

Collaborative Cardiovascular Risk-reduction in Primary Care: Design of the CCARP study

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Background/Rationale

Multidisciplinary and collaborative protocols have been shown to enhance cardiovascular risk reduction strategies in primary care settings.¹⁻¹⁰ However, we believe additional studies are required to discover the factors that will facilitate real world success. As such, we have identified several key characteristics that we feel must be in place to make collaborative protocols more realistic and generalizable to the real world (Table 1).

The objective of the Collaborative Cardiovascular Risk-reduction in Primary Care (CCARP) study is to evaluate the success of a specific and reproducible “protocol” of cardiovascular care that is designed for nonspecialist pharmacists who have the opportunity to work collaboratively with a typical fee-for-service physician practice.

Methods

We designed a randomized, controlled trial that compares a pharmacist intervention (following the CCARP “protocol”) with that of usual care for the purpose of reducing cardiovascular risk among primary care patients. The setting for this study is a large family medicine practice in Saskatoon, Saskatchewan. The study has received ethics

approval from the University of Saskatchewan’s Biomedical Ethics Board.

Patient selection/recruitment

Eligible patients include those with a high-moderate or high-risk classification ($\geq 15\%$ 10-year risk of cardiac death or non-fatal myocardial infarction) as determined by the Framingham risk calculation, or those exhibiting a coronary artery disease risk equivalent (coronary artery disease, peripheral artery disease, cerebrovascular disease, or diabetes mellitus).¹¹ Exclusion criteria include those with severe psychiatric conditions or dementia, symptomatic heart failure (NYHA class III or IV), terminal illness, concurrent participation in an investigational study, or women who are pregnant or lactating. Due to privacy concerns, patients can only be recruited through physician or self-referral.

Treatment groups

After informed consent has been obtained, the pharmacist completes a medication history of the patient. Patient’s individual risk factors are identified and his or her 10-year risk for cardiac death or non-fatal myocardial infarction is determined. Basic information on cardiovascular disease (CVD)

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TABLE 1 Characteristics required for practical and generalizable collaborative protocols

Setting	Protocols must be tailored to fee-for-service physician practices, which serve the vast majority of primary care patients in Canada.
Efficiency	Pharmacists must impact as many at-risk patients as possible. Poor efficiency will drive costs too high for realistic implementation and sustainability in primary care.
Reproducibility	Terms such as “reinforcement” and “patient support” are vague and open to a wide variety of interpretations. In order to ensure reliability of the protocol, specific activities that achieve these goals should be clearly outlined.
Simplicity	All protocol activities, including patient education and follow-up, should remain straightforward and practical, so that pharmacists who are not specialists in cardiovascular therapeutics can deliver the program optimally.
Credentials	Protocols must not be so complex as to require an advanced or specialist degree, which can hinder the opportunity for widespread implementation.
Focus	Although recommending evidence-based therapies is an important part of many collaborative protocols, we feel that primary care pharmacists should focus on regular follow-up and support of patients for the purpose of achieving long-term adherence.

risk reduction strategies is discussed and written material is provided. An emphasis is placed on clinical targets and the recommended pharmacological management, as outlined by current clinical practice guidelines.¹¹⁻¹⁴ Patients who meet all the inclusion criteria are randomized into 1 of 2 treatment groups: the follow-up group (intervention) or the single contact group (usual care). Randomization lists were generated in permuted blocks of 4 and stratified for each physician.

Patients randomized into the single contact group will receive no further contact with the pharmacist, and will return to their usual physician care. Those randomized to the follow-up group will receive continuous follow-up and reinforcement by the pharmacist at a minimum of every 8 weeks. Follow-up occurs in person, by telephone, mail, or electronic mail.

Although the delivery of information during follow-up visits is patient-specific and does not require that a standardized content be covered, form letters and patient contact strategies have been developed to provide a “protocol” to help guide pharmacists in their ongoing support for patients. Providing a large amount of information during a single follow-up, unless specifically requested by the patient, is discouraged. Emphasis is placed on short follow-up contacts that focus on reminding and “congratulating” or encouraging patients with respect to adherence and clinical targets. Potential triggers for patient follow-up are outlined in Box 1. Each patient contact is documented to include the date, method of intervention

BOX 1 Triggers for patient follow-up in treatment group

- Communication of relevant laboratory results in comparison to goals
- Within 7 to 10 days after the initiation or change of medication to assess tolerability
- Within 7 to 10 days after experiencing an adverse event to ensure resolution
- To ensure patient was able to procure necessary follow-up appointments
- In patients who are at goal or are stable: mailouts providing patients with clinical goal reminders, disease-specific information, exercise program, or dietary information as appropriate

and information provided.

A list of baseline and follow-up laboratory tests was pre-determined (Box 2), and is ordered by physicians at the time of patient referral. Other relevant laboratory tests may be ordered at the request of the pharmacist. All patients are to be followed for a minimum of 6 months.

Outcome measures

The primary endpoint is the mean reduction in global cardiovascular risk status as measured by the Framingham risk calculator. Because Framingham risk scores are not validated for secondary prevention situations, we have developed and are currently testing another indicator of global cardiovascular

BOX 2 Baseline and follow-up laboratory tests

- Lipid panel
- Fasting blood glucose
- HbA1c (if applicable)
- Renal function tests (creatinine, microalbumin, electrolytes)
- Liver function tests (AST, ALT)
- Thyroid-stimulating hormone (TSH)

risk improvement, the CRI20 (not discussed here), that will be used to measure risk reduction success. Secondary endpoints include individual modifiable CVD risk factors, development of cardiovascular

events, optimal drug utilization rates, and long-term medication adherence.

Sample size

A sample size of 154 (77 in each treatment group) will provide 80% power to detect a 2-point reduction in the 10-year coronary artery disease risk score with a one-tailed alpha of 5%. The expected effect size was estimated from an unpublished primary care initiative previously conducted in Saskatchewan.

Current status of the study

The first patient was randomized in August 2006, and as of March 2006, 158 patients have been randomized. The study is expected to be completed late summer 2007. ■

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