## Telemedicine cardiovascular risk reduction in Veterans

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**Background** Patients with co-occurrence of hypertension, hyperlipidemia, and diabetes have an increased risk of cardiovascular disease (CVD) events. Comprehensive programs addressing both tailored patient self-management and pharmacotherapy are needed to address barriers to optimal cardiovascular risk reduction. We are examining a Clinical pharmacy specialist—, telephone-administered intervention, relying on home monitoring, with a goal of providing tailored medication and behavioral intervention to Veterans with CVD risk.

**Methods** Randomized controlled trial including patients with hypertension (blood pressure >150/100 mm Hg) or elevated low density liporotein (>130 mg/dL). Longitudinal changes in CVD risk profile and improvement in health behaviors over time will be examined.

**Conclusion** Given the national prevalence of CVD and the dismal rates of risk factor control, intensive but easily disseminated interventions are required to treat this epidemic. This study will be an important step in testing the effectiveness of a behavioral and medication intervention to improve CVD control among Veterans. (Am Heart J 2013;165:501-8.)

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the United States; more than 80% of veterans have at least 2 CVD risk factors. Patients can decrease CVD risk through lifestyle changes, but changes may be difficult to maintain. Medication use is another risk reduction strategy, but 20% to 50% of patients are non-adherent. Despite the availability of

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E-mail: stephanie.melnyk@va.gov 0002-8703/\$ - see front matter Published by Mosby, Inc. http://dx.doi.org/10.1016/j.ahj.2012.08.005 effective therapy for diabetes, hypertension, and hypercholesterolemia, only 13% of Veterans with CVD achieve target control.  $^{3,4}$ 

Comprehensive CVD programs that employ tailored patient self-management, pharmacotherapy and behavioral interventions are needed for cardiovascular risk reduction. The Veterans Affairs (VA) has increasingly emphasized a patient aligned care teams, or PACT. The PACT is an application of the patient-centered medical home<sup>5</sup> that emphasizes team delivery of patient-centered care, coordination across specialties, open access, and value-driven care.<sup>5</sup> PACTs stress the utility of non-face-to-face interventions. These encounters may reduce patients' travel cost, reduce clinic no-show appointments, and may supplant some clinic visits. Telephone-based care may be critical in supporting the PACT vision of coordination across different settings of care while improving access to care.

The professional role of the person making the telephone calls is equally important. Clinical pharmacist specialists (CPS) have training to provide behavioral interventions and intensive medication management needed in this high-risk CVD population. A CPS is a pharmacist who has completed post-graduate residency training, is credentialed to prescribe, adjust, and monitor pharmacotherapy. CPS-directed care with clinical collaboration has demonstrated improvement in the management of the individual major CVD risk factors in outpatients. We are conducting a randomized trial to evaluate CITIES, a CPS-delivered intervention administered by telephone to

Veterans with poorly controlled hypertension and/or hypercholesterolemia. We describe the trial and the intervention utilizing a clinical pharmacist specialist.

## **Methods**

## Design, setting, and recruitment

We are conducting a 12-month intervention comparing patients receiving the intervention to an educational control group among Veterans affiliated with primary care. The Durham VA Medical Center Institutional Review Board approved the study.

#### Inclusion criteria

Patients are eligible if they: (1) live in North Carolina or Virginia, (2) are  $\geq$ 40 years of age, (3) are enrolled in one of three primary care clinics affiliated with the Durham VA Medical Center (at least 1 visit with assigned primary care provider [PCP] in the past year), (4) have a diagnosis of hypertension or hypercholesterolemia, and 5) have poorly controlled hypertension mean clinic BP of >150/100 mm Hg and/or hypercholesterolemia low-density lipoprotein (LDL) value >130 mg/dL in the last year.

#### Exclusion criteria

Patients are excluded if they: (1) have a diagnosis of metastatic cancer, dementia, active psychosis or serum creatinine >2.5 mg/dl or no lab value on file and/or on dialysis; (2) reside in a nursing home; (3) are unable to see/read type printing on magazines/books; (4) have difficulty hearing on the telephone; (5) have limited/no access to a telephone; (6) have been hospitalized with a stroke, myocardial infarction, or cardiac surgery in the past 3 months; or (7) who are actively enrolled in another clinical trial or clinical pharmacy services (Table I).

#### Sample identification

Participants meeting inclusion criteria 1 to 5 are initially identified from electronic medical records. The lists of identified patients are sorted by upcoming appointment (Figure 1). Patients meeting initial screening criteria are mailed an introductory letter signed by their PCP. The remaining patients who qualify are contacted by study personnel for additional eligibility screening and to schedule an in-person meeting. Once informed consent to participate has been obtained from patients, the baseline outcome assessment are completed. Patients are randomized to the intervention or the control group; randomization is stratified by gender, smoking, and diabetes status. Patients randomized to the control group receive educational material about CVD reduction but have no CPS contact.

#### Intervention

During 12 monthly phone calls, medication adjustments are made at intervals based on patients' self management, laboratory values, medication interactions, reported and observed medication side effects, clinical assessment, patients' report of medication adherence, and disease monitoring. During these phone calls, the CPS also delivers a tailored behavioral, concomitant telemedicine intervention to improve treatment

adherence, exercise, diet, weight and smoking cessation. In particular, the CPS focuses on (1) expanding patients' understanding of each medication and its role in disease management; (2) education on preventive care; and (3) offering strategies to enhance adherence.

The initial 2 encounters provide an intense review and complete medication history of the patients' current and discontinued cardiovascular medications. The encounters also provide comprehensive medication education based on patients' current understanding of their cardiovascular medications.

### Self-management component

Home blood pressure monitors. Patients randomized to the intervention receive a VA-issued home blood pressure (BP) monitor. Patients receive training on BP monitor use and are instructed to use it every other day. <sup>2,8</sup> When the CPS contacts patients at the month before the potential medication management activation, the pharmacist reminds individuals to record their BP values. Poor BP control detected by home monitoring is defined as an average bi-weekly BP that falls above the threshold (<135/85 for non-diabetics and <130/80 for diabetics).<sup>2</sup>

**Glucose monitors.** Insulin dependent patients, anticipated 50% of the study cohort based upon a prior study, <sup>9</sup> are requested to perform daily self-monitored blood glucose testing equal to their number of daily insulin doses. Patients who are managed on oral hypoglycemic medications alone are encouraged to monitor blood glucose (BG) at least one time per week or if signs or symptoms of hypoglycemia occur based on VA policy. <sup>10</sup> We evaluate each patient's monitoring technique at baseline, 6-month, and 12-month follow-up interviews.

## Medication management intervention and time intervals

The goal of the intervention is to supplement clinic-based management to more efficiently implement interventions that may otherwise be left until the next appointment. This model has worked well in previous VA studies.<sup>2</sup> For patients who require a prescription change, the pharmacist communicates the change with the VA pharmacy. At the next monthly contact, the pharmacist will assess new symptoms (eg, hypotension, hypoglycemia). This will allow adequate time for the patient to obtain medication and get accustomed to the change. Any medication change that requires additional testing is ordered and followed-up. In cases where a medication change is made, a note is generated for the patient's medical record and co-signed by the patient's PCP acknowledging receipt of the treatment plan. This algorithmic method of assessing the need for medication management and providing documentation was previously tested.<sup>2</sup> When serious adverse events occur, the pharmacist consults with the patient's PCP and study clinicians to take appropriate action and/or make further recommendations.

### Blood pressure

Individuals are instructed to record BP values for at least two weeks prior to the 2-, 4-, 6-, 8- and 10-month CPS contacts, when medication management activation for hypertension may occur. A home BP value of >135/85 mm Hg is considered poorly controlled BP in patients without diabetes even though it is

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