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Key Components of Success in a Randomized Trial of Blood Pressure Telemonitoring with Medication Therapy Management (MTM) Pharmacists

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Availability of supporting data:

The datasets used during the current study are available from the corresponding author on reasonable request.

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Abstract

Objectives: The Hyperlink trial tested a 12-month intervention of home blood pressure (BP) telemonitoring with pharmacist case management in adults with uncontrolled hypertension. The intervention resulted in improved BP control compared with usual care at both 6 (72% vs. 45%, P < 0.001) and 12 months (71% vs. 53%, P=.005). We sought to investigate factors contributing to intervention success.

Design: Mixed-methods analysis of process of care data, patient focus groups, and pharmacist interviews.

Setting and Participants: Data from 228 intervention patients were examined from the original 450 patients randomly assigned from 16 primary care clinics. Five patient focus groups and 4 pharmacist interviews were conducted to ascertain the patient and pharmacist perspective. Focus group and interview data were coded, and themes relevant to pharmacists were identified.

Outcome measures: Home BP readings of <135/85 mmHg and patient focus group and pharmacist interview themes.

Results: Mean BP at the intake visit was 148/85 mmHg. Antihypertensive medications were adjusted in 10% of patients at the initial in-person visit, 33% at phone visit 1, 36% at phone visit 2, and 19% at phone visit 3. Thereafter, medication changes declined. The mean home BP for patients at the first phone visit was 136/80 mmHg, 126/74 mmHg at 3 months, and 123/73 mmHg at 5 months, with little change thereafter. Key components of success from patient and pharmacist

interviews included a strong patient/pharmacist relationship, individualized treatment plans, and frequent phone contact with the pharmacist.

Conclusion: Frequent adjustments to the antihypertensive treatment regimen based on home BP telemonitoring resulted in rapid lowering of BP. Our results suggest that an intensive phone-based intervention with the key components of medication adjustments, a strong patient and pharmacist relationship, and individualized treatment plans can achieve BP control in only 3 months in many patients with uncontrolled hypertension.

Trial registration: https://www.ClinicalTrials.gov . Registered 28 October 2008.

Background

Strong evidence supports the effectiveness of team-based care for chronic conditions like hypertension, especially when pharmacists or nurses are added to the primary care team and are able to make independent medication management decisions. Based on this evidence, newly updated 2017 U.S. hypertension guidelines recommend structured team-based care including other health professionals as part of multifaceted approach to improving the quality of hypertension care. The clinical pharmacist role focuses on patient education and comprehensive medication management, including identifying medication-related problems and initiating, modifying, and discontinuing medication. However, few studies have examined the detailed process of care by which expanded team care including a pharmacist achieves better results.

Good evidence from a systematic review and meta-analysis also supports the effectiveness of home blood pressure (BP) monitoring when combined with additional patient support.³ Trials of home BP monitoring alone had minimal effect on blood pressure compared to usual care, while trials that included nurse- or pharmacist-led interventions like lifestyle counseling and systematic medication titration lowered systolic BP (SBP) by an average of 6 mm Hg and more than doubled the probability of BP control at 12 months. Telehealth strategies were recommended by the 2017 guideline to improve BP control with moderate strength, based on several randomized controlled trials.² Telemonitoring is a telehealth method that uses wireless technology to transmit BP measurements from devices in patients' homes and communities to storage points where they can be analyzed and acted upon by clinicians.

The Hyperlink trial tested a 12-month intervention in 16 primary care clinics combining home BP telemonitoring with pharmacist case management in patients with uncontrolled hypertension. 4,5 The intervention resulted in improved BP control compared with usual care at both 6 (72% vs. 45%, P< 0.001) and 12 months (71% vs. 53%, P=.005), and higher BP control continued at 18 months (72% vs. 57%, P= 0.003). At 6 months, the difference in lowering of SBP between the intervention and usual care groups was 11.3 mm Hg, with 2 main mediating factors: an increase in medication treatment intensity (explained 24% of intervention effect) and increase in home BP monitor use (explained 19% of intervention effect). Although self-reported medication adherence and salt intake improved more in the telemonitoring intervention (TI) group than in the usual care (UC) group, we did not find these factors to be significant mediators of the intervention effect. To shed further light on

understanding the critical factors for success in achieving BP goal, this paper presents results from analyzing the care process used by the pharmacists in the intervention clinics, the time course of BP lowering and medication adjustments, and key components of success from the patient and pharmacist perspective.⁷

Methods

Study Design

The study was a 2-arm cluster randomized clinical trial conducted at HealthPartners Medical Group, a multispecialty practice in the Minneapolis-St. Paul metropolitan area that is part of an integrated health system.⁴ All participants provided informed consent, and the study protocol was approved by the HealthPartners Institutional Review Board.

Study Subjects and Study Sites:

We used electronic data to identify and contact by mail and telephone 14,692 adult patients who had BP 140/90 mm Hg at the 2 most recent primary care encounters in the previous year. Study participants were further required to have uncontrolled BP (140/90 mm Hg or 130/80 mm Hg if diabetes or kidney disease was present) based on the average of 3 automated measurements taken using a standardized protocol in the research clinic. Medical exclusion criteria included stage 4 or 5 kidney disease or albumin-creatinine ratio >700 mg/g creatinine; acute coronary syndrome, coronary revascularization, or stroke within past 3 months; known secondary causes of hypertension; pregnancy; class III or IV New York Heart Association heart failure, or known left ventricular ejection fraction <30%. Of 2,020 patients who were screened for the study, 450 were eligible and agreed to participate.

Of 21 HealthPartners primary care clinics in 2009, 16 had a medication therapy management (MTM) pharmacist onsite at least once weekly. At these clinics, a collaborative practice agreement between pharmacists and primary care physicians allowed pharmacists to prescribe and change antihypertensive therapy within specified parameters. The 16 study clinics were randomly assigned to either the TI (n = 8) or UC (n = 8) group. Four MTM pharmacists worked in TI clinics. Patients were linked to their clinic by self-report and assigned a treatment accordingly. All consenting patients were blinded before randomization but were informed of their treatment assignment post-randomization.

Intervention Strategy

Intervention patients received home monitors (A&D Medical 767PC® automated oscillometric BP monitor, San Jose, CA) that stored and transmitted BP data to a secure website via modem (AMC Health, New York, NY). Pharmacists met with patients for a 1-hour in-person visit within 2 weeks of the baseline research clinic visit, during which they reviewed the patient's relevant history, covered general teaching points about hypertension, and instructed them on using the home BP telemonitor system and the individualized home BP goal (ie, <135/85 mm Hg or <125/75 mm Hg for patients with diabetes or kidney disease). 9,10 Patients were instructed to transmit at least 6 BP measurements weekly (3 in the morning and 3 in the evening).

The intervention group patients used a home BP telemonitor to transmit BP readings to a study pharmacist, who consulted with them over the phone every 2 to 4 weeks during the first 6 months and at 2-month intervals thereafter. They adjusted antihypertensive therapy using a guideline-based treatment algorithm to reach a BP goal of <135/85 mm Hg (<125/75 mm Hg for patients with diabetes or kidney disease).

During the first 6 months of the intervention, patients and pharmacists met every 2 weeks via phone until BP control was sustained for 6 weeks, then the frequency was reduced to monthly. During intervention months 7–12, phone visits took place every 2 months. Thus, there was 1 mandatory in-person visit and 9 mandatory telephone visits. After 12 months, patients returned the telemonitors and received no further pharmacist support through the study. A previous analysis found that patients sent at least 6 BP measurements per week 73% of the time during the first 6 months of the intervention and that 88% of expected phone visits were conducted. 11

During phone visits, pharmacists emphasized lifestyle changes and medication adherence. They assessed and adjusted antihypertensive drug therapy based on an algorithm using the percentage of home BP readings meeting goal. 4.5 If at least 75% of readings since the last visit met BP goal, no medication changes were generally suggested. If less than 75% of readings met goal, the algorithm recommended treatment intensification according to recommended treatment guidelines. Regardless of BP control, if patients experienced adverse effects, the drug dosage could be lowered or the drug changed. Pharmacists communicated with patients' primary care teams through the electronic medical record following each visit. During the study period, UC patients worked with their primary care physicians as usual. This could include referral to an MTM pharmacist for consultation (1 or 2 visits without telephone follow-up or prolonged monitoring) and conventional home BP measurement.

Quantitative Analysis

Baseline characteristics were gathered through measurements (weight, BP) and a survey at the baseline research clinic visit. Participants were asked to bring all medications to the visit, where antihypertensive medication names, class, dose, and frequency of administration were recorded. All measurements were repeated at the 6-month and 12-month research clinic visits.

All post-based quantitative data are based on the 224 patients of 228 in the TI group who had an in-person intake visit with the MTM pharmacist. The percentage of patients having 75% or more of their home BPs at goal as determined by the MTM pharmacists' review of home BPs was plotted for each phone visit. The percentage of patients having an antihypertensive medication adjustment made by the MTM pharmacist at each visit and the mean number of antihypertensive medication classes at the end of each MTM pharmacist visit was plotted. We also report the percentage of patients at each MTM pharmacist visit who were classified as having >80% adherence to all of their antihypertensive medications as determined by the pharmacist. Pharmacists assessed medication adherence based on patient self-report and review of a pharmacy claims database (when available). All analyses were conducted in SAS 9.4 (SAS Institute, Cary, NC).

SBP and diastolic BP (DBP) at the in-person MTM pharmacist visit was based on the mean of 3 BP measurements. For all later phone visits, the pharmacist was able to view all available home BP measurements for the patient on a website. The website included tabular and graphical displays and summary measures (mean SBP and DBP, home BP goal, and proportion of BP readings below the individual goal.) Pharmacists used the latter summary measure to code patients as having <75% or >=75% of home BPs at goal. MTM pharmacists typically viewed the previous 2 weeks of home BP data before a phone visit, and were notified between visits by email if BP was significantly elevated as determined by pre-set safety alerts.

At each visit, the MTM pharmacist recorded the specific antihypertensive drug classes and count of classes the patient was taking at the start of the visit and updated the medication list if changes were made during the visit. In addition, a patient was coded as having a treatment intensification at a specific MTM pharmacist visit when the pharmacist indicated adding or increasing an antihypertensive medication.

Qualitative methods:

We designed patient focus groups aimed at learning about patients' experiences with and treatment for high BP during the intervention. Participants were eligible after they completed their 54-month outcome research clinic visit and indicated they would be interested in participating in a focus group. Five patient focus groups were held with TI group patients, stratified by whether BP was controlled, uncontrolled, or intermittently controlled at each follow-up time point. A total of 23 patients were included, with 2–7 patients attending each focus group. The focus groups were held between December 2014 and December 2015 in the research clinic. Groups were facilitated by the study project manager, with support and note-taking by a clinic research coordinator. The topics included perceptions of and experience with high BP, medications and side effects, home BP monitoring, and the relationship with the pharmacist and care team. Focus groups were approximately 90 minutes long and were recorded and transcribed verbatim.

We also conducted 4 semi-structured interviews with pharmacists between May and August 2015 to understand their clinical perspective of the intervention. Interview topics included how pharmacists explained their role to patients, interactions with physicians, patient-pharmacist relationship, and conversations with patients about medications and side effects related to high BP. Two interviews were conducted in the pharmacists' clinic office, and 2 were done via phone because the pharmacists were no longer working for the organization. Interviews were approximately 1 hour long and were recorded and transcribed verbatim. This mixed-methods paper includes themes relevant to the pharmacist from our focus groups and pharmacist interviews.

Focus group and structured interview data were analyzed by 5 research staff using grounded theory, and coding was validated by 2 research staff applying codes to the data. Initial themes were identified and coded in NVivo10. 12-14

Results

Quantitative Results

The characteristics of the study population and main results have been published elsewhere.⁵ Briefly, the study population (n=450) had a mean age of 61 years, was 45% female and 82% non-Hispanic white, and was well-educated (48% college graduates). Comorbid conditions were common: 54% were obese; 10% had previous cardiovascular disease; 19% had diabetes; and 19% had chronic kidney disease. The BP at enrollment was 148/85 mm Hg, and the mean number of antihypertensive medication classes was 1.7. The characteristics of the study population were well-balanced between the TI and UC groups.

Among intervention group patients, home SBP declined from 143 to 122 mm Hg, and DBP declined from 85 to 72 mm Hg over the active study intervention period of 12 months, with the steepest drop over the first 3 months (Figure 1). The proportion of participants with >75% home BP at goal (the cut point for not routinely recommending additional therapy changes) increased from 13% at 1 month and plateaued at 45% to 55% starting at month 3 (Figure 2).

Pharmacists intensified pharmacologic treatment in 10% of participants at the in-person intake visit, 33% at the first telephone visit, 36% at the second telephone visit, 19% at the third telephone visit, and 11% at the fourth telephone visit at month 3 (Figure 3). During the same period, end-of-visit antihypertensive medication number increased from 1.9 to 2.4. Thereafter, medication intensification decreased, and the number of medications reached a steady state at 2.5 by 6 months (Figure 3). The pharmacists' assessment of patient adherence to antihypertensive medications (defined as 80% adherence to all antihypertensive medications) was 49% at the intake visit and 91% at the first telephone visit. Thereafter, the proportion adherent remained >90% (range, 93% to 99%) for the remainder of the intervention period.

Qualitative Results

We identified several themes among patients and pharmacists from our qualitative data which are outlined in table 1.

- 1-Patients expressed the importance of the relationship with the pharmacist. For some patients, this developed over time, with initial hesitation by patients that improved with repeated contact with the pharmacist. The home telemonitoring device was a tool for communication, as frequent BP readings by patients combined with phone calls back to the patient by the pharmacist provided the context for patients to understand the need for medication changes and work together toward a treatment goal. Patients found the frequent contact with the pharmacist supportive and helpful.
- 2-Patients and pharmacists expressed the importance of an <u>individual treatment plan to</u> <u>overcome reluctance to start or add medication</u>. We repeatedly heard patients describe the process of finding a unique treatment plan that was "right for them." Frequent contact with the pharmacist seemed to help facilitate "finding the right one" with respect to medication regimen. Pharmacists highlighted this aspect of treatment as well and, at times, needed to

slow down or stop treatment intensification to fit individual needs, preferences, or safety concerns.

3. <u>Communication among clinical staff</u> was important to patients. Patients expressed the importance of their doctor being aware of the medication changes made by the pharmacist. Not all patients felt that their doctor was aware that they were involved in the hypertension program, and this bothered some patients. There were varying levels of collaboration among physicians with the hypertension program. Although the vast majority of doctors were collaborative with the pharmacist protocol, a minority were not, creating some tension, which was expressed by the pharmacists. Collaboration with physicians improved over time as physicians became more comfortable with MTM pharmacists managing hypertension.

4. The importance of having <u>frequent phone contact with the pharmacist</u>. Patients found it helpful to have frequent and immediate feedback from the pharmacist based on their home BP readings, in contrast to long intervals between visits with physicians. They appreciated the time the pharmacist spent with them to reach a shared goal and the ability to access the pharmacist if they had medication questions.

Discussion:

In summary, the intervention was accompanied by a rapid drop in BP during the first 3 months, with little additional decline thereafter. Most of the medication adjustments occurred during the first 2 months, and pharmacists' assessment of adherence was high after the initial in-person visit. Our results are consistent with previous studies showing improved BP control and more rapid time to achieving goal in team-based care involving pharmacists. 15–20

This study adds to the literature by highlighting specific components of care that lead to success in quickly reaching BP goal for most patients. Key factors include frequent home BP monitoring, regular contact with a pharmacist, and serial medication adjustments that resulted in additional antihypertensive medications.

The qualitative work further delineates aspects of the intervention that were helpful from a patient and pharmacist perspective. Namely, we found that both patients and pharmacists valued a strong patient-pharmacist relationship. Other studies have confirmed that a strong patient-provider relationship improves patient satisfaction, understanding of their medical condition and shared decision making. Patients valued the additional attention they received from the pharmacists and felt accountable to the pharmacist for keeping up with their measurements and appointments. Home BP monitoring facilitated opportunities for regular communication and decision making between patients and pharmacist, allowing for frequent medication changes to occur based on real-time BP readings. Patients had ready access to the pharmacist which provided direct communication if a medication was causing side effects, with prompt changes in the treatment plan, if needed. This approach fostered an individualized treatment plan for each patient, a component both patients and pharmacists felt to be important in BP management.

Pharmacists and patients sometimes negotiated about the medication changes the patient was willing to try. Pharmacists were able to point out the consistency of high home BP readings as a reason to intensify treatment, and patients were often more willing to accept these recommendations than they would have been based on a single office BP reading. This sheds light on our observation that younger patients were more likely to benefit from the intervention than older patients, which we speculate may be because they are earlier in the process of accepting their hypertension diagnosis.²⁷

We learned some valuable information from the patient focus groups about how to improve the intervention. Some patients were unfamiliar with the qualifications of the pharmacists to adjust medication. While patients came to value the pharmacist as a member of their care team, they felt it important that their care was well-coordinated between different members of the team. Patients wanted their primary physician to be aware of any recommended medication changes by the pharmacist. The visit note from each patient-pharmacist interaction was electronically sent to the primary physician; however, due to the high volume of electronic messages physicians receive each day, these notes were often overlooked, compromising the goal of keeping the physician informed.

These lessons have been incorporated into an updated intervention that is being tested in an ongoing pragmatic trial funded by the Patient-Centered Outcomes Research Institute (IHS-1507–31146). In this trial, the primary care physician is prompted to sign the referral to the MTM pharmacist for home blood pressure management and discuss the reason for the referral with the patient. We hope that this will result in more engagement by the clinicians. Additionally, home blood pressure readings will be available in the electronic health record for physicians to review if desired.

Limitations

Several limitations should be kept in mind when interpreting the study results. This study was done in a large health care system in Minnesota that utilizes a single electronic health record; therefore, the findings may not be generalizable to other types of health care settings. The 450 study participants were from a much larger group of 14,692 potentially eligible patients. They were probably more likely to be motivated to control their BP and adhere to the interventions than a less selected group. Additionally, important groups such as the uninsured and minority populations were under-represented in our study. The BP reductions between the first and second points shown in Figure 1 may be exaggerated due to the tendency for home BP to be lower than BP measured during the in-person clinic visit with the pharmacist. Medication adherence was estimated by pharmacists in most cases, and our previous analyses do not support improved medication adherence as a major component of intervention effectiveness in this group of insured patients.²⁸

Conclusions

We found rapid improvement in BP during the first 3 months of a pharmacist-led telemonitoring intervention. Tailored adjustments to the antihypertension treatment regimen with frequent patient contact were key contributing factors in reaching BP goal quickly.

Therefore, an intensive intervention of this type can achieve BP goal within 3 months in many patients with uncontrolled hypertension and should be strongly considered for health systems working to improve BP control.

As we embrace and strengthen team care for patients with chronic disease, it is important to incorporate personalized care that includes trusting relationships, mutual goals and individualized treatment. This is no small task in our fragmented health care system, yet one that both patients and pharmacists found valuable and necessary to reach the mutual health goal. Since this includes frequent contact and readily available access, we need to continue to build these components into our team based care models. This information should be helpful to care systems and payers considering whether to adopt similar interventions.

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Abbreviations:

TI telemonitoring intervention

UC usual care

BP blood pressure

SBP systolic blood pressure

DBP diastolic blood pressure

MTM medication therapy management

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Key points:

Background

 Strong evidence supports the effectiveness of team-based care for chronic conditions like hypertension

 Previous Hyperlink trial demonstrated improved BP control using home telemonitoring and pharmacist case management

Findings:

- BP control was achieved in 3 months in many patients
- Key components of intervention success were use of home monitor and frequent medication changes over the phone
- Patients and pharmacists valued strong patient/pharmacist relationship and individualized treatment plans

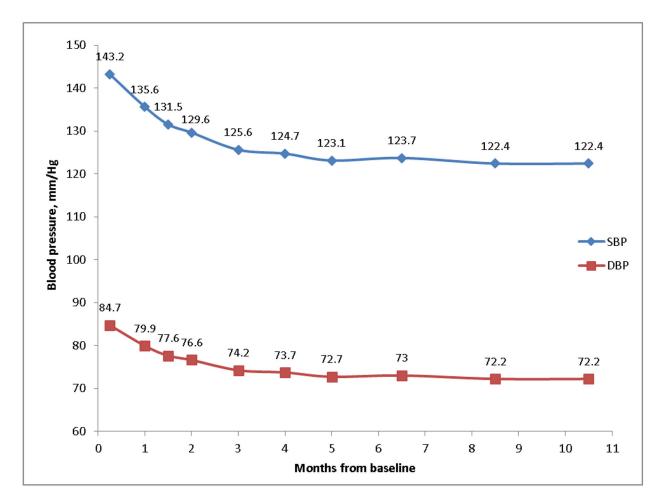


Figure 1. Mean home systolic and diastolic blood pressure

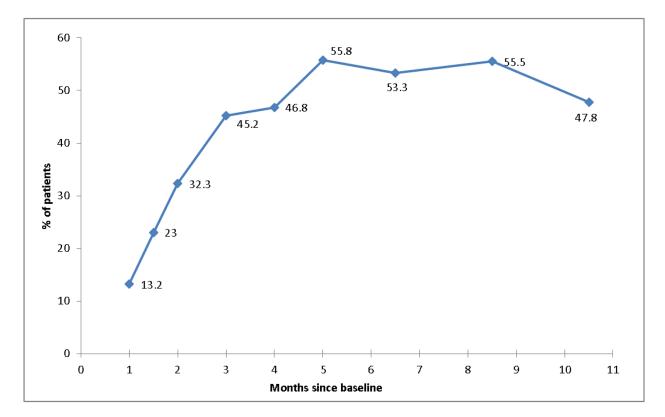


Figure 2. Percentage of patients having >75% of home blood pressure measurements at goal.

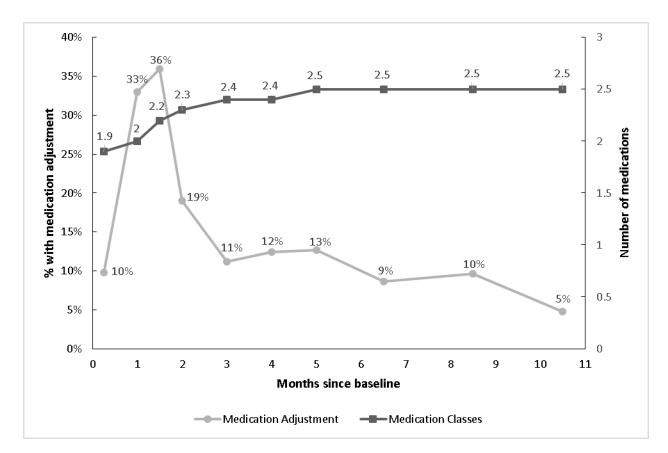


Figure 3.Mean number of antihypertensive medication classes and percentage of patients having a medication adjustment made by the medication therapy management pharmacist.

 Table 1.

 Themes and examples from patient focus groups and pharmacist interviews

Theme	Examples
Relationship between patient and pharmacist	(patient) "I was taken aback when I first signed up and got into the study and found out I was working with a pharmacist instead of a doctor. 'What does he know about high blood pressure?' Obviously, he knows a heck of a lot, but that was what occurred to me. This is a pill roller." (patient) "She gave me the confidence. She took away that 'It's all my fault, no matter what I do. It's my fault.' She changed the 'It's my fault' to 'You may have so your father, your grandfather, your great grandfather, all your relatives. Okay, we are talking about you, and we can do something to help'." (patient) "It was supportive for me, not fear, really. I just didn't want to be wasting his time. So whatever I had, I wanted to have something to report, which would help the study and help mehaving the opportunity to speak with a pharmacist on a regular basis felt kind of specialI was getting special attention from the pharmacist rather than just meeting for 15 minutes with my doctor and going back home again. That was very positive." (pharmacist) "I think it just went back to the relationship I had developed with them that made them trust me as a practitioner and be willing to take those recommendations." (pharmacist) "they have one little reading when they go into the office, and that maybe they just ran in there, and that can be really frustrating. I was like, 'I don't feel like that's even accurate, and now I'm getting treated because of this random reading.' I think it gets them on board like, 'Hey, your blood pressure really is high. It's not just a today thing, because look, you've been checking it for a week.' And so, if anything, it made it easier to put people on meds."
Individual treatment plan	(patient) "Got switched medications, I think, about 2 times, and then we finally got it to one that really worked." (patient) "I had never been on any kind of medication at all. Always been very healthy. So that was a kind of shock. I don't want to have to take blood pressure medicine. I really didn't like it at all. I was feeling down about it, but it did the job, except for the amlodipine, which I had to get out of, and that's where Ryan was helpful. He said, 'Okay, well that didn't work, let's try you on something else'." (patient) "I wasn't very happy about it. She asked me to take 2. I said, 'No, I'm not taking 2.' She said, 'Okay. Well let's start with one and a half'. So I did. As I started taking it and it was getting in my system, things started changing for me." (pharmacist) "They need that close monitoring. They need someone to ask questions to who can really take the time and listen to them and really work with them to modify the regimen that suits them best, considering all those different factors that we've mentioned that may prevent the patient from being successful, and really working with them and understanding what's going on to help them achieve those goals."
Communication between clinical staff	(patient) "I don't know. I just enjoyed being in the study. I enjoyed doing the – being forced to take my blood pressure, because now, I've fallen back, and maybe I don't even do it maybe every couple of weeks checking. I know I should do it more than that. It was satisfying to have that. Actually, what I was doing seemed to make a difference with the help of the Hyperlink study. I'd meet over the phone with the pharmacist. Kind of interesting – my pharmacist and my doctor had little bit of this, because the doctor was – he was saying, 'Well, am I taking care of your blood pressure, or is the pharmacist?" He wasn't even aware that I was part of this study, which might be a little bit of a weakness. My family practice guy probably should have heard about it." (pharmacist) "I think the vast majority [of physicians] appreciate it [role pharmacists play in caring for patients with hypertension], because it takes away a lot of their day-to-day minutiae work. There's a handful that like to be in total control, and that's not going to change. But I think we've been around long enough and hopefully have demonstrated our abilities to improve care that they're comfortable with it. That's the impression I get anyway."
Importance of frequent phone contact with pharmacist	(patient) " It was just that tweak here and tweak there on that medication. It made a difference, and it was with the pharmacist. Now, my doctor was fine, and I would make regular visits to her. But that pharmacist could see and take the time to look at all the readings. So it does. For me, it made the biggest difference in the whole world." (patient) "Yeah. Like I said, she called me every week. She had the number of my cell phone. I'd be at work or whatever, she'd call me. 'How's things going? Everything working out good and stuff?' Like I said, whenever I'd send the readings, she would look at them, then call me right away. 'Hey, I looked at them; everything looked good'." "Like I said, the couple of adjustments that she made and then the communication back and forth between us, I think it helped a lot. It really did, because I went through a handful of years with my doctor just, 'Try this, come back in 6 months,' whereas she stayed on it. Like I said, for years, I haven't had to change my medication, and that's a good thing." (patient) "It was that being part of the program and knowing that I would be speaking with a pharmacist. She encouraged me to be more mindful of the issue of taking the medication, whatever stage we were in, or a particular medicine to do it and not forget about it." (pharmacist)"I think what helped the most was just the instant feedback that they get. The numbers that they get on a 3-times-a-week basis, either now that something was working or something wasn't working, and then that helps them realize that it is a problem, or something else needs to be done."