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Electronic Communications and Home Blood Pressure Monitoring (e-BP) study: Design, delivery, and evaluation framework

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Abstract

Background—Randomized controlled trials have provided unequivocal evidence that treatment of hypertension decreases mortality and major disability from cardiovascular disease; however, blood pressure remains inadequately treated in most affected individuals. This large gap continues despite the facts that more than 90% of adults with hypertension have health insurance, and hypertension is the leading cause of visits to the doctor. New approaches are needed to improve hypertension care.

Objectives—The Electronic Communications and Home Blood Pressure Monitoring (e-BP) study is a three-arm randomized controlled trial designed to determine whether care based on the Chronic Care Model and delivered over the Internet improves hypertension care. The primary study outcomes are systolic, diastolic, and blood pressure control; secondary outcomes are medication adherence, patient self-efficacy, satisfaction and quality of life, and healthcare utilization and costs.

Methods—Hypertensive patients receiving care at Group Health medical centers are eligible if they have uncontrolled blood pressure on two screening visits and access to the Web and an e-mail address. Study participants are randomly assigned to three intervention groups: (a) usual care; (b) home blood pressure monitoring receipt and proficiency training on its use and the Group Health secure patient website (with secure e-mail access to their healthcare provider, access to a shared medical record, prescription refill and other services); or (c) this plus pharmacist care management (collaborative care management between the patient, the pharmacist, and the patient's physician via a secure patient website and the electronic medical record).

Conclusion—We will determine whether a new model of patient-centered care that leverages Web communications, self-monitoring, and collaborative care management improves hypertension control. If this model proves successful and cost-effective, similar interventions could be used to improve the care of large numbers of patients with uncontrolled hypertension.

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1. Introduction

Hypertension is one of the leading causes of death worldwide [1]. In the United States about 65 million Americans, almost one in three adults, have hypertension, defined as a sustained blood pressure of $\geq 140/90$ mm Hg [2,3]. Randomized controlled trials have provided unequivocal evidence that lowering blood pressure with antihypertensive medications decreases mortality and major disability from cardiovascular and renal disease; however, hypertension remains inadequately treated in most affected individuals [4–7]. This large gap continues despite the facts that more than 90% of adults with hypertension have health insurance [8], and hypertension is the leading cause of visits to the doctor [9]. If blood pressure control could be improved, cardiovascular morbidity and mortality would decrease significantly.

Traditional medical care focuses on one-on-one doctor/patient interactions at a medical center visit, missing many opportunities to influence patient care positively. Only 20% of patients' healthcare occurs in the office; the other 80% is performed at home and is based on the patients' knowledge, beliefs, and attitudes [10]. Self-management refers to the patient's ability to manage symptoms, treatment, lifestyle, and psychosocial changes related to the care of an ongoing medical condition. Self-management support comprises the information, tools, and skills patients receive from healthcare professionals to assist them in the self-care of their chronic condition. Bodenheimer describes self-management and self-management support as collaborative, with healthcare professionals as experts on disease and patients as experts on their lives [11]. Lorig et al. recently demonstrated that a chronic disease self-management support program could be successfully delivered over the Web [12,13]. Self-management support appears to be particularly effective when it is systematically integrated into clinical care [14,15]. Care or case management is of particular interest, because it provides assistance to patients in the self-management of their chronic conditions and planned proactive and reactive care with the goal of improving intermediate and long-term disease outcomes. Self-management support and care management interventions have been delivered successfully to improve clinical outcomes for patients with coronary artery disease [16,17], asthma and chronic obstructive pulmonary disease (COPD) [18,19], diabetes [20–22], congestive heart failure [23,24], arthritis [25], and other chronic diseases [26]. The benefits of self-management (including self-monitoring of blood pressure) and self-management support have been less certain for hypertension [27]. In a recent meta-analysis by Walsh et al., the largest improvement in hypertension control came from adding a healthcare team member other than a physician, e.g., a nurse or pharmacist, to focus on hypertension care [28].

Wagner, Austin, and Von Korff developed the Chronic Care Model [29] at Group Health Cooperative as a guide to improving care of chronic illness (Fig. 1). The model predicts that improvement in its six interrelated components—self-management support, clinical information systems, delivery system redesign, decision support, healthcare organization, and community resources—can produce system reform in which informed, activated patients interact collaboratively with prepared practice teams. The Chronic Care Model has been implemented in multiple health settings and has led to improved clinical outcomes related to chronic illness [29–31], but it has not yet been applied to the care of hypertension.

We describe here the Electronic Communications and Home Blood Pressure Monitoring (e-BP) study, a three-arm randomized controlled trial that uses the Chronic Care Model for planning. We hypothesize that blood pressure will be lower for patients with uncontrolled hypertension who receive a self-management intervention—including receiving a home blood pressure monitor and proficiency training on using both it and a secure patient website that includes e-mail, medication refills, and other self-care tools—than for those receiving usual care. We also hypothesize that the blood pressure of patients with uncontrolled hypertension

who receive a self-management intervention as above plus ongoing care management from a clinical pharmacist that includes ongoing iterative patient-centered care with collaborative decision making and goal setting via a secure patient website and in parallel with care processes and communications to the patient's physician via the electronic medical record—will have better blood pressure control than usual care. If these interventions are successful, we will determine the differential cost-effectiveness of each. To our knowledge, this is also the first study that uses a healthcare organization's patient website site to assist patients with self-management and care-management of their hypertension. This is also the first study we know of to use the Chronic Care Model to plan implementation strategies to improve hypertension control.

2. Trial design and methods

2.1. Overview

The e-BP study is a three-arm randomized controlled trial comparing two interventions to improve hypertension control to usual care (Fig. 2). Group 1 participants receive usual care (UC), which at Group Health includes access to secure Web services (with a shared medical record between patients and providers, secure e-mail, medication refill and appointment services, laboratory and test results, a health library, and links to healthcare organization and community resources). Group 2 (BPM-I) participants additionally receive a home blood pressure monitor, a proficiency training session on using it, and a proficiency training session on Web-based services. Group 3 (BPM-I + Pharm) participants receive all of the above plus collaborative care management support provided by clinical pharmacists via the Web. The specific aims of this study are to assess the above interventions on the following: (a) change in diastolic, systolic, and the mean diastolic and systolic blood pressure; and (b) proportion of patients with adequately controlled blood pressure (defined as a mean of ≤ 140 mm Hg systolic and ≤ 90 mm Hg diastolic blood pressure at the one-year follow-up visit). Secondary aims include assessing intervention effects on medication adherence, quality of life and patient satisfaction, patient self-efficacy, utilization, and costs of care.

2.2. Study setting

The study setting is Group Health, a large nonprofit integrated delivery system that provides both medical coverage and care to more than 520,000 residents of Washington State and Idaho. This study is being conducted at 10 Group Health–owned primary care medical centers in the Puget Sound Region. Family practitioners (90%) and internists (10%), over 95% of whom are certified by their respective boards, provide primary care for adults. Each full-time physician cares for a defined panel of 2100 patients on average. Medical centers are divided into teams, which consist of three to four physicians, registered nurses (RNs), licensed practical nurses (LPNs), medical assistants, and a physician assistant or nurse practitioner in some instances. Almost all patients age 65 and older are Medicare patients, while most patients under age 65 are in commercial plans. About 3% are on Medicaid, and 4% are in the Basic Health Plan (health insurance subsidized by Washington State). The Group Health institutional review board (IRB) approved the study, and a Data Safety Monitoring Board (DSMB) was appointed to review study procedures and adverse events.

2.3. Initial inclusion and exclusionary criteria

Potential subjects aged 25–75 and continuously enrolled in Group Health for at least one year are identified through administrative data sources. They must not only have a diagnosis of hypertension through an outpatient diagnostic code but also be currently taking antihypertensive medications. Automated data are also used to exclude patients who have heart disease (ischemic or valvular heart disease or arrhythmias), diabetes, renal failure, dementia, serious psychiatric disorders (e.g., schizophrenia), treatment with chemotherapeutic,

immunosuppressant, or antiretroviral agents, or hospitalization within three months. We exclude these groups because participants randomized to the pharmacist intervention would receive hypertension care using specific medication protocols that did not factor in more complicated decision-making that might be required for elderly patients, those with serious comorbidities or needing cardiovascular medications for other reasons. At Group Health, approximately 14,000 patients met the initial criteria for eligibility.

2.4. Recruitment

Fig 2 depicts recruitment and study flow. Those eligible based on automated data are sent recruitment letters to introduce the study. The research assistants then call potential participants to confirm eligibility, including the ability to use a computer in English, regular access to the Web, an e-mail address, and medication coverage that lets them refill prescriptions at Group Health (most Group Health patients have all these). Those pregnant or planning either to move away from the area or to change health plans in the next 12 months are excluded. Those eligible and willing to be screened further are given an appointment to see a research specialist at their medical center.

At the first of two screening visits, participants give informed consent to have their blood pressure, weight, and height measured and are signed up for secure access to the Group Health patient website (MyGroupHealth) if they have not already done so. Arm size is measured for the appropriate cuff size; those whose arms exceed the limits for the largest cuff size are excluded. Blood pressure measurements are taken using a validated Omron Hem-705CP oscillometric automated manometer (“A/A” performance classification under the British Hypertension Society criteria and passed the Association for the Advancement of Medical Instrumentation) [32,33]. The first blood pressure reading is thrown out and two more readings are taken. If the average diastolic blood pressure is 90–109 mm Hg and the systolic blood pressure is 140–199 mm Hg, the participant is eligible for a second screening visit. Recruits whose diastolic blood pressure is ≥ 110 mm Hg or systolic blood pressure is ≥ 200 mm Hg are not eligible for the study, and study staff arrange follow-up care. At the second screening visit, blood pressure measurements are repeated as above. Patients whose diastolic blood pressure is 90–109 mm Hg and systolic blood pressure is 140–199 mm Hg at both visits are eligible for the study and if willing are asked to give informed consent to do so. At the end of both visits 1 and 2, all participants receive a \$10 gift card to thank them for their time and participation.

2.5. Random assignment

We use a block randomization design to ensure balance within centers and baseline systolic blood pressure measurements. First, we stratify participants into two groups: baseline systolic blood pressure ≥ 160 mm Hg and < 160 mm Hg. Within these two groups, we randomly assign sequential blocks of three, six, or nine to the three intervention groups. Each study coordinator at a given centre is provided packets of nine envelopes from each of the two systolic blood pressure groups and told to take the first envelope from the top of the given blood pressure group to balance intervention assignment within centre and blood pressure groups.

After the envelopes are opened, a two-step process is used to determine random assignment to intervention groups. The first occurs after consent is signed: The research specialist opens an opaque envelope with the pre-assigned random number showing designation into one of two groups: group 1 (usual care); or a combination of groups 2 and 3. Group 1 [usual care (UC)] patients receive instructions about their blood pressure as described below. Groups 2 and 3 receive training in home blood pressure monitoring and Web communication. Following the training, a second opaque envelope is opened, and they are randomly assigned to be in either Group 2 [home blood pressure monitoring and Web self-management support (BPM-I)] or Group 3 [home blood pressure monitoring, Web self-management support, and pharmaceutical

care (BPM-I + Pharm)]. This two-step process was chosen to ensure equal level of training of the home blood pressure monitor and Web between the two intervention groups 2 and 3. All enrolled and randomly assigned participants are followed for a total of 12 months and upon completion of study interventions return for a third follow-up visit.

2.6. Interventions

Table 1 lists the intervention components according to the Chronic Care Model. A description follows, detailing how these are applied to each intervention arm.

2.6.1. Group 1 interventions: Usual care—We call group 1 (UC) an intervention group because Group Health already routinely uses some of the Chronic Care Model components that can potentially be brought to bear on hypertension (Table 1):

1. **Decision support:** Group Health has a hypertension committee, and guidelines (similar to JNC7 but adapted to local processes) are available on Group Health's intranet (internal website), InContext. These guidelines provide clinicians with specific decision support related to the diagnosis and treatment of hypertension, including stepped-care medication recommendations and links to patient materials on lifestyle factors related to both blood pressure and cardiovascular disease and to resources within the organization and the community for managing these risk factors (e.g., smoking cessation and weight management programs).
2. **Clinical information systems:** Group Health has a comprehensive electronic medical record (Epic Systems Corporation's EpicCare®) for charting, ordering, reviewing results, and coordination of care; paper records are not used. Blood pressure is captured as a discrete variable, and values can be plotted on a graph over time. The electronic medical record has registries and alerts for patients with certain chronic conditions, including coronary artery disease, diabetes, and depression; so care teams can track evidence-based care events, e.g., receipt of specific medications and dates and results of recommended tests. No registry exists for patients with hypertension without other co-morbidities, but physicians, teams, or clinics can make their own patient lists if they desire.
3. **Delivery design:** Each medical center has its own pharmacy staffed by pharmacy technicians and clinical pharmacists. Clinical pharmacists assist practice teams in translating evidence-based recommendations for medication choices, coordination of care, and help with specific initiatives, e.g., intensifying lipid-lowering treatment or working with Medicare patients on issues related to polypharmacy and high-risk medications. Most Group Health patients have prescription medication coverage and are charged a co-pay for formulary-approved medications. Pharmaceutical care (provided by clinical pharmacists onsite or by telephone) has been successfully used to increase the use of statins and angiotensin-converting enzyme (ACE) inhibitors in patients with heart disease and diabetes, but has not yet been applied to the care of hypertension.
4. **Patient self-management support:** Patients who verify their identity and obtain a password have access to a shared, interactive, electronic medical record via a secure patient website (Fig. 3), MyGroupHealth. Patients can view their medical center visit diagnoses, vital signs (including blood pressure and weight with graphs of these over time), medications, allergies, immunizations, laboratory results, and visit-related patient instructions. They can refill medications, get them mailed to their home at no extra charge, and communicate with their healthcare team by secure e-mail. They also have access to an extensive health library and can find lists of resources provided by the health plan and the community related to self-management support and healthy

lifestyles services that may not be available in smaller health plans, including smoking cessation (the nationally recognized Free & Clear program, available to all patients as a covered benefit), self-referrals to see a registered dietician, and health education classes pertaining to a variety of health topics at medical center sites. Weight management programs are available, and patients can choose to participate in group classes or individual counseling at various sites or by telephone. Group Health also offers a senior fitness benefit for Medicare patients, Silver Sneakers, which provides free membership to exercise facilities and the Lifetime Fitness Health Program at community centers. Thus, Group Health already offers many tools to help patients in their own self-management; but physician and patient self-referral is dependent on the physician's mentioning the service or the patient's independent discovery.

5. **Healthcare organization:** Several factors influence hypertension care at Group Health. While Group Health covers all visits and services related to hypertension, co-pays are required for every visit, including nurse visits for blood pressure measurement. Most Medicare patients have partial or complete medication coverage; and most of those insured by commercial plans (employer contributed) also have coverage, but co-pays of \$10 to \$30 per monthly prescription generally apply. Group Health's hypertension care is also influenced by its private, nonprofit accreditation board, the National Committee for Quality Assurance (NCQA), which publishes measurements of quality and service known as the HEDIS[®] (Health Plan Employer Data and Information Set) score [34]. These measures are published publicly, can be used to compare health plans, and include a measure for hypertension: the proportion of patients with hypertension who achieved a blood pressure $\leq 140/90$ mm Hg. Group Health has put considerable effort in improving its HEDIS performance results (and improving the quality of care in general). Typical tools include automated reminds in the electronic medical record, outreach letters to patients, and additional personnel to support care of chronic conditions and screening. While some of these efforts influence hypertension care (such as reminders to check potassium for those on diuretics), care for hypertensive patients without other co-morbidities has not been specifically targeted
6. **Community resources:** Group Health keeps a list of available community resources on its website (<http://www.ghc.org/>) and publishes other events in its patients' news magazine *Northwest Health* (<http://www.ghc.org/features/index.jhtml>).

In summary, usual care for hypertension at Group Health already includes components of the six domains recommended in the Chronic Care Model. However, self-management tools, training, and skills needed for self-care of hypertension are provided passively (patients need to discover this on their own or with their physician's assistance). All consenting participants have access to the services for hypertension described above and also receive a blood pressure card with their measurements, the goal for medical center blood pressure measurement ($<140/90$ mm Hg), and the Group Health hypertension pamphlet. Group 1 (UC) participants are specifically informed that their blood pressure is not in control and that they should work with their physician and healthcare team to get it under control.

2.6.2. Groups 2 and 3 interventions: Home blood pressure monitoring and Web communications—Patients randomly assigned to groups 2 (BPM-I) and 3 (BPM-I + Pharm) receive all the materials given to group 1 (UC) and additional components of the Chronic Care Model (Table 1) using Group Health's integrated information systems. Groups 2 (BPM-I) and 3 (BPM-I + Pharm) patients also receive a self-management support intervention: a home blood pressure monitor and proficiency training on its use and Group Health's Web-based services. Group 3 patients (BPM-I + Pharm) receive all of this plus a collaborative care management support provided by clinical pharmacists via the Web.

Group 2 and 3 participants receive the validated Omron Hem-705CP [32] (with the cuff size based on their arm measurement) and proficiency training on its use (demonstrating they can use it without help). They are advised to check their blood pressure at least two days a week and record two measurements each time, based on evidence that eight recordings over two weeks is sufficient to calculate average blood pressure [35]. They also receive a pamphlet with written instructions on home blood pressure measurement and their home blood pressure goal: =135/85 mm Hg. Consensus has not yet been reached about which target home blood pressure number to use for decision making; but in several large clinical trials and a meta-analysis, a home blood pressure of 135/85 mm Hg was roughly equivalent to a clinic blood pressure of 140/90 mm Hg [36,37].

Participants in groups 2 and 3 also receive proficiency training in using the secure patient website, MyGroupHealth (Fig. 3) including: viewing their medical record (current medical conditions, medications, lab and test results, allergies, immunizations, and visit-related care instructions); refilling their medications; and viewing and sending secure e-mail messages. They also receive a quick tour of a few of the other resources available on the website, including the health library, Healthwise® Knowledgebase, and Group Health and community programs to help them with lifestyle changes (e.g., physical activity and weight management programs). Once training is complete, a second opaque envelope is opened and subjects are randomly assigned to groups 2 (BPM-I) and 3 (BPM-I + Pharm). Then Group 2 (BPM-I) patients are told that their blood pressure is not in control and to work with their physician and team to get it <140/90 mm Hg in the medical center and <135/85 mm Hg at home. Group 2 participants are encouraged to use home blood pressure monitoring and resources available on MyGroupHealth (secure messaging to their healthcare team, access to portions of their medical record, medication refill services, the Healthwise Knowledgebase, and links to community resources) as additional ways to improve their hypertension control.

2.6.3. Group 3 interventions: Home blood pressure monitoring, Web communications, the electronic medical record, and pharmacist care management—

Fig. 4 depicts pharmacist care management. In conjunction with a patient's primary care team, pharmacists use electronic messaging, the patient-shared medical record, and the office-based electronic medical record to support ongoing care between office visits.

Group 3 (BPM-I + Pharm) participants receive all the interventions described above. Additionally, they are informed that they have been assigned to receive care from a clinical pharmacist who will collaborate with them and their physician to improve their blood pressure control. A research specialist enters the participant's medical record number, blood pressure recordings, weight, and height into the Group Health Pharmacy Medication Use Management (MUM) database, alerting the pharmacists that they have a new patient. After notification, the clinical pharmacist sends the participant a secure e-mail welcoming message, introducing himself or herself and reiterating that the two of them will be working together with the physician (who is named) to improve blood pressure control. The clinical pharmacist asks the participant's preference for a time for the initial intake telephone call. The pharmacists also send a staff message informing the patient's physician that they will use Group Health's hypertension guideline (stepped medication protocol and other aspects of hypertension care) to improve the patient's blood pressure control and will work collaboratively with the patient and the physician to answer questions or clinical concerns. The pharmacist calls the patient and conducts an intake telephone interview. The pharmacist and patient review and confirm information already available on their electronic medical record, including the patient's diagnosis of hypertension, other chronic conditions, medication list, allergies, and most recent relevant laboratory tests. They also ask questions related to adherence with medications and current and past side effects from antihypertensive medications. They refer to the Group Health hypertension pamphlet and ask the patient to choose a lifestyle activity to work on (healthy

diet, reducing salt intake, reducing weight, increasing physical activity, moderating alcohol use, or tobacco cessation). The pharmacist then summarizes this information obtained and, with the patient's assistance, collaboratively creates an action plan. The action plan has been successfully used to plan self-management in Chronic Care Model interventions [38,39]. The action plan has five components: (a) instructions for monitoring blood pressure; (b) current medication list; (c) healthy-lifestyle choice behavior-change activity; (d) proposed changes to the action plan (e.g., increasing a medication dosage); and (e) plans for follow-up (needed laboratory tests and next communication). The pharmacist e-mails this plan to the patient, copying the physician. The action plan becomes the template for ongoing communication. Then, pharmacists encourage participants to communicate with them mainly by secure e-mail over MyGroupHealth; however, they also discuss their own availability by telephone and the availability of the patient's own physician for in-person visits if needed or preferred. The pharmacist makes medication changes based on treatment protocols; the pharmacists have formal prescriptive authority as approved by the state medical board to make guideline-based changes. The pharmacists have additional protocols for laboratory testing [including baseline electrocardiograms (EKGs)] and follow-up care. If any abnormality of clinical concern arises, the pharmacist notifies the physician and requests instructions for follow-up management. Pharmacists also make recommendations for aspirin use if five-year cardiovascular risk score is $\geq 5\%$ with no contraindications, and for lipid-lowering based on cardiovascular risk and fasting serum low-density lipoprotein (LDL) level [40,41].

Secure e-mail communication occurs every two weeks for the first two months or longer until blood pressure is controlled (defined as an average home blood pressure of $<135/85$ mm Hg). The pharmacist uses the action plan to document medication changes, laboratory orders, and the follow-up plan. The MUM database reminds the pharmacist when a contact by e-mail communication is due and when laboratory tests are abnormal or missed. Once home blood pressure is at goal or lower, pharmacists can decrease contacts to once a month for the third to sixth month and then every two months until the end of the intervention at one year. Pharmacists could also collaboratively decide with the patient and his or her physician to deviate from this schedule if required by individual circumstances. The pharmacist transfers care (in part or ongoing) to the patient's physician or a specialist when there is a clinical concern or a specific preference. Pharmacists track how much time they spend providing care for e-BP patients.

2.6.5. Clinical pharmacist training and monitoring—Three clinical pharmacists working at three different Group Health primary care medical centers were trained to participate in the e-BP study at two training sessions of three hours each. At the first training session, the pharmacists reviewed the e-BP study design and goals, the Group Health hypertension guidelines (similar to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure) [42], and an overview of the e-BP intervention. The second session included an interactive review of Group Health Web services and their use for the e-BP study, including the pharmacist MUM database, the electronic medical record (EpicCare®), adverse event procedures, and motivational interviewing training. The pharmacists already use MUM and Epic for their day-to-day work, so training was primarily related to using these tools for the e-BP study. The pharmacists received a manual of operations with all protocols related to pharmacy care including: medication treatment algorithms based on the Group Health guideline and JNC7; laboratory and EKG testing; a step-by-step guide for the telephone intake questions and making an action plan; and safety procedures and adverse event reporting instructions and forms. Pharmacists received training in using patient-centered approaches to behavior change, including general principles of motivational interviewing (express empathy, develop discrepancy, roll with resistance, and support self-efficacy), with specific examples related to medication adherence, side effect management, and health risk behavior [43]. Pharmacists role-played how to apply

these techniques in telephone interviews and electronic message contacts during the training before any actual contacts with study participants.

The pharmacists receive oversight from the Group Health director of clinical pharmacy services and the physician investigator who has expertise in hypertension care. The pharmacists can send secure e-mail messages to this physician anytime they have a clinical or study concern; however, pharmacists primarily communicate with patients' primary care physicians for clinical concerns. The pharmacists spend on average about 15% of their time caring for e-BP patients and the rest doing usual medical center pharmacy work. The pharmacists, study hypertension physician, director of pharmacy services, project manager, and study psychologist share a monthly telephone conference call to discuss clinical and study concerns and to review and update pharmacy care protocols. Pharmacists also attend research meetings twice a year to share their perspectives and provide feedback to the study team.

2. 7. Adverse event reporting

Adverse event monitoring is tracked by the following three methods: (a) pharmacist, participant, or study personnel report; (b) weekly reviews of automated data, checking for hospitalizations or death of study participants; and (c) three-month mailed questionnaires with this text: "Have you experienced any new and serious health problems since you enrolled in the e-BP study about three months ago? If yes, please describe." Any adverse event is categorized, per the National Institutes of Health (NIH), as a serious adverse event (SAE) if it is life-threatening or fatal, requires or prolongs a hospitalization, or results in a major disability. All other adverse events (AE) are categorized as minor (no change in treatment required), moderate (resolves or is stabilized with minor changes), or severe (requires an emergency room visit or the patient remains ill). SAEs and AEs are categorized as expected or unexpected. Expected AEs include medication side effects or reactions that the package insert describes or that the consent forms mention specifically.

3. Data collection and outcome measures

Table 2 portrays study outcomes, their measurement, and data sources. Baseline and outcome measurements are obtained from automated data, eligibility screening telephone survey questions, baseline and one-year follow-up in-person measurements (blood pressure, weight, and height), and baseline and follow-up questionnaires. Baseline data (T1), including blood pressure, weight, height, and questionnaire responses, are obtained before random assignment, and are thus blinded. Time 2 measurements (T2) are obtained at the end of follow-up at approximately 12 months (active interventions end at 12 months, and T2 data is collected between 11 and 14 months) by research specialists who have had no previous exposure to the patient and are unaware of their group assignment (which patients are asked, before the visit, not to reveal).

3.1. Primary outcomes

Primary outcomes will include: changes in diastolic, systolic, and mean arterial blood pressure at 12-month follow-up visit (T2) compared to baseline blood pressures (T1) (screening visit 1 and 2 blood pressure averages) and the percentage of participants in each group with controlled hypertension based on diastolic and systolic blood pressures taken at T2. All blood pressures are taken using validated Omron Hem-705CP oscillometric automated manometers.

3.2. Secondary outcomes

3.2.1. Adherence to hypertension medications and use of preferred antihypertensive medications—Secondary outcomes of medication adherence and use of preferred antihypertensive medications (those recommended by Group Health and the JNC7)

will be measured using Group Health's pharmacy database, which records every prescription fill date, prescribing provider, drug name and strength, quantity dispensed, and instructions (i.e., "sig"). This system captures over 95% of prescriptions that Group Health patients fill [44,45]. Group Health Center for Health Studies has developed computer algorithms to assess presence of "inadequate" and "adequate" antidepressant treatment using refill data [46]. These same criteria will be used to assess antihypertensive medication use. The accuracy of Group Health pharmacy refill data has been tested in measuring adherence with medications, with a Kappa of 0.52 at one month and 0.65 at four months [46]. Christensen and Goldberg have determined that a period of ≥ 90 days is necessary to classify adherence rates accurately. We measure adherence 90 days prior to baseline and 90 days prior to 12 months to assess this [47,48]. Preferred medication is defined according to JNC7 for hypertension care and will be obtained from the same database, identifying the proportion of patients in each intervention arm on low-dose thiazides (≤ 25 mg), ACE inhibitors, angiotensin receptor blockers (ARBs), beta-blockers, calcium channel blockers, or a combination of these at baseline (T1) and one-year follow-up (T2). Patients are considered to be on preferred medications if they take these medications and do not use other groups of medications (e.g., alpha-blockers and high-dose thiazides). Patients on all four types of the preferred medications plus one non-preferred agent are considered to be using preferred medications.

3.2.2. Quality of life and patient satisfaction—Patient quality-of-life outcomes are collected at T1 and T2 by patient questionnaire using the SF-12 [49,50], a 12-item measure of functional impairment in eight specific domains (general health perceptions, physical functioning, role performance-physical, role performance-emotional, bodily pain, social functioning, energy/vitality, and mental health). We will compare results at T1 and T2 to determine the effects of the intervention on quality of life and general functioning. Patients with hypertension on medications generally have more symptoms and lower quality-of-life scores (in all domains) than adults of the same age who are not on antihypertensive medications [51]. Patient satisfaction with their individual healthcare from their physician, pharmacists, Web services, and the health plan will be measured by questionnaire at T1 and T2. The questionnaire includes a combination of validated scales developed by Ware et al. [52],[53] questions used in the HEDIS tool by NCQA to measure patient satisfaction with care processes, whether patients would recommend Group Health to a relative, and whether they plan to re-enroll.

3.2.3. Changes in patient self-management and self-efficacy—Changes in patient self-management will be measured using the Patient Activation Measurement (PAM) [54] and the Patient Assessment of Chronic Care (PACIC) tools [55]. Psychometric analysis has demonstrated that the PAM tool is a highly reliable and valid measure of the development of patient self-activation in four progressive stages of patient self-belief: that they (a) have an important role in managing their chronic condition, (b) have the necessary knowledge and confidence to take action, (c) engage in actions to improve health, and (d) stay the course in face of stress and difficult circumstances. The PACIC tool collects patient-reported actions and care congruent with the Chronic Care Model, for five specific domains: patient activation, delivery system design/decision support, goal setting, problem solving, and follow-up. Validation testing of the tool has shown that each domain has good internal consistency for brief scales and moderate test/re-test reliability ($r = 0.58$ over three months) and correlates moderately to measures of patient activation ($r = 0.32$ – 0.60 , mean 0.50 ; $p < .0001$) compared to the PAM. For this e-BP study, we developed and piloted a patient self-efficacy questionnaire using standards for key processes of self-efficacy previously established by Bandura [56]. This scale measures self-efficacy for hypertension self-management skills including blood pressure self-monitoring, communicating with healthcare providers, and medication adherence.

3.2.4. Process measures—Process measures related to the intervention components will be collected from automated databases including utilizing the patient website (MyGroupHealth) and Group Health pharmacy services during the intervention period T1–T2. Baseline use of MyGroupHealth for the six months before the intervention will be ascertained including the specific types of intranet use (defined as number of calendar days with any use) for each group including entry to the site, use of secure messaging, and use of pharmacy refill services. For the BPM-I + Pharm arm, use of secure messaging with the pharmacist will be documented by counts of individual messages and of message threads. Medication utilization for antihypertensive medications will be assessed for all three groups to determine the number on one, two, three, or four or more different antihypertensive medications, and the number with a new antihypertensive medication prescribed during the study period. Utilization of Group Health self-management support services in the last 12 months (the Free & Clear tobacco cessation program, Silver Sneakers, Lifetime Fitness, Take Charge Weight Management Program, and ADAPT, Group Health's alcohol and drug program) will be measured by self-report on the questionnaires at T1 and T2.

3.2.5. Cost-effectiveness analyses—We will conduct an incremental cost-effectiveness analysis (CEA) of the BPM-I and the BPM-I + Pharm strategies to achieve blood pressure control among patients with hypertension for a minimum of one year following randomization from the perspective of the health care system. From that perspective, cost-effectiveness will be measured as the mean change in diastolic, systolic, and mean blood pressure observed and the proportion of patients with adequately controlled blood pressure, defined as mean blood pressure <140/90 mm Hg. The first level of analysis will provide estimates of the direct medical care costs per patient of implementing each intervention. Next, we will determine the costs of hypertension care and to what degree either the BPM-I or the BPM-I + Pharm changed them.

Relevant costs from a health plan/health system perspective are the resources necessary to deliver the intervention as well as the change in all medical care costs that derive from the intervention and that the plan or system incurred. Capital and hardware costs of the intervention (e.g., blood pressure monitors) will be tracked through invoices; health services cost will be obtained from Group Health's decision support system. All costs will be expressed in local market terms rather than using Group Health-specific costs to avoid idiosyncrasies of Group Health's purchasing or human resource policies. Even if Group Health lets the research team use some existing resources without charge, we will estimate all the expenses necessary for each intervention arm assuming that the health plan incurs all of the additional expenditures required to implement the screening guidelines. Evaluation costs incurred to satisfy research objectives will not be included, as these would not be incurred in a real-world application of the blood pressure control programs we are studying. All costs will be inflation adjusted and reported in current-year dollars at the conclusion of the trial.

To conduct a CEA from a health plan/health system perspective, we will estimate the Incremental Cost Effective Ratios (ICERs) [57] associated with program goals. ICER yields the additional cost incurred through one intervention to improve on the outcomes obtained from a reference strategy and is given by the following equation: $ICER = [C_i - C_j]/[E_i - E_j]$; where $C_{i,j}$ and $E_{i,j}$ are the costs and effectiveness associated with the i th and j th strategies. We will estimate the ICER for the BPM-I and BPM-I + Pharm strategies relative to usual care and to each other. We will perform sensitivity analyses to examine the influence of uncertainty in the variables and assumptions used in our CEAs [58]. Manning, Fryback, and Weinstein recommend that analysts present one-way tests of sensitivity about assumptions made in conducting a cost-effectiveness analysis; but they urge researchers to adopt one of several more rigorous approaches to assess cost-effectiveness model performance [59]. We will estimate model performance through confidence intervals estimated in a probabilistic manner using Monte Carlo simulation [58,60]. Through this approach, all model parameters are allowed to

take a range of values described by the specified distributions that represent the uncertainty in their estimation. In this way, probabilistic sensitivity analyses allow for the effects of joint uncertainty across all parameters in the model under consideration. Monte Carlo simulation then selects values at random from the distributions, and by repeating this process at least 1000 times via computer, the 95% confidence intervals for the impact on cost-effectiveness can be estimated by approximation to the normal distribution [61,62]. Among the advantages of this approach is that none of the underlying model parameters have to be normally distributed.

The U.S. Public Health Service panel on cost-effectiveness recommends a CEA framework that measures effectiveness through quality-adjusted life years (QALYs), which provide a means for discussing duration of life- and health-related quality of life in a combined measure [60]. QALYs are an appropriate measure when a health plan or health system is considering implementing a variety of preventive or health services options to have a common metric for evaluating the relative efficiency of certain investments in health, such as decreased cardiovascular events. Given the timeframe of this intervention, however, it is unlikely that cardiovascular endpoints (e.g., strokes and myocardial infarction) will be significantly changed. Therefore, our focus will be primarily on the health plan/payer perspective.

3.2.6. Covariates—Information on medications and demographic characteristics, including age, sex, medical center, and healthcare plan, will be obtained from automated databases on all subjects who are sent an invitation to participate in the e-BP study. At the recruitment telephone call, additional information is collected for those willing to provide it, including, using U.S. Census questions [63,64] for ethnicity, marital status, education level, employment status, general health status (using the first general health question from the SF12 tool) [50], and whether they have computer and Web access and an e-mail address (an eligibility requirement). We will compare the characteristics of those ineligible, eligible but refusing, and randomly assigned. Additionally data collected at baseline (T1) and the 12-month follow-up (T2) includes weight, height, income, tobacco and alcohol use status, physical-activity-level (Godin [65]) and stage-of-change questionnaires ([66]), and a single question for fruit and vegetable intake (as validated by Beresford et al. [67]). Participants in each intervention group have access to or are offered a wide variety of lifestyle interventions to improve hypertension control and decrease cardiovascular risk (an important part of self-management, which is included in the Chronic Care Model); but this variety exceeds the study's power to associate any particular intervention with a specific type of lifestyle change. However, participants' baseline lifestyle behaviors might be an important moderator of intervention effects [e.g., body mass index (BMI) and tobacco or alcohol use], and we will look at both participation in a lifestyle change program (as a binary variable (yes/no)) and BMI as sentinel markers of mediator effects.

3.3. Statistical methods

3.3.1. Sample size calculation—This study is powered to detect a clinically meaningful difference in average improvement between baseline and 12-month systolic blood pressure of 4 mm Hg and diastolic blood pressure of 3 mm Hg between group 1 (UC) and group 3 (BP-I + Pharm). Our sample size is 260 per treatment arm, for a total of 780 study participants, using the formula for a normal approximation to compare two independent means. We assumed that the standard deviation for difference in systolic blood pressure from baseline to 12 months is 14.5 mm Hg and difference in diastolic blood pressure from baseline to 12 months is 10 mm Hg, an 80% follow-up rate, an 80% power for systolic blood pressure, and an 86% power for diastolic blood pressure. Standard deviations were derived from data given in Rogers and from the Cardiovascular Health Research Unit, which has followed hypertensive patients at Group Health for the last 15 years [68].

A sample size of 260 per treatment arm will give us 80% power to detect an effect of 11.7% improvement in controlled blood pressure in group 3 compared to UC at 12-month follow-up. This assumes that 20% of the UC group will obtain controlled blood pressure at the 12-month follow-up (note that everyone at baseline had uncontrolled blood pressure) due to regression to the mean and changes in treatment regiment, 80% follow-up, and normal approximation without the continuity correction.

3.3.2 Statistical analysis plan—For the continuous outcomes, change in systolic blood pressure and change in diastolic blood pressure from baseline, our statistical analyses will consist of linear regression models to compare the three intervention groups while adjusting for baseline patient characteristics including age, gender, race, marital status, BMI, exercise, tobacco use, drinking patterns, educational levels, and medical center. We will assume an intent-to-treat principle. For our binary outcome, controlled blood pressure defined as systolic blood pressure <140 mm Hg and diastolic blood pressure <90 mm Hg at the 12-month follow-up. We will use logistic regression to compare the three intervention groups, adjusting for the same variables as for the continuous outcomes.

We will adjust only for those baseline patient characteristics that are found to be statistically significant to the outcome of interest. Due to randomization, we would expect the baseline variables not to be confounders, but rather precision variables to increase our power to detect a difference between intervention arms. Therefore, previous power calculations were conservative, assuming no adjustment for baseline covariates. Secondary analyses will include unadjusted linear regression models comparing the three intervention groups. We will use multiple imputation methods, assuming MAR as needed if the intervention arms have differential missingness [69]. We will also implement further sensitivity analyses using: best-case (assume all blood pressure measurements improved) for the control arms missing outcomes; worst-case (assume all blood pressure measurements worsened) for the active intervention arms missing outcomes; best-case for all intervention arms; and worst-case for all interventions.

4. Discussion

This three-arm randomized controlled trial compares usual care of hypertension to two interventions that use the Chronic Care Model for planning via a secure patient website and the electronic medical record to deliver: (a) a self-management support intervention; and (b) this plus collaborative care management support, to improve hypertension care.

The self-management support intervention includes receipt of a home blood pressure monitor and proficiency training on using it. Self-monitoring of blood sugar has been shown to improve important health outcomes in diabetes and is a standard part of self-care [19,70]. However, the role of home blood pressure monitoring has been less certain [71–73] despite: the availability of validated, inexpensive, and easy-to-use electronic monitors [33]; high acceptability of home blood pressure monitoring to patients [74]; documented problems associated with office blood pressure measurements [75]; and recent evidence showing good correlation between home blood pressure recordings and clinical endpoints [76,77]. The JNC7 [42] states that “home blood pressure monitoring may be useful for some patients,” but gives no specific guidelines for using it. Fahey [13], in a meta-analysis for the Cochrane Collaborative, found that self-monitoring resulted in a significant decline in diastolic blood pressure, but a non-significant trend toward improved hypertension control. In a meta-analysis by Cappuccio, self-monitoring patients had significantly lower systolic and diastolic blood pressure and were more likely to achieve predetermined blood pressure targets, particularly if they were actively involved in monitoring their blood pressure [78].

The Chronic Care Model provides a map for designing a multifaceted, multi-level integrated intervention, which can be directly replicated in different care settings. Attention to, and integration of, all the six domains (Fig. 1) improves patient functional and health outcomes but has yet to be applied to the care of hypertension. We chose to study interventions of increasing intensity, with group 2 (BPM-I) receiving self-management support tools and training, while group 3 (BPM-I + Pharm) receives additional pharmacist care management. In a study testing self-management support plus pharmaceutical care for asthma, self-management support alone was sufficient to improve outcomes [19]. It might be possible that patients on their own could improve their hypertension care by using home blood pressure monitors and communicating these by e-mail directly to their healthcare team; and as noted above, self-monitoring of blood pressure studies improved blood pressure control [78]. In a recent meta-analysis, while home blood pressure monitoring and patient education strategies positively influenced blood pressure control, adding a healthcare team member to focus specifically on hypertension resulted in greater changes, particularly if the assigned person managed medication adjustments [28]. Methods for integration of the team member into routine care and the costs of this care were less certain. We use clinical pharmacists as the agents for changing the design of the care-delivery system, because they perform similar roles at Group Health for other chronic conditions with improved rates of statin and ACE inhibitor use in patients with heart disease and diabetes. Studies show that pharmacy care interventions have positive effects on blood pressure control and medication adherence [79–82]. Depending on local resources, however, these functions could be delegated to nurses, who might have more comfort with aspects of care unrelated to medications (e.g., lifestyle issues or clinical concerns).

This study has several limitations. The interventions take place within an integrated healthcare setting. Physicians in private or small group practice may not have access to the same resources, including patient websites and electronic medical records. Substantial capital investments and provider time are required to implement electronic information, communication, and charting systems. Healthcare provided electronically is generally not reimbursed [83]. Additionally, many patients (particularly those in socioeconomically disadvantaged or older age groups) do not have access to the Internet [84]. However, access to the Internet is rapidly increasing in all age, socioeconomic, and ethnic groups, with over 70% of the American population connected as of 2006 [85]. The population in this study also may be unique, in that the Pacific Northwest has a smaller proportion of racial and ethnic minorities, in particular African Americans, than other parts of the country. African Americans have a higher incidence of hypertension and poorer control than other ethnic groups [86] and may be more likely to refuse to participate in a study [87]. Another potential limitation is that patients receive their blood pressure monitor and training at their home medical center, but all other interventions occur remotely. If the pharmacists were located in each medical center, they might be able to serve as a local champion for improving hypertension care and potentially diffuse evidence-based hypertension care to other healthcare providers. Closer geographic proximity to the patient and the provider also might add a personal touch (particularly for communications with the physician). Using few pharmacists, however, let the hypertension specialist supervise them closely and let them become experienced with hypertension care. Many healthcare insurance companies and physician practices are already outsourcing care for chronic conditions to care management teams at remote sites [88]; however, most often this is not directly linked with other aspects of the patients' healthcare, as was possible for this intervention. With increasing dissemination and availability of information technology services, adding care management processes outside of the physician's office will become simpler to integrate into routine care. In this study, pharmacists managed only those patients who had benign essential hypertension; those with more complex problems were excluded. Pharmacists could provide most care without directly involving the physician: Communication was routine, and collaboration occurred for any clinical concerns, but the physician did not have to respond or place orders. Based on our review of the literature and later the Walsh meta-analysis [28], we hypothesized that family physicians

often are too busy to do the iterative work required for ongoing management of blood pressure; and pharmacist focus and autonomy (within the guidelines of a protocol) would lead to increased hypertensive medication adjustment and improve blood pressure control.

Additionally, as care was delivered over the Internet, we wanted to assure safety before testing more complex scenarios. A patient-centered approach might justifiably focus on the patient and all their conditions and not just hypertension and cardiovascular risk. If this intervention is successful, algorithms could be designed and tested to care for patients with diabetes, heart disease, and other conditions. On the other hand, many patients with hypertension have no other chronic conditions, and most have uncontrolled hypertension.

This study also has several notable strengths. Group Health already employs many of the components of the Chronic Care Model shown to be effective in improving chronic care. Group Health has guidelines, decision support, self-management support tools, and healthcare system and linked community resources to assist patients and providers in the care of hypertension. A particular strength is the organization's robust clinical information system, which includes a secure patient website and an electronic medical record. In *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Institute of Medicine recommends that information technology be used to improve patient-centered care [89]. A Rand Corporation analysis predicted that wider use of information technology would result in improved healthcare outcomes and efficiency, and lower costs [90]. Goldberg et al. [91] demonstrated the feasibility of a Web-based disease management module that lets patients with diabetes upload their blood glucose readings, view portions of their medical record, and e-mail their provider. This study will test the effectiveness of training and encouraging patients to use the secure patient website to improve their hypertension control. The study will also determine whether pharmacist care provided over the Web, linking the patient website and the electronic medical record, improves hypertension control. If successful and cost-effective, home blood pressure monitoring and electronic communication could be used to improve the care for large numbers of patients with hypertension.

5. Conclusion

If blood pressure control could be improved, cardiovascular morbidity and mortality would decrease significantly [2]. We will determine whether a new model of care that uses self-monitoring, Web communications, and collaborative care management to shift the focus from the office into patients' lives improves hypertension care. We will randomly assign patients with uncontrolled hypertension to receive one of three interventions: (a) usual care; (b) a self-care management intervention including receipt of a home blood pressure monitor and proficiency training on use of a patient website; or (c) this plus collaborative pharmacist care management via a secure patient website and the electronic medical record. The primary study outcomes are systolic, diastolic, and mean blood pressure and blood pressure control; secondary outcomes are medication adherence, patient self-efficacy, satisfaction and quality of life, and healthcare utilization. To our knowledge, this is the first study to use the Chronic Care Model to plan implementation strategies to improve hypertension control. This is also the first study we know of that uses Web-based support within a healthcare system to assist patients with self-management of their hypertension. If successful and cost-effective, home blood pressure monitoring and electronic communication could be used to improve care for many patients with hypertension.

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Fig. 1.
Chronic Care Model. Reprinted, with permission, from Wagner et al., *Managed Care Quarterly*, 1999;7(3):56–66

Fig. 2.
Electronic Communications and Home Blood Pressure Monitoring (e-BP) study design overview

*This is from a test site, and the names are not real.

Fig. 3.
Screen shot of Group Health's secure website MyGroupHealth*

Fig. 4.
Pharmacist collaborative care management

Table 1
Intervention components by intervention group for Electronic Communications and Home Blood Pressure Monitoring (e-BP) study

Intervention component	Group 1: Usual care	Group 2: Self- management support (BPM – Web)	Group 3: Self- management support and care management (BPM – Web + Pharm)	Relationship to Chronic Care Model
MyGroupHealth website *				
Access to MyGroupHealth website	Yes	Yes	Yes	1,5
ID verified secure access	Yes	Yes	Yes	1
Proficiency training use of Web tools	No	Yes	Yes	1,4
Active support for use of Web tools	No	No	Yes	1,3,4
Home blood pressure monitor				
Receive training and technical support	No	Yes	Yes	4
Blood pressure reporting to pharmacist	No	No	Yes	1,3,4
Pharmacist self-management support and collaborative care				
Telephone visit	No	No	Yes	3
Medication review	No	No	Yes	1,3
Chart and test results review	No	No	Yes	1,3
Pharmacist use of decision support tools	No	No	Yes	1,2
Pharmacist/patient Web communication	No	No	Yes	1,3,4
Patient motivational counseling	No	No	Yes	1,3,4
Pharmacist/provider EMR **	No	No	Yes	3,4,5
communication				
Pharmacist clinical oversight	No	No	Yes	2,3
Healthcare system and community resources				
Use of Group Health promotion and community programs (smoking, weight, fitness, dietary & alcohol):				
Passive availability	Yes	Yes	Yes	5,6
Active assistance	No	No	Yes	3,4,5,6
HEDIS® audit and feedback	Yes	Yes	Yes	5

* MyGroupHealth website includes secure access to a shared electronic medical record with e-mail, current medical problems, allergies, immunizations, laboratory results, office visit summaries, prescription refills, appointment services, the Healthwise Knowledgebase® medical library, and links to community resources

** EMR = Electronic medical record, including patient medical records with documentation of encounters (office visits, telephone, and e-mail encounters), laboratory, x-ray and test results, order entry, staff and patient messaging, decision support, and healthcare system and community resources.

Chronic Care Model – components by domain and number:

1. Clinical information systems	3. Delivery system design change	5. Healthcare system
2. Decision support	4. Self-management support	6. Community resources

Table 2
Outcome measurements for Electronic Communications and Home Blood Pressure Monitoring (e-BP) study

Aim	Outcome	Measurement	Data sources	Collection schedule
Process outcomes #1	Utilization of the website	"Page Requests" to the website, Web-based secure messaging, and pharmacy refills	Group Health automated data	Pre-T1 X T1-T2 X T2
	Medication changes	Number of new medications	Group Health's automated pharmacy system	X X
	Utilization of Group Health programs to decrease blood pressure and CVD risks	Use of GH behavior change programs (smoking cessation, dietitian, weight management, physical activity, substance abuse)	Automated data and patient surveys	X X X
Primary outcomes #2	Change in diastolic, systolic, and mean blood pressure	Recorded blood pressure taken by research assistant blinded to subject's intervention group	Validated Omron® Hem-705 automatic cuff	X X
	Percent with controlled blood pressure	Recorded blood pressure taken by research assistant blinded to subject's intervention group	Validated Omron® Hem-705 automatic cuff	X X
Secondary aims #4	Adherence with blood pressure medication use, use of preferred antihypertensive medications	Prescription fills	Group Health's automated pharmacy system	X X
	General health status, senses of self-efficacy and satisfaction with medical care	SF 36, self-efficacy scales, and patient satisfaction questions	Patient Survey	X X
	Patterns of utilization	Utilization of outpatient visits, telephone and e-mail encounters, and procedures (lab, EKG, and x-ray)	Group Health automated data	X
	Incremental cost effectiveness	Costs of care and capital expenditures	Group Health automated data and patient survey	X