Randomized controlled trial to evaluate an ambulatory integrated primary care management program for patients with dyslipidemia: TEAM Study

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Rational: Although lipid-lowering medications are known to reduce the risk of premature mortality, coronary heart disease and stroke, up to 60% of patients starting medication do not stay on it long enough to have any beneficial impact on their health. Among those on treatment, only 38% are at or below their target lipid levels. Hydroxymethyl glutaryl coenzyme A reductase inhibitors (statins) tend not to be titrated with 77% of patients remaining on their starting dose. In Quebec, a new legislation redefines the practice of pharmacy. Pharmacists may now initiate or adjust drug therapy, according to a prescription, and request laboratory analyses when needed. This legislation is unique and has not yet been widely applied. However, it enlarges the potential for co-management of pharmacotherapy by physicians and pharmacists. Up-to-now, no study has evaluated the impact of a truly integrated primary care (IPC) intervention model where physicians and pharmacists would be co-responsible for the management of drug therapy. As a starting point, we are proposing to conduct a cluster randomized controlled trial to compare the efficacy of an IPC model to the usual care (UC) model for patients with dyslipidemia initiating statin treatment or those already on statin treatment but inadequately controlled.

Objectives: Primary objective: To compare the mean change in LDL-cholesterol and total cholesterol/HDL-cholesterol ratio from baseline to month 12 in patients assigned to the IPC and the UC interventions. Secondary objectives: We will also compare: 1) the mean change in other CVD risk factors (e.g. total-cholesterol, HDL-cholesterol, triglycerides, blood pressure, body mass index, and glycosylated hemoglobin); 2) the proportion of patients who have reached all the serum lipid target levels as defined in the Canadian dyslipidemia treatment guidelines; 3) the adherence and persistence with lipid-lowering medication; and 4) the patient satisfaction with pharmaceutical and medical care, level of knowledge, perception of risks and benefits and level of decisional conflict at month 12 in both groups.

Research Plan: A three-year cluster randomized controlled trial will be conducted among patients initiating statin medication and those already on statin medication but inadequately controlled. A total of 16 clusters will be recruited. Each cluster will be composed of at least one community pharmacy (≥ 3 pharmacists/pharmacy) and participating family physicians (≥ 5 physicians) in the same geographical area. Clusters will be randomized to either the UC or the IPC intervention. Each cluster will recruit 12 to 15 patients. Pharmacists assigned to the IPC intervention will participate in an eight-hour integrated care workshop to review the current clinical guidelines on the treatment of dyslipidemia, the monitoring of pharmacotherapy, and the treatment protocol. In addition, pharmacists and physicians assigned to the IPC intervention will participate in a three-hour integrated care workshop prior to recruiting patients. The IPC treatment protocol includes a treatment algorithm, describes the roles of the treating physicians and pharmacists and provides standardized prescription form and period report form. The treatment algorithm is conformed to the Canadian treatment guidelines and has been designed to maximize treatment efficiency. The physicians will be responsible for the diagnosis and the prescription of the initial statin treatment. Thereafter, the pharmacists will be responsible for the monitoring of the effectiveness and safety of the treatment. They will request laboratory tests at pre-specified time interval and perform protocol-driven dosage adjustments. Patients will be followed for 12 months. They will attend a medical evaluation visit at baseline and month 12 to complete study questionnaires, have their blood pressure, weight and height measured, and provide blood sample.

Relevance: This project may enable us to propose an effective, validated and applicable form of intervention for patients under treatment in private medical clinics, family-medicine groups, family-medicine teaching units, and CLSCs. Given the high prevalence of dyslipidemia and the sub-optimal management of patients with these conditions under the present system, we believe that the proposed model may improve the efficiency of drug therapy and therefore patients' cardiovascular health. Eventually, the findings generated by this project could come into general application for other chronic diseases.