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We came up with the idea for this study because osteoporosis continues to be underdiagnosed and undertreated. Screening programs for early detection of patients at high risk for an osteoporotic fracture are highly needed and the community pharmacy may be a perfect environment for the development of these types of programs.

# Design of a randomized trial of a community pharmacist–initiated screening and intervention program for osteoporosis

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## Background

Osteoporosis has a significant impact on patients and the health care system;<sup>1</sup> however, it remains underdiagnosed and undertreated.<sup>2,3</sup> Innovative methods of identifying patients at high risk of osteoporosis need to be established. Community pharmacies provide an optimum setting for preventative health programs, as they are easily accessible and patients often see their pharmacist more than any other health provider. Pharmacists' involvement in health screening and disease management has been described for a variety of areas.<sup>4-7</sup> The purpose of this study is to determine the effect of a community pharmacist–initiated multifaceted intervention on increasing the diagnosis and treatment of osteoporosis in patients at high risk of fracture.

## Methods

This study is a randomized, controlled multi-site trial involving community pharmacies in the greater Edmonton metropolitan area (the Capital Health region). Participating com-

munity pharmacists will screen patients  $\geq 50$  years of age according to the Osteoporosis Canada Clinical Practice Guidelines<sup>1</sup> recommendations for who should be evaluated for osteoporosis. Those subjects meeting the inclusion criteria will be approached for written informed consent to participate in the study and then randomized either to the osteoporosis intervention group or the control group. Patients in the intervention group will be asked to return to the pharmacy at a designated time during an assigned clinic day to participate in an individual 45-minute educational session. Pharmacists will educate patients about osteoporosis, perform quantitative ultrasound (QUS) measurements using the CUBA Clinical Bone Density Sonometer, and refer patients to their primary care physician for further assessment/treatment. The results of the heel ultrasound will be faxed to the patient's primary care physician, along with a clinical interpretation. Patients in the intervention group will be contacted by phone at two and eight weeks, and asked to return to the pharmacy at 16 weeks to assess the attainment of the primary and secondary outcomes.

The control group will reflect "usual care" in the community pharmacy with respect to osteoporosis management. Usual care patients will receive a pamphlet on osteoporosis from Osteoporosis Canada and a follow-up appointment in 16 weeks to assess the attainment of the primary and second-

## Implications for practice

It is hoped that the findings of this study will encourage the implementation of similar innovative strategies for osteoporosis screening and will help increase overall osteoporosis awareness.

In addition, this study will provide further support for the role community pharmacists can play in screening and education of patients with chronic diseases.

Alternatively, if this project proves ineffective or even associated with harm, different models of osteoporosis screening of patients at high risk for osteoporosis will need to be investigated.

ary outcomes. After close-out at week 16, usual care patients will be offered the components of the intervention, but will not be studied further.

The primary outcome measure will be either a composite endpoint of the performance of a bone mineral density test *or* a new prescription for an osteoporosis medication. Secondary outcome measures will include each component of the primary outcome: use of calcium and vitamin D supplements, patient's osteoporosis-related knowledge,

changes in generic health status, and osteoporosis-specific quality of life

### Current status of study

The study was launched in October 2005 and is currently taking place in 12 Save-On-Foods pharmacies in the Capital Health Region. The study is being conducted through the University of Alberta Centre for Community Pharmacy Research and Interdisciplinary Strategies (COMPRIS). ■

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