacist Model of Hypertension Management in Nashville
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Implementing the Los Angeles Barber-Pharmacist Model of HYPERTENSION MANAGEMENT IN NASHVILLE

A Barber-Pharmacist-Physician Partnership for Blood Pressure Management

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Study Support Provided By:
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ABBREVIATIONS

ACE – Angiotensin-converting enzyme
ARB – Angiotensin II Receptor Blocker
BP – Blood Pressure
CAPI – Computer Assisted Personal Interviewing
CCB – Calcium-channel blocker
CLIA – Clinical Laboratory Improvement Amendments
CRF – Case Report Form
CS – Cedars-Sinai
CTSI – Clinical and Translational Science Institute
DCC – Data Coordinating Center
DSMB – Data Safety Monitoring Committee
GFR – Glomerular Filtration Rate
Hg – Mercury
HIPAA – Health Insurance Portability and Accountability Act
HTN – Hypertension
IRB – Institutional Review Board
LA – Los Angeles
MD – Doctor of Medicine
mm – millimeters
NCATS – National Center for Advancing Translational Science
NH – Non-Hispanic
NHLBI – National Heart, Lung, and Blood Institute
NIH – National Institutes of Health
PHI – Protected Health Information
PI – Principal Investigator
SAE/UPs – Serious Adverse Events and serious Unanticipated Problems
UCLA – University of California, Los Angeles

AMENDMENTS

Itemized Protocol Changes

Protocol			
Section	**Version**	**Date**	**Description of Change**
Overall Protocol	2.0	2/24/20	▪ Formatting changes throughout ▪ Removed iStat language ▪ Added PARTNER CKD Registry IRB approval number ▪ Replaced "Field Interviewer" with "Research Coordinator" ▪ Updated Table of Contents ▪ Removed previous Appendix 13 "Barber Training Manual"
Study Summary	2.0	2/24/20	▪ Added Clinicaltrials.gov # ▪ Added Phase 2A
Introduction: Study Oversight	2.0	2/24/20	▪ Updated DSMB language
4. Participant Selection and Withdrawal *4.2.1 Pre-screening and enrollment of participants*	2.0	2/24/20	▪ Language update: SV2 appointment window change from 1 week to 3 weeks
5. Study Intervention *5.1 Blood pressure readings by barbers* *5.2 Clinical pharmacist evaluation and counseling* *5.5 Laboratory Measurement*	2.0	2/24/20	▪ Language update: Added location language, replaced iStat language, added documentation language
7. Study Procedures and Visits *7.1.1 Initial Screening Day* *7.1.6 Barber Survey* *7.2 Client Compensation* *7.3 Barber and barbershop reimbursement*	2.0	2/24/20	▪ Added Barber Survey Description ▪ Added method of contact language ▪ Updated method of reimbursement language ▪ Added documentation & reimbursement language
References	2.0	2/25/20	▪ Updated reference numbers
Appendix 3	2.0	2/24/20	▪ Updated Collaborative Pharmacy Practice Agreement
Appendix 5	2.0	2/24/20	▪ Updated Hypertension Management Algorithm
Appendix 6	2.0	2/24/20	▪ Added 6B.5 Barber Exit Interview ▪ Updated Appendix 6C: Blood Pressure Information Card with contact names ▪ Added Appendix 6G: Participant Treatment Report Example
Appendix 6B.1 (SV1)	2.0	2/24/20	▪ Removed Gift Card
Appendix 6B.4 (6-Month Visit Survey)	2.0	2/24/20	▪ Removed Appointment for Second Visit section
Appendix 7	2.0	2/24/20	▪ Edited "basic metabolic panels" language to "laboratory tests"
Appendix 9	2.0	2/24/20	▪ Updated Flow Diagram for Expedited Reporting of Serious Adverse Events and Serious Unanticipated Problems (SAE/UP)

STUDY SUMMARY

Title	IMPLEMENTING THE LOS ANGELES BARBER-PHARMACIST MODEL OF HYPERTENSION MANAGEMENT IN NASHVILLE
Short Title	Barbershop Nashville
NIH Grant Number	UL1TR001881-03S2
Protocol Number	NSH-BP001
Clinicaltrials.gov Registration	NCT04232124
Phase	2A
Design	Open label, single arm pre-test/post-test design, with no comparator
Study Duration	6-Months
Clinical Site(s)	Vanderbilt University Medical Center; Community partners (Barbershops)
Data Coordinating Center	Cedars-Sinai Health System & University of California Los Angeles (UCLA) Program contact: [redacted], PhD (UCLA)
Primary Objectives	Establish network of Nashville barbershops engaged in clinical research; localized version of the LA-BP program
Secondary Objectives	Evaluate the impact of a pilot multicomponent intervention to optimize blood pressure control among adult black men in Nashville
Number of Participants	56 clients
Inclusion criteria	Adults 35-79 years old, non-Hispanic black males, patron of one of the participating barbershops ($\geq$ 4 haircuts in the last 6 months), Systolic BP > 140 on two screening days
Interventions	Clinical pharmacist counseling & medication management; Barber encouragement & BP measurement
Primary outcomes	a. Recruitment/retention of participants b. Intervention Fidelity c. Clinical efficacy: BP at 6-months; participant satisfaction
Statistical methodology	Primary analyses will estimate the average change in systolic blood pressure from baseline to 6 months and derive its 95% confidence interval. Secondary analyses will measure associations between relevant baseline covariates and BP at 6-months. Logistic regression will be used to identify covariates that predict a participant's response. Longitudinal analyses using mixed effects models of serial systolic BP measurements obtained at each individual visit from baseline to 6 months will also be conducted.
Study oversight	Data Safety Monitoring Committee

Reviewed and approved by:

David Harrison, MD, Principal Investigator Date:

Barry Carter, PharmD, Chair, Data Safety Monitoring Committee Date:

INTRODUCTION

1. Background

Black men face a shorter life expectancy than white men because of higher prevalence and worse outcome from many diseases: most notably hypertension (HTN) and its cardiovascular complications but also chronic kidney disease, tobacco-related diseases, prostate and lung cancer, depression, and HIV/AIDS.[1] Much more clinical research is needed to identify underlying causes and develop effective countermeasures to reduce this pervasive disparity. The first critical step is to find more effective means of engaging black men in clinical research. Several barriers have been proposed, especially distrust of physicians and fear of being exploited by researchers. Black men are less likely than black women to see the need for regular medical check-ups and thus are under-represented in standard medical settings where most research is based. Black barbershops are uniquely positioned in the community for promoting health and health research among male patrons in a relaxed social setting.

Engaging underrepresented groups in clinical research is both a challenge and a public health priority for reducing health disparities.[2] Engaging non-Hispanic black individuals—particularly black men—in research has been especially challenging. For example, the age-adjusted death rate from prostate cancer is 3-times higher for black men than white men but black men comprise <4% of patients in National Cancer Institute prostate cancer trials.[3] The HTN-related death rate also is 3 times higher in black men than white men.[4] However, in the Dallas Heart Study, which addressed this disparity, the in-home phlebotomy participation rate was 64% among black men vs. 72% among black women and 82% and 86% among white men and women, respectively.[5] Black men are under-represented in traditional medical settings, where most clinical research is based. However, traditional outreach efforts have not been very productive. In Dallas County Community Oriented Primary Care Clinics, <20% of black clinic patients with HTN are men. In a recent trial that recruited black patients from community pharmacies in Wisconsin for an intervention trial to improve medication refill rates, only 1/3 of the ~ 600 black patients enrolled were men.[6] *Together, all these data underscore the need to reach out to non-traditional community partners and develop health messages that resonate with black men.*

Black barbershops are a unique social setting in which black men to openly discuss important issues in their lives—including health—with barbers (trusted community members with a loyal clientele) and other black men. Barbershop health outreach is well-established but previously untested as a vehicle to engage black men as participants in research. A series of successful intervention trials in other cities serve as a model to evaluate the implementation of a pilot trial in Nashville. A key issue is distrust of doctors and fear exploitation by researchers—a reaction to unequal medical treatment[9] and prior scientific misconduct as in the Tuskegee Syphilis Study.[10] In the 1920s, indigent black men in Alabama were recruited by the U.S. Public Health Service for this natural history study before penicillin was discovered as effective treatment for syphilis; however, participants were not informed of the study's true purpose and they were not offered appropriate antibiotic treatment for 30 years after the discovery of penicillin. Thus, before asking barbers to encourage their loyal male patrons to engage in research, participation should entail some medical benefit. In this case, the clientele of each barbershop is offered a free in-shop BP screening with specific instructions for appropriate medical follow-up. Men with uncontrolled HTN who enroll in the Nashville intervention pilot will get accurate BP checks in the barbershop and a concierge clinical pharmacist to meet them regularly in their barbershop, prescribe BP medicine under the supervision of a physician, optimize BP, and check blood electrolytes.

Addressing high BP is an excellent way to build trust. BP measurement is non-invasive. The BP cuff is a familiar iconic symbol of healthcare and community screening programs. HTN is

particularly devastating for black men and is the main reason why average life expectancy is still less than for white men.[11] High BP medication reduces the risk of heart attack, stroke, heart failure, and premature death for all patient groups, including black men.[12] HTN exemplifies the barriers to effective chronic disease management in general. High BP signifies multiple related health issues (such as dyslipidemia, metabolic syndrome, diabetes, tobacco addiction) that also will come to medical attention.

Prior research trials in Dallas, Texas and then Los Angeles, California, supported by NIH NHLBI, showed that barbershops can support health services research and provide effective HTN screening, referral, and follow up centers for black men. The Los Angeles study developed a network of 60 black barbershops across Los Angeles county and leveraged this network to evaluate an enhanced barber-pharmacist team approach to manage chronic diseases (starting with HTN) in barbershops. The barbershops enrolled 320 hypertensive black male patrons to participate in a 12-month HTN trial with 97% cohort retention. Also, the screening process generated a local registry of >2,500 LA County black male barbershop patrons who consented to be re-contacted about potential participation in future research studies. This protocol builds on this considerable progress by conducting a proof-of-concept study to evaluate the implementation of a study protocol over a 6-month period in Nashville.

2. Study Objective and Aim

The overall objective of this study is to establish an effective network of barbershop research hubs in Nashville.

Aim 1. *Execute a smaller version of the LA Barbershop BP Study through the new Nashville network as the test case for: A) recruiting regular patrons with uncontrolled HTN, B) conducting a research protocol and evaluating a HTN intervention; and C) creating a local registry of potential subjects as platform for enrolling black men in future research studies.*

There is no formal hypothesis testing regarding patient-level outcomes, however this study will evaluate:

a) the ability of the barbershop-based research methodology to recruit and retain black men in a clinical trial;

b) intervention fidelity by the barbers, pharmacist, and hypertensive male participants; and

c) intervention effectiveness on the primary outcome of systolic BP and patient satisfaction.

All screening participants will also be offered opportunity to participate in a separate research registry (Patients' Research Networking and Engagement Registry for Cardiovascular and Kidney Disease: PARTNER CKD; VUMC IRB# 191374).

3. Study Design and Overview

Single arm, pre-test/post-test (Phase 2A) design, with no comparator group.

4. Participant Selection and Withdrawal

4.1 Barbers & Barbershops

North Nashville has approximately 1.6 black barbershops per square mile, with only 3.4 miles being the maximum distance between shops. *Thus, North Nashville is well-suited to develop barbershops as hubs for much needed HTN health services research.* Barbershops in this area will be prioritized, however other areas will be considered as needed to meet participation goals.

A lead study barber or investigator will identify and recruit 8 Nashville barbershops with civic-minded owners and large well-established clienteles to serve as the initial core group of research hubs. Barbershop owners will be approached to have an in-person meeting with study personnel to fully discuss the project, the activities and expectations and answer any questions or concerns. If the barbershop owner agrees to participate as a location, they will sign a Letter of Collaboration (Appendix 6A). The target will be 8 barbershops.

Barbershops will meet these general selection criteria: a) NH black owner; b) estimated >95% black male clientele as reported by the owner; c) 10+ years in business; d) barbers' commitment to the study; and e) large enough clientele to enroll >7 patrons with high BP.

Once a barbershop has agreed to participate, each barber working within that shop will be approached for participation in the study as a barber (secondary participant). The only inclusion criteria are that the barber is fluent in English and willing to commit to training. They will be approached in person to discuss the activities of participation. All barber questions will be answered. If the barber agrees to participate, he will sign the VUMC IRB approved barber consent form. The barber will agree to participate in study training. If they do not complete study training, they will not participate. Barbers may withdraw from participation at any time by informing the study personnel verbally or in writing.

4.2 Participant Inclusion & Exclusion Criteria for participants

Inclusion criteria:

a. Adults 35-79 years old
b. Self-identify as Non-Hispanic black male
c. Patron of one of the participating barbershops ($\geq$ 4 haircuts in the last 6 months)
d. Systolic BP > 140 mm Hg on two screening days at least one day apart

Exclusion criteria:

a. Severe cognitive impairment
b. Non-fluent in English
c. Women
d. Age < 35 years or > 79 years
e. Systolic BP < 140 mm Hg at either screening
f. Currently receiving chemotherapy for cancer
g. Organ transplant patient
h. Currently receiving dialysis
i. Other conditions the physician investigators deem unsafe to participate
j. Plans to move/relocate in next 12-months and/or travel out-of-area for > 1 month

4.2.1 Pre-screening and enrollment of participants

Trained study personnel will screen the black male clientele of the study barbershops to identify and enroll regular patrons 35-79 years of age with systolic BP >140 on two screening days to participate in a 6-month trial of medication therapy management and BP monitoring in their barbershops.

The research staff will be on-site in each barbershop and will offer free BP screening to all adults entering each barbershop for a total of approximately 4 weeks, or until recruitment targets have been met for each barbershop. Those with systolic BP >140 mm Hg will be asked to return within 3 weeks to: (a) complete a 2nd set of BPs, (b) complete the visit screening questionnaires (see Appendices 6B.1-6B.2), and (c) bring their pill bottles to screening visit 2 so that medication data can be transcribed.

Eligible participants at screening visit 2 will be offered the opportunity to participate in the study. An informed discussion will occur with the study personnel during which all questions may be answered. If the participant agrees, written informed consent will be obtained emphasizing this is a voluntary study and participation may be withdrawn at any time.

The participant's existing physician (VUMC) or Dr. [redacted] (or other study physician), must sign the collaborative practice agreement (see Appendix 3) for the pharmacist to provide care and also to prescribe medications within this study protocol. All participants in this study will execute a visit with the study MD for an evaluation to establish care, supported by the funding for this proposal (e.g. NIH). If the participant is seen by a VUMC physician, and that physician would prefer to serve as the supervising physician of the pharmacist including all regulatory oversight this will be permitted. These visits will be performed after enrollment, but prior to any hypertension management.

Interviewers will invite patrons who screen-fail to join a new separately VUMC IRB approved registry (IRB# 191374) by giving their informed written consent to be re-contacted about their potential participation in future research studies. Those completing the 6-month HTN study also will be invited to join the registry.

4.3 Participant member cards
Participants enrolled in the study will be given information about the study and this may include a study member card inclusive of study contact information.

5. Study Intervention
5.1 Blood pressure readings by barbers
Barbers will participate in training prior to implementation of the trial. This training will include skills training on BP measurement and use of the BP machine, the study protocol, and educational counseling for participants. The training will be performed by either collaborating researchers from the UCLA-CS CTSI or from local study personnel, led by the local study clinical pharmacist or an investigator.

Barbers will frequently check and transmit the BP readings (See Section 5.4) of their enrolled patrons and motivate them to work with the clinical pharmacist, who will meet them in their barbershops or other mutually agreed location to optimize BP medication.

5.2 Clinical Pharmacist evaluation and counseling
With the VUMC or study physicians' permission and oversight, the pharmacist will promote patient activation, intensify drug therapy under a collaborative practice agreement as permitted by Tennessee state law, send progress notes to the participants' physicians with their permission, and ensure appropriate safety monitoring after each medication change. The study clinical pharmacist will follow the trial's medication algorithm, which is consistent and not different than standard of care. The pharmacist will preferably be certified as a Clinical Hypertension Specialist from the American Society of Hypertension.

The pharmacist will meet each participant in his barbershop or other mutually agreed location every week at first and then less often (monthly) once the target BP goal has been achieved. The pharmacist will send progress notes to the participants' physicians after each encounter. Pharmacist will share treatment/BP reports with enrolled participants during their visits. These reports are generated by the data collection center (UCLA) and shared with the study team. (Appendix 6G). The pharmacist will work with the research assistant to schedule participant

appointments with the pharmacist, make reminder calls, and obtain or share medical records from the participants' physicians.

5.3 Role model posters
Prior research has shown that role model posters of actual study participants contributes to successful retention of participants throughout the trial. The Nashville pharmacist and study team will interview the participants and those who achieve BP control will be invited to become a study role model.

If they agree, the research assistant will take a photograph of the role model, and (with the model's approval) have the poster generated at a copy shop and place it on the wall of the barbershop. Each poster models one of two desired behaviors (have the barber check the BP after every haircut or meet the pharmacist in the barbershop), and, in the model's own words, briefly states one common barrier to the behavior change, one facilitating factor, and one positive outcome.

5.4 Blood Pressure measurement and data transmission
UCLA-CS will supply Nashville with Barbershop BP Carts. These nurses' carts are modified with a highly-rated automated BP monitor that is programmed to take 5 readings, which upload immediately to a desktop computer that automatically transmits the readings by secure internet to the Westat server in Rockville, MD; then de-identified data are transmitted every evening to the UCLA-CS CTSI under the supervision of Dr. [redacted], or approved personnel at UCLA. Westat, Inc. is the data management company that collaborated with the LA Barbershop study and will offer ongoing support to this study, leveraging its already developed methodology.

5.5 Laboratory Measurement
Vanderbilt General Clinical Research, or a licensed trained clinician, will perform phlebotomy and facilitate lab services for study participants as needed. Most Common will be serum basic metabolic panel, but others may be considered as clinically indicated. Study pharmacist will review laboratory results, consult the physician, and determine an appropriate medication regimen for the subject based on the laboratory results. The pharmacist or study physician will generate relevant orders as needed & complete medical record documentation

5.6 Monitoring the fidelity of the Intervention
Treatment fidelity involves three components: 1) *treatment delivery*, 2) *receipt*, and 3) *enactment*. *Treatment delivery* by barbers (BP checks) will be assessed by the pharmacists who will provide extra training during the first intervention week. After observing a mock barber-patron interaction, the assistant will complete detailed checklists to evaluate performance of the desired competencies and intervention delivery, followed by constructive feedback.

Treatment delivery by pharmacists will be reviewed by our HTN specialists (Dr. [redacted] or other study designated physician), who will review with the pharmacists each week their progress notes to ensure adherence to the study algorithm as well as perform quality performance review. *Treatment receipt* will be assessed a) by pharmacists during each in-person visit by reviewing shared goals with patrons and their understanding of BP levels and medications; and b) by patient satisfaction scores at a 6-month evaluation. *Treatment enactment* will be monitored throughout the trial by numbers of barber encounters, pharmacist encounters, and model posters.

6. Ascertainment of Outcomes
6.1 Recruitment and retention of black men
All people screened at each of the screening days will be tabulated and descriptive statistics performed. For those that enroll, their activities throughout the 6-month study timeline will be

monitored closely and similarly tabulated. This will be depicted in a study flow diagram. Reasons for non-participation or withdrawal will be ascertained by asking the participant.

6.2 Intervention fidelity by participant type

Examples of the measures to evaluate intervention fidelity include:

Participant Type	**Measure**	**How assessed**
Barber	Number of BP checks (count)	Count per participant; sum by barber
	% Visit with BP check	BP value cross check with barber schedule, voucher redemption and/or participant self-report
Pharmacist	% Visits with medication intensification	Review of pharmacist notes; med lists
	% Visits with various drug classes	Review of pharmacist notes; med lists
	% Visits with use of 1st line meds	Review of pharmacist notes; med lists
	% Visits with GCRC	Review of pharmacist notes;
	% Visits with GCRC follow-up	Review of pharmacist notes; MD letter
Participant	Number of visits with pharmacist	Review of pharmacist notes
	% offered & accepted role modeling	Role model invitations & posters

6.3 Clinical efficacy

6.3.1 6-month Systolic Blood Pressure

The study's primary clinical outcome is the change in systolic BP assessed 6 months after enrollment. Systolic BP is a more powerful predictor of cardiovascular events than diastolic BP;[12-15] Interviewers will be trained to measure BP using an accurate oscillometric monitor,[16] with participants seated after 10 min of rest. For each participant, the correctly sized arm cuff will be determined, recorded, and used for all subsequent BPs. For baseline and endpoint data, interviewers will take five consecutive BP readings over a period of 5 minutes on each participant. The final three readings (assuming 5 successful measurements) will be averaged to obtain a stable mean value, which will be used to calculate BP outcomes. If there are only four successful measurements, the last two are averaged. If there are less than four measurements, it is considered insufficient and requires another attempt to obtain a minimum of four measurements. Other secondary BP-related outcomes are the: 1) increase in the number of BP drugs of different classes per regimen—the best indicator of BP treatment intensification;[18] 2) change in percentage of regimens with specified first-line BP drug classes; and 3) reported adverse drug reactions.

6.3.2 6-month patient satisfaction

The questionnaire will include validated widely-accepted scales on: patient satisfaction by the 20-item Patient Assessment of Chronic Illness Care (PACIC) scale,[20] which has modules on patient activation, delivery system design/decision support, goal setting, problem-solving/contextual counseling, and follow-up/coordination; and medication adherence by the 12-item Adherence to Refills and Medications Scale.[21] The PACIC is generally available for use per its website (http://www.improvingchroniccare.org/index.php?p=User_Info&s=227), and permission for use of the ARMS has been secured specific to this study.

7. Study Procedures and Visits

7.1 Screening

Identification and consenting of eligible patrons for the HTN pilot study will be performed by research coordinators trained in BP measurement, study procedures, research ethics, and cultural competency.

7.1.1 Initial screening day

For the 1st month of the study, all adult black men entering the study barbershop will be offered free BP screenings. This will be in person. Men with systolic BP >140 mm Hg will be asked to return within 3 weeks for a second screening visit. They will be given a reminder appointment card. The research team member will call the potential participant to remind them of SV2 appointment no more than 3 times in the eligibility interval. All men completing this initial screening visit will receive a water bottle or other similar gift as a token of appreciation. The script and content of the screening visit are described in Appendix 6B.1 (Screening Visit 1 Survey). All data collected in this screening visit will be directly entered into the on-site study computer to a secure web portal specific to this study. This is managed by study collaborator Westat, Inc.

In addition, all men completing the first screening visit (regardless of their eligibility to join the HTN pilot trial), will be invited to join a registry by providing their contact information and informed written consent to be re-contacted about their potential participation in future research studies. This is a separate IRB approved study with its own procedures and documents (Patients' Research Networking and Engagement Registry for Cardiovascular and Kidney Disease; PARTNER CKD; VUMC IRB# 191374).

7.1.2 Second screening day

Those invited to participate in the second screening visit will be asked to: (1) complete a 2nd set of BP measurements and health questionnaire (Appendix 6B.2; Screening Visit 2) and (2) bring their pill bottles to the barbershop for interviewers to transcribe medication data. Subjects with systolic BP >140 mmHg on both days who meet all other inclusion criteria will be enrolled after informed written consent has been obtained by the research coordinators.

7.1.3 Enrollment & Initial activities

Informed consent will be obtained, and the participant will provide written documentation.

Visit questionnaires for baseline (Appendix 6B.2), 3-month telephone visit, and 6-month endpoint assessment visits will be completed by research coordinators when they interview subjects in barbershops, or by telephone interview. The data will include detailed demographic and identification information: marital status, phone number, address, and email address. Structured response items will include barbershop patronage, hypertension/medication history, comorbid conditions/family history, medication adherence, quality of life, health care access and utilization, and satisfaction with medical care. Five BP measurements will be taken and recorded at baseline using the same cuff size as recorded at screening.

7.1.4 Intervention from enrollment through 6-months

Pharmacist Progress Note forms will be completed by the pharmacist after each visit. This will be entered into a REDCap database maintained at VUMC by the VUMC study personnel. Data will include past medical history, medication allergies, list of current medications, subjective comments, objective observations, 5 blood pressure measurements, assessment, and plan. In addition, pharmacist will go through a complete checklist of medication-related problems, which is included in the Progress Note, at each encounter (see Appendix 6D & 6E). A checklist of actions/interventions will also be completed. If an adverse event is reported, the pharmacist will

complete an Adverse Event form. Pharmacist and/or physician will also record all necessary information in the VUMC electronic medical record.

The research team will attempt to contact subjects who have not had a haircut in 4 weeks. We will make phone calls and send reminder cards to complete the pharmacist visits as well as 3-month telephone and 6-month data collection.

7.1.5 Study close visit (6-months)
The research assistant will perform a blood pressure assessment and questionnaires as in Appendix 6B.4.

Data will be collected on performance and acceptability of the study protocol using open ended interview questions.

7.1.6 Barber survey
All participating barbers will be asked to complete a brief survey about their experiences in the study (Appendix 6B.5). This data will be collected in REDCap and by hard copy and summarized for descriptive reporting.

7.2 Client compensation
Participants will be offered $25 at the completion of the second screening visit regardless of eligibility. Participants will be offered $25 for each visit completed with the study physician or the clinical pharmacist (up to 6 visits; the participant may have additional visits if needed without additional compensation), $15 for the telephone interview and $100 at the completion of the final 6-month visit. Participants will also be offered a monthly $25 haircut voucher in addition to the above. The total potential compensation if all study activities are completed is $440 (direct payment and haircut vouchers). Participants may be asked to complete a W-9 form to receive payment.

Mode of compensation will be through a Subject Participation Debit card program and / or pre-paid gift cards, or check.

7.3 Barber and barbershop compensation
Each barbershop will receive a flat fee of $1000.00 ($500.00 at the beginning of the study and $500.00 after study completion). Each barber will receive $10.00 per BP measurement per client for up to 2 maximum per month for 6 months. Given that each barbershop will have approximately 7 participants, this would equate to $840.00 per shop (14 x 6 months = 84 BP measurements = $840.00 per shop). Barbers will also redeem submitted study hair cut vouchers ($25.00/each). Barbers and barbershops may be asked to complete a W9 form to receive payment. Payment will be by check, or prepaid gift card for activity over the prior month.

8. Statistical Analysis Plan

Primary analysis (clinical outcomes):

Since this study has no comparison group, our initial analysis will focus on estimating the average change in systolic BP from baseline to 6 months and derive its 95% confidence interval, that is, our goal is to estimate $d = E[SBP_{6m} - SBP_0]$, where ***E*** stands for expectation, and SBP_0 and SBP_{6m} denote baseline and 6 months systolic BP, respectively. Let d_{ij} be the systolic BP change score from baseline to 6 months on individual *j* in barbershop *i*. Define

$$\bar{d}_i = \frac{\sum_{j=1}^{m_i} d_{ij}}{m_i}$$

the observed mean change of systolic BP in barbershop *i*, where m_i is the sample size for barbershop *i*. An estimate of d can be derived using weighted average of $\bar{d}_i$ over all the n barbershops (n = 8 in this study). The optimal weights are given by the reciprocal of the variance of each cluster summary:[22]

$$w_i = \frac{m_i}{1+ \rho(m_i-1)},$$

where ρ is the intracluster correlation coefficient (ICC). Thus, we estimate d by $\bar{d}$:

$$\bar{d} = \frac{\sum_{i=1}^{n} w_i \bar{d}_i}{\sum_{i=1}^{n} w_i}.$$

The 95% confidence interval is given by $\bar{d} \pm t_{v,0.025}\, s_w/\sqrt{\sum_{i=1}^{n} w_i}$, where the degrees of freedom v for the t-distribution is $\sum_{i=1}^{n} w_i - 1$ and s_w is the square root of the empirical variance estimate calculated as

$$s_w^2 = \frac{\sum_{i=1}^{n} w_i(\bar{d}_i-\bar{d})^2}{n-1}.$$

Secondary Analyses:

Three sets of secondary analyses will be conducted. First, we will examine the impact of baseline covariates on the outcome. We will focus on the same covariates used in the LA Barbershop study: baseline systolic BP, high cholesterol (yes/no), and whether there is a doctor for routine medical care (yes/no). Graphs for blood pressure trajectories and latent class growth analysis will be used to classify the participants into those who respond well to the intervention and those who do not respond well. Important covariates that predict participant's response will be identified via logistic regression. Second, we will conduct longitudinal analysis of serial systolic BP obtained on each individual from baseline to 6 months via linear mixed effects models. The analysis will adjust for the covariates identified above. We will examine the trend (trajectory) by graphical tools and model it accordingly. This will be done for each barbershop separately. Third, we will compare data from this study with the intervention arm of the LA Barbershop study to see if there is a systematic difference. The comparison will be done for the change score of systolic BP at 6 months as well as the longitudinal measurements of systolic BP. If no systematic difference is found, systolic BP data from this study will be merged with the intervention arm of the LA Barbershop study, and this combined intervention group will be compared to the control arm of the LA study via the same analytic approach in our previous publication.[23]

Additionally, the PACIC and ARMS data will be reported descriptively. Unadjusted correlations between baseline characteristics and each of these measures will be performed. In exploratory analyses only, we will also examine correlations between baseline PACIC and BP outcomes. We will also describe any changes in the PACIC or ARMS scores over the two visits during the study.

Plan for handling missing data

We expect missing BP data due to dropout and/or intermittent missing data at the individual level but not at the shop level, where dropout is expected at baseline when accrual targets are unmet; after baseline, missing data will be from individuals not shops. The following analyses will be

conducted if the rate of missing data exceeds 10% at 6 months. Without knowing the exact missing data mechanism beforehand, we will compare results of two sets of analyses: (1) The 1st set is based on multiple imputations, i.e., missing BP data "filled in" by imputed values. Five imputed datasets are generated by the Markov Chain Monte Carlo method.[24] Analysis will be conducted within each imputed dataset using linear mixed effects models. Results of imputed datasets will be combined to produce final estimates. This approach assumes data are missing at random (MAR): the mechanism that gives rise to missing data relies on observed data only. However, missing data from cohort attrition and intermittent missing data due to low treatment efficacy may be missing not at random (MNAR); the probability of missing data may be related to unobserved (and possibly high) BP. Here the multiple imputation method will produce biased efficacy estimates. (2) The 2nd approach relies on joint modeling of longitudinal BP data and missing data mechanisms for dropout and intermittent missing data MNAR.[25] Latent random variables are used to associate linear mixed effects model of longitudinal outcome to missing data mechanisms. Thus, the MAR mechanism is a special case under this general joint model, which potentially allows comparison with multiple imputation results. But if the two approaches produce different results, missing data are likely MNAR and results from the joint model will be used. To handle missing data, we employ a less restrictive assumption that missing data are non-ignorable, where the probability of missingness is related to unobserved data. Extending from prior literature, we allow missingness probability depending on latent compliance category and unobserved outcomes. Note that this is a pre-test/post-test design; thus, the identification of missing data models is not as powerful as it would be in a longitudinal design.

9. Adverse Events

9.1 Potential Adverse Events from study interventions

The likelihood of adverse events beyond those that may be expected as a result of hypertension medication management are minimal.

Loss of confidentiality is a serious risk in any clinical research; however, is not likely given the safeguards we have established to protect and maintain the research data collection, transmission, and storage.

Anxiety is a rare and typically not serious potential risk associated with high BP caused by learning that one's BP is elevated. Study personnel will undergo training in all study procedures which will include appropriate interaction with subjects.

Uncontrolled hypertension is associated with increased risks of known hypertensive complications including cardiovascular events, stroke, heart failure, and chronic kidney disease. These risks are not due to study procedures but are intrinsic to the condition of all subjects being enrolled. The purpose of our study is to reduce these risks by better management of HTN.

During the data collection periods (baseline, 6-month follow-up), all subjects will receive a form with their BP reading, an explanation of the accepted cutoff values for normal and high BP, and suggestion for medical follow-up based on the degree of elevation as below: (Appendix 6C)

- For normal BP range of below 120/80 mm Hg, subjects are advised to see a doctor at least once a year to maintain good health.
- For high normal range BP of 120/80 mm Hg -139/89 mm Hg, subjects are advised to see a doctor within 6 months.
- For elevated BP range of 140/90 mm Hg -159/99 mm Hg, subjects are advised to see a doctor within the next 1 month.

- For very elevated BP range of 160/100 mm Hg -179/109 mm Hg, subjects are advised to see a doctor within the next 2 weeks.
- For extremely elevated BP range of 180/110 mm Hg -199/119 mm Hg, subjects are advised to see a doctor in the next 3 days.
- For alarmingly elevated BP of 200/120 mm Hg or higher, subjects are advised to see their physician urgently or go to the nearest emergency room.

During the intervention period, subjects will be referred to the pharmacist for personalized health management and to their barber for frequent BP monitoring and social support. The risks of uncontrolled HTN are not due to study procedures but are intrinsic to the condition of all subjects being enrolled.

Adverse drug reactions:
Although not common, there are potential serious adverse drug reactions associated with BP medication, but the most common side-effects from blood pressure medication are not serious and resolve within three days after the medication has been stopped. In addition, excessive fall in blood pressure is a potential serious risk of any blood pressure medication.

9.2 Monitoring for Adverse Events
Adverse Events procedures and forms are included in the Appendix (Appendices 8-12). These forms include description of the event, event onset and end date, disease-related complications, checklist of drug or non-drug related events, severity scale, whether or not the event was related to study procedures, event pattern, actions taken with study drug, whether or not hospitalization and/or medication(s) were required.

To track potential adverse events from added medications, pharmacist will 1) provide details about potential adverse reactions to each drug prescribed, 2) instruct subjects to call the pharmacist immediately if they suspect an adverse drug reaction, 3) reduce or stop medication if systolic BP falls below 110 mmHg or diastolic BP falls below 60 mmHg as recommended by all current practice guidelines, 4) make an additional follow-up phone call one week after medication changes, 5) go through a complete check list of potential adverse events at each encounter (in person visit and via telephone) to assess the presence and severity of all reported reactions, 6) send a detailed Progress Note (Appendix 6D & 6F) to the subjects' physicians after every in-person and telephone encounter with the subjects. The Progress Note used for the in-person and telephone encounters will have a complete check list of potential adverse drug reactions to every class of blood pressure medication included in the signed treatment protocol. The adverse drug reaction check list includes the following items:

- Calcium channel blocker: lower extremity edema, bradycardia, hypotension, gingival hyperplasia
- Angiotensin converting enzyme inhibitor/angiotensin receptor: cough, hyperkalemia, acute renal failure, alopecia, angioedema
- Thiazide/thiazide-like diuretic: erectile dysfunction, hyperglycemia, hyperuricemia, gout, hypokalemia, hyponatremia
- Vasodilating beta-blocker: wheezing, erectile dysfunction, depression, heart block
- Aldosterone antagonist: gynecomastia, hyperkalemia, acute renal failure, erectile dysfunction
- Alpha blocker: dizziness, orthostatic hypotension, lower extremity edema, heart failure
- Centrally acting sympatholytic: rebound hypertension, dry mouth, somnolence
- Direct Vasodilator: headache, palpitations, shortness of breath, lupus (hydralazine), pericarditis (hydralazine)
- Loop diuretic: acute renal failure, hypokalemia

In addition, the study physicians will meet regularly with the pharmacist to review Progress Note and ensure protocol adherence. Subjects will receive detailed instructions from the pharmacist about potential adverse reactions to each drug prescribed and to call the pharmacist immediately if they suspect an adverse drug reaction. This will occur locally at VUMC. In addition, the study physician at Cedars Sinai will review de-identified progress notes for adherence to the study hypertension algorithm and to offer any further oversight recommendations.

9.3 Reporting of Adverse Events

When a serious adverse event is reported pharmacist will complete the Adverse Event form immediately and will submit it to the IRB within 24 hours of the event. This will include notification of the study PI, the overseeing physician, and review by the DSMB of if the event is or may be related to the study activities.

Pharmacist will instruct subjects experiencing non-serious adverse events to discontinue the medication causing the adverse event and will call these subjects back 3 days later to ensure that side-effects have completely resolved. All encounters will be documented as described above. Pharmacist will instruct subjects to call 911 and go to the nearest emergency room for any symptoms suggestive of heart attack, stroke, other serious medical condition, or extremely rare serious adverse events from BP medication (e.g., severe angioedema from an ACE inhibitor).

10. Data Management

10.1 Data coordinating Center and Data Entry Overview

The coordinators/study personnel and the pharmacist will collect and transmit data electronically via a secure internet connection to the existing Westat server, which transmits the data to the UCLA CTSI Data Coordinating Center.

Data collected by the designated pharmacist on the Progress Note will be collected and maintained in a VUMC REDCap Study database. This deidentified dataset will be shared with the coordinating center (UCLA) and other approved study investigators. Pharmacist Progress Note; copies of Adverse Event and Study Completion/Termination forms; copies of surveys conducted by research coordinators; copies of informed consent forms/HIPAA waivers; authorization for release of medical records; medical records sent by the subjects' physicians; transmitted barber BP measurements; and signed collaborative practice agreements will be placed in the subject's research chart which will be stored in a locked cabinet only accessible by the research team and maintained indefinitely. Hard copies of informed consent documents will be stored in a secured locked cabinet at Vanderbilt University Medical Center - Center for Health Services Research. Additionally, electronic files may be stored on password protected Center for Health Services Research servers that are only accessible to approved study personnel.

The following individuals will have access to individually identifiable private information about human subjects: VUMC study personnel as designated to the IRB will have access to the data collected at screening, baseline, 3-month and 6-month assessment visits. The data management team, Westat Inc, will have access to identified information during screening and the study data collection. The database manager at the UCLA DCC will have access to the data collected by research coordinators but these will be de-identified. The pharmacist will have access to the data collected by research coordinators, data provided by the subject's own physician, the BP measurements transmitted by the barber, and the information obtained directly from the subject. The study subject's own physician will have access to the data collected by the barber and by the pharmacist.

10.2 Computer and Data Security

Interviewer teams will collect the data on forms programmed onto the Westat CAPI Device that is a web-based portal and will be accessible only to approved and trained study personnel. To protect private health information: 1) each potential subject is given a unique code name upon screening, 2) CAPI devices are password protected; the data are continually uploaded to a secured server and the laptop is automatically erased- if the laptop is stolen, it contains no data; 3) the survey data are encrypted and transferred via a secure web-based system to the data management software and hardware systems at Westat's Rockville, Maryland central offices. Periodically, the encrypted de-identified data are transferred to the DCC at UCLA, 4) once the UCLA data manager reviews the validity and completeness of data, the data is deleted from the Westat servers and maintained solely at UCLA; 5) the linking file to PHI is locked and stored at Vanderbilt. Except for the Westat system, all other data management elements have been used in many previous NIH trials. Westat's system has been used in many previous research projects.

11. Study Oversight

This trial will be monitored by the same DSMB board monitoring as The LA Barbershop Blood Pressure Study (R01 HL 117983), and it will utilize a similar DSMB plan. The DSMB is responsible for safeguarding the interests of study participants by assessing the safety and efficacy of study procedures, and by periodic monitoring of safety data and the overall conduct of the study. The DSMB reviews the following types of safety data: 1) quarterly reports from the UCLA DCC; 2) annual reports from DSMB meetings; and 3) expedited reports from the PI on individual SAE/UPs or concerning trends identified by the Physician Monitors. After reviewing pertinent reports, the DSMB determines whether any trend that may be identified is related to the trial. After each DSMB meeting, the study team will prepare a draft report for the DSMB Chair to review and sign. The VUMC PI will transmit it to the VUMC IRB. The report summarizes the recommendations of the DSMB regarding the safety and continuance of the study and should be sent to the PI within 60 days after a DSMB meeting. If the DSMB identifies a concerning safety trend related to the trial, the Board makes a recommendation to NIH NCATS through the NCATS Project Officer, and to the PI, who will transmit the recommendations to the IRB at Vanderbilt and Westat. This recommendation includes actions that should be taken to protect current and potential participants. The DSMB is chaired by [redacted] (licensed pharmacist and board-certified pharmacotherapy specialist) who is experienced with DSMBs. Other DSMB members are [redacted] (Emeritus Professor of Biostatistics, Cornell University, Ithaca, New York) and [redacted] (Professor of Medicine/Cardiology, Tulane University School of Medicine, New Orleans, Louisiana).

REFERENCES

1. Barnett, E., et al., *Men and heart disease: An atlas of racial and ethnic disparities in mortality.* 2001.
2. Prevention, U.S.D.o.H.a.H.S.C.f.D.C.a. *A Closer Look at African American Men and High Blood Pressure Control*. 2018; Available from: http://www.cdc.gov/bloodpressure/docs/african_american_sourcebook.pdf.
3. Randolph, T.C., et al., *Associations Between Blood Pressure and Outcomes Among Blacks in the Jackson Heart Study.* J Am Heart Assoc, 2016. **5**(12).
4. Go, A.S., *Heart Disease and Stroke Statistics-2013 Update: A Report From the American Heart Association (vol 127, pg e6, 2013).* Circulation, 2013. **127**(23): p. E841-E841.
5. Jones, L. and K. Wells, *Strategies for academic and clinician engagement in community-participatory partnered research.* JAMA, 2007. **297**(4): p. 407-10.
6. Merrill, R.M. and O.W. Brawley, *Prostate cancer incidence and mortality rates among white and black men.* Epidemiology, 1997. **8**(2): p. 126-31.
7. Victor, R.G., et al., *The Dallas Heart Study: A population-based probability sample for the multidisciplinary study of ethnic differences in cardiovascular health.* American Journal of Cardiology, 2004. **93**(12): p. 1473-1480.
8. Victor, R.G., et al., *Factors associated with hypertension awareness, treatment, and control in Dallas County, Texas.* Arch Intern Med, 2008. **168**(12): p. 1285-93.
9. Svarstad, B.L., et al., *Improving refill adherence and hypertension control in black patients: Wisconsin TEAM trial.* J Am Pharm Assoc (2003), 2013. **53**(5): p. 520-9.
10. White, R.M., *Unraveling the Tuskegee Study of Untreated Syphilis.* Arch Intern Med, 2000. **160**(5): p. 585-98.
11. Wang, J.G., et al., *Systolic and diastolic blood pressure lowering as determinants of cardiovascular outcome.* Hypertension, 2005. **45**(5): p. 907-13.
12. Victor, R.G., et al., *A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops.* New England Journal of Medicine, 2018. **378**(14): p. 1291-1301.
13. Franklin, S.S., *Cardiovascular risks related to increased diastolic, systolic and pulse pressure - An epidemiologist's point of view.* Pathologie Biologie, 1999. **47**(6): p. 594-603.
14. Franklin, S.S., et al., *Single versus combined blood pressure components and risk for cardiovascular disease: the Framingham Heart Study.* Circulation, 2009. **119**(2): p. 243-50.
15. Parati, G., et al., *European Society of Hypertension practice guidelines for home blood pressure monitoring.* J Hum Hypertens, 2010. **24**(12): p. 779-85.
16. Whyte, J.L., et al., *The challenge of controlling systolic blood pressure: data from the National Health and Nutrition Examination Survey (NHANES III), 1988--1994.* J Clin Hypertens (Greenwich), 2001. **3**(4): p. 211-6.

17. Anwar, Y.A., et al., *Evaluation of the Datascope Accutorr Plus according to the recommendations of the Association for the Advancement of Medical Instrumentation.* Blood Press Monit, 1997. **2**(2): p. 105-110.

18. Kronish, I.M., et al., *Meta-analysis: impact of drug class on adherence to antihypertensives.* Circulation, 2011. **123**(15): p. 1611-21.

19. Glasgow, R.E., et al., *Development and validation of the Patient Assessment of Chronic Illness Care (PACIC).* Med Care, 2005. **43**(5): p. 436-44.

20. Kripalani, S., et al., *Development and evaluation of the Adherence to Refills and Medications Scale (ARMS) among low-literacy patients with chronic disease.* Value Health, 2009. **12**(1): p. 118-23.

21. Andresen, E.M., et al., *Retest reliability of surveillance questions on health related quality of life.* J Epidemiol Community Health, 2003. **57**(5): p. 339-43.

22. Hayes, R.J. and L.H. Moulton, *Cluster randomised trials*. 2017: Chapman and Hall/CRC.

23. Wong, M.D., et al., *The contribution of specific causes of death to sex differences in mortality.* Public Health Reports, 2006. **121**(6): p. 746-754.

24. Elashoff, R. and N. Li, *Joint modeling of longitudinal and time-to-event data*. 2016: CRC Press.

25. Schafer, J.L., *Analysis of incomplete multivariate data*. 1997: Chapman and Hall/CRC.

APPENDIX 1: PARTICIPATING VUMC RESEARCHERS IN ADDITION TO PRINCIPAL INVESTIGATOR

[redacted]

APPENDIX 2: STUDY SCHEDULE

Summary of Protocol Visits and Assessments

Study Assessment	Screening Visit #1	Screening Visit #2	Pharmacist or Physician Visits	Barber Visits	3-month Follow-up Call	6-month Follow-up Visit
Visit Time Window		+1 days – 8 weeks			+/- 2 weeks	+/- 2 weeks
Eligibility Assessment						
Inclusion/Exclusion	X					
Informed Consent		X				
Patient Medical Information						
Targeted PMH		X	X			
Recording Rx Information		X	X			X
Efficacy Assessment						
BP Measurements	X	X	X	X		X
PACIC Questions		X				X
ARMS Survey		X				X
Safety Assessments						
Adverse Events			X		X	X

APPENDIX 3: CLINICAL PHARMACIST COLLABORATIVE PRACTICE AGREEMENT

Collaborative Pharmacy Practice Agreement

"Implementing the Los Angeles Barber-Pharmacist Model of Hypertension Management in Nashville" Study

Medical Director: [redacted]

Definitions

Collaborative Pharmacy Practice Agreement ("Agreement"): A formal, voluntary and mutual agreement between the pharmacist and healthcare providers listed herein to provide collaborative patient care services, optimize medication use, and achieve desired patient outcomes to patients under the care of Prescribers, and whose patients are participants in the study titled "Implementing the Los Angeles Barber-Pharmacist Model of Hypertension Management in Nashville" for the treatment of hypertension. This Agreement defines the scope of patient care services authorized to be provided by the pharmacist, as well as the specific patient populations, prescription drugs, and diseases and conditions covered under this Agreement.

Collaborating Professionals: Pharmacist and Prescribers, as defined below.

[redacted]

[redacted]

[redacted]

[redacted]

Collaborative Pharmacy Practice Agreement

I. **Collaborative Pharmacy Practice and Pharmacist Qualifications**. Each Pharmacist named above is authorized to provide professional services within the scope of pharmacy practice as defined under Tennessee state law and within the collaborative pharmacy practice guidelines as described under this Agreement. Each Pharmacist (i) has been awarded a Doctor of Pharmacy degree from a program accredited by the Accreditation Council for Pharmacy Education, or has been awarded a Bachelor of Science in pharmacy and been in the continuous, active practice of pharmacy; and (ii) holds a current unrestricted license in good standing to practice pharmacy in the State of Tennessee.

II. **Pharmacist Scope of Services**. The Pharmacist is authorized to provide the collaborative pharmacy services ("Services") as further described in Exhibit A, attached hereto and incorporated herein, as it relates to the care of Prescribers' patients who Prescribers have identified as subject to the collaborative treatment plan in accordance with Section XII.

III. Pharmacist Responsibilities.

A. Provide all Services in accordance with this Agreement under the supervision of, or in direct consultation with the applicable Prescriber and maintain contact with and document communication with each Prescriber;

B. Provide Services only to patients for whom a current patient referral has been provided by Prescriber in accordance with Section XII;

C. Document all services in the medical record on the same day the service is provided, including but not limited to patient/family education, patient assessments and plans and all medication orders;

D. Utilize an area for in-person, telephonic or other approved consultations with patients that ensures the confidentiality of the communication;

E. When issuing a prescription order, as defined in T.C.A. § 63-10-204, or medical order, as defined in T.C.A. §63-10-204, issue the prescription order or medical order in accordance with the requirements set forth in T.A.C. § 1140-03-.03 and within the terms set forth in this Agreement;

F. Provide documentation of an initial prescription or a modification or discontinuation of a prescription to the Prescriber within 24 hours of issuance through the medical record, unless more urgent notification is required under the circumstances and note the action taken in the patient's medical record;

G. Comply with all of the policies and procedures applicable to Vanderbilt University Medical Center ("VUMC") pharmacy staff, all Tennessee Board of Pharmacy rules and regulations, all guidelines, rules and standards of practice of the Tennessee Board of Medical Examiners, the Tennessee Board of Osteopathic Examiners, and all other Tennessee Health Related Boards, and all applicable laws and regulations governing the rendering of Services hereunder; and

H. Complete at least ten (10) hours of the biennially required thirty (30) hours of continuing education in topics related to the clinical practice of pharmacy, as mutually determined by the Collaborating Professionals.

IV. Prescriber Responsibilities.

A. Retain ultimate authority and professional responsibility for his/ her patients for the management of their drug therapy including routine review of pharmacy documentation in the electronic medical record.

B. Establish and maintain a physician/provider-patient relationship with each patient receiving Services under this Agreement;

C. Be available at all times through direct telecommunication for consultation, assistance and direction to the Pharmacist, or make arrangements for a substitute physician to be available;

D. Prepare a referral for each patient in accordance with Section XII and maintain the patient referral in the patient's medical record; and

E. Authorize only those Services within the routine scope of practice and services delivered by Prescriber to be provided by Pharmacist under this Agreement.

V. Term and Termination.

A. Term. This Agreement shall become effective on _____, 201__ ("Effective Date") and shall remain in effect for two (2) years. This Agreement shall automatically extend for additional terms of one (1) year each; provided, however, that the Agreement must be reviewed and updated at least every two (2) years as evidenced by signatures of all Collaborating Professionals, the Medical Director and the Pharmacy Director.

B. Termination. This Agreement may be terminated at any time by mutual agreement of the Collaborating Professionals. Any individual Collaborating Professional may terminate his or her participation in this Agreement upon thirty (30) days written notice to the Medical Director and Pharmacy Director and all participating Collaborating Professionals. The Medical Director or the Pharmacy Director may terminate this Agreement immediately upon written notice to all other parties to the Agreement.

C. Amendments. This Agreement may be amended, including the addition of prescriber(s) and pharmacist(s), by mutual agreement of all Collaborating Professionals, the Medical Director and the Pharmacy Director.

VI. Termination of Collaborating Professional.

A Collaborating Professional may be automatically excluded from participation in this Agreement upon the occurrence of any of the following, as determined by the Collaborating Professional's supervisor in accordance with VUMC policies and procedures:

A. If Collaborating Professional's license to practice medicine or pharmacy in Tennessee, as applicable, is suspended, revoked, materially limited or not renewed.

B. If Collaborating Professional's right to prescribe is limited, suspended or revoked by VUMC or any applicable federal or state agency.

C. If Collaborating Professional fails or refuses to abide by VUMC policies and procedures or the terms of this Agreement.

D. If Collaborating Professional engages in "Willful Misconduct". The term "Willful Misconduct" shall mean only (i) arrest or indictment for, or conviction of, any crime; (ii) disruptive, unprofessional, inappropriate or unethical conduct as determined by the Medical Director or Pharmacy Director, in his or her sole discretion; (iii) fraud or theft relating to the practice of medicine or pharmacy, or (iv) a determination made in good faith by VUMC that the Collaborating Professional has failed to provide adequate patient care or that the health, safety, or welfare of patients is jeopardized.

E. If the Collaborating Professional is excluded from participation in any federal healthcare program.

F. If the Collaborating Professional consistently fails to meet the quality and performance measures set forth in Exhibit B in accordance with Section IX.

VII. **Documentation and Communication**. All Services and communications related to each patient will be documented in VUMC's electronic health record, which is accessible by all Collaborating Professionals.

VIII. **Method for Reporting Adverse Events to the Prescriber**. All significant adverse effects or toxicities identified by the Pharmacist will be documented in the patient's research record and communicated to the Prescriber in accordance with applicable VUMC policies and procedures. Significant events would include adverse events requiring therapy discontinuation planned for longer than 72 hours.

IX. **Quality Assessment**. The Medical Director and Pharmacy Director shall evaluate the quality of care provided for the patients treated pursuant to the Agreement in accordance with the objective performance goals described in Exhibit B, attached hereto and made a part hereof by this reference. The results of the quality assessments shall be aggregated and reviewed by the Collaborating Professionals at least quarterly. In addition, the Prescribers shall also provide monthly patient record review consisting of at least five percent (5%) of his or her patients treated pursuant to the Agreement. The quality assessments performed pursuant to this Section IX shall be documented and retained by VUMC, and available for review by representatives of the applicable licensing boards for at least ten (10) years. All such quality assessments, reports, material and other documentation shall be created, used, annotated and maintained by a Quality Improvement Committee (QIC) pursuant to T.C.A. §§ 63-1-150 and 68-11-272.

X. **Override Protocol**. A Prescriber shall override the actions taken by the Collaborating Pharmacist specific to services provided under the Agreement if he or she determines that the override is essential to the optimal health outcomes or safety of the patient and shall communicate such overrides to the Collaborating Pharmacist via VUMC's electronic health record and to the patient in accordance with applicable VUMC policies and procedures.

XI. **Biannual Review.** The Pharmacy, Therapeutics and Diagnostics (PT&D) Committee shall review this Agreement at least once every two years.

XII. **Patient Referrals**. Each Prescriber must complete a referral for each patient, as described in Exhibit C, which shall include, but not be limited to, a drug-specific, disease or condition-specific plan of care for the patient. The referral will be maintained in the patient's medical record. VUMC pharmacy meets the definition of an Institutional-based pharmacy setting under T.C.A. § 1140-03-.17, and as such, is not required to obtain a general consent from patient's subject to Collaborative Pharmacy Practice Agreements

XIII. **Medical Records**. Each Collaborating Professional shall maintain appropriate, accurate and complete medical records and business records in accordance with applicable law and VUMC record retention policies. The medical records of the Services provided hereunder will be maintained for a period of at least ten (10) years.

XIV. **Accessibility.** The Medical Director, Prescriber and Pharmacy Director shall maintain a copy of this Agreement, including any addendum, modification or termination at VUMC,

which shall be accessible to each Collaborating Professional and made available to the applicable regulatory board for review upon request.

XV. **Compliance with Laws.** Each party represents and warrants that he or she shall comply with all applicable state and federal statutes, rules, regulations, including all laws and ethical principles concerning confidentiality of all individually identifiable health information, including, but not limited to, medical records.

XVI. **Written Attestation.** The Medical Director and Pharmacy Director shall file a written attestation with the licensing boards for all Collaborating Professionals participating in this Agreement notifying those boards of the existence of this Agreement. The written attestation shall include the names of all signatories and Collaborating Professionals participating in this Agreement, the effective date of this Agreement and a description of the scope of the services covered by this Agreement.

[Signature Pages Follow]

Collaborative Pharmacy Practice Agreement

"Implementing the Los Angeles Barber-Pharmacist Model of Hypertension Management in Nashville" Study

Signature Page

The Pharmacy Practice Act allows pharmacists to practice under a Collaborative Pharmacy Practice Agreement with individual healthcare providers in order to provide patient care services, optimize medication use, and achieve desired patients' outcomes. By signing this document, the named Physician(s) agree that the named Pharmacist may enter into a Collaborative Pharmacy Practice Agreement to provide care for their patients.

PRESCRIBERS:

_____

_____ _____

[Insert Prescriber Name, Credentials, and Title] Date

_____ _____

[Insert Prescriber Name, Credentials, and Title] Date

_____ _____

[Insert Prescriber Name, Credentials, and Title] Date

_____ _____

[Insert Prescriber Name, Credentials, and Title] Date

PHARMACIST:

_____ _____

[Insert Pharmacist Name, Credentials, and Title] Date

[Additional Signature Page Follows]

COLLABORATIVE PHARMACY PRACTICE AGREEMENT APPROVED BY:

MEDICAL DIRECTOR:

_____ _____

[Insert Medical Director Name, Credentials, and Title] Date

PHARMACY DIRECTOR:

_____ _____

[Insert Pharmacy Director Name, Credentials, and Title] Date

DATE APPROVED BY PT&D COMMITTEE: _____

Expires 24 months from date of PT&D Committee VUMC Policy Reference: Collaborative Pharmacy Practice Agreements

Exhibit A

Pharmacist Services

A. Provide patient care and drug therapy management services to those patients who are being managed for hypertension.

B. Provide drug therapy management services with respect to the medications commonly used to treat the above listed disorders. These medications may include angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, calcium channel blockers, diuretics, beta-blockers, aldosterone blockers, central sympatholytics, alpha blockers, nitrates or other vasodilators. Order medication-related laboratory tests or obtain results from a fingerstick using a CLIA-waived point of care device. These laboratory tests may include blood chemistry/electrolyte panels or serum creatinine.

C. Obtain pertinent information about the patient's medical condition including signs and symptoms of illness, past and present medications, adverse effects, and medication adherence.

D. Continue, renew or order medications based on the below criteria:

    a. The medication is on patient's medication list, or the Prescriber's notes or other information documented in the patient's medical record indicate need for medication. Controlled substances (Schedule 2-5) are not eligible under this Collaborative Pharmacy Practice Agreement.

    b. The patient must have been evaluated by a Prescriber in the within the past 6 months and enrolled in the study titled "Implementing the Los Angeles Barber-Pharmacist Model of Hypertension Management in Nashville." For patients who are seen annually, the patient must have been seen within the past 12 months.

    c. Prior to authorizing a renewal of the medication, the Pharmacist evaluates the following: (i) Presence of medication on the patient summary and/or clinical communication, and (ii) Presence of requisite diagnostic testing or completed visit information.

    d. The Pharmacist may authorize renewals of an expired prescription previously prescribed by a Prescriber for up to 6 months.

E. Authorize a change in prescriptions from 30-day supply to 90-day supply if requested by patient or required by insurance.

F. Authorize a new prescription for dose or dosage form changes.

G. Authorize prescriptions for new medications that are documented in a patient's medical record but have not been generated as a prescription order.

H. Discontinue medications causing clinically significant drug interactions or adverse reactions and report all such occurrences in accordance with Section VIII.

I. Educate patients concerning disease states, medication benefits and potential adverse effects and toxicity, and medication adherence.

Exhibit B

Quality Performance Review: Performance Metrics and Protocols

Monthly Patient Record Review:

Each month, the Collaborating Pharmacist will have 5% of treated patients reviewed by the authorizing Physician(s) for the following quality indicators:

- Documentation of provider referral
- Correct drug/therapy
- Correct dose
- Correct duration
- Any prescription errors
- Adherence to practice agreement requirements

The reviewing Physician will communicate their findings with the pharmacist, Pharmacy Director and the Medical Director. Opportunities for improvement will be identified and implemented as appropriate. Monthly reports will be collated and included in the Quarterly Quality Assessments.

Quarterly Quality Assessment:

The Pharmacist and Medical Director meet quarterly in order to conduct a formal Quality Assessment of the Collaborative Pharmacy Practice Agreement in order to ensure that the patient care goals are being met and to identify opportunities for improvement. Such quarterly review shall include consideration of any changes necessary to the Agreement, authorized formulary, and patient orders, patient education and medication adherence strategies, increased or improved monitoring of side effects and the need for further testing and screening. In addition, data will be collected from the patient medical record for accuracy and completeness of treatment plans, and to meet the quality metrics specified below.

Quality Indicators:

- Medication history updated
- Medication reconciliation documented
- Allergy Documentation
- Patient education documented
- Summary of Adverse Drug Events reported
- Quantitative review of number of patients cared for, new drug starts, drug or dose modifications, drug discontinuations and lab tests ordered
- Any other quality assessments requested by Medical or Pharmacy Directors, Collaborating Providers, or Pharmacy, Therapeutics & Diagnostics Committee recommendations.

The Quarterly Quality Assessment will be reviewed by the pharmacist, Pharmacy Director and Medical Director. Opportunities for improvement will be identified and implemented as appropriate. These reports will be presented to the appropriate Pharmacy & Therapeutics Subcommittee and Pharmacy, Therapeutics & Diagnostics Committee and retained for at least ten (10) years.

Exhibit C

Pharmacy Collaborative Practice Referral Template

Collaborating Prescribers document a referral for each patient subject to the Collaborative Pharmacy Practice Agreement in accordance with Section VII of the Agreement, which is maintained in the patient's medical record, and the Collaborative Pharmacist provides services only to patients for whom a current patient referral has been provided by a Collaborating Prescriber. All patient referrals containing a drug-specific, disease or condition-specific plan of care shall be made part of each patient's medical record.

Collaborative Pharmacy Practice Referral – Participation in "Implementing the Los Angeles Barber-Pharmacist Model of Hypertension Management in Nashville" Study

Collaborating Prescriber: _____

Collaborating Pharmacist: [redacted]

Date of Service: TBD

I hereby refer this patient to the above-named Pharmacist(s) to carry out the plan of care stated in the electronic medical record for this patient per the criteria below.

A. Provide patient care and drug therapy management services to those patients who are being managed for hypertension.

B. Provide drug therapy management services with respect to the medications commonly used to treat the above listed disorders and order medication-related laboratory tests. These medications include angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, calcium channel blockers, diuretics, beta-blockers, aldosterone blockers, central sympatholytics, alpha blockers, nitrates or other vasodilators. Order medication-related laboratory tests or obtain results from a fingerstick using a CLIA-waived point of care device. These laboratory tests may include blood chemistry/electrolyte panels or serum creatinine.

C. Obtain pertinent information about the patient's medical condition including signs and symptoms of illness, past and present medications, adverse effects, and medication adherence.

D. Continue, renew or order medications based on the below criteria:

    a. The medication is on patient's medication list, or the Prescriber's notes in the patient's medical record indicate need for medication. Controlled substances (Schedule 2-5) are not eligible under this Collaborative Pharmacy Practice Agreement

    b. The patient must have been evaluated by the Prescriber within the past 6 months. For patients who are seen annually, the patient must have been seen within the past 12 months.

    c. Prior to authorizing a renewal of the medication, the Pharmacist evaluates the following: (i) Presence of medication on the patient summary and/or clinical communication, and (ii) Presence of requisite diagnostic testing or completed visit information.

d. The Pharmacist may authorize renewals of an expired prescription previously prescribed by a Prescriber for up to 6 months.

E. Authorize a change in prescriptions from 30-day supply to 90-day supply if requested by patient or required by insurance.

F. Authorize a new prescription for dose or dosage form changes.

G. Authorize prescriptions for new medications that are documented in a patient's medical record but have not been generated as a prescription order.

H. Discontinue medications causing drug interactions or adverse reactions and report all such occurrences in accordance with Section VIII of the Agreement.

I. Educate patients concerning disease states, medication benefits and potential adverse effects and toxicity, and medication adherence.

Electronically Signed by:

APPENDIX 4: TENNESSEE STATE PHARMACY LAW (CHAPTER 1140-03)

[1]In accordance with Tennessee State Pharmacy Law and the Rules of the Tennessee Board of Pharmacy Chapter 1140-03 Standards of Practice, a clinical pharmacist has the following responsibilities for pharmaceutical care:

(1) Patient counseling

(a) Upon the receipt of a medical or prescription order and following a review of the patient's record, a pharmacist shall personally counsel the patient or caregiver "face-to- face" if the patient or caregiver is present. If the patient or caregiver is not present, a pharmacist shall make a reasonable effort to counsel through alternative means.

(b) Alternative forms of patient information may be used to supplement, but not replace, face-to-face patient counseling.

(c) Patient counseling, as described herein, shall also be required for outpatients of hospitals or other institutional facilities dispensing medical and prescription orders and for patients when medications are dispensed on discharge from the hospital or other institutional facility.

(d) Patient counseling as described in this rule shall not be required for inpatients of an institutional or long-term care facility.

(e) Patient counseling shall cover matters, which in the exercise of the pharmacist's professional judgement, the pharmacist deems significant including:

1. The name and description of the medication;
2. The dosage form, dose, route of administration, and duration of drug therapy;
3. Special directions and precautions for preparation, administration, and use by the patient;
4. Common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
5. Techniques for self-monitoring drug therapy;
6. Proper storage;
7. Prescription refill information; and
8. Action to be taken in the event of a missed dose.

(f) Upon the receipt of a request for a refill of a medical or prescription order, a pharmacist or a person designated by the pharmacist shall offer for the pharmacist to personally counsel the patient or caregiver. Counseling as described in (e) above is not required unless requested by the patient or deemed necessary in the professional judgment of the pharmacist.

(g) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such counseling.

(2) Patient Profiling.

(a) A patient's record system shall be maintained by all pharmacy practice sites for patients for whom medical and prescription orders are dispensed. The patient's record system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously

dispensed medical and prescription orders at the time a medical or prescription order is presented.

(b) In order to effectively counsel patients, the pharmacist or a person designated by the pharmacist shall, through communication with the patient, caregiver, or agent make a reasonable effort to obtain, record, and maintain the following information for each patient of the individual pharmacy practice site.

1. Name, address, telephone number.

2. Date of birth (age), gender.

3. An individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

4. Pharmacist's comments as deemed relevant. This may be done manually or by computer.

(3) Drug Regimen Review.

(a) A pharmacist shall be responsible for a reasonable review of a patient's record prior to dispensing each medical or prescription order. The review shall include evaluating the medical and prescription order for:

1. Over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindication;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions

Footnotes:

[1]The Tennessee Board of Pharmacy Standards of Practice 2017 Recommendations. https://publications.tnsosfiles.com/rules/1140/1140-03.20170220.pdf. Last accessed March 16, 2019.

APPENDIX 5: HYPERTENSION MANAGEMENT ALGORITHM

Figure 1: Workflow

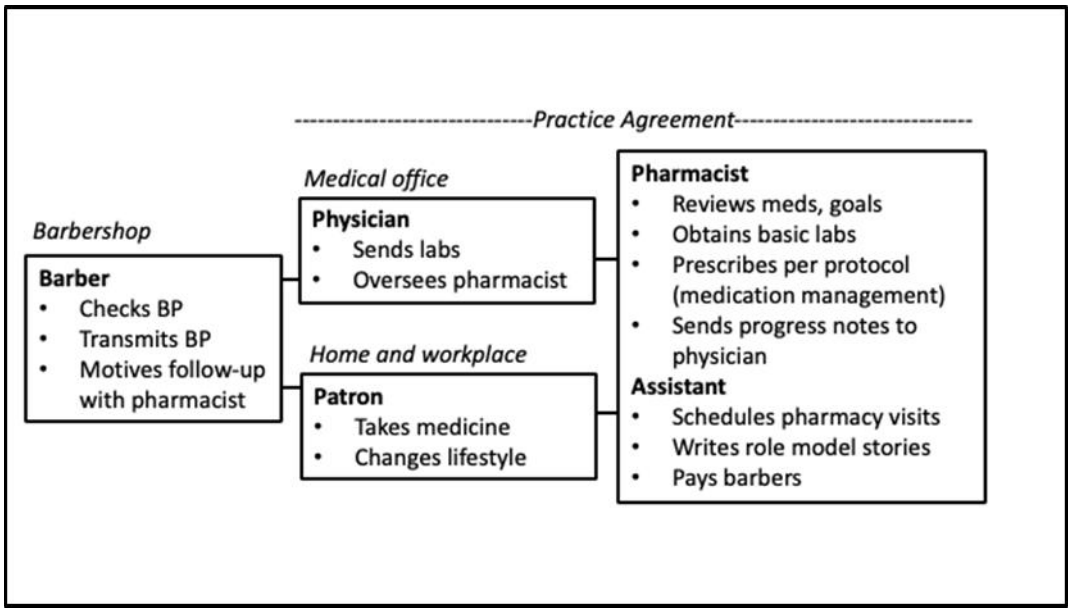


Figure 2. Hypertension standard of care treatment algorithm [references noted below]

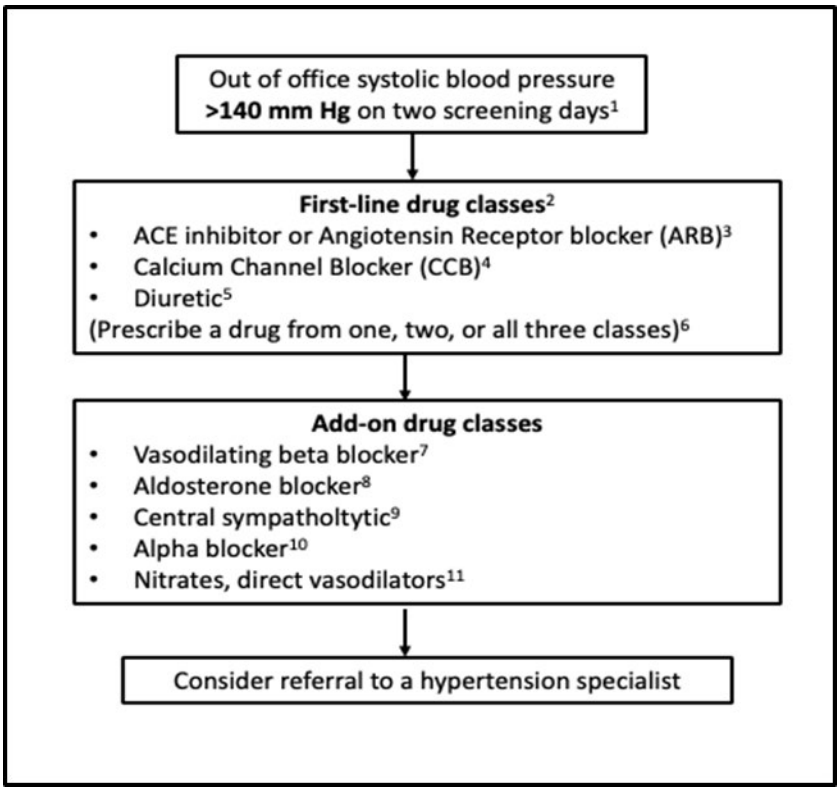
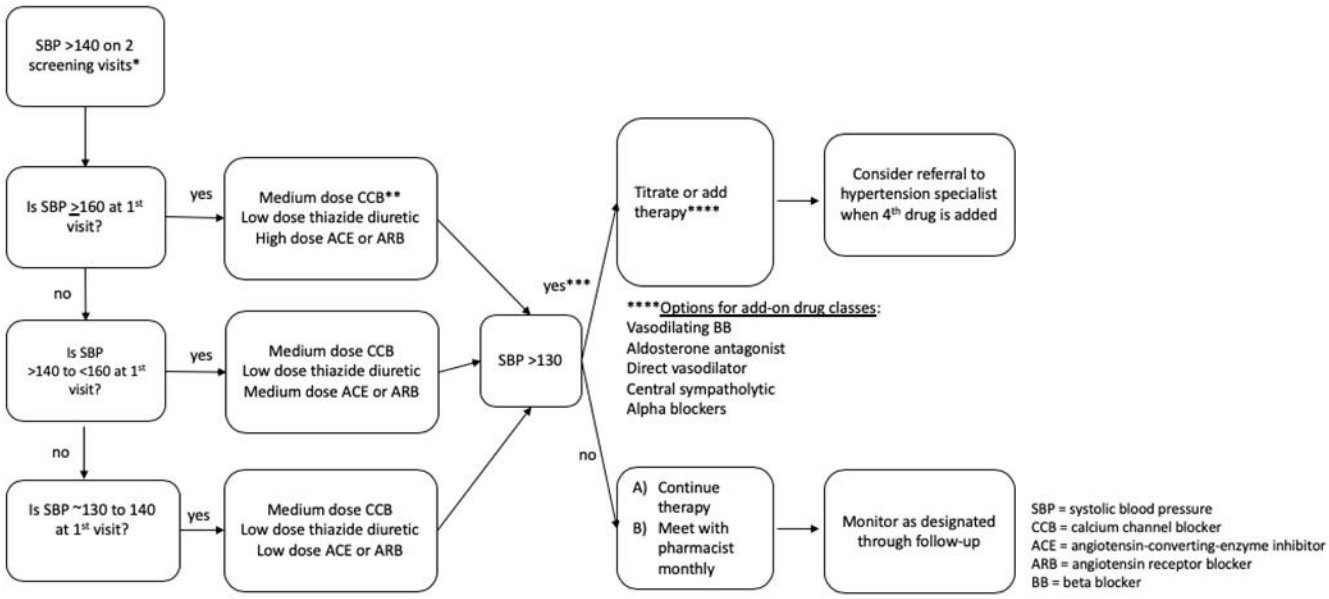


Figure 3. Sample Workflow



*Consider monotherapy if > 75 years old with SBP < 140 or if participant is antihypertensive agent-naive. A second agent should be added at the 1 week visit if participant asymptomatic and SBP ≥ 130.
** Prescribe a drug from one, two, or all three classes. Indapamide is first-line preferred diuretic
***If patient has symptoms (dizziness, headache) with SBP <130, consider nightly dosing or alternative agent and ensure adequate fluid intake
****See table on next page for sample dosing. Thiazides will be avoided as first-line in this study given participant concerns of adverse side effect profile (sexual dysfunction) as demonstrated in Los Angeles Barbershop Study

Table 1. List of preferred drugs and doses*

	Calcium channel blocker	Angiotensin-converting-enzyme inhibitor	Angiotensin receptor blocker	Thiazide diuretic	Vasodilating beta blocker	Aldosterone antagonist	Direct vasodilator	Central sympatholytic	Alpha-blocker
Low dose	2.5 mg amlodipine 30 mg nifedipine	10 mg lisinopril 10 mg benazepril	75 mg irbesartan 20 mg telmisartan	0.625 mg indapamide 12.5 mg chlorthalidone	6.25 mg carvedilol bid	12.5 mg spironolactone 25 mg eplerenone	25 mg hydralazine tid	0.5 mg guanfacine	1 mg terazosin
Medium dose	5 mg amlodipine 60 mg nifedipine	20 mg lisinopril 20 mg benazepril	150 mg irbesartan 40 mg telmisartan	1.25 mg indapamide 25 mg chlorthalidone	12.5 mg carvedilol bid	25 mg spironolactone 50 mg eplerenone	50 mg hydralazine tid	1 mg guanfacine	5 mg terazosin
High dose	10 mg amlodipine 90 mg nifedipine	40 mg lisinopril 40 mg benazepril	300 mg irbesartan 80 mg telmisartan	2.5 mg indapamide 50 mg chlorthalidone	25 mg carvedilol bid	50 mg+ spironolactone 50 mg+ eplerenone	100 mg hydralazine tid	2 mg guanfacine	10 mg terazosin

* Daily dosing unless otherwise specified. Does not encompass all possible combinations and individual treatment selection can still be up to the clinician in partnership with the patient

Table 2. Preferred Anti-hypertensive Drugs in Specific Conditions

Condition	Drug(s)
Hypertensive patients in general	CCB, ACE-I or ARB, D
Hypertension in older patients	CCB, ACE-I or ARB, D
Hypertension with left ventricular hypertrophy	ARB, D, CCB
Hypertension in patients with diabetes mellitus	CCB, ACE-I or ARB, D
Hypertension in patients with diabetic nephropathy	ARB, D
Hypertension in patients with non-diabetic chronic kidney disease	ACE-I, BB, D
Blood pressure reduction for secondary prevention of coronary events	ACE-I, CCB, BB, D
Blood pressure reduction for secondary prevention of stroke	ACE-I + D, CCB
Blood pressure management for patients with heart failure	D, BB, ACE-I, ARB, aldosterone antagonists

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; BB, beta-blocker; BP, blood pressure; CCB, calcium channel blocker; D,diuretic

Adapted from the 2013 ESH/ESC Guidelines for the Management of Arterial Hypertension. Mancia G. et al., J Hypertens. 2013; 31:1281-1356; and from Victor RG and Libby P: Systemic Hypertension: Management. Chp 44 In Braunwald's Heart Disease, 10th Edition, DL Mann, DP Zipes, P Libby, and RO Bonow Eds., Elsevier, 2014.

Footnotes:

[1] TG Pickering et al., Call to action on use and reimbursement for home blood pressure monitoring: executive summary: a joint scientific statement from the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association. *Hypertension*. 2008;521-9.

[2] In accordance with multiple published hypertension treatment guidelines:

- James PA, Oparil S, Carter BL et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8). JAMA 2013; 311(5), 507-520
- Weber MA, Schiffrin EL, White WB et al. Clinical Practice Guidelines for the Management of Hypertension in the community: a statement by the American Society of Hypertension and the International Society of Hypertension. J Clin Hypertens (Greenwich) 2014;16:14-26.

- Go AS, Bauman M, King SM et al. An Effective Approach to High Blood Pressure Control: A Science Advisory From the American Heart Association, the American College of Cardiology, and the Centers for Disease Control and Prevention. Hypertension 2013. : DA - 20131118
- Mancia G, Fagard R, Narkiewicz K et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). 2013. J.Hypertens. 31(7), 1281-1357
- Canadian Hypertension Education Program (CHEP) 2013 Recommendations. 2013. 12-26-2013.
  http://www.hypertension.ca/chep. Last accessed 2-9-2014.
- Flack JM et al., Management of High Blood Pressure in Blacks: An Update of the International Society on Hypertension in Blacks Consensus Statement. *Hypertension* 2010;56:780-800.

[3] Combined use of an ACE inhibitor and an ARB is contraindicated. ONTARGET Investigators, Cardiovascular and renal outcomes with telmisartan, ramipril, or both in people at high risk for vascular events. N Engl J Med 2008;358:1547-1559.
[4] Amlodipine is the calcium channel blocker proven to reduce cardiovascular events in most hypertension trials.
[5] Chlorthalidone is the thiazide diuretic proven to reduce cardiovascular events in most hypertension trials. Chlorthalidone or a loop diuretic is indicated in chronic kidney disease.
[6]Most hypertensive patients require combination drug therapy to achieve blood pressure treatment goals.
[7]Vasodilating beta blockers (e.g., carvedilol) are stronger blood pressure-lowering agents than standard beta blockers and do not elevate blood glucose. Unless contraindicated, beta blockers are first-line therapy for treatment of angina pectoris, after myocardial infarction, and heart failure.
[8]Aldosterone blockers can be added if on thiazide and eGFR $\geq$ 60 ml/min/1.73m^2 and serum K $\leq$ 4.5.
[9]Long-acting central sympatholytic agents (e.g., guanfacine) are preferred over short-acting clonidine to avoid rebound hypertension.
[10] Alpha blockers are indicated for men with protatism.
[11] Nitrates and vasodilators (e.g., hydralazine) are only used if other agents are not effective.

Within each class, specific drugs prescribed will vary somewhat based on individual insurance plans. Whenever possible, the pharmacist will prescribe high-dose pills which will be cut initially to cut cost and improve efficiency of dose-titration.

Preferred drugs (once daily/long acting/evidence-based/cost):
CCB- amlodipine, nifedipine
ARB- telmisartan, irbesartan
ACEI- Lisinopril, benazepril
Thiazide- indapamide, chlorthalidone
Vasodilating beta-blocker- carvedilol
Aldosterone antagonist-spironolactone, eplerenone
Direct vasodilator- hydralazine
Central sympatholytic- guanfacine
Alpha-blocker- terazosin

APPENDIX 6: STUDY FORMS, MATERIALS, AND SURVEYS

Appendix 6A: Barbershop/Owner Letter of Collaboration

MEMORANDUM OF AGREEMENT

To: David Harrison, MD, FACC, FAHA
[redacted]
Nashville, [redacted]

Re: Cut Your Pressure Too: Implementing the Barbershop Blood Pressure in Nashville

Dear Dr. Harrison,

My barbers and I understand that high blood pressure is a condition that can cause potentially deadly side effects that affects many of our customers. I understand that you and your study team will approach customers in the barbershop to determine if they are eligible and would like to participate in the "Cut Your Pressure Too" study and that many of the study procedures (including blood pressure measurements and interviews) will take place in the barbershop.

As one of the study's designated barbershop owners/managers, I certify that I have the authority to agree to allow the "Cut Your Pressure Too" study to take place in the barbershop, specifically:

Name of barbershop: _____

Address of barbershop: _____

And I agree to:

- Permit the barbershop and the barbers to participate fully in the "Cut Your Pressure Too" study for the duration of the study, which I understand is approximately 9 – 12 months.
- Provide space in the barbershop and permit study staff to interview customers and conduct the study for the duration of the study.
- Permit training for participating barbers to measure blood pressure and to participate in other study-related procedures in the barbershop.
- Permit barbers to offer blood pressure checks to each study-eligible customer who chooses to join the study 1 to 2 times per month for 6 months when they come in for haircuts.
- Permit the transmission of the blood pressure readings from the barbershop to the study's Clinical Pharmacist and other approved study personnel.
- Permit the posting of Role Model Stories (posters) in the barbershop of customers who have joined the study.
- Display the Role Model Story posters in my barbershop for the duration of the study.
- The shop owner will be compensated $1000 over the course of the study, $500 will be received upon enrollment of the first participant at the shop and the other $500 will be received at the completion of the shop's participation. This will be paid as a check.

- During the study, I agree to permit the barbers who join the study to be compensated by the study utilizing a debit card or pre-paid gift card system. The system allows the research team to directly add payments to each barber's card instead of taking weeks to process a check and mail it. Payment requests will be checked and approved within 48 – hours on business days or by the following Tuesday if initiated on a weekend. The attached IRS W-9 form is required for tax purposes in order to receive compensation from the study. All personal information is stored by VUMC and the debit card vendor in a secure fashion and will be deleted from the debit card system once the study has been completed and the funds on the card have been exhausted. This information will not be shared with any third parties and will be kept confidential.
- I understand that the "Cut Your Pressure Too" research study has been reviewed and approved by the Vanderbilt University Medical Center Institutional Review Board and that I can request a copy of that approval from you.

I understand and agree to permit barbershop customers who choose to join the study to also be compensated by the study team with haircut vouchers ($25 per haircut) and $10 per blood pressure check with up to 2 blood pressures checks per eligible customer per month (maximum of 12 measurements; 2 per month per customer). As the owner/manager of this barbershop, I certify that I have the authority and hereby agree to redeem the haircut vouchers as described above with the understanding that those vouchers will be reimbursed to the barbershop by the study team.

Sincerely yours,

Barbershop Manager/Owner _____ Date: _____

Dr. David Harrison (Principal Investigator): _____ Date: _____

Authorized:

[redacted], Director, Office of Contracts Management: _____

Date: _____

Appendix 6B: Study Surveys/forms / Appendix 6B.1: Screening Visit 1

CUT YOUR PRESSURE TOO:

The Nashville Barbershop Blood Pressure Study

Screening Visit 1 Questionnaire

- **Introduction and Verbal Consent**

  My name is _____ and I am offering free blood pressure screening to all men in the barbershop who are at least 35 years old as part of the Nashville Barbershop Blood Pressure Study being conducted by Vanderbilt University Medical Center. Are you between 35-79 years old (born anytime from 1940 to 1984) and interested in having your blood pressure checked?" [NOTE: SCRIPT ABOVE WILL NOT BE IN CAPI. WILL BE ON INTRODUCTION CARD PROVIDED TO INTERVIEWERS]

  - IF PERSON AGREES, ASSIGN CASE ID Number
  - REVIEW INFORMATION SHEET
  - SEE INFORMATION SHEET ON TWO-STEP SCREENING PROCEDURES

- **Screening Questions**

1. What is your **Date of Birth**? Month _____Day_____Year_____

   [INTERVIEWER: IF CUSTOMER DOES NOT WANT TO PROVIDE FULL DATE OF BIRTH, ASK FOR JUST MONTH AND YEAR - ENTER -8 (REFUSED) FOR DAY]

2. What is your name?
   Prefix _____
   First Name _____
   Middle Name _____
   Last Name _____
   Suffix_____
   Nickname_____

3. How long have you been a customer at this barbershop?
   IF 1 YEAR OR MORE ENTER YEARS ONLY.
   IF 0-11 MONTHS, ENTER MONTHS ONLY.
   IF REFUSED ENTER -8 IN YEARS ONLY.
   IF DON'T KNOW, ENTER -9 IN YEARS ONLY.
   _____ (YEARS) (varname: **BarbershopHowLong)**
   _____ (MONTHS) ONLY ENTER IF 0-11 MONTHS
   (varname: **BarbershopHowLongMth)**
   LESS THAN SIX MONTHS (INELIGIBLE)
   DON'T KNOW
   REFUSED

4. In the last 6 months, how many times did you come to this barbershop? Would you say… [INTERVIEWER: PROBE FOR BEST ESTIMATE, AS NEEDED] (varname: **BarbershopHowOften)**
   a. 0 to 3 times,
   b. 4 to 6 times,
   c. 7 to 10 times,
   d. 11 to 15 times, or
   e. More than 15 times?

   DON'T KNOW
   REFUSED
   [INELIGIBLE IF = (a)]

5. Is this your main barbershop? (varname: **YourBarbershop**)
   a. YES
   b. NO (INELIGIBLE)
   c. DON'T KNOW
   d. REFUSED

6. Do you have plans to change barbershops during the next 6 months? (varname: **BarbershopChange**)
   a. YES (INELIGBLE)
   b. NO
   c. DON'T KNOW
   d. REFUSED

7. Do you have plans to move away from the Nashville area during the next 6 months? (varname: NSH**move**)
   a. YES (INELIGIBLE)
   b. NO
   c. DON'T KNOW
   d. REFUSED

8. Do you consider yourself Black or African American? (varname: **RaceBlack**)
   a. YES
   b. NO (INELIGIBLE)
   c. DON'T KNOW
   d. REFUSED

9. Do you consider yourself to be of Hispanic, Latino, or Spanish origin? (varname: **Latino**)
   a. YES (INELGIBLE)
   b. NO
   c. DON'T KNOW
   d. REFUSED

- **CV Disease risk factors and comorbid conditions**

10. How tall are you? (varname: **HeightFeet, HeightInches**)
    [INTERVIEWER: ENTER -8 FOR REFUSED, ENTER -9 FOR DON'T KNOW]

    _____ Feet _____ Inches
    DON'T KNOW
    REFUSED

11. How much do you weigh? (varname: **Weight**)

    [INTERVIEWER: ENTER -8 FOR REFUSED, ENTER -9 FOR DON'T KNOW]

    _____ LBS
    DON'T KNOW
    REFUSED

Next, I am going to ask you a few questions about your health.

12. Has a doctor ever told you that you have… (check all that apply):
    a. High blood pressure (Hypertension) (varname: C_HBP)
    b. Diabetes (varname: C_Diabetes)
    c. Heart Attack (varname: C_HeartAttack)
    d. Heart Failure [INTERVIEWER: THIS MEANS ENLARGED AND WEAKENED HEART] (varname: C_HeartFailure)
    e. High Cholesterol (varname: C_HighCholesterol)
    f. Enlarged Prostate (varname: C_EnlargedProstate)
    g. Prostate Cancer (varname: C_ProstateCancer)
    h. Stroke (varname: C_Stroke)
    i. Asthma (varname: C_Asthma)
    j. Sleep Apnea (varname: C_SleepApnea)
    k. Kidney Disease (varname: C_KidneyDisease)
    l. NONE OF THE ABOVE (varname: C_None)
    m. DON'T KNOW (varname: C_DK)
    n. REFUSED (varname: C_RF)

- **Medical Exclusion criteria**

13. a). Are you a kidney dialysis patient? (varname: **Dialysis**)
    a. YES (INELIGIBLE)
    b. NO
    c. DON'T KNOW
    d. REFUSED

13. b). Have you ever received an organ transplant? (varname: **Transplant**)
    a. YES (INELIGIBLE)
    b. NO
    c. DON'T KNOW
    d. REFUSED

14. Are you currently a cancer patient receiving chemotherapy? (varname: **Chemo**)
    a. YES (INELIGIBLE)
    b. NO
    c. DON'T KNOW
    d. REFUSED

- **Current Medications**

15. Are you taking any of the following **PRESCRIPTION** medications? (check all that apply)
    a. Blood pressure pills (varname: M_BPPills)
    b. Water pills (diuretics) (varname: M_WaterPills)
    c. Insulin or pills for diabetes (varname: M_Insulin)
    d. Pills for enlarged prostate (varname: M_Prostate)
    e. NONE OF THE ABOVE (varname: M_None)
    f. DON'T KNOW (varname: M_DK)
    g. REFUSED (varname: M_RF)

- **Nocturia Questions**

16. During the **past 30 days**, how many times per night did you most typically get up to urinate, from the time you went to bed at night until the time you got up in the morning? [INTERVIEWER: SHOWCARD 1, PROBE FOR AN AVERAGE ON TYPICAL NIGHT] (varname: **Nocturnia**)

    [INTERVIEWER: SHOW CARD 1]
    a. 0 (SKIP TO BP MEASUREMENT)
    b. 1
    c. 2
    d. 3
    e. 4
    f. 5 OR MORE
    g. DON'T KNOW (SKIP TO BP MEASUREMENT)
    h. REFUSED (SKIP TO BP MEASUREMENT)

17. Now, using a scale from 0 to 10, with 0 indicating '**not at all**' and 10 being '**a great deal**, please tell me how much does it bother you? (INTERVIEWER: REPEAT QUESTION IF NEEDED: to get up to urinate, from the time you went to bed at night until the time you got up in the morning?) INTERVIEWER: SHOWCARD 2 (varname: Nocturnia2)

[INTERVIEWER: SHOW CARD 2]

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10	DK	REFUSED
Not at all										**A great**		

- **Blood Pressure Measurement**

Now, I will take your blood pressure readings. First, I need to determine your cuff size.

18. MEASURE CUFF SIZE: (varname: **CuffSize**)
    SIZE CUFF [CHECK ONE]:
    a. SMALL (SMALL ADULT)
    b. MEDIUM (ADULT)
    c. LARGE (LARGE ADULT)

NOTE: CUFF SIZE WILL BE AUTOMATICALLY POPULATED FOR FUTURE VISITS.
The machine will automatically take readings over the next few minutes.
INTERVIEWER: PLEASE HAVE PARTICIPANT SIT COMFORTABLY IN THE CHAIR

- WITH FEET FLAT ON THE FLOOR
- RIGHT ARM SUPPORTED AT HEART LEVEL
- WAIT 5 MINUTES FOR PARTICIPANT TO REST BEFORE TAKING BP READINGS
- TURN MACHINE AWAY FROM SUBJECT'S VIEW
- INSTRUCT SUBJECT NOT TO TALK DURING BP'S
- DO NOT SPEAK TO SUBJECT DURING BP
- AFTER STARTING BP READINGS, WALK AWAY FOR A FEW MINUTES, AND THEN CHECK TO SEE IF 5 READINGS HAVE BEEN COMPLETED

[INTERVIEWER: PROCEED TO CARETRENDS BLOOD PRESSURE PROCEDURE.]

THE SUBJECT ID IS _____

19. [INTERVIEWER: HOW MANY BLOOD PRESSURE READINGS WERE TAKEN?] _____

[INTERVIEWER: WAIT UNTIL BP MEASUREMENTS ARE COMPLETE, REMOVE BP CUFF, THEN CLICK NEXT TO RETRIEVE BP READINGS...]

[INTERVIEWER: WAIT UNTIL BP MEASUREMENTS ARE COMPLETE, REMOVE BP CUFF, THEN CLICK NEXT TO RETRIEVE BP READINGS...]

NOW TRYING TO RETRIEVE PRESSURE READINGS FROM THE SERVER.

	Systolic	Diastolic
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____
f.	_____	_____
g.	_____	_____
h.	_____	_____
i.	_____	_____
j.	_____	_____

[INTERVIEWER: IF BP MEASUREMENTS ARE NOT DISPLAYED CLICK THE BUTTON BELOW. IF NO MEASURMENTS ARE RETURNED, CLICK NEXT TO PROCEED TO MANUAL BP ENTRY.]

INTERVIEWER: CHECK HERE TO FORCE MANUAL BP SCREEN TO DISPLAY ____ (NOTE THIS IS NEEDED IN CASE ALL OF CARETRENDS READINGS DO NOT TRANSMIT]

IT WAS NOT POSSIBLE TO RETRIEVE THE READINGS FROM THE SERVIER. PLEASE ENTER THEN MANUALLY [INTERVIEWER: ENTER BP READINGS IN THE ORDER TAKEN. NOTE: BP READINGS ARE LISTED IN REVERSE ORDER ON THE CARE TRENDS SCREEN.]

READING DATE _____

	Systolic	Diastolic	Time
1	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____
4	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
8.	_____	_____	_____
9.	_____	_____	_____
10.	_____	_____	_____

Compute average of BP Readings Systolic_____ Diastolic _____

On the participant's blood pressure card, record the following:

- Participant name (from question 2) (CONFIRM NAME AND SPELLING)
- Today's date: _____
- Average blood pressure readings [BASED ON READINGS 3, 4, AND 5 (IF 5 OR MORE READINGS); BASED ON READINGS 3 AND 4 (IF 4 READINGS); MINIMUM OF 4 TOTAL READINGS]
- IF LESS THAN 4 READINGS, DISPLAY INSUFFICIENT READINGS AND TRY TO CONDUCT ANOTHER SESSION

If the BP is **200/120 or higher**, say the following:

Your blood pressure is dangerously high today and you need to seek medical attention without delay. Please call 911 to go to the nearest emergency room. Take this card with you to show to the emergency room doctor. If they have any questions, the doctor may call the number listed on your card.

- **Statement was read to participant: Check YES**.

If the BP is **180/110 – 199/119**, say the following:
Your blood pressure is very high today. Please see a doctor within the next 3 days. Take this card with you to your doctor. If they have any questions, the doctor may call the number listed on your card.

- **Statement was read to participant: Check YES**

- **Eligibility for 2nd Screening Visit**= YES if:

  - Age 35 to 79, **AND**
  - ≥ 6 months of patronage at this barbershop, **AND**
  - Reports 4 or more visits to the barbershop over the previous 6 months, **AND**
  - Main barbershop, **AND**
  - Does not plan to change barbershops in the next 6, **AND**
  - Does not plan to move away from Nashville area in next 6 months, **AND**
  - Self-identified Black/African American, **AND**
  - Not Hispanic, Latino or Spanish origin, **AND**
  - Not on kidney dialysis and not an organ transplant patient AND
  - Not a cancer patient receiving chemotherapy, **AND**
  - Average of systolic blood pressure readings ≥140 mmHg

If participant is **ineligible for second screening**, then say:

Based on your information, you are not eligible for the next phase of this study. However, you may be eligible for future studies. (varname: **FutureStudiesS1**)

[INTERVIEWER, PLEASE FOLLOW CONSENT PROCEDURES FOR FUTURE STUDIES]

[INTERVIEWER: DID CUSTOMER CONSENT TO BEING IN FUTURE STUDIES AND FILL OUT CONTACT INFORMATION?]

YES
NO

Thank you for taking the time today to help us learn more about high blood pressure in African American men. Here is a gift (water bottle) as a small token of our appreciation.

IF CUSTOMER ASKS TO HAVE HIS BP READINGS, YOU WILL TAKE TWO BP READINGS AND PROVIDE THE SECOND READING TO HIM ON BP CARD. DO NOT START THE CARETRENDS PROGRAM ON THE LAPTOP IF VERY HIGH BP, READ SCRIPT FOR SEEKING MEDICAL CARE.

IF PARTICIPANT MAY BE ELIGIBLE, BUT DID NOT PROVIDE INFORMATION FOR ONE OF THE ELIGIBILITY QUESTIONS, CAPI WILL ALLOW YOU TO GO BACK AND TRY TO RE-ASK MISSING QUESTIONS

If participant is **eligible for second screening**, say the following:

Based on your information, you are eligible for a 2nd screening visit. We need a second visit to determine your eligibility for enrollment in the study.

- **Appointment for Second Screening and Personal Contact Information**

  Let's make an appointment for your second screening visit. The sooner the better, even tomorrow would be great.

  [INTERVIEWER: THE LAST DAY IS **[_____]**

  a. Schedule appointment for second screening (varname: AppointDOW)
     i. Day of Week:
        1. MONDAY
        2. TUESDAY
        3. WEDNESDAY
        4. THURSDAY
        5. FRIDAY
        6. SATURDAY
        7. SUNDAY
        8. REFUSED
        9. DON'T KNOW

     ii. Date: ____/_____/_____ (varname: AppointDate)

     iii. Time: _____ (varname: AppointTime)

  b. I would like to record your contact information to send you a reminder

     Your Home Phone #: (_____) _____ - _____
     Your Cell phone #: (_____) _____ - _____
     Your Work phone #: (_____) _____ - _____

     REFUSED PHONE

     NEED AT LEAST ONE ANSWER FOR PHONE OR REFUSED ABOVE TO CONTINUE

Phone # of a close friend (_____) _____ - _____ Name _____
Phone # of a relative: (_____) _____ - _____ Name _____
Your Email: _____@_____

Your mailing address:
Address
Apt/Suite
City
State
Zip Code
REFUSED ADDRESS
NEED ADDRESS OR REFUSED FILLED IN ABOVE TO CONTINUE

c. What is the best way to contact you? (varname: BestWayToContact)
   a. HOME PHONE
   b. CELL PHONE: CALL
   c. CELL PHONE: TEXT
   d. WORK PHONE
   e. FRIEND PHONE
   f. RELATIVE PHONE
   g. EMAIL
   h. MAIL
   i. OTHER SPECIFY _____
   j. DON'T KNOW
   k. REFUSED

d. What is the best time to reach you? (varname: BestTimeToContact)
   a. MORNING
   b. AFTERNOON
   c. EVENING
   d. REFUSED
   e. DON'T KNOW

e. What are the best days to reach you? (varname: BestDaysToContact)
   a. Monday-Friday
   b. Saturday-Sunday
   c. DON'T KNOW
   d. REFUSED

f. Who is your regular barber? (varname: **BarberName)**

_____

DISPLAY PARTICIPANT NAME AND ID

GIVE BAG WITH STUDY LOGO FOR THEIR PILL BOTTLES, DOCTOR'S CARD, AND INSURANCE CARD TO BRING BACK NEXT TIME.

GIVE APPOINTMENT CARD WITH THE FOLLOWING INFORMATION:

APPOINTMENT DATE & TIME

BARBERSHOP NAME AND ADDRESS

SUPERVISOR CONTACT INFORMATION FOR RESCHEDULING

Thank you for taking the time today to help us learn more about high blood pressure in African American men. Here is a gift (water bottle) as a small token of our appreciation.

ENTER COMMENTS, CORRECTIONS, OR ANY OTHER RELEVANT INFORMATION ABOUT THE RESPONDENT: (varname: CommentScreener1)

Appendix 6B.2: Screening Visit 2; Baseline (if enrolled)

CUT YOUR PRESSURE TOO:

The Nashville Barbershop Blood Pressure Study

Health Questionnaire

(Screening Visit 2/Baseline)

Thank you for coming today. First, I need to bring up our information from your last visit and then I have a few questions. We can start now.

CHECK ID AND NAME ON DATABASE TO ENSURE THEY COMPLETED THE SCREENING VISIT ONE, WERE FOUND ELIGIBLE, AND WERE SCHEDULED FOR SCREENING VISIT 2.

INTERVIEWER: PLEASE VERIFY THAT YOU HAVE SELECTED THE CORRECT SUBJECT

SUBJECT NAME _____

SUBJECT ID _____

DATE OF BIRTH _____

BARBERSHOP _____

[REVIEW INFORMATION SHEET – parts relevant to second screening]

Part 1: Blood Pressure Measurement

[POPULATE CUFF SIZE USED IN SCREENING VISIT 1]

Now, I will take your blood pressure readings.

The machine will automatically take readings over the next few minutes.

INTERVIEWER: PLEASE HAVE PARTICIPANT SIT COMFORTABLY IN THE CHAIR

- WITH FEET FLAT ON THE FLOOR
- RIGHT ARM SUPPORTED AT HEART LEVEL
- WAIT 5 MINUTES FOR PARTICIPANT TO REST BEFORE TAKING BP READINGS
- TURN MACHINE AWAY FROM SUBJECT'S VIEW
- INSTRUCT SUBJECT NOT TO TALK DURING BP'S
- DO NOT SPEAK TO SUBJECT DURING BP
- AFTER STARTING BP READINGS, WALK AWAY FOR A FEW MINUTES, AND THEN CHECK TO SEE IF 5 READINGS HAVE BEEN COMPLETED

[INTERVIEWER: PROCEED TO CARETRENDS BLOOD PRESSURE PROCEDURE.]

THE SUBJECT ID IS _____

1. [INTERVIEWER: HOW MANY BLOOD PRESSURE READINGS WERE TAKEN?]

_____

[INTERVIEWER: WAIT UNTIL BP MEASUREMENTS ARE COMPLETE, REMOVE BP CUFF, THEN CLICK NEXT TO RETRIEVE BP READINGS...]

NOW TRYING TO RETRIEVE PRESSURE READINGS FROM THE SERVER.

	Systolic	Diastolic
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____
f.	_____	_____
g.	_____	_____
h.	_____	_____
i.	_____	_____
j.	_____	_____

[INTERVIEWER: IF BP MEASUREMENTS ARE NOT DISPLAYED CLICK THE BUTTON BELOW. IF NO MEASURMENTS ARE RETURNED, CLICK NEXT TO PROCEED TO MANUAL BP ENTRY.]

INTERVIEWER: CHECK HERE TO FORCE MANUAL BP SCREEN TO DISPLAY ____ (NOTE THIS IS NEEDED IN CASE ALL OF CARETRENDS READINGS DO NOT TRANSMIT]

IT WAS NOT POSSIBLE TO RETRIEVE THE READINGS FROM THE SERVIER. PLEASE ENTER THEN MANUALLY [INTERVIEWER: ENTER BP READINGS IN THE ORDER TAKEN. NOTE: BP READINGS ARE LISTED IN REVERSE ORDER ON THE CARE TRENDS SCREEN.]

READING DATE _____

	Systolic	Diastolic	Time
1	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
8.	_____	_____	_____
9.	_____	_____	_____
10.	_____	_____	_____

Compute average of BP Readings Systolic _____ Diastolic _____
(varname: **SysAvg, DiaAvg**)

On the participant's blood pressure card, record the following:

- Participant name (from question 2) (CONFIRM NAME AND SPELLING)
- Today's date: _____
- Average blood pressure readings [BASED ON READINGS 3, 4, AND 5 (IF 5 OR MORE READINGS); BASED ON READINGS 3 AND 4 (IF 4 READINGS); MINIMUM OF 4 TOTAL READINGS]
- IF LESS THAN 4 READINGS, DISPLAY INSUFFICIENT READINGS AND TRY TO CONDUCT ANOTHER SESSION

If the BP is **200/120 or higher**, say the following:

Your blood pressure is dangerously high today and you need to seek medical attention without delay. Please call 911 to go to the nearest emergency room. Take this card with you to show to the emergency room doctor. If they have any questions, the doctor may call the number listed on your card.

- **Statement was read to participant: Check YES**.

If the BP is **180/110 – 199/119**, say the following:

Your blood pressure is very high today. Please see a doctor within the next 3 days. Take this card with you to your doctor. If they have any questions, the doctor may call the number listed on your card.

- **Statement was read to participant: Check YES**

Ineligible Participant:

Based on your information, you are not eligible for the next phase of this study. However, you may be eligible for future studies. [INTERVIEWER: PLEASE FOLLOW CONSENT PROCEDURES FOR FUTURE STUDIES]

INTERVIEWER: DID CUSTOMER CONSENT TO BEING IN FUTURE STUDIES AND FILL OUT CONTACT INFORMATION.

A. YES
B. NO

If yes, skip to gift card and then proceed to Registry Consent Form.
If no, skip to gift card.

Eligible Participant:

IF PARTICIPANT PREVIOUSLY PROVIDED A HOME OR CELL PHONE AND ADDRESS, GO TO CONSENT FOR RESEARCH AND USE AND DISCLOSURE OF INFORMTION. ELSE, WE WILL DISPLAY SCREEN TO TRY AND OBTAIN THIS INFO AS FOLLOWS:

IF NO PHONE, DISPLAY THE FOLLOWING:

CONTACT INFORMATION

ELIGIBILITY WARNING

[INTERVIEWER: WE DO NOT HAVE A HOME OR CELL PHONE NUMBER FOR THIS CUSTOMER

We don't have a home or cell phone number on file for you. It's important we are able to contact you.

Phone _____
Phone Type
A. Home
B. Mobile/Cell

IF NO ADDRESS, DISPLAY THE FOLLOWING:
Note

[INTERVIEWER: WE DO NOT HAVE AN ADDRESS FOR THIS CUSTOMER

We don't have a mailing address on file for you.

Street Address 1 _____
Street Address 2 _____
City _____
State _____
Zip _____

Your high blood pressure readings today indicate that you meet the requirements to go on to the 6- month study. We would now like to take the opportunity to fully explain the study to you and obtain your informed consent in writing and gather some information via a health questionnaire. May we proceed?

INTERVIEWER CHECK:

2. CONSENT FOR RESEARCH AND USE AND DISCLOSURE OF INFORMATION, including use of health information (HIPAA)

   ____ CONSENT FOR RESEARCH AGREED (varname: **Consent_Research)**

3. INTERVIEWER CHECK
   ____ PARTICIPANT SIGNED INFORMED CONSENT (varname: **ConsentResult)**
   ____ PARTICIPANT REFUSED

4. REASONS FOR REFUSAL _____ (varname: **ConsentRefusedReason)**

If decline participation skip to gift card/compensation for screening visit 2.

Part 1: Health and Healthcare Questions
CV Disease and Risk

5. *Has anyone in your immediate family (for example, mother, father, sister, brother, or children) ever had high blood pressure?* (varname: **FamilyHighBP)**
   a. YES
   b. NO
   c. DON'T KNOW
   d. REFUSED

6. *Have you smoked at least 100 cigarettes or cigars in your lifetime?* (varname: **Smoke100)**
   a. YES
   b. NO (SKIP TO QUESTION 8)
   c. DON'T KNOW (SKIP TO QUESTION 8)
   d. REFUSED (SKIP TO QUESTION 8)

7. *Have you smoked at all in the last year?* (varname: **SmokeLastYear)**
   a. YES
   b. NO (SKIP TO QUESTION 7.3)
   c. DON'T KNOW (SKIP TO QUESTION 7.3)
   d. REFUSED (SKIP TO QUESTION 7.3)

   7.1. Have you smoked at all in the last 30 days? (varname: **SmokeLast30Days)**
   a. YES
   b. NO (SKIP TO QUESTION 7.3)
   c. DON'T KNOW (SKIP TO QUESTION 7.3)
   d. REFUSED (SKIP TO QUESTION 7.3)

   7.2. During the past 30 days, on average, about how many cigarettes did you smoke in a day? (varname: **SmokeNumPerDay30)**

   _____ (SKIP TO QUESTION 8)

   DON'T KNOW (SKIP TO QUESTION 8)
   REFUSED (SKIP TO QUESTION 8)

   7.3. On average, over the entire time you have smoked, how many cigarettes have you usually smoked per day? (varname: **SmokeNumPerDayLifetime)**

   _____

   DON'T KNOW
   REFUSED

7.4. How old were you when you quit smoking? (varname: **SmokeQuitAge)**

_____

DON'T KNOW
REFUSED

Perceived Health

8. *Overall, how would you rate your health? Would you say…* (varname: **OverallHealth)**
   a. Excellent
   b. Very Good
   c. Good
   d. Fair
   e. Poor
   f. Very Poor
   g. DON'T KNOW
   h. REFUSED

BP Medication Adherence (Adherence to Refills and Medications (ARMS) Scale

9. *Have you ever had blood pressure medication prescribed or refilled?* (varname: **BPMedsEver)**
   a. YES
   b. NO (SKIP TO QUESTION 22)
   c. DON'T KNOW (SKIP TO QUESTION 22)
   d. REFUSED (SKIP TO QUESTION 22)

BP Medication Adherence (Adherence to Refills and Medications (ARMS) Scale)
(Kripalani, Risser, Gatti, & Jacobson, 2009)

It is common for people to miss taking their medicine from time to time, or to take it differently than prescribed. I would like to ask you about how you actually take your blood pressure medicines. There are no right or wrong answers. For each question, please answer "none of the time," "some of the time," "most of the time," or "all of the time."

10. How often do you forget to take your medicine? (varname: **forgetmed**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

11. How often do you decide not to take your medicine? (varname: **decidenottakemed**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

12. How often do you forget to get prescriptions filled? (varname: **prescrip_fill**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

13. How often do you run out of medicine? (varname: **medrunout**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

14. How often do you skip a dose of your medicine before you go to the doctor? (varname_**doseskip**)

    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

15. How often do you miss taking your medicine when you feel better? (varname: **medfeelbetter**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

16. How often do you miss taking your medicine when you feel sick? (varname: **medfeelsick**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

17. How often do you miss taking your medicine when you are careless? (varname: **medcareless**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

18. How often do you change the dose of your medicines to suit your needs (like when you take more or less pills than you're supposed to)? (varname: **medchange**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

19. How often do you forget to take your medicine when you are supposed to take it more than once a day? (varname: **forget_med_multiple**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

20. How often do you put off refilling your medicines because they cost too much money? (varname: **medrefillmoney**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

21. How often do you plan ahead and refill your medicines before they run out? (varname: **medrefillplan**) [PROGRAMMING: THESE ANSWERS ARE NUMBERED IN REVERSE ON PURPOSE]
    (4) None
    (3) Some
    (2) Most
    (1) All
    DON'T KNOW
    REFUSED

Patient Assessment of Chronic Illness Care (PACIC). (Glasgow RE et al. Med Care 2005; 43(5): 436-44)

22. Have you received medical care for high blood pressure in the last 6 months? (varname: **BPCare6Mos)**
    a. YES
    b. NO (SKIP TO QUESTION 43)
    c. DON'T KNOW (SKIP TO QUESTION 43)
    d. REFUSED (SKIP TO QUESTION 43)

INTRO A: Staying healthy can be difficult when you have a chronic condition. We would like to learn about the type of help with your condition you get from your health care team. This might include your regular doctor, his or her nurse, or a physician's assistant who treats your illness. Your answers will be kept confidential and will not be shared with your physician or clinic.

INTERVIEWER: USE SHOWCARD 3

Think about the following statement:

*Over the **past 6 months, when** I received care for my chronic conditions, I was:*

23. *Asked for my ideas when we made a treatment plan.* (varname: **CDIdeas)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

24. *Given choices about treatment to think about.* (varname: **CDChoices)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

25. *Asked to talk about any problems with my medicines or their effects.* (varname: **CDProblems)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

26. *Given a written list of things I should do to improve my health*. (varname: **CDImprove)**
    a. None of the time
    b. little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

27. *Satisfied that my care was well-organized.* (varname: **CDOrganized)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

28. *Shown how what I did to take care of myself influenced my condition.* (varname: **CDInfluenced)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

29. *Asked to talk about my goals in caring for my condition.* (varname: **CDGoals)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

30. *Helped to set specific goals to improve my eating or exercise.* (varname: **CDEating)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

31. *Given a copy of my treatment plan.* (varname: **CDWritten)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED
32. *Encouraged to go to a specific group or class to help me cope with my chronic condition.* (varname: **CDCope)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

33. *Asked questions, either directly or on a survey, about my health habits.* (varname: **CDQuestions)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

34. *Sure, that my doctor or, nurse thought about my values, beliefs, and traditions when they recommended treatments to me?* (varname: **CDValues)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

35. *Helped to make a treatment plan that I could carry out in my daily life.* (varname: **CDDaily)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

36. *Helped to plan ahead so I could take care of my condition even in hard times.* (varname: **CDHardTimes)**

a. None of the time
b. A little of the time
c. Some of the time
d. Most of the time
e. Always
f. DON'T KNOW
g. REFUSED

37. *Asked how my chronic condition affects my life.* (varname: **CDAffects)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

38. *Contacted after a visit to see how things were going.* (varname: **CDContacted)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

39. *Encouraged to attend programs in the community that could help me.* (varname: **CDPrograms)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

40. *Referred to a dietitian, health educator, or counselor.* (varname: **CDReferred)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

41. *Told how my visits with other types of doctors, like an eye doctor or other specialist helped my treatment.* (varname: **CDDoctors)**
    a. None of the time

b. A little of the time
c. Some of the time
d. Most of the time
e. Always
f. DON'T KNOW
g. REFUSED

42. *Asked how my visits with other doctors were going.* (varname: **CDVisits)**

a. None of the time
b. A little of the time
c. Some of the time
d. Most of the time
e. Always
f. DON'T KNOW
g. REFUSED

Demographics: Asked only on Screening Day 2

43. *Are you currently married, or living with someone as if you were married (i.e. domestic partner)?* (varname: **Married)**

a. YES
b. NO
c. DON'T KNOW
d. REFUSED

44. What is the highest degree or level of education you have completed? **(varname: HighestEd)**

a. LESS THAN HIGH SCHOOL
b. HIGH SCHOOL GRADUATE (INCLUDES EQUIVALENCY/GED)
c. SOME COLLEGE OR ASSOCIATE'S DEGREE
d. BACHELOR'S DEGREE
e. GRADUATE OR PROFESSIONAL DEGREE.

45. *Which of the income group best represents your annual household income?* (INTERVIEWER: SHOW CARD 4) (varname: **AnnualHHIncome)**

a. $0-$15,999
b. $16,000-$24,999
c. $25,000-$39,999
d. $40,000-$49,999
e. $50,000-$74,999
f. $75,000-$99,999
g. $100,00 or more
h. DON'T KNOW
i. REFUSED

46/47. *How many people, including yourself, do you support with this income? [NOTE IF DK/REF ABOVE, CHANGE QUESTION AS FOLLOWS: How many people, including yourself are supported with your annual household income?] This could include your*

spouse, your significant other, children, parents, or other household members. (varname: **NumHHMembers)**

[INTERVIEWER: ENTER -8 FOR REFUSED, ENTER -9 FOR DON'T KNOW]

_____ *people*	*(UNLESS 45 = DK/REF, SKIP TO 48)*
DON'T KNOW	*(SKIP TO 48)*
REFUSED	*(SKIP TO 48)*

48. *[ONLY DISPLAY IN CAPI IF QUESTION 45 = DON'T KNOW OR REFUSED] Is your total household income above or below (pick household size)?* (varname: **HHSizeToIncome)**

Family of 1 - $13,000
Family of 2 - $15,500
Family of 3 - $19,500
Family of 4 - $23,500
Family of 5 - $27,500
Family of 6 - $32,000
Family of 7 - $36,000
Family of 8 - $40,000
DON'T KNOW
REFUSED

a. Above
b. Below

Access to Healthcare: Asked only at Screening Day 2

Now I will need the information you brought with you. First let me ask you,

49. *Is there one medical clinic or office building that you go to for routine medical care?* (varname: **ClinicRoutine)**

a. YES
b. NO (SKIP TO QUESTION 51)
c. DON'T KNOW (SKIP TO QUESTION 51)
d. REFUSED (SKIP TO QUESTION 51)

50. *I will need to record information about the medical clinic or office building:*

a. Name of clinic or office: _____
b. Street Address: _____
c. City: _____
d. Phone #: (_____) _____ - _____
e. Fax #: (_____) _____ - _____
f. Email: _____

51. *Is there one particular doctor whom you see for routine medical care?* (varname: **DoctorRoutine)**

a. YES
b. NO (SKIP TO QUESTION 53 IF QUESTION 49= YES; ELSE SKIP TO QUESTION 54)
c. DON'T KNOW (SKIP TO QUESTION 53 IF QUESTION 49= YES; ELSE SKIP TO QUESTION 54)
d. REFUSED (SKIP TO QUESTION 53 IF QUESTION 49= YES; ELSE SKIP TO QUESTION 54)

52. *Doctor's Contact Information*
    a. Doctor's name: _____
    b. Doctor's phone #: (_____) _____ - _____
    c. Fax #: (_____) _____ - _____
    d. Email: _____

53. *In the last 3 months, how many times, if ever, have you visited this doctor or clinic for medical care?* _____ (varname: **VisitDr3Mos)**
    DON'T KNOW
    REFUSED

54. *Did you bring your medical insurance card with you today?* (varname: **InsuranceCard)**
    a. YES
    b. NO (SKIP TO QUESTION 56)
    c. DON'T KNOW (SKIP TO QUESTION 56)
    d. REFUSED (SKIP TO QUESTION 56)

55. *Now I will record your medical insurance information from your medical insurance card.*
    [Examples: Anthem Blue Cross Blue Shield HMO, Medicare Part A/B]
    a. Insurance carrier: _____ (varname: **InsuranceCarrier)**
    b. Plan Type (HMO, PPO, EPO, POS): _____ (varname: **InsurancePlanType)**

56. Have you needed to go to the Emergency Room or been hospitalized in the past 3 months? (varname: **ER3Mos)**
    a. YES
    b. NO (SKIP TO QUESTION 60)
    c. DON'T KNOW (SKIP TO QUESTION 60)
    d. REFUSED (SKIP TO QUESTION 60)

57. For what reason? _____ (varname: **ERReason)**

58. What date were you in the hospital or emergency room? Month __ Day ___ Year (varname: **ERDate)**

59. What hospital or emergency room did you visit? _____ (varname: **ERName)**

60.Have you experienced any of the following in the past 3 months? (CHECK ALL THAT APPLY) [INTERVIEWER: USE SHOWCARD 6]
□ A) swollen ankles (varname: AR_SwollenAnkles, RS_SwollenAnkles)
□ B) swollen gums (varname: AR_SwollenGums, RS_SwollenGums)
□ C) swelling of the lips, throat, and/or tongue (varname: AR_SwelingLips, RS_SwelingLips)
□ D) hair loss (varname: AR_HairLoss, RS_HairLoss)
□ E) erectile dysfunction (varname: AR_ErectileDisfunction, RS_ErectileDisfunction)
□ F) gout (varname: AR_Gout, RS_Gout)
□ G) difficulty breathing or wheezing (varname: AR_DifficultyBreathing, RS_DifficultyBreathing)
□ H) dry cough (varname: AR_DryCough, RS_DryCough)
□ I) depression (varname: AR_Depression, RS_Depression)
□ J) headache (varname: AR_Headache, RS_Headache)
□ K) palpitations (feeling that your heart is pounding or racing) (varname: AR_Palpitations, RS_Palpitations)
□ L) breast tenderness or enlargement (varname: AR_BreastTenderness, RS_BreastTenderness)
□ M) excessive sleepiness during the day (varname: AR_ExcessiveSleepiness, RS_ExcessiveSleepiness)
□ N) dizziness (varname: AR_Dizziness, RS_Dizziness)
□ O) skin rash (varname: AR_SkinRash, RS_SkinRash)
□ NONE OF THE ABOVE (SKIP TO QUESTION 75) (varname: AR_None)
□ DON'T KNOW (SKIP TO QUESTION 75) (varname: AR_DK)
□ REFUSED (SKIP TO QUESTION 75) (varname: AR_RF)

60-74:
[NOTE: ONE QUESTION FOR EACH ITEM IDENTIFIED IN 60] How severe was the reaction? Was it… [FOR EACH ITEM FOR 60, THIS QUESTION SHOULD INCLUDE BOTH THE ITEM AND THE LETTER, SO THAT WE CAN REFER TO SHOWCARD IF NEEDED]
□ Mild (I did not need to see my doctor)
□ Moderate (I needed to see my doctor)
□ Severe (I was hospitalized)
□ Life-threatening (I was hospitalized in the intensive care unit (ICU))
□ DON'T KNOW
□ REFUSED

AFTER ALL ITEMS ARE ASKED GO TO QUESTION 75

Current Medications

75. *Are you taking any prescription medication for any medical condition?* (varname: **AnyMeds)**
a. Yes
b. No (SKIP TO QUESTION 97)
c. DON'T KNOW (SKIP TO QUESTION 97)
d. REFUSED (SKIP TO QUESTION 97)

76. *Did you bring the medication with you today?* (varname: **BringMeds)**
a. YES (SKIP TO QUESTION 80)
b. NO

[If No, ask: When is the earliest you can bring in your medication? The sooner the better, even tomorrow would be great.
[INTERVIEW: THE LAST DAY IS ___]

- Schedule follow up date:

77. Day of Week:
    a. MONDAY
    b. TUESDAY
    c. WEDNESDAY
    d. THURSDAY
    e. FRIDAY
    f. SATURDAY
    g. SUNDAY

78. Date: ____/_____/_____

79. Time: _____

INTERVIEWER TO BREAK OFF HERE AND RE-START AFTER PARTICIPANT BRINGS MEDS.

80-95. *Now I will record the name, dose, how often you are to take the medication(s) you brought in today and prescriber information.*

ALLOW FOR DROPDOWN LIST FOR BP MEDICATIONS. OTHER NON-BP MEDICATIONS JUST ALLOW FOR ENTERING NAME OF MEDICINE (OTHER NON-BP MEDS IS FIRST OPTION ON LIST).

FOR EACH BP MED: [CAN PUT IN UP TO 15 MEDS—QUESTIONS 80-95]

(varname: **DrugMed01 – DrugMed15)**
(varname: **NonBPMed01– NonBPMed15)**

DOSE _____ (varname: **DoseMed01 – DoseMed15)**

DOSE PER DAY (response options = ½, 1, 2, 3, weekly, every night
(varname: **DosePerDayMed01– DosePerDayMed15)**

PRESCRIBER FIRST NAME _____
(varname: **PrescriberFirstMed01– PrescriberFirstMed15)**

PRESCRIBER LAST NAME _____
(varname: **PrescriberLastMed01– PrescriberLastMed15)**

96. *MEDICATION COMMENTS (*varname: **MedComment***)*
_____

TEMPORARY ID CARD – FILL OUT TEMPORARY ID CARD
ONLY INTERVEIWER: LET CUSTOMER KNOW HE SHOULD RECEIVE HIS PERMANENT STUDY ID CARD BY MAIL IN ABOUT 2 WEEKS.

DISPLAY PARTICIPANT NAME AND ID

Incentives--Gift Cards

Thank you for taking the time to participate in the second screening. You will be receiving $25 for completion of this study visit either by pre-paid gift card, a reloadable gift card or check.

[INTERVIEWER: AFTER ENTERING GIFT CARD NUMBER, VERIFY THAT THE NUMBERS WERE ENTERED CORRECTLY]

ENTER GIFT CARD NUMBER(S)

GIFT CARD FOR SCREEDING VISIT COMPLETION # _____ (varname: **VoucherNumVisitComplete)**

GIFT CARD FOR ENROLLED PATIENT Baseline Encounter completed # _____ (varname: **VoucherNumMedDrInfo)**

Screening Visit 2/Baseline

EXPLAIN NEXT STEPS—

MENTION ABOUT STUDY PHARMACIST AND BARBER VISITS. REFER TO STUDY INCENTIVES. BARBER WILL TAKE THEIR BLOOD PRESSURE DURING REGULAR HAIRCUT VISITS 1-2 TIMES PER MONTH. IF PARTICIPANT HAS BP TAKEN AT LEAST ONCE PER MONTH, HE WILL RECEIVE ONE HAIRCUT VOUCHER EACH MONTH OVER THE NEXT 6 MONTHS. FOR EACH IN PERSON VISIT WITH PHARMACIST, HE WILL GET A $25 GIFT CARD or payment to a reloadable debit card.

MENTION THAT THE PHARMACIST WILL CALL THE PARTICIPANT WITHIN 24 HOURS TO SCHEDULE AN APPOINTMENT

MENTION THAT THE NEXT STUDY CONTACT WILL BE A CALL IN 3 MONTHS TO CONDUCT A BRIEF PHONE INTERVIEW. HE WILL GET A $15 GIFT CARD FOR COMPLETING THE PHONE INTERVIEW. ALSO, THERE WILL BE AN IN PERSON INTERVIEW AT THE BARBERSHOP AFTER 6 MONTHS. FOR COMPLETING THE 6 MONTH VISIT, PARTICIPANT GETS A $100 GIFT CARD.

Thank you for your time.

[INTERVIEWER: ENTER COMMENTS, CORRECTIONS, OR ANY OTHER RELEVANT INFORMATION ABOUT THE RESPONDENT]

IMPORTANT--AFTER EXITING INTERVIEW VERIFY CONTACT INFORMATION IN SMS AND TRY TO OBTAIN ANY MISSING INFORMATION (FOR EXAMPLE, ADDRESS, PHONE NUMBERS)

Appendix 6B.3: 3-Month Telephone Survey

Three-Month Telephone Interview

PHONE NUMBERS [DISPLAY NUMBERS IN SMS]
CONTACT HISTORY [DISPLAY CONTACT HISTORY OF 3 MONTH CALL]
Subject Name: [DISPLAY PARTICIPANT NAME]
Best Way to Contact: [DISPLAY BEST WAY TO CONTACT]
Best Time to Contact: [DISPLAY BEST TIME TO CONTACT]
Best Days to Contact: [DISPLAY BEST DAYS TO CONTACT]

May I speak with <NAME OF PARTICIPANT>?
RESULTS:
Data Collector:

Codes	Interim Labels
1	RNA
2	Refusal
5	AM [GO TO SCRIPT]
7	Questionable ring
8	Problem
11	Number resolved
31	Busy
32	Dead Air
41	General Call Back/ General Appt.
42	Exact Appt.
61	Language/Hearing-Speech
ND	Deceased
NP	Not available

Answering Machine:
Hello, my name is [NAME OF INTERVIEWER] from Vanderbilt University Medical Center. I'm calling {FIRST NAME} {LAST NAME} regarding a 5-minute telephone interview for the Barbershop Study. Upon completion of the interview, you will receive $15. Please call us at [PHONE NUMBER]. Thank you.
COMMENT ABOUT AM MESSAGE

_____

1. Just to confirm, am I speaking with [NAME]?

☐YES ..... 1 (GO TO RESULT)
☐NO ..... 2 (GO TO RESULT)

Hi, my name is [NAME OF INTERVIEWER].
I am a telephone interviewer with the Nashville Barbershop Blood Pressure Study in which you are participating at [NAME OF BARBERSHOP]
This is a quick five-minute call to ask a few health questions.
By completing this short survey, you will receive $15.

2. In the last 3 months, have you seen a doctor about your blood pressure? (varname: **SeenDr**)
   a. Yes
   b. No {GO TO QUESTION 4}
   c. DON'T KNOW {GO TO QUESTION 4}
   d. REFUSED {GO TO QUESTION 4}

3. In the last 3 months, how many times did you see a doctor about your blood pressure?
   _____ (varname: **SeenDrTimes**)
   DON'T KNOW
   REFUSED

4. [IF DOCTOR AVAILABLE FROM PREVIOUS SURVEY] In the last 3 months, have you changed the doctor who is responsible for managing your blood pressure? The Doctor's name we have on file is [NAME OF DOCTOR FROM PREVIOUS INTERVIEW]:

   [IF NO DOCTOR AVAILABLE FROM PREVIOUS SURVEY] Do you have a doctor who is responsible for managing your blood pressure? (varname: **VerifyDr**)

   a. Yes
   b. No {GO TO QUESTION 6}
   c. DON'T KNOW {GO TO QUESTION 6}
   d. REFUSED {GO TO QUESTION 6}

5. What is this doctor's name? (SubjectProtected)
   Doctor's Name _____
   Phone _____
   Fax # _____
   E-mail _____

6. [IF INSURANCE INFO AVAILABLE FROM PREVIOUS SURVEY] In the last 3 months, have you changed your medical insurance plan? The insurance information I have on file is: [NAME OF INSURANCE PLAN FROM PREVIOUS INTERVIEW] (varname: **InsuranceCard**)
   a. Yes
   b. No
   c. DON'T KNOW
   d. REFUSED

   [IF NO INSURANCE INFO AVAILABLE FROM PREVIOUS SURVEY] Do you have medical insurance?

7. What is the insurance carrier?
   Insurance Carrier: _____ (varname: **InsuranceCarrier**)
   Plan Type: (HMO, PPO, EPO, POS) _____ (varname: **InsurancePlanType**)

8. Now I would like to confirm contact information we have for you.
   [IF ADDRESS IN SMS] Do you have a new mailing address? The address(es) we have on file is [(ADDRESSES) IN SMS]

[IF NO ADDRESS IN SMS] Can I get a mailing address we could use to contact you if necessary? (varname: **VerifyAddress**)

a. Yes
b. No [GO TO QUESTION 9a]

9. What is your mailing address? (SubjectProtected)

Address_____
Apt/Suite _____
City _____
State _____
Zip _____

9a. [INTERVIEWER: FOR EACH PHONE LISTED BELOW:

READ THE STATEMENT WITH PHONE NUMBER
IF PHONE NUMBER NO LONGER CURRENT, SELECT EDIT, SET PHONE STATUS TO INACTIVE, AND SELECT UPDATE.]

[HOME/WORK/CELL] Can you still be reached at _____?

[FRIEND/RELATIVE] I have _____ as a friend/relative's number who will know how to contact you. Is this still current?

[INTERVIEWER: AFTER VERIFYING EACH PHONE ASK:]
Other than the phone numbers I just asked about, are there any other phone numbers you can be reached at?

[INTERVIEWER: IF YES: CLICK NEW PHONE, ENTER INFORMATION, AND CLICK ADD.] (SubjectProtected)

10. [IF E-MAIL ADDRESS IN SMS] Do you have a new e-mail address? The e-mail address I have on file is: [E-MAIL ADDRESS IN SMS]?

[IF NO E-MAIL ADDRESS in SMS] Do you have an e-mail address we could use to contact you? (varname: **VerifyEmail**)

a. Yes
b. No {GO TO QUESTION 12}
c. REFUSED

11. What is your e-mail address? _____ (SubjectProtected)

12. Now I have a few questions about your health.
In the past 3 months, have you needed to go to the Emergency Room or been hospitalized? (varname: **ER3Mos**)
a. Yes
b. No {GO TO QUESTION 16}
c. DON'T KNOW {GO TO QUESTION 16}
d. REFUSED {GO TO QUESTION 16}

13. For what reason? _____ (varname: **ERReason**)

14. What date were you in the hospital or emergency room? Month __ Day ___ Year (varname: **ERDate**)

15. What hospital or emergency room did you visit? _____(varname: **ERName**)

16. In the past 3 months, have you experienced any of the following? (CHECK ALL THAT APPLY)
□ swollen ankles (varname: (a) AR**_SwollenAnkles, RS_AR_SwollenAnkles**)
□ swollen gums (varname: (b) **AR_SwollenGums, RS_SwollenGums**)
□ swelling of the lips, throat, and/or tongue (varname: (c) **AR_SwelingLips, RS_SwelingLips**)
□ hair loss (varname: (d) **AR_HairLoss, RS_HairLoss**)
□ erectile dysfunction (varname: (e) **AR_ErectileDisfunction, RS_ErectileDisfunction**)
□ gout (varname: (f) **AR_Gout, RS_Gout**)
□ difficulty breathing or wheezing (varname: (g) AR**_DifficultyBreathing, RS_DifficultyBreathing**)
□ dry cough (varname: (h) **AR_DryCough, RS_DryCough**)
□ depression (varname: (i) **AR_Depression, RS_Depression**)
□ headache (varname: (j) **AR_Headache, RS_Headache**)
□ palpitations (feeling that your heart is pounding or racing) (varname: (k) **AR_Palpitations, RS_Palpitations**)
□ breast tenderness or enlargement (varname: (l) **AR_BreastTenderness, RS_BreastTenderness**)
□ excessive sleepiness during the day (varname: (m) **AR_ExcessiveSleepiness, RS_ExcessiveSleepiness**)
□ dizziness (varname: (n) **AR_Dizziness, RS_Dizziness**)
□ skin rash (varname: (o) **AR_SkinRash, RS_SkinRash**)
□ NONE OF THE ABOVE (varname: (p) **AR_None**)
□ DON'T KNOW (varname: (q) **AR_DK**)
□ REFUSED (varname: (r) **AR_RF**)

16-30. IF YES FOR ANY ITEM IN 16, ASK ABOUT IT:
Think about your…
[NAME OF CONDITION MENTIONED IN 16] How severe was the reaction? Was it?
□ Mild (I did not need to see my doctor about the reaction)
□ Moderate (I needed to see my doctor about the reaction)
□ Severe (I was hospitalized)
□ Life-threatening (I was hospitalized in the intensive care unit (ICU))
□ DON'T KNOW
□ REFUSED

32. Do you have any additional comments? (varname: **M3_EndComment**)

Thank you for your time. I will be calling you again in 3 months to schedule your six-month in-person visit with me or one of my fellow research coordinators.

Appendix 6B.4: 6-Month Visit Survey

CUT YOUR PRESSURE TOO:
The Nashville Barbershop Blood Pressure Study
Health Questionnaire
(6-Month Follow-up)

Thank you for coming today. First, I need to bring up our information from your last visit and then I have a few questions. We can start now.

CHECK ID AND NAME ON DATABASE TO ENSURE YOU HAVE PULLED UP THE CORRECT PERSON

INTERVIEWER: PLEASE VERIFY THAT YOU HAVE SELECTED THE CORRECT SUBJECT

SUBJECT NAME _____

SUBJECT ID _____

DATE OF BIRTH _____

BARBERSHOP _____

[INSTRUCT PARTICIPANT TO USE THE RESTROOM BEFORE YOU GET STARTED]

Blood Pressure Measurement

Now, I will take your blood pressure readings.

[POPULATE CUFF SIZE USED IN SCREENING VISIT 1]

The machine will automatically take readings over the next few minutes.

- [INTERVIEWER: PLEASE HAVE PARTICIPANT SIT COMFORTABLY IN THE CHAIR
- WITH FEET FLAT ON THE FLOOR,
- RIGHT ARM SUPPORTED AT HEART LEVEL,
- **WAIT 5 MINUTES FOR PARTICIPANT TO REST BEFORE TAKING BP READINGS,**
- TURN MACHINE AWAY FROM SUBJECT'S VIEW,
- INSTRUCT SUBJECT NOT TO TALK DURING BP'S, AND
- DO NOT SPEAK TO SUBJECT DURING BP.
- **AFTER STARTING BP READINGS, WALK AWAY FOR A FEW MINUTES, AND THEN CHECK TO SEE IF 5 READINGS HAVE BEEN COMPLETED.]**

[INTERVIEWER: PROCEED TO CARETRENDS BLOOD PRESSURE PROCEDURE.]
THE SUBJECT ID IS _____

1. INTERVIEWER: HOW MANY BLOOD PRESSURE READINGS WERE TAKEN?]
_____

[INTERVIEWER: WAIT UNTIL BP MEASUREMENTS ARE COMPLETE, REMOVE BP CUFF, THEN CLICK NEXT TO RETRIEVE BP READINGS...]

NOW TRYING TO RETRIEVE PRESSURE READINGS FROM THE SERVER.

	Systolic	Diastolic
a.	_____	_____
b.	_____	_____
c.	_____	_____
d.	_____	_____
e.	_____	_____
f.	_____	_____
g.	_____	_____
h.	_____	_____
i.	_____	_____
j.	_____	_____

[INTERVIEWER: IF BP MEASUREMENTS ARE NOT DISPLAYED CLICK THE BUTTON BELOW. IF NO MEASURMENTS ARE RETURNED, CLICK NEXT TO PROCEED TO MANUAL BP ENTRY.]
INTERVIEWER: CHECK HERE TO FORCE MANUAL BP SCREEN TO DISPLAY ____
(NOTE THIS IS NEEDED IN CASE ALL OF CARETRENDS READINGS DO NOT TRANSMIT]

IT WAS NOT POSSIBLE TO RETRIEVE THE READINGS FROM THE SERVIER. PLEASE ENTER MANUALLY.

[INTERVIEWER: ENTER BP READINGS IN THE ORDER TAKEN. NOTE: BP READINGS ARE LISTED IN REVERSE ORDER ON THE CARE TRENDS SCREEN.]

REASONS FOR MANUAL BP ENTRY
_____

READING DATE
_____

	Systolic	Diastolic	Time
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
8.	_____	_____	_____
9.	_____	_____	_____
10.	_____	_____	_____

Compute average of BP Readings Systolic _____ Diastolic _____
(varname: **SysAvg, DiaAvg**)

On the participant's blood pressure card, record the following:

- Participant name (from question 2) (CONFIRM NAME AND SPELLING)
- Today's date: _____
- Average blood pressure readings [BASED ON READINGS 3, 4, AND 5 (IF 5 OR MORE READINGS); BASED ON READINGS 3 AND 4 (IF 4 READINGS); MINIMUM OF 4 TOTAL READINGS]
- IF LESS THAN 4 READINGS, DISPLAY INSUFFICIENT READINGS AND TRY TO CONDUCT ANOTHER SESSION

If the BP is **200/120 or higher**, say the following:

Your blood pressure is dangerously high today and you need to seek medical attention without delay. Please call 911 to go to the nearest emergency room. Take this card with you to show to the emergency room doctor. If they have any questions, the doctor may call the number listed on your card.

- **Statement was read to participant: Check YES**.

If the BP is **180/110 – 199/119**, say the following:

Your blood pressure is very high today. Please see a doctor within the next 3 days. Take this card with you to your doctor. If they have any questions, the doctor may call the number listed on your card.

- **Statement was read to participant: Check YES**

- **Part 1: Health and Healthcare Questions**

Patient Satisfaction with Chronic Disease Care Scale

For the past **6 months**, you have had a pharmacist bring medical care to your barbershop working with you and your doctor or the study doctor to control your blood pressure. This is a new program and we appreciate your confidential feedback on how it's working.
Patient Assessment of Chronic Illness Care (PACIC). (Glasgow RE et al. Med Care 2005; 43(5): 436-44)

INTRO: Staying healthy can be difficult when you have a chronic condition. We would like to learn about the type of help with your condition you get from your health care team. This might include your regular doctor, his or her nurse, or a physician's assistant who treats your illness. Your answers will be kept confidential and will not be shared with your physician or clinic.

INTERVIEWER: USE SHOWCARD 3

Think about the following statement:

*Over the **past 6 months, when** I received care for my chronic conditions, I was:*

2. *Asked for my ideas when we made a treatment plan.* (varname: **CDIdeas)**
   a. None of the time
   b. A little of the time
   c. Some of the time
   d. Most of the time
   e. Always
   f. DON'T KNOW
   g. REFUSED

3. *Given choices about treatment to think about.* (varname: **CDChoices)**
   a. None of the time
   b. A little of the time
   c. Some of the time
   d. Most of the time
   e. Always
   f. DON'T KNOW
   h. REFUSED

4. *Asked to talk about any problems with my medicines or their effects.* (varname: **CDProblems)**
   a. None of the time
   b. A little of the time
   c. Some of the time
   d. Most of the time
   e. Always
   f. DON'T KNOW
   g. REFUSED

5. *Given a written list of things I should do to improve my health*. (varname: **CDImprove)**
   a. None of the time
   b. little of the time
   c. Some of the time
   d. Most of the time
   e. Always
   f. DON'T KNOW
   g. REFUSED

6. *Satisfied that my care was well-organized.* (varname: **CDOrganized)**
   a. None of the time
   b. A little of the time
   c. Some of the time
   d. Most of the time
   e. Always
   f. DON'T KNOW
   g. REFUSED

7. *Shown how what I did to take care of myself influenced my condition.* (varname: **CDInfluenced)**
   a. None of the time
   b. A little of the time
   c. Some of the time
   d. Most of the time
   e. Always
   f. DON'T KNOW
   g. REFUSED

8. *Asked to talk about my goals in caring for my condition.* (varname: **CDGoals)**
   a. None of the time
   b. A little of the time
   c. Some of the time
   d. Most of the time
   e. Always
   f. DON'T KNOW
   g. REFUSED

9. *Helped to set specific goals to improve my eating or exercise.* (varname: **CDEating)**
   a. None of the time
   b. A little of the time
   c. Some of the time
   d. Most of the time
   e. Always
   f. DON'T KNOW
   g. REFUSED

10. *Given a copy of my treatment plan.* (varname: **CDWritten)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

11. *Encouraged to go to a specific group or class to help me cope with my chronic condition.* (varname: **CDCope)**

    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

12. *Asked questions, either directly or on a survey, about my health habits.* (varname: **CDQuestions)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

13. *Sure that my doctor or, nurse thought about my values, beliefs, and traditions when they recommended treatments to me?* (varname: **CDValues)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

14. *Helped to make a treatment plan that I could carry out in my daily life.* (varname: **CDDaily)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

15. *Helped to plan ahead so I could take care of my condition even in hard times.* (varname: **CDHardTimes)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

16. *Asked how my chronic condition affects my life.* (varname: **CDAffects)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

17. *Contacted after a visit to see how things were going.* (varname: **CDContacted)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

18. *Encouraged to attend programs in the community that could help me.* (varname: **CDPrograms)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

19. *Referred to a dietitian, health educator, or counselor.* (varname: **CDReferred)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

20. *Told how my visits with other types of doctors, like an eye doctor or other specialist helped my treatment.* (varname: **CDDoctors)**
    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

21. *Asked how my visits with other doctors were going.* (varname: **CDVisits)**

    a. None of the time
    b. A little of the time
    c. Some of the time
    d. Most of the time
    e. Always
    f. DON'T KNOW
    g. REFUSED

DEMOGRPAHICS

CV DISEASE AND RISK

INTERVIEWER: We asked you similar questions when you entered the study, and we very much appreciate you answering again even if your answers have not changed.

22.1) Have you smoked at least 100 cigarettes or cigars in your lifetime? (varname: **Smoke100)**

a. YES
b. NO (SKIP TO QUESTION 23)
c. DON'T KNOW (SKIP TO QUESTION 23)
d. REFUSED (SKIP TO QUESTION 23)

22.2) Have you smoked at all in the last year? (varname: **SmokeLastYear)**

a. YES
b. NO (SKIP TO QUESTION 22.5)
c. DON'T KNOW (SKIP TO QUESTION 22.5)
d. REFUSED (SKIP TO QUESTION 22.5)

22.3) Have you smoked at all in the last 30 days? (varname: **SmokeLast30Days)**

a. YES
b. NO (SKIP TO QUESTION 22.5)
c. DON'T KNOW (SKIP TO QUESTION 22.5)
d. REFUSED (SKIP TO QUESTION 22.5)

22.4) During the past 30 days, on average, about how many cigarettes did you smoke in a day? (varname: **SmokeNumPerDay30)**

_____ (SKIP TO QUESTION 23)
DON'T KNOW (SKIP TO QUESTION 23)
REFUSED (SKIP TO QUESTION 23)

22.5) On average, over the entire time you have smoked, how many cigarettes have you usually smoked per day? (varname: **SmokeNumPerDayLifetime)**

_____
DON'T KNOW
REFUSED

22.6) How old were you when you quit smoking? (varname: **SmokeQuitAge)**

_____
DON'T KNOW
REFUSED

Perceived Health

23. *Overall, how would you rate your health? Would you say…* (varname: **OverallHealth)**
    a. Excellent
    b. Very Good
    c. Good
    d. Fair
    e. Poor
    f. Very Poor
    g. DON'T KNOW
    h. REFUSED

BP Medication Adherence Adherence to Refills and Medications (ARMS) Scale; (Adherence to Refills and Medications (ARMS) Scale; Kripalani, Risser, Gatti, & Jacobson, 2009)

It is common for people to miss taking their medicine from time to time, or to take it differently than prescribed. I would like to ask you about how you actually take your blood pressure medicines. There are no right or wrong answers. For each question, please answer "none of the time," "some of the time," "most of the time," or "all of the time."

24. How often do you forget to take your medicine? (varname: **forgetmed**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

25. How often do you decide not to take your medicine? (varname: **decidenottakemed**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

26. How often do you forget to get prescriptions filled? (varname: **prescrip_fill**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

27. How often do you run out of medicine? (varname: **medrunout**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

28. How often do you skip a dose of your medicine before you go to the doctor? (varname_**doseskip**)

    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

29. How often do you miss taking your medicine when you feel better? (varname: **medfeelbetter**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

30. How often do you miss taking your medicine when you feel sick? (varname: **medfeelsick**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

31. How often do you miss taking your medicine when you are careless? (varname: **medcareless**)
    (1) None
    (2) Some
    (3) Most
    (4) All
    DON'T KNOW
    REFUSED

32. How often do you change the dose of your medicines to suit your needs (like when you take more or less pills than you're supposed to)? (varname: **medchange**)
(1) None
(2) Some
(3) Most
(4) All
DON'T KNOW
REFUSED

33. How often do you forget to take your medicine when you are supposed to take it more than once a day? (varname: **forget_med_multiple**)
(1) None
(2) Some
(3) Most
(4) All
DON'T KNOW
REFUSED

34. How often do you put off refilling your medicines because they cost too much money? (varname: **medrefillmoney**)
(1) None
(2) Some
(3) Most
(4) All
DON'T KNOW
REFUSED

35. How often do you plan ahead and refill your medicines before they run out? (varname: **medrefillplan**) [PROGRAMMING: THESE ANSWERS ARE NUMBERED IN REVERSE ON PURPOSE]
(4) None
(3) Some
(2) Most
(1) All
DON'T KNOW
REFUSED

Frequency of MEDICAL APPOINTMENTS FOR HYPERTENSION

36. In the last **6 months**, have you had a medical appointment for your blood pressure? This could have been with your personal doctor, heart specialist, nurse, or pharmacist. (varname: **SeenDr**)
a. YES
b. NO {GO TO QUESTION 38}
c. DON'T KNOW {GO TO QUESTION 38}
d. REFUSED {GO TO QUESTION 38}

37. In the last **6 months**, how many of these appointments have you had? _____ (varname: **SeenDrTimes**)
DON'T KNOW
REFUSED

Nocturia

38. During the **past 30 days**, how many times per night did you typically get up to urinate, from the time you went to bed at night until the time you got up in the morning? **(varname: Nocturnia)**

[SHOWCARD 1 - PROBE FOR AN AVERAGE OR TYPICAL NIGHT]

a. 0 (GO TO QUESTION 40)
b. 1
c. 2
d. 3
e. 4
f. 5 OR MORE
g. DON'T KNOW (GO TO QUESTION 40)
h. REFUSED (GO TO QUESTION 40)

39. Now using a scale from 0 to 10, with 0 indicating '**not at all'** and 10 being '**a great deal**, please tell me how much does it bother you? (REPEAT QUESTION IF NEEDED: to get up to urinate, from the time you went to bed at night until the time you got up in the morning?) **(varname: Nocturnia2)**

[SHOW CARD 2]

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10 DK REF

Not at all **A great deal**

40. In the **last 3 months**, how many times have you visited a doctor or clinic for any type of medical care? _____ **(varname: VisitDr3Mos)**

ADVERSE EVENTS

41. Have you needed to go to the Emergency Room or been hospitalized in the past 3 months? (varname: **ER3Mos)**

a. YES
b. NO (SKIP TO QUESTION 45)
c. DON'T KNOW (SKIP TO QUESTION 45)
d. REFUSED (SKIP TO QUESTION 45)

42. For what reason? _____
(varname: **ERReason)**

43. What date were you in the hospital or emergency room? Month __ Day ___ Year
(varname: **ERDate)**

44. What hospital or emergency room did you visit? _____
(varname: **ERName)**

45. Have you experienced any of the following in the past 3 months? (CHECK ALL THAT APPLY) [INTERVIEWER: USE SHOWCARD 6]

□ A) swollen ankles (varname: AR_SwollenAnkles, RS_SwollenAnkles)
□ B) swollen gums (varname: AR_SwollenGums, RS_SwollenGums)
□ C) swelling of the lips, throat, and/or tongue (varname: AR_SwelingLips, RS_SwelingLips)
□ D) hair loss (varname: AR_HairLoss, RS_HairLoss)
□ E) erectile dysfunction (varname: AR_ErectileDisfunction, RS_ErectileDisfunction)
□ F) gout (varname: AR_Gout, RS_Gout)
□ G) difficulty breathing or wheezing (varname: AR_DifficultyBreathing, RS_DifficultyBreathing)
□ H) dry cough (varname: AR_DryCough, RS_DryCough)
□ I) depression (varname: AR_Depression, RS_Depression)
□ J) headache (varname: AR_Headache, RS_Headache)
□ K) palpitations (feeling that your heart is pounding or racing) (varname: AR_Palpitations, RS_Palpitations)
□ L) breast tenderness or enlargement (varname: AR_BreastTenderness, RS_BreastTenderness)
□ M) excessive sleepiness during the day (varname: AR_ExcessiveSleepiness, RS_ExcessiveSleepiness)
□ N) dizziness (varname: AR_Dizziness, RS_Dizziness)
□ O) skin rash (varname: AR_SkinRash, RS_SkinRash)
□ NONE OF THE ABOVE (SKIP TO QUESTION 60) (varname: AR_None)
□ DON'T KNOW (SKIP TO QUESTION 60) (varname: AR_DK)
□ REFUSED (SKIP TO QUESTION 60) (varname: AR_RF)

45-59.
[NOTE: ONE QUESTION FOR EACH ITEM IDENTIFIED IN 45] Was it… [FOR EACH ITEM FOR 45, THIS QUESTION SHOULD INCLUDE BOTH THE ITEM AND THE LETTER, SO THAT WE CAN REFER TO SHOWCARD IF NEEDED]

□ Mild (I did not need to see my doctor)
□ Moderate (I needed to see my doctor)
□ Severe (I was hospitalized)
□ Life-threatening (I was hospitalized in the intensive care unit (ICU))
□ DON'T KNOW
□ REFUSED

AFTER ALL ITEMS ARE ASKED GO TO QUESTION 60

<u>Current Medications</u>

60. *Are you taking **<u>any</u>** prescription medication for any medical condition?* (varname: **AnyMeds**)

e. Yes
f. No (GO TO QUESTION 78)
g. DON'T KNOW (GO TO QUESTION 78)
h. REFUSED (GO TO QUESTION 78)

62. *Did you bring the medication with you today?* (varname: **BringMeds**)

a. YES
b. NO (GO TO QUESTION 78)

63-76. *Now I will record the name, dose, how often you are to take the medication(s) you brought in today and prescriber information.*

ALLOW FOR DROP DOWN LIST FOR BP MEDICATIONS. OTHER NON-BP MEDICATIONS JUST ALLOW FOR ENTERING NAME OF MEDICINE (OTHER NON-BP MEDS IS FIRST OPTION ON LIST).

FOR EACH BP MED: [CAN PUT IN UP TO 15 MEDS—QUESTIONS 62-76]

(varname: **DrugMed01 – DrugMed15)**
(varname: **NonBPMed01– NonBPMed15)**

DOSE _____ (varname: **DoseMed01 – DoseMed15)**

DOSE PER DAY (response options = ½, 1, 2, 3, weekly, every night
(varname: **DosePerDayMed01– DosePerDayMed15)**

PRESCRIBER FIRST NAME _____
(varname: **PrescriberFirstMed01– PrescriberFirstMed15)**

PRESCRIBER LAST NAME _____
(varname: **PrescriberLastMed01– PrescriberLastMed15)**

77. *MEDICATION COMMENTS (*varname: **MedComment***)*

The following questions refer to your experiences as a barbershop patron in this Barber-Physician-Pharmacist Program. In answering these questions, please consider your barber measuring your blood pressure as well as your pharmacist meeting with you as part of this program.

78. What impressed you most about the Program? (varname: **ProgImpressed***)*

79. What did you like least about the Program? (varname: **ProgLeastLiked***)*

80. What recommendations would you offer to improve the Program? (varname: **ProgRecommend***)*

81. Do you know of any other barbershops that would be interested in participating in the program? [INTERVIEWER, IF YES, RECORD THE NAMES AND LOCATIONS OF BARBERSHOPS] (varname: **ProgOthShops***)*

Gift card

Thank you for taking the time to participate in the 6 Month Follow-up.

(CHECK SMS TO SEE IF PARTICIPANT HAS BEEN ISSUED A RELOADABLE DEBIT CARD. IF HE HAS A DEBIT CARD TELL HIM THAT $100 WILL BE ADDED TO HIS CARD BY THE NEXT BUSINESS DAY.)

Here is a $100 gift card ($100 will be added to your study debit card) for completing the 6-month Interview and for bringing your prescription pill bottles.

[IF PARTICIPANT HAS debit card, ENTER NONE FOR GIFTCARD NUMBER]

*GIFTCARD #*_____ (varname: **GiftCardNum)**

[INTERVIEWER, PLEASE FOLLOW CONSENT PROCEDURES FOR FUTURE STUDIES]

[INTERVIEWER: DID CUSTOMER CONSENT TO BEING IN FUTURE STUDIES AND FILL OUT CONTACT INFORMATION?]
(varname: **FutureStudiesS1**)

YES
NO

[INTERVIEWER, IF PARTICIPANT ASKS ABOUT STUDY RESULTS, YOU CAN MENTION THAT WE WILL BE SENDING PARTICIPANTS RESULTS AT THE END OF THE STUDY (LIKELY NOT UNTIL THE END OF 2020 AT THE EARLIEST)

Thank you for your time. We greatly appreciate your participation in the study.

[INTERVIEWER: ENTER COMMENTS, CORRECTIONS, OR ANY OTHER RELEVANT INFORMATION ABOUT THE RESPONDENT] **(**varname **Comment) (**varname 6 month: **Comment6m**)

IMPORTANT--AFTER EXITING INTERVIEW VERIFY CONTACT INFORMATION IN SMS AND TRY TO OBTAIN ANY MISSING INFORMATION (FOR EXAMPLE, ADDRESS, PHONE NUMBERS)

Appendix 6B.5: Barber Exit Interview

Barber Exit Interview

Study ID: _____ Barbershop: _____

Below is a list of questions to determine your overall satisfaction in participating in the Nashville Implementation of the LA Barbershop Hypertension Study-Pilot trial. We appreciate your participation and value your feedback. Please select one of the options per question as your answer. Thank you.

Please choose one of the following:	Not at all	A little bit	Somewhat	Quite a bit	Very much
1. How satisfied were you working with the VUMC staff throughout the Nashville Barbershop study?	1	2	3	4	5
2. Did you find that this study has brought positive community engagement to your barbershop?	1	2	3	4	5
3. Do you feel that this study strengthened the relationship between you and your clientele?	1	2	3	4	5
4. With the provided training, how confident were you as a Barber participating in the Nashville Barbershop study?	1	2	3	4	5
5. Did you find that using the blood pressure machine interrupted your workflow providing haircuts?	1	2	3	4	5
6. Did you find that using the blood pressure machine was bothersome?	1	2	3	4	5
7. Overall, how satisfied were you participating in the Nashville Barbershop study?	1	2	3	4	5

If you have additional comments or further explanation of the questions above, please provide your response below:

_____

_____

_____

_____

Appendix 6C: Blood Pressure Information Card

"Cut Your Pressure Too" Blood Pressure Card

Participant's Name: _____

Your blood pressure on: _____ was _____/_____
Date (Systolic/Diastolic)

If your blood pressure is:

- Below 120 / 80, it is within the normal range Please SEE A DOCTOR AT LEAST ONCE A YEAR TO MAINTAIN GOOD HEALTH.
- 120/80 - 139/89, it is in the high normal range Please SEE A DOCTOR WITHIN 6 MONTHS.
- 140/90 - 159/99, it is elevated Please SEE A DOCTOR WITHIN THE NEXT 1 MONTH.
- 160/100 — 179/109, it is very elevated Please SEE A DOCTOR WITHIN THE NEXT 2 WEEKS.
- 180/110 – 199/119 or higher, it is extremely elevated Please SEE A DOCTOR WITHIN THE NEXT 3 DAYS.
- 200/120 or higher, it is DANGEROUSLY elevated Please GO TO THE NEAREST EMERGENCY ROOM IMMEDIATELY. If you have further questions, please call (615) 322-5000.

If you are having chest pain, difficulty breathing, blurry vision, confusion, dizziness, or headache, you should seek immediate medical attention. Please see the Provider referral list for information on where to find a doctor.

Thank you for participating in the Cut Your Pressure Too: The Nashville Barbershop Blood Pressure Study.

[redacted]
Medical Director
Cut Your Pressure Too project-Nashville
[redacted]

[redacted]
Clinical Pharmacist
[redacted]

Appendix 6D: Template Pharmacist Note

Patient Information

Patient Name: _____ ID #: ___ DOB: ____Patient Contact Info: phone ___ email: ___

Treating Physician: _____Physician Contact Information: phone: _____ fax: ____email: _____

Date of Today's Visit: _____ Appointment Start Time: _____

Location of Today's Visit:

☐	Pharmacy → Pharmacy Name_____
☐	Barbershop → Location _____
☐	Other→ Location Name_____

S/

☐	Patient reports tolerating antihypertensive medication well without side effects.
☐	Patient complains of experiencing an adverse drug reaction to antihypertensive medication.
☐	Patient complains of intolerance to antihypertensive medication regimen.
☐	Patient states there has been a significant interval change in health status.
☐	Other:
	Comments:

O/Medication Allergies:

Medication	Reaction	Severity
1)		
2)		
3)		

Current Medications:

Medication	Dosage Form	Dose	Frequency	Date Last Filled
1)				
2)				
3)				
4)				
5)				
6)				
7)				
8)				
9)				
10)				

Associated Medical Problems:

☐	DM
☐	CAD
☐	Stroke
☐	Heart Failure
☐	Hypercholesterolemia
☐	CKD
☐	Asthma / COPD
☐	Heart Block

☐ Other/Comments: Click here to enter text.

Patient's BP in Barbershop on: Click here to enter a date. **Patient's BP today (only if no interval Barber-BP):**

BP 1		HR 1	
BP 2		HR 2	
BP 3		HR 3	
BP 4		HR 4	
BP 5		HR 5	
BP 6		HR 6	
BP 7		HR 7	
BP 8		HR 8	

BP 1		HR 1	
BP 2		HR 2	
BP 3		HR 3	
BP 4		HR 4	
BP 5		HR 5	
BP 6		HR 6	
BP 7		HR 7	
BP 8		HR 8	

Cuff Size:

- ☐ Medium
- ☐ Large
- ☐ Extra-large

Labs on: Click here to enter a date. **Source of Labs:** ❑ POC or ❑ Laboratory

Na		K		SCr		eGFR		Glu	

Targeted PE:

Angioedema: ❑ No ❑ Yes Gingival hyperplasia: ❑ No ❑ Yes
Peripheral Edema ❑ No ❑ Yes Skin Rash ❑ No ❑ Yes

A/

- ☐ BP at goal at barbershop or today (if no interval barbershop BP); no changes in therapy warranted
- ☐ BP above goal at barbershop or today (if no interval barbershop BP); possible reasons for BP elevation include (check all that apply):
  - ☐ Patient's HTN is being undertreated
  - ☐ Patient prescribed non-protocol medication
  - ☐ Patient non-adherence
  - ☐ Other/Comments: Click here to enter text.

Antihypertensive Medication-Related Problems Identified:

- ☐ Medication regimen not per protocol (not optimal based on current evidence/guidelines)
- ☐ Medication regimen insufficient to reach treatment goals (dose, interval, # of medications)
- ☐ Patient on short acting medication
- ☐ Contraindication
- ☐ Adverse Drug Reaction
- ☐ Drug interaction
- ☐ Drug therapy duplication
- ☐ Medication misuse/ poor adherence
- ☐ Abnormal lab result not addressed

☐	Dose discrepancy between patient use and prescribed therapy
☐	Other/Comments: _____

P/Actions/Interventions:

☐	Medication Changes
☐	Antihypertensive Regimen Intensification Medication(s) added: _____ Medication dosage increased: _____
☐	Antihypertensive Regimen Substitution to protocol preferred regimen Medication(s) taper: _____ Medication(s) discontinued: _____ Medication(s) added: _____
☐	Antihypertensive Regimen De-escalation: Medication(s) taper: _____ Medication(s) discontinued: _____
☐	Change PRN to scheduled
☐	Substitute dosage form: _____
☐	Patient provided refills: _____
☐	No medication changes necessary
	Patient Monitoring
☐	Patient requires labs to be ordered or obtain POC labs
☐	Make appointment with PCP
☐	Patient Education/Therapeutic Lifestyle Changes
☐	Discussed purpose/general mechanism of action of medications, as well as proper use
☐	Dietary changes (DASH diet, sodium restriction)
☐	Exercise
☐	Alcohol intake reduction
☐	Smoking reduction/cessation
☐	Patient Activation
☐	Patient asked about medication concerns
☐	Patient set steps he plans to take to reach blood pressure goal
☐	Patient & pharmacist collaborated on treatment plan
☐	Patient provided with treatment plan including steps he plans to take to improve HTN
☐	Discussed Role Model Stories in Barbershop
☐	Patient given educated about new medication, medication dispensed to patient
	Other/Comments:

Prescription(s)/Refills given to patient/filled by pharmacy
(Drug, dose, qty, sig: _____)
(Drug, dose, qty, sig: _____)
Additional Notes: _____
Next Barber BP Visit: _____
Next Pharmacist Phone Call: _____ Next Pharmacist Visit: _____
Visit End Time: _____

Appendix 6E: Adverse Event Form

PATIENT ID: DATE FORM COMPLETED:

HAS SUBJECT EXPERIENCED ANY ADVERSE EVENTS SINCE LAST VISIT?	□ YES □ NO
IF YES, DESCRIPTION OF THE EVENT: _____ EVENT ONSET DATE: _____/_____/_____ □ OR CHECK IF CONTINUING FROM LAST VISIT EVENT END DATE: _____/_____/_____ □ OR CHECK IF PRESENT AT THIS VISIT	
HAS PARTICIPANT GONE TO ER OR HOSPITAL SINCE THE LAST VISIT OR PHONE CALL?	□ YES □ NO
IF YES, DESCRIPTION OF EVENT: REASON FOR HOSPITALIZATION/ER VISIT: _____ WHAT WAS THE DATE: _____ WHAT HOSPITAL OR ER: _____	

DRUG	INTERVAL DRUG REACTIONS
□ CCB (CALCIUM CHANNEL BLOCKER)	□ ANKLE EDEMA □ HYPOTENSION □ BRADYCARDIA □ GINGIVAL HYPERPLASIA
□ ACE-INHIBITOR	□ COUGH □ ACUTE KIDNEY INJURY □ ANGIOEDEMA □ HYPERKALEMIA
□ ARB (ANGIOTENSIN RECEPTOR BLOCKER)	□ ALOPECIA □ ACUTE KIDNEY INJURY
□ THIAZIDE	□ ERECTILE DYSFUNCTION □ GOUT □ HYPERGLYCEMIA □ HYPOKALEMIA □ HYPONATREMIA
□ BETA BLOCKER	□ WHEEZING □ HEART BLOCK □ ERECTILE DYSFUNCTION □ DEPRESSION
□ ALPHA BLOCKER	□ DIZZINESS □ ANKLE EDEMA □ HEART FAILURE
□ LOOP DIURETIC	□ ACUTE KIDNEY INJURY □ HYPOKALEMIA
□ CLONIDINE (CENTRAL SYMPATHOLYTIC)	□ REBOUND HYPERTENSION □ DRY MOUTH □ SOMNOLENCE
□ DIRECT VASODILATORS	□ HEADACHE □ PALPITATIONS □ SHORTNESS OF BREATH □ LUPUS (hydralazine) □ PERICARDITIS (hydralazine)
□ ALDOSTERONE BLOCKER	□ BREAST TENDERNESS/ ENLARGEMENT □ HYPERKALEMIA □ ACUTE KIDNEY INJURY □ ERECTILE DYSFUNCTION

PHARMACIST SIGNATURE PRINT NAME DATE

SEVERITY GRADE (PLEASE CIRCLE ONE):

1 = Grade 1: Mild AE (minor; no specific medical intervention; asymptomatic laboratory findings only, radiographic findings only; marginal clinical relevance)
2 = Grade 2: Moderate AE (minimal intervention; local intervention; noninvasive intervention [packing, cautery])
3 = Grade 3: Severe and undesirable AE (significant symptoms requiring hospitalization or invasive intervention; transfusion; elective interventional radiological procedure; therapeutic endoscopy or operation)
4 = Grade 4: Life-threatening or disabling AE (complicated by acute, life-threatening metabolic or cardiovascular complications such as circulatory failure, hemorrhage, sepsis. Life-threatening physiologic consequences; need for intensive care or emergent invasive procedure; emergent interventional radiological procedure, therapeutic endoscopy or operation)
5 = Grade 5: Fatal AE

RELATIONSHIP TO STUDY DRUG (PLEASE CIRCLE ONE):

1 = ***Probably Related*****.** This category applies to those adverse events that are considered with a high degree of certainty to be related to the test drug.
2= ***Possibly Related*****.** This category applies to those adverse events for which a cause and effect relationship between the study drug and the AE has not been previously demonstrated and it appears unlikely from the known effects of the drug but cannot be ruled out with certainty.
3= ***Unlikely Related*****.** In general, this category is applicable to adverse events that does not follow a reasonable temporal sequence related to drug administration or it is likely to be explained by other known characteristics of the participant or their treatment for other conditions; or t does not follow a pattern/manner known or suspected to be related to study drug

EVENT PATTERN (PLEASE CIRCLE ONE):

1 = Continuous
2 = Intermittent
3 = Unknown

ACTION TAKEN WITH STUDY DRUG (PLEASE CIRCLE ONE):

1 = No action, continued on study drug without interruption
2 = No change, was not on study drug at the time of AE
3 = Temporary discontinuation of study drug **4 =** Permanently Discontinued of study drug

HOSPITALIZATION REQUIRED (PLEASE CIRCLE ONE):

0 = No
1 = Yes

MEDICATIONS REQUIRED (PLEASE CIRCLE ONE):

0 = No
1 = Yes

1/17/2012

Appendix 6F: Example Study Pharmacist to Non-Study Physician Letters

DATE

Dear Dr. **NAME**,

As you know your patient, Mr. **FIRST AND LAST NAME** is participating in the Barbershop Study conducted by Vanderbilt University Medical Center in order to determine the effectiveness of a novel community-partnered approach to help control hypertension. We are writing you today to inform you of your patient's progress and to share forthcoming treatment recommendations with you.

Unfortunately, Mr. **LAST NAME**'s BP was not at goal and was most recently XXX/XX when measured at his barbershop on **DATE**.

The following changes were made to his medication regimen [EXAMPLE]:

1. Amlodipine 5 mg once daily was added
2. Benazepril 10 mg once daily was increased to Benazepril 20 mg once daily

His **current medication regimen** is:

1. Amlodipine 5 mg once daily
2. Benazepril 20 mg once daily

Attached is a note detailing the pharmacist-patient visit for your review. The barber will continue to monitor Mr. **LAST NAME**'s blood pressure on a monthly basis and report the readings to the study pharmacist, who will continue to work closely with Mr. **LAST NAME** for the remainder of his participation in the project and will continually update you on his progress.

Please do not hesitate to call us if you have any questions or concerns.

Sincerely,

[redacted]
Clinical Pharmacist
Phone: XXX-XXX-XXXX

Date of Visit: **XX/XX/XXXX**

Patient: **FIRST AND LAST NAME**, DOB: **XX/XX/XXXX**

Treating Physician: Dr. **LAST NAME**

Location of Visit: **ADDRESS**

Associated Medical Problems: **(i.e. Diabetes Mellitus Type II, Lupus)**

S: This is a 41-year-old African American man presenting for a first visit with study pharmacist in the Barbershop research study. Mr. **LAST NAME** reports tolerating his current antihypertensive regimen (Benazepril 10 mg once a day) well without side effects (denies cough, signs/symptoms of angioedema).

O: Patient's blood pressure in the barbershop (BP average of the final 3 of 5 BP readings):

X/XX/XX	169/94
X/XX/XX	152/88
X/XX/XX	139/79

BP Cuff Size: Medium

Labs on **DATE**:

Na	138	K	4.4	SCr	0.82	eGFR	127	Glu	209

A:

Patient's antihypertensive medication regimen requires intensification and continued monitoring. Current antihypertensive regimen:

Benazepril	10 mg once daily

P:

Mr. **LAST NAME** may benefit from the addition of Amlodipine 5 mg once daily and increasing his benazepril dosage. Unfortunately, Lotrel (amlodipine/benazepril) is not covered by his insurance formulary.
New Regimen (per study algorithm):

Benazepril	20 mg daily
Amlodipine	5 mg daily

Prescription called into PHARMACY (XXX-XXX-XXXX, spoke with Janet). We will monitor Mr. **LAST NAME**'s BP and I will call him in a few days to see how he is tolerating his new medication regimen.

Jane Doe, PharmD
Clinical Pharmacist
Phone: XXX-XXX-XXXX

Appendix 6G: Participant Treatment Report Example Template

CUT YOUR PRESSURE TOO

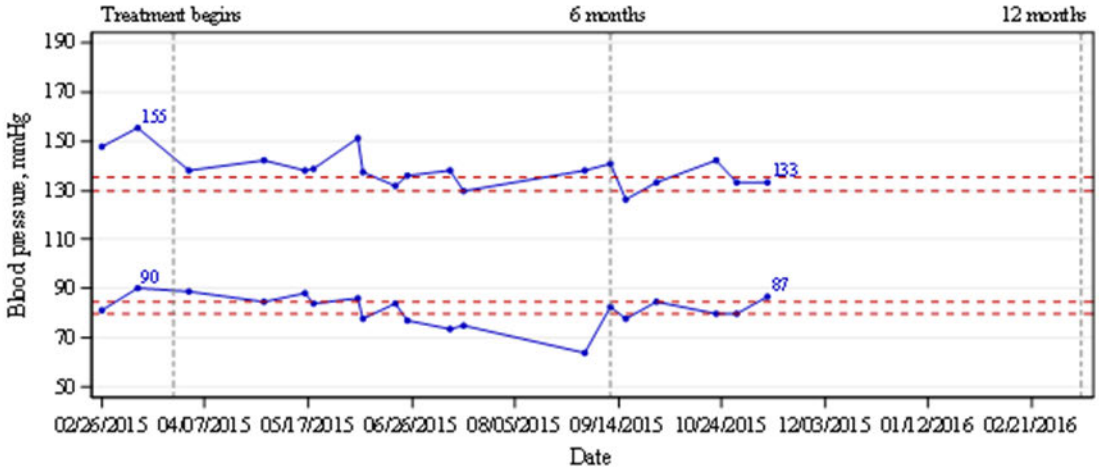
Implementing the Los Angeles Barber-Pharmacist Model of Hypertension Management in Nashville

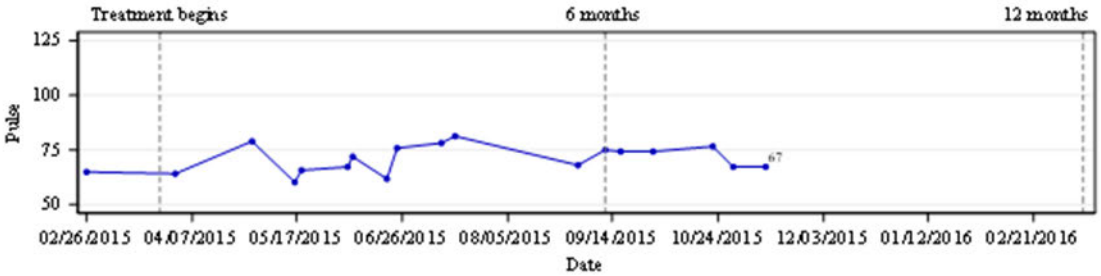
PARTICIPANT TREATMENT REPORT

SUBJECT ID: XXX
SITE: [Barbershop Name]
AGE: XX

PHARM VISIT DATE: XX/XX/XXXX
PHARM VISIT NUM: X

INITIAL MEDICATION /BLOOD PRESSURES	CURRENT MEDICATIONS/BLOOD PRESSURE
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.
INITIAL MEDICATION /OTHER	**CURRENT MEDICATIONS/OTHER**
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.
6.	6.
7.	7.
8.	8.





Final Medications at Each Pharmacist Visit		
	Med type	
	BP	Non-BP
Visit	Medication	Medication
1		
2		
3		
4		
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APPENDIX 7: DATA SAFETY MONITORING COMMITTEE PLAN/ SAE FORMS

Preamble

The monitoring of SAE/UPs is an important process for ensuring the safety of subjects participating in clinical research. This document establishes a set of procedures for collecting, evaluating, and reporting SAE/UPs in the study.

There will be two sources of safety data in this community-level intervention trial:

(1) Research coordinators will obtain patient-reported adverse events/unanticipated problems on emergency department visits, hospitalizations, death, and specific blood pressure medication side-effects at baseline, 3 months and 6 months. They will obtain baseline data and 6-month data during in-person interviews with participants in their barbershops or through listed contact information. They will obtain 3- data as part of scheduled phone calls to collect data on interval changes in health.

(2) The study's Lead Clinical Pharmacist will obtain additional data on adverse events and unanticipated problems. He/she will collect data on patient-reported adverse events from monthly scheduled in-person or phone encounters plus additional follow up phone calls after every BP medication change. He/she also will collect safety data from Laboratory tests ordered when indicated during the intervention period.

Key Components of the Safety Monitoring Plan

Definitions of Adverse Events and Unanticipated Problems are presented in Appendix 8.

A flow diagram for expedited reporting of Serious Adverse Events/Serious Unanticipated Problems is presented in Appendix 9. A summary of the key components of the monitoring process to be undertaken to detect and report SAE/UPs for the study is presented below:

1. **The UCLA Data Coordinating Center (DCC):** The DCC receives submitted electronic reports of AE/UPs from research coordinators and from the Lead Clinical Pharmacist. If AE/UP is marked as serious on the electronic case report form and thus meets the criteria for expedited reporting, an automatic e-mail notification is sent immediately to both Physician Monitors and the PI; their roles are described later. For non-serious AE/UPs, the DCC will provide blinded quarterly safety reports to the DSMB, and PI who will forward the reports to the IRB (Vanderbilt University). As the DCC only receives de-identified information, the local VUMC study team will link any collected data also in real time with the affected participant. This will be acted upon immediately as described here.

2. **Physician Monitors:** The Physician Monitors serve two major roles in the evaluation of SAE/UPs for the trial: 1) ongoing, real-time reviews of all individual SAE/UPs from the research assistant or clinical pharmacist (VUMC), review the medical records, make a rapid determination if the event indeed is serious and is related to research participation, and complete and forward to the PI the Physician Monitor Report of SAE/UPs shown in Appendix 12; and 2) monthly reviews of cumulative SAE data to judge whether there are concerning trends in the occurrence of events.

3. **DSMB:** The DSMB is responsible for safeguarding the interests of study participants by assessing the safety and efficacy of study procedures, and by periodic monitoring of safety data and the overall conduct of the study. The DSMB reviews the following types of safety data: 1) quarterly reports from the UCLA DCC; 2) annual reports from DSMB meetings; and 3) expedited reports from the PI on individual SAE/UPs or concerning trends identified by the Physician Monitors. After reviewing pertinent reports, the DSMB determines whether any trend that may be identified is related to the trial. After each DSMB meeting, the study team will prepare a draft report for the DSMB Chair to review and sign. The VUMC PI will transmit it to the VUMC IRB. The report summarizes the recommendations of the DSMB regarding the safety and continuance of the study and should be sent to the PI within 60 days after a DSMB meeting. The DSMB serves in an advisory role to Vanderbilt University Medical Center. If the DSMB identifies a concerning safety trend related to the trial, the Board makes a recommendation to NCATS through the Project Officer, and to the PI, who will transmit the recommendations to the participating VUMC IRB. This recommendation includes actions that should be taken to protect current and potential participants.

4. **PI:** For expedited reporting of any individual SAE/UP, the PI will forward the report from the Physician Monitors to the NCATS or NHLBI and the participating IRBs within 7 days of its detection along with an appropriate plan to address it, if feasible. After each scheduled DSMB meeting, the PI receives a summary report from the DSMB Chair that summarizes the DSMB deliberations and recommendations.

Definition of Serious Adverse Events (SAEs) See also Appendix 8

As defined by NHLBI (http://www.nhlbi.nih.gov/crg/glossary.php#serious), serious adverse events (SAEs) are considered to be those events that result in at least one of the following outcomes:

1. Death
2. Life-threatening
3. Inpatient hospitalization or prolongation of an existing hospitalization
4. Persistent or significant disability/incapacity
5. A congenital anomaly/birth defect
6. Other events that might jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above

Definition of Unanticipated Problems See Also Appendix 8

As specified by NHLBI policy (http://www.nhlbi.nih.gov/funding/policies/adverse.htm) an unanticipated problem (UP) is considered to be any event or problem that is:

1. unexpected; and
2. possibly, probably, or definitely related to study participation; and
3. suggests greater risk of harm to study participant(s) than was previously known or recognized.

An unanticipated problem is classified as serious if the event results in an emergency department visit, hospitalization, or death.

Procedures for Reviewing and Reporting SAE/Ups

The Study personnel, in previous consultation with NHLBI, have established the following procedures for reviewing and reporting SAE/UPs.

1. Reporting of SAE/UPS by the Principal Investigator (PI)

The PI is responsible for prompt reporting of all SAE/UPs, as described below.

2. Submission of the Case Report Form for SAE/Ups (see Appendices 10-12)

Adverse events forms will be electronically entered into the study database by research coordinators or by the Lead Study Pharmacist as well as maintained in the VUMC hard copy research charts. Pharmacist documents will also be maintained in the VUMC REDCap study database.

Detection and Initial Processing of SAE/Ups

1. The electronic database is updated every 24 hours and is programmed to automatically send immediate e-mail notification of any new SAE/UP to both Physician Monitors and the PI. The report contains all information on the SAE/UP that was entered into the database.

2. The DCC Database Manager sends summary cumulative reports of SAE/UPs to the Physician Monitors monthly. The Physician Monitor who has been assigned to that quarter reviews the summary report to determine if any concerning trends are noted.

3. If a serious problem or trend is suspected, the Physician Monitors would request that the PI forward the information to the DSMB.

Physician Monitors

[redacted] will serve as Physician Monitors for this study. If neither is available another study MD will be designated in their absence as needed. [redacted] as Cedars Sinai will also serve in this oversight role. The Physician Monitors are assigned the responsibility of serving as lead Physician Monitor during alternating calendar quarters. The Lead Physician Monitor completes the form but reviews it together with the other Physician Monitor. The Physician Monitors are given limited access to the study database only to enter a Physician Monitor SAE/UP Report Form (see Appendix 12) for each reported SAE/UP. The form serves as the monitor's evaluation of each reported SAE/UP. A description of the process for Physician Monitor evaluation of UPs/SAEs is presented below.

1. The Physician Monitor evaluates each SAE/UP to determine if it is unexpected and possibly, probably, or definitely related to the study intervention, and completes the Physician Monitor SAE/UP Report Form (Appendix 12) online within three (3) business days of receipt. Physician Monitors use the Comments section of the form when needed to clarify the context or assumptions used in answering form questions.

2. If the participant went to the emergency department, was hospitalized, or died, the Physician Monitor will need to request and review the medical records. The Study Coordinator will facilitate this process by obtaining a signed HIPAA waiver and request for release of medical records from the participant or his designee.

3. The DCC Database Manager prepares ***quarterly*** SAE/UP reports that include: 1) all SAE/UPs; 2) all SAE/UPs related to study participation; and 3) a summary of the SAE monitoring process. The monthly report is emailed to both Physician Monitors, who review the SAE/UP reports for any concerning trends. Should any concerns arise due to observed trends, the lead Physician Monitor for that quarter sends a written recommendation to the PI requesting that the report be forwarded to the DSMB.

Procedure for Expedited Reporting of SAE/Ups (see Appendix 9)

1. Expedited SAE/UP reports from the PI should include the following:
    - Study title, grant number, PI name
    - Description and date of the event or problem, including why it merits expedited reporting
    - When it becomes available, date(s) on which the SAE/UP was detected by the DCC and e-mail alerts sent to the Physician Monitors and PI, and the date on which the PI sent his report to the NCATS, and applicable oversight bodies (relevant IRBs, the DSMB, Office for Human Research Protections).
    - Any corrective action planned or taken in response to the SAE/UP (e.g., study suspension, consent or protocol changes, additional training or security measures).
    - Signature of the PI

2. All communications from the relevant oversight bodies regarding any expedited UP/SAE must be reported to NCATS.

3. The PI is responsible for forwarding any IRB decisions regarding UPs/SAEs to the DSMB, as noted above.

Quarterly Reporting of SAE/Ups to the DSMB

Each quarter, the study biostatistician sends cumulative summary tables of all SAEs, all related SAE/UPs to the DSMB.

Interim Monitoring Plan

There will be no interim analyses for futility.

SAE/UPs Reports

Each ***quarter***, the UCLA DCC prepares cumulative SAE/UPs reports for review by the Physician Monitors. Cumulative SAE/UPs reports are transmitted to the DSMB for review each quarter, and cumulative summary reports are prepared for each teleconference or in-person closed session meeting of the DSMB.

SAE/UP tables are included in the monthly cumulative reports from the DCC to the Physician Monitors:

- Summary data on all SAE/UPs
- Summary of SAE/UPs Related to the Research
- Summary of Serious Adverse Event Monitoring Process
- Listing of individual SAE/UPs

APPENDIX 8 RELEVANT DEFINITIONS OF SAFETY TERMS PER NIH NHLBI POLICY

Adverse Event - Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. An adverse event (also referred to as an adverse experience) can also be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, without any judgment about causality. An adverse event can arise from any use of a drug (e.g., off label use, use in combination with another drug) and from any route of administration, formulation or dose, including overdose.

Serious Adverse Event (SAE) – An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse reaction, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

Unanticipated Problem - any incident, experience, or outcome that meets all of the following criteria: 1) unexpected 2) related or possibly related to participation in the research; and 3) suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

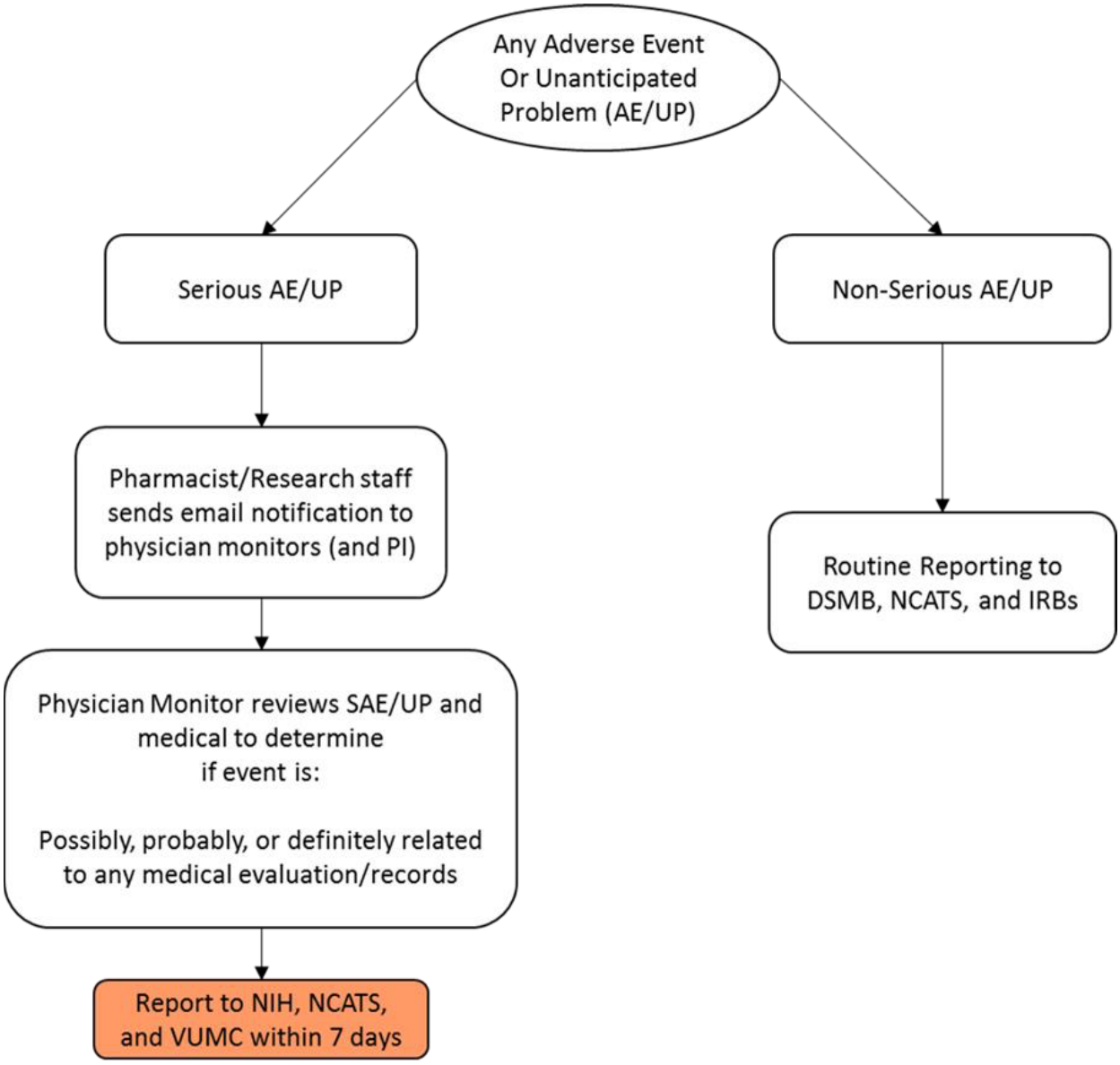
OHRP considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

(1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB- approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

(2) related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

(3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

APPENDIX 9 FLOW DIAGRAM FOR EXPEDITED REPORTING OF SERIOUS ADVERSE EVENTS AND SERIOUS UNANTICIPATED PROBLEMS (SAE/UP)



APPENDIX 10 RESEARCH ASSISTANT AE/UP FORM
(Completed at Baseline and 3, 6-month follow up – embedded within those forms also)

Interviewer/Research Assistant AE/UP Form

1. In the past 3 months, have you gone to the Emergency Room or been hospitalized?
    a. Yes
    b. No

2. If yes to #1, please ask the following questions:
    a. For what reason were you hospitalized or in the emergency room?
    _____
    b. What date were you in the hospital or emergency room? ___/____/____
    c. What hospital or emergency room did you visit? _____

3. In the past 3 months, have you experienced any of the following? (check all that apply)
    □ swollen ankles
    □ swollen gums
    □ swelling of the lips, throat, and/or tongue
    □ hair loss
    □ erectile dysfunction
    □ gout
    □ difficulty breathing or wheezing
    □ dry cough
    □ depression
    □ headache
    □ palpitations (feeling that your heart is pounding or racing)
    □ breast tenderness or enlargement
    □ excessive sleepiness during the day
    □ dizziness
    □ skin rash

4. If yes for any #3, rate severity: How severe was the reaction?
    □ Mild (I did not need to see my doctor about the reaction)
    □ Moderate (I needed to see my doctor about the reaction)
    □ Severe (I was hospitalized)
    □ Life-threatening (I was hospitalized in the intensive care unit (ICU)

APPENDIX 11 CLINICAL PHARMACIST AE/UP FORM – SEE APPENDIX 6E

APPENDIX 12 PHYSICIAN MONITOR SAE/UP REPORT FORM

Physician Monitor Report of a SAE/UP

1. Date of SAE: __ __/__ __/__ __ __ __ (mm/dd/yyyy)

2. Date site became aware of SAE: __ __/__ __/__ __ __ __ (mm/dd/yyyy)

3. Description of SAE: _____

4. Check the outcomes that are attributed to the SAE in the medical record or reported by the subject (check all that apply):

□ a. Death

a.1 Death Date: __ __/__ __/__ __ __ __ (mm/dd/yyyy)

□ b. Life-threatening condition

□ c. Hospitalization – initial or prolonged

□ d. Disability

□ e. Congenital anomaly

□ f. Required intervention to prevent permanent impairment/damage

Option 4.f should be used for an event that does not result in death, a life-threatening condition, hospitalization, disability or congenital deformity, but that did jeopardize the subject and that required a specific medical intervention to prevent one or more of outcomes 4.a – 4.e from occurring.

□ g. Important medical event as determined by the site PI or designee

Option 4.g should only be chosen when a site judges the event to represent significant hazard or harm to a research subject.

OR

□ h. None of the above

***** If you checked one or more of items 4.a – 4.g, continue to complete the remaining sections.**

If you checked 4h (None of the above)**, this is not a serious event.** You do not need to complete the rest of this form.

6. Was the SAE an exacerbation of a pre-existing condition (i.e. existing prior to enrollment)?
□ Yes □ No

7. Was the SAE related or might it have been related to an antihypertensive medication?
□ Yes □ No

If yes, please list the medication(s) that might have been related to the event:

Medication:	**Stopped because of Adverse Event?**
a. _____	□ Yes □ No
b. _____	□ Yes □ No
c. _____	□ Yes □ No

8. Do you believe the SAE was unexpected in terms of severity or frequency?
□ Yes □ No

If yes, why?
_____

9. Do you believe the SAE was possibly related to participation in the research?
□ Yes □ No

If yes, why?
_____

10. Do you believe the SAE suggests that the research places subjects or others at greater risk of harm than was previously known or recognized?
□ Yes □ No

If yes, why?
_____

11. Describe relevant scans/tests/laboratory data related to the SAE, including dates.

_____

12. Describe other relevant history, including pre-existing medical conditions (e.g. allergies, smoking and alcohol use, hepatic/renal dysfunction).
_____