A randomized controlled trial of a pharmacist consultation program for family physicians and their elderly patients

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Abstract

Background: Pharmacists can improve patient outcomes in institutional and pharmacy settings, but little is known about their effectiveness as consultants to primary care physicians. We examined whether an intervention by a specially trained pharmacist could reduce the number of daily medication units taken by elderly patients, as well as costs and health care use.

Methods: We conducted a randomized controlled trial in family practices in 24 sites in Ontario. We randomly allocated 48 randomly selected family physicians (69.6% participation rate) to the intervention or the control arm, along with 889 (69.5% participation rate) of their randomly selected community-dwelling, elderly patients who were taking 5 or more medications daily. In the intervention group, pharmacists conducted face-to-face medication reviews with the patients and then gave written recommendations to the physicians to resolve any drug-related problems. Process outcomes included the number of drug-related problems identified among the senior citizens in the intervention arm and the proportion of recommendations implemented by the physicians.

Results: After 5 months, seniors in the intervention and control groups were taking a mean of 12.4 and 12.2 medication units per day respectively (p = 0.50). There were no statistically significant differences in health care use or costs between groups. A mean of 2.5 drug-related problems per senior was identified in the intervention arm. Physicians implemented or attempted to implement 72.3% (790/1093) of the recommendations.

Interpretation: The intervention did not have a significant effect on patient outcomes. However, physicians were receptive to the recommendations to resolve drug-related problems, suggesting that collaboration between physicians and pharmacists is feasible.

The advent of effective pharmacologic management of many acute and chronic conditions and the aging population have contributed to increased medication use among elderly patients in particular. However, using multiple medications may lead to problems, including inappropriate dosing, drug interactions, adverse drug reactions, therapeutic failure and patient noncompliance. Studies of elderly patients have estimated that some 6%–28% of hospital admissions or readmissions are attributable to these unintended events. Inappropriate prescribing has been detected in the prescriptions of 4%–53% of community-dwelling seniors and is associated with increased risks of hospital admission and emergency department visits.

Pharmacists represent a potential, currently underused resource for optimizing the use of medications. Several studies of hospital ambulatory care clinics have shown that a pharmacist consultant can reduce health service use and costs and can improve the appropriateness of drug prescribing for elderly patients. The effectiveness of pharmacist interventions has been demonstrated in 3 recent studies of pharmacists who consulted directly with elderly patients in the pharmacy setting. However, the effectiveness of pharmacist consultants in helping family physicians to manage the drug therapy of their elderly patients has not been reported.

We report the results of a paired cluster randomized controlled trial of specially trained community pharmacists who acted as consultants to primary care physicians after completing drug therapy assessments with senior citizens in the offices of their family physicians. The primary end point was daily units of medication taken, with the intent of reducing regimen complexity and improving patient outcomes.

Methods

The methods used to recruit community pharmacists, family physicians and their elderly patients have been described elsewhere. A convenience sample of 24 pharmacists who had received additional post-university training in the prevention, identification and resolution of drug-related problems was approached in 16 towns or cities in southern Ontario. All family physicians who practised in each pharmacist’s postal code area made up the sampling frame. A random sample of physicians in each postal code area was generated, and physicians were approached by telephone until 2 (1 pair) had been recruited in each...
area (Fig. 1). About 20 randomly chosen eligible senior citizens per practice (cluster) were recruited (range 7–23 per practice) by the office staff of the practice from August to November 1999. Patients were eligible for inclusion in our study if they were aged 65 years or more, taking 5 or more medications, had been seen by their physician within the past 12 months, had no evidence of cognitive impairment and could understand English. Patients were excluded if they had planned surgery, were on a nursing home waiting list or were receiving palliative care. The study was approved by the Research Ethics Board of Hamilton Health Sciences.

Before the physicians were randomly allocated, 1 of 8 specially trained research nurses assigned to each practice administered questionnaires designed to collect data on sociodemographic characteristics, medication use and quality of life from the study patients. A list of current and past medical conditions was compiled by the nurse for each patient and confirmed by his or her physician. An ICD-9 (International Classification of Diseases, ninth revision) code was assigned for each diagnosis and reviewed by a family physician (J.S.).

The pair of physicians in each postal code area were randomly allocated, in a concealed fashion, to the intervention or control group, using a central telephone randomization procedure based on computer-generated random numbers (Fig. 1). Randomization was conducted by a research team member (J.K.) who was blinded to the practices’ identities. Study patients in practices allocated to the control group received usual care from their physicians. Neither family physicians nor their patients were blinded to their allocation group.

A study patient in a practice randomly allocated to the intervention group had a structured medication assessment by the pharmacist in the physician’s office. After the interview, the pharmacist wrote a consultation letter to the physician that summarized the patient’s medications, identified drug-related problems and recommended actions to resolve any such problems. The pharmacist subsequently met with the physician to discuss the consultation letter. After the meetings, physicians used a data collection form to indicate which recommendations they intended to implement and when. The pharmacist and physician met again 3 months later to discuss progress in implementing the recommendations. Five months after the initial visit, the pharmacist met with the physician to determine which recommendations had been put in place. One and 3 months after meeting with the physician, the pharmacist monitored each patient’s drug therapy using a semistructured telephone interview with the patient.

Drug-related problem is defined in pharmaceutical care as any undesirable event experienced by a patient that involved or was suspected of involving drug therapy and that actually or potentially interfered with a desired patient outcome. Eight categories of drug-related problems (Table 1) are widely used by pharmacists to administer patient-centred care. The intervention model to identify, resolve and prevent drug-related problems was deemed to be feasible and acceptable for implementation in primary care based on a pilot study with input from family physicians and pharmacists. Drug-related problems were determined by the pharmacist consultants using information from the patients’ medical charts, the face-to-face interviews and the medication reviews, and they were recorded on a standardized data form.

Research nurses interviewed the patients in both groups and recorded their current use of prescribed and over-the-counter medications. The nurses returned to the same practices and requested that the patients not mention whether they had met with a phar-

![Fig. 1: Flow diagram showing the recruitment of family physicians and patients into the randomized controlled trial. R = randomization.](image-url)
macist. However, the extent to which the research group alloca-

tion became known to the nurses was not formally assessed.

The primary end-point measure was a reduction in the daily
units of medication taken, as a surrogate for optimized drug ther-

apy. A unit was defined as 1 tablet, 1 teaspoon, 1 drop (eye), 1 ap-
plication of cream or ointment, or 1 dose of insulin. Other short-
term outcome measures that were thought to reflect optimized
drug therapy included the costs of medications, health services use, and health-related costs and quality of life.

The number of units and costs of daily prescription and over-
the-counter medications were determined for each patient at the
beginning and end of the study. Ontario Drug Benefit Program
prices were used as the cost of the drugs covered under this plan.
All other prices were obtained from a commercial drug wholesaler
database or from local pharmacies, if absent from the database.
Average daily costs were calculated for all medications.

Information was gathered on the use of health services during
the study period from the patients’ medical charts and from diaries
completed by the patients for health services that would not nor-
mally be in the medical charts. Fees for physician services were ob-
tained from the Ontario Schedule of Benefits for Insured Medical
Services. The cost of hospital stays and other health services costs
were obtained from an area hospital that was participating in the
Ontario Case Costing Project (www.occp.com). A hospital stay was
considered to be medication-related if it had “probably” or “defi-
nitely” resulted from the effects of a medication or medications on a
patient’s health. To separate hospital stays caused by medication
problems from other hospital stays, 2 experts who were unaware of
study subjects’ allocation (L.D. and a physician) independently as-
essed each hospital stay as medication-related or not, using a list of
the senior’s medications and medical conditions at baseline, the rea-
son for admission and the death certificate, if applicable. Any dis-
agreements were resolved by discussion. The Medical Outcomes
Study 36-item Short Form (SF-36)28 quality-of-life survey was self-
administered at the enrolment and exit interviews.

To evaluate the implementation process within the pharma-
cist–physician pairs, we also determined physician perception of
the service and the extent to which physicians agreed with the rec-
commendations made by the pharmacists for the patients in the in-
tervention arm. In addition, each pharmacist–physician pair
jointly assessed whether each recommendation had been imple-
mented (fully or partially) or attempted.

The experimental unit (and the unit of analysis) was the family
physician, and the patients were considered to be nested within
each physician’s practice.27 The desired sample size of 48 physi-
cians with 15 patients per physician was estimated using an intra-

### Table 1: Drug-related problems identified by pharmacists in the 387 elderly patients in the intervention (pharmacist consultation) group*

<table>
<thead>
<tr>
<th>Drug-related problem</th>
<th>No. of times problem identified</th>
<th>No. of times physicians intended to implement pharmacists’ recommendation</th>
<th>No. of times physicians implemented pharmacists’ recommendation†</th>
<th>Example of each drug-related problem (and a corresponding recommendation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient is not</td>
<td></td>
<td></td>
<td></td>
<td>Patient is at risk of a cardiac event (Add ACE-inhibitor)</td>
</tr>
<tr>
<td>receiving a required</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>drug</td>
<td>305</td>
<td>230</td>
<td>207</td>
<td></td>
</tr>
<tr>
<td>Patient is not taking</td>
<td></td>
<td></td>
<td></td>
<td>Patient has constant arthritis pain and is using ibuprofen as</td>
</tr>
<tr>
<td>an appropriate drug</td>
<td>212</td>
<td>158</td>
<td>153</td>
<td>needed (Change to acetaminophen 500 –1000 mg†)</td>
</tr>
<tr>
<td>Patient is not taking</td>
<td></td>
<td></td>
<td></td>
<td>Patient is not getting the full benefit from an</td>
</tr>
<tr>
<td>a drug appropriately</td>
<td>144</td>
<td>106</td>
<td>116</td>
<td>antihypertensive drug (Patient should take amlodipine besylate</td>
</tr>
<tr>
<td>Patient is taking</td>
<td></td>
<td></td>
<td></td>
<td>regularly instead of sporadically)</td>
</tr>
<tr>
<td>too little drug</td>
<td>108</td>
<td>86</td>
<td>77</td>
<td>Patient is taking a suboptimal dose of salbutamol (Increase dose)</td>
</tr>
<tr>
<td>Patient is taking a</td>
<td></td>
<td></td>
<td></td>
<td>Patient is taking clarithromycin when there is no</td>
</tr>
<tr>
<td>drug for which he or</td>
<td></td>
<td></td>
<td></td>
<td>indication at present time (Discontinue medication)</td>
</tr>
<tr>
<td>she has no indication</td>
<td>98</td>
<td>64</td>
<td>69</td>
<td></td>
</tr>
<tr>
<td>Patient is having an</td>
<td></td>
<td></td>
<td></td>
<td>Patient is experiencing constipation from ferrous</td>
</tr>
<tr>
<td>adverse drug reaction</td>
<td>90</td>
<td>61</td>
<td>60</td>
<td>gluconate, 300 mg 3 times daily by mouth, while ferritin is normal</td>
</tr>
<tr>
<td>Patient is taking</td>
<td></td>
<td></td>
<td></td>
<td>(Discontinue ferrous gluconate)</td>
</tr>
<tr>
<td>too much drug</td>
<td>89</td>
<td>78</td>
<td>72</td>
<td>Patient is experiencing confusion and shakiness, blood glucose is</td>
</tr>
<tr>
<td>Patient is experiencing</td>
<td></td>
<td></td>
<td></td>
<td>2.8 mmol/L (Decrease dose of glyburide from 10 mg daily to 5 mg)</td>
</tr>
<tr>
<td>a drug interaction</td>
<td>47</td>
<td>39</td>
<td>36</td>
<td>Patient is at risk of decreased therapeutic effect as a result of</td>
</tr>
</tbody>
</table>

Note: ACE = angiotensin-converting-enzyme.

*These are patients who either completed the trial or died during the trial.

†Includes full, partial or attempted implementation. Physicians sometimes implemented recommendations by trial end that they had initially not intended to implement.

‡Recommendation based on guidelines in effect at the time of the intervention.
cluster correlation coefficient of 0.08 for daily units of medication, based on a pilot study\textsuperscript{27} and the desire to detect a 15% reduction in daily units of medications in the intervention arm, as compared with the control arm. The hypothesized effect size was based on the results of the pilot study\textsuperscript{27} and was felt to represent a clinically important reduction in the number of daily medication units. To account for the design, both sample size calculations and the analysis were based on a random effects meta-analysis across cluster pairs, proposed by Thompson and colleagues.\textsuperscript{30} In this method, the mean differences in the outcome variables between groups are weighted averages of the mean differences across clusters, or practices, and are compared using an asymptotic test. A one-tailed type I error (alpha) of 0.05 was used for all statistical tests, with a power of 80% to detect the difference.

Results

Of the 69 eligible, randomly selected physicians approached, 48 (69.6%) agreed to participate (Fig. 1). The characteristics of physicians in the intervention and control arms of the study are shown in Table 2. In the 48 participating family practices, 1279 eligible, randomly selected seniors were approached and 889 (69.5%) consented to participate (Fig. 1). After random allocation of the physicians, there were 458 seniors in the control group and 431 in the intervention group. The 2 patient groups had similar demographic and medical characteristics and daily medication use (Table 3).

After 5 months, the mean number of daily prescription and over-the-counter medication units was similar in the intervention arm, with a mean of 12.4 (SD 2.1, range 0–9). After meeting with the pharmacists in 79.8% (344/431) of the seniors in the intervention group, with a mean of 2.5 per senior (standard deviation [SD] 2.1, range 0–9). After meeting with the pharmacists, the physicians reported that they intended to implement 76.6% (837/1093) of the pharmacists’ recommendations. After 5 months, the physicians had succeeded in fully implementing 46.3% (506/1093) of these recommendations and partially implementing 9.3% (102/1093). For 16.7% (182/1093) of the recommendations, implementation had been attempted but was not successful.

The frequency of the various drug-related problems and examples of recommendations are shown in Table 1. The most common drug-related problem identified was the presence of a condition or risk that was not being treated with a required drug. The average length of meeting with a physician, per patient, was 16.4 (SD 8.1) minutes. Physicians reported that they had learned something new as a result of 53.2% (176/331) of the pharmacist consultations. Perceived-impact forms were not completed by physicians for the consultations concerning the other 48 patients.

Reasons for not fully implementing the recommendations included patient reluctance, a previous attempt and failure of the same strategy recommended by the pharmacist, and the inability to deal with a recommendation within 5 months because other more urgent issues had arisen with the patient. The mean health care use and associated costs over the study period for the 2 groups appear in Table 4 at

### Table 2: Characteristics of the family physicians randomly allocated to the intervention (pharmacist consultation) and control groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (and %) of physicians*</td>
<td>No. (and %) of physicians*</td>
</tr>
<tr>
<td></td>
<td>Intervention group</td>
<td>Control group</td>
</tr>
<tr>
<td>Female sex</td>
<td>9.0 (37.5)</td>
<td>7.0 (29.2)</td>
</tr>
<tr>
<td>Certified with the College of Family Physicians of Canada</td>
<td>14.0 (58.3)</td>
<td>8.0 (33.3)</td>
</tr>
<tr>
<td>Mean no. of years since medical school graduation (and SD)</td>
<td>21.3 (12.8)</td>
<td>22.0 (8.0)</td>
</tr>
</tbody>
</table>

Note: SD = standard deviation.

*Unless stated otherwise.

### Table 3: Baseline characteristics of the 889 patient participants at study enrolment (unclustered results)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (and %) of participants*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (and SD), yr</td>
<td>Intervention group</td>
</tr>
<tr>
<td>Mean length of time with physician (and SD), yr</td>
<td>74.0 (6.1)</td>
</tr>
<tr>
<td>Female sex</td>
<td>10.2 (9.0)</td>
</tr>
<tr>
<td>Married/common-law spouse</td>
<td>277 (64.3)</td>
</tr>
<tr>
<td>Born in Canada</td>
<td>251 (58.2)</td>
</tr>
<tr>
<td>Education†</td>
<td>258 (59.9)</td>
</tr>
<tr>
<td>Elementary</td>
<td>115 (26.9)</td>
</tr>
<tr>
<td>High school</td>
<td>217 (50.8)</td>
</tr>
<tr>
<td>College/university</td>
<td>95 (22.2)</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>45 (10.4)</td>
</tr>
<tr>
<td>Current user</td>
<td>151 (35.0)</td>
</tr>
<tr>
<td>Never used</td>
<td>235 (54.5)</td>
</tr>
<tr>
<td>Alcohol use</td>
<td>238 (55.2)</td>
</tr>
<tr>
<td>Current user</td>
<td>165 (38.3)</td>
</tr>
<tr>
<td>Past user</td>
<td>8.0 (20.1)</td>
</tr>
<tr>
<td>Never used</td>
<td>146 (34.3)</td>
</tr>
</tbody>
</table>

*Unless stated otherwise.

†Data are missing for 4 participants in the intervention group and for 1 participant in the control group.
www.cmaj.ca. Including the cost of the pharmacist intervention and only drug-related hospital stays, the mean cost of health care resources per senior was $1281.27 in the intervention group and $1299.37 in the control group (p = 0.45). A decline in the mean scores for health-related quality of life was observed for the seniors in both groups for all of the subscales of the SF-36 quality-of-life survey from baseline to study exit, except for physical functioning in the control group, with no significant differences between the groups (see Table 5 at www.cmaj.ca).

**Interpretation**

The concept that pharmacists can have a positive impact on patients’ drug therapy is becoming widely accepted as a result of encouraging randomized trial evidence. Although we did not find statistically significant effects of the pharmacist interventions on the number and cost of medications, health care use and cost, or health-related quality of life, the physicians did act on the majority of recommendations made by the pharmacists. This demonstrates that the 2 professional disciplines were able to collaborate to improve the pharmacotherapy of elderly patients.

Several randomized trials have shown that pharmacists with specialized training can improve prescribing and reduce health care use and medication costs. Pharmacists have also been shown to improve clinical measures in patients with hypertension, hyperlipidemia and diabetes. However, these findings were limited in their generalizability to pharmacists collaborating with family physicians in their offices. Widespread interventions in primary care with pharmacists with advanced training (PharmD degrees) would not be feasible at this time in Canada because of the small number of individuals trained. Our study examined a generalizable and implementable pharmacist consultation program using resources that already existed in the community.

The results of studies examining the effects of consultations with community pharmacists without specialized training have been inconclusive to date. Pharmacists who have directly interacted with patients in the pharmacy setting have been able to improve cholesterol levels, prescribing outcomes and compliance. However, pharmacist interventions were not found to improve clinical measures in patients with reactive airways disease or to improve quality of life, even for the seniors in both groups for all of the subscales of the SF-36 quality-of-life survey from baseline to study exit, except for physical functioning in the control group, with no significant differences between the groups (see Table 5 at www.cmaj.ca).

A strength of this study was the high participation rate from both randomly selected physicians and their elderly patients. Participating community physicians worked in both rural and urban locations and were not part of academic practices. The local pharmacists did have additional training but were not so different from other community pharmacists that the intervention would not be replicable. In contrast to other models in which pharmacists have directly counselled and managed patients, the intent of our model was to provide family physicians with an on-site service for their patients. By removing the pharmacists from their pharmacies, we hoped that they would be perceived as health care professionals without a conflict of interest in providing patient care.

Although no improvements in patient outcomes were found, this study has demonstrated the feasibility and acceptability of a collaborative relationship between family physicians and local, specially trained pharmacists.
Acknowledgements: We gratefully acknowledge the family physicians, pharmacists and the senior citizens who participated in this study. We thank Lesley Lavack, Assistant Dean, Faculty of Pharmacy, University of Toronto, for her assistance with recruiting and training the pharmacists. We also thank Dr. Stuart MacLeod for his expertise in assessing hospital admissions and for overall support of the project.

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References


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