

Community Pharmacist Training-and-Communication Network and Drug-Related Problems in Patients With CKD: A Multicenter, Cluster-Randomized, Controlled Trial

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Background: Appropriate training for community pharmacists may improve the quality of medication use. Few studies have reported the impact of such programs on medication management for patients with chronic kidney disease (CKD).

Study Design: Multicenter, cluster-randomized, controlled trial.

Setting & Participants: Patients with CKD stage 3a, 3b, or 4 from 6 CKD clinics (Quebec, Canada) and their community pharmacies.

Intervention: Each cluster (a pharmacy and its patients) was randomly assigned to either ProFiL, a training-and-communication network program, or the control group. ProFiL pharmacists completed a 90-minute interactive web-based training program on use of medications in CKD and received a clinical guide, patients' clinical summaries, and facilitated access to the CKD clinic.

Outcomes: Drug-related problems (primary outcome), pharmacists' knowledge and clinical skills, and patients' clinical attributes (eg, blood pressure and glycated hemoglobin concentration).

Measurements: Drug-related problems were evaluated the year before and after the recruitment of patients using a validated set of significant drug-related problems, the Pharmacotherapy Assessment in Chronic Renal Disease (PAIR) criteria. Pharmacists' questionnaires were completed at baseline and after 1 year. Clinical attributes were documented at baseline and after 1 year using available information in medical charts.

Results: 207 community pharmacies, 494 pharmacists, and 442 patients with CKD participated. After 1 year, the mean number of drug-related problems per patient decreased from 2.16 to 1.60 and from 1.70 to 1.62 in the ProFiL and control groups, respectively. The difference in reduction of drug-related problems per patient between the ProFiL and control groups was -0.32 (95% CI, -0.63 to -0.01). Improvements in knowledge (difference, 4.5%; 95% CI, 1.6%-7.4%) and clinical competencies (difference, 7.4%; 95% CI, 3.5%-11.3%) were observed among ProFiL pharmacists. No significant differences in clinical attributes were observed across the groups.

Limitations: High proportion of missing data on knowledge and clinical skills questionnaire (34.6%) and clinical attributes (11.1%).

Conclusions: Providing community pharmacists with essential clinical data, appropriate training, and support from hospital pharmacists with expertise in nephrology increases pharmacists' knowledge and reduces drug-related problems in patients with CKD who are followed up in clinics incorporating a multidisciplinary health care team.

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INDEX WORDS: Chronic kidney disease (CKD); community pharmacy; CKD clinic; drug-related problems (DRPs); training program; clinical competency; medication use; randomized controlled trial (RCT).

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Chronic kidney disease (CKD) is a significant health problem^{1,2} affecting more than 20 million American adults (10%)³ and 3 million (12%) Canadian adults.⁴⁻⁶ These patients are at higher risk for hospitalization, cardiovascular disease, and death.⁷ The incidence of end-stage renal disease nearly doubled from 2000 to 2010,⁸ which has magnified its economic and societal burden.

In CKD clinics in Quebec, Canada, patients are followed up by multidisciplinary teams of health care professionals, including pharmacists, to slow progression of the disease, prevent cardiovascular disease, and manage complications.⁹⁻¹⁴ These patients remain at high risk for drug-related problems due to their age, multiple comorbid conditions, complex drug therapy, and the use of over-the-counter medications and natural health products.¹⁵⁻¹⁷ As primary care providers, Canadian community pharmacists play an important role in ensuring the efficacy and safety of their medication.

ProFiL was a training-and-communication network program to support community pharmacists in the management of drug therapy for patients with CKD.¹⁸ It included a 90-minute interactive web-training program, a clinical guide (a booklet on CKD drug therapy), a clinical summary of their patients with information on their kidney function, and a consultation service with pharmacists working in a CKD clinic.

The objectives of this study were to assess the impact of the ProFiL program on the quality of medication use (primary objective) and changes in the clinical attributes of patients with CKD, as well as the clinical practices, knowledge, and clinical skills of community pharmacists.

METHODS

Study Design

A multicenter, unblinded, cluster-randomized, controlled trial was conducted. Patients were recruited in 6 CKD clinics in Quebec: the Cité-de-la-Santé hospital, the Maisonneuve-Rosemont hospital, the Centre hospitalier universitaire de Sherbrooke, the Charles LeMoine hospital, the McGill University Health Center, and the Jewish General Hospital. After patients were recruited, their community pharmacies were invited to participate. Each cluster (a community pharmacy and its study patients) was randomly assigned to either ProFiL or the control group. ProFiL pharmacists had access to the ProFiL program, and control pharmacists continued to provide their usual care. Patients were followed up for 1 year. Patients and pharmacists were evaluated at baseline (T0) and at 12 months (T12).

The study was approved by the research and ethics committees of the Centre Hospitalier de l'Université de Montréal, the Centre de Santé et des Services Sociaux de Laval, the Maisonneuve-Rosemont Hospital, the Charles LeMoine Hospital, the McGill University Health Centre, the Centre Hospitalier Universitaire de Sherbrooke, and the Jewish General Hospital (approval number: MP-CSSS-LAV-11-001). Patients and community pharmacists

gave their individual consent to participate and signed an informed consent form. The CKD clinics received monetary compensation from the research grant for pharmacists and nurses to prepare clinical summaries and for pharmacists to provide consultation service to community pharmacists. No other monetary compensation was provided.

Study Population

First, the CKD clinics were recruited. They were eligible if a pharmacist from the clinic agreed to provide consultation service to community pharmacists and a nurse or a pharmacist agreed to complete a clinical summary for study patients at T0 and T12.

Thereafter, patients were recruited in CKD clinics. To be eligible, patients had to meet the following criteria: (1) be 18 years or older, (2) have CKD stage 3a or 3b (estimated glomerular filtration rate [eGFR] of 30-59 mL/min/1.73 m² as estimated using the 4-variable MDRD [Modification of Diet in Renal Disease] Study equation or CKD-EPI [CKD Epidemiology Collaboration] creatinine equation [both equations in isotope-dilution mass spectrometry-traceable version]) or stage 4 (eGFR of 15-29 mL/min/1.73 m²), (3) be able to speak and read French or English, and (4) agree to be followed up by their usual community pharmacy for the duration of the study.

After patients agreed to participate, the pharmacists at their usual community pharmacy were invited to participate. To be eligible, pharmacies had to meet the following criteria: (1) a sufficient number of pharmacists had to agree to participate (for pharmacies open 7 days per week and with ≤250 prescriptions per day, participating pharmacists had to cover at least 35 working hours per week; for those with >250 prescriptions per day, participating pharmacists had to cover at least 60 working hours; for pharmacies open <7 days per week, participating pharmacists had to cover ≥50% of the working hours), and (2) 1 pharmacist had to agree to be responsible for the study.

Pharmacists working in more than 1 participating pharmacy were assigned to the pharmacy at which they worked most of the time. Pharmacies having patients from more than 1 CKD clinic were randomly assigned only once.

Randomization

A cluster was defined as a community pharmacy and its participating pharmacists and patients. Following the recruitment of its first patient, each cluster was randomly assigned to either the ProFiL group or the control group. Pharmacies were randomly assigned only once, and subsequently recruited patients were automatically assigned to the corresponding group. The randomization was stratified by CKD clinic and the community pharmacists' workload (≤30 or >30 prescriptions per hour). We also blocked the randomization, with 3 and 6 clusters per block, and balanced the randomization within each block (2:1 ratio of ProFiL to control). We continued recruiting patients after randomization to up to a maximum of 20 patients per cluster. The randomization scheme was generated by a statistician using SAS, version 9.2, software (SAS Institute Inc). A research assistant prepared opaque numbered envelopes with randomization instructions to be opened in strict sequential order.

ProFiL Program

The ProFiL program comprised training-and-communication components for community pharmacists. The training included a 90-minute web-based interactive program supported by a clinical guide. The web-based training is described in detail elsewhere.^{18,19} Briefly, a systematic approach was proposed to prevent, detect, and manage the drug-related problems included in the Pharmacotherapy Assessment in Chronic Renal Disease (PAIR) criteria (see the "Quality of Medication Use" section for a complete description of the PAIR criteria). Using 2 clinical vignettes,

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