

# Impact of a pharmaceutical care model for non-institutionalised elderly: results of a randomised, controlled trial

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**Objectives** — To measure the impact of a community-based geriatric pharmaceutical care model on specific process measures.

**Methods** — The model was evaluated using a prospective, randomised, controlled study design. Clients who self-presented or were referred by Home Care were eligible if they were 65 years of age or older, non-institutionalised, taking two or more prescribed or non-prescribed medications, and willing to provide signed informed consent. A pharmacist conducted a comprehensive drug therapy review on test clients, then addressed issues with the client and/or the client's physician, with follow-up as required. Measurements included number of drugs, drug knowledge, adherence to therapy, cost of prescribed medicines, and number of reported symptoms obtained from a home medication history conducted by trained volunteers, the provincial prescription claims database, and response to a physician survey.

**Setting** — The pharmaceutical care model was situated within a community-based interdisciplinary health clinic targeting non-institutionalised elderly.

**Key findings** — One hundred and thirty-five clients were randomised to test (n=69) or control (n=66). A mean of 14.4 (SD 4.6) potential or actual issues were identified in test clients. Ninety-four per cent of physicians agreed with at least one of the pharmacist's recommendations but only 230 of 794 recommendations by the pharmacist (29 per cent) resulted in a change. There was no difference in overall number of prescribed or over-the-counter medications, drug costs, symptoms reported, drug knowledge or medication adherence between test and control groups post-intervention.

**Future research** — Further research is needed to identify barriers to changing drug use behaviour and facilitating acceptance of pharmaceutical care in the community.

THE elderly are the largest consumers of prescription medications. In Manitoba, in 1996, 84.1 per cent of seniors received at least one prescription drug, and they purchased 35.6 per cent of all prescriptions while comprising only 13.6 per cent of the population.<sup>1</sup> It is estimated that by the year 2041, seniors will make up 22-25 per cent of the Canadian population and medication use by the elderly will continue to have a significant influence on the health and economics of our ageing society.<sup>2</sup>

Although appropriate drug use is recognised as a very cost-effective component of health care expenditure,<sup>3</sup> medication-related problems in the elderly are prevalent. Studies suggest that comprehensive medication reviews conducted by pharmacists identify potential or actual medication-related issues in at least 80 per cent of elderly patients.<sup>4-6</sup> Between 12 and 46 per cent of

drugs prescribed for the elderly are either inappropriate or unnecessary.<sup>7-11</sup> It has also been estimated that about 50 per cent of patients, including the elderly, do not adhere to prescribed regimens.<sup>12</sup> Drug-related problems are often significant and have been associated with at least 19 per cent of hospitalisations of the elderly.<sup>13</sup>

Pharmaceutical care is a philosophy of patient-focused pharmacy care which has been widely accepted as the future standard for pharmacy practice.<sup>14-17</sup> Pharmaceutical care involves conducting a medication history, assessment of potential or actual drug-related issues, intervention, documentation and follow-up. It has been estimated that if pharmaceutical care was provided in all ambulatory care pharmacy settings in the United States, the occurrence of negative therapeutic outcomes would be reduced by 53-63 per cent and approximately 60 per cent of direct

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costs associated with drug-related morbidity and mortality would be avoided.<sup>18</sup> However, this has not been confirmed in the existing pharmaceutical care research literature which is limited in both quality and quantity.<sup>19</sup>

The objectives of this research project were: (1) to determine number, type and outcome of drug-related issues identified in a sample of non-institutionalised elderly who received pharmaceutical care; (2) to measure the impact of the recently developed pharmaceutical care model on specific process measures, including number of drugs, drug knowledge, adherence to therapy as well as the cost of prescribed medicines and number of symptoms; and (3) to document physician satisfaction with the pharmacy consultation services provided and compliance with recommendations.

## Methods

A model of pharmaceutical care was developed within Lions Place for Health, a community-based, interdisciplinary health clinic. Clients self-presented to the clinic or were referred by Home Care (a provincial programme offering health services and assistance with daily living activities for individuals at risk of institutionalisation). Clients were eligible for study if they were 65 years or older, non-institutionalised and taking two or more prescribed or non-prescribed medications. This study received the approval of the University of Manitoba Faculty Committee on the Use of Human Subjects in Research and all subjects provided informed consent prior to their participation.

A detailed home medication history (HMH) was conducted by trained staff or volunteers on all clients. Volunteers participated in a three-hour training session and were supervised by a pharmacist consultant during the first interview. The HMH was a standardised instrument designed to gather specific, detailed information on drug therapy and on certain medication-taking behaviours.<sup>4</sup> The instrument was determined to be at least 70 per cent reliable when used by lay volunteers.<sup>20</sup> Consistent with a comprehensive model of pharmaceutical care, it addressed many areas of medication use including use of prescribed and non-prescribed medications, social drugs (caffeine, nicotine, alcohol), home remedies (eg, mustard plaster, goose grease, copper arthritis bracelets), the client's daily routine and medication regimen, their adherence to therapy, contact and willingness to communicate with health care professionals, financial impact of drug therapy, problems clients experienced taking or using medications due to physical or sensory limitations, symptoms experienced, and past medication allergies and intolerances. Symptoms were determined by asking the client to respond to the question: "In the past month, have you experienced any . . ." outlining a checklist

of 22 different symptoms (plus "other") read out by the interviewer and, for each symptom experienced, its frequency of occurrence (daily, weekly, monthly or less often). During the HMH, the cost of each prescribed medication was recorded from the label and a projected annual cost of each medication was calculated. Other data collected during the HMH included demographic data (age, gender, housing status, race, income, education level) as well as the client's Manitoba Health Number.

Using a computer generated randomisation list, clients were assigned to either a test or control group. All clients were informed, in a letter, of their allocation. The HMH was reviewed by a pharmacist consultant (with a Bachelor of Science degree in pharmacy) on test clients to identify and document potential and actual drug-related issues. The pharmacist was trained and supervised by a clinical pharmacist (with a Doctorate of Pharmacy) with expertise in geriatrics. Intervention with the physician was provided in the form of a letter summarising the information gathered and the pharmacist consultant's recommendations and comments. Clients consulted a wide range of physicians who were not necessarily known or geographically close to the pharmacist. Recommendations were reviewed for appropriateness by a consultant geriatrician prior to forwarding to the physician. The date the letter was sent to the physician was considered to be the intervention date. Intervention with test clients involved patient counselling in a private office or at their home supplemented with written information. The pharmacist met with test clients, as required, for follow-up to monitor specific therapeutic endpoints and to identify and resolve other issues as they arose. Further details regarding the comprehensive process for pharmaceutical care was described in the pilot project reports.<sup>5,21</sup>

The HMHs on control clients were reviewed by a different pharmacist who referred clients to their usual pharmacist but answered any immediate concerns. Clients considered to be at risk of "life-threatening" drug-related problems by the "control" pharmacist were required to withdraw from the study. Six months after the intervention date the HMH was re-administered by blinded, trained volunteers.

A second data source, the provincial prescription claims database, also provided information on number of drugs, adherence to therapy, and cost of medicines. Information from this data source was compared one year pre- and one year post-intervention date. A report on adherence calculation methods was previously published.<sup>22</sup> The calculation used in this study is illustrated below:

$$\text{Per cent adherence} = \frac{\text{sum of "days supply" in interval} \times 100}{\text{actual number of days in interval between first and last fill}}$$

Drug-related issues identified in the letter written to the physician and the client's information sheet were categorised by a pharmacist and a nurse. Results of the pilot project<sup>5</sup> led us to adapt the categories for drug-related problems originally proposed by Strand *et al* (see reference 5). We defined two groups of drug-related issues: direct issues, which were associated with specific pharmacotherapy, and associated issues, which were behaviours or circumstances which had the potential to lead to adverse medication events.

In order to assess whether the issues identified and addressed by the pharmacist for "test" clients were resolved, HMHs were reviewed independently by a nurse and a pharmacist. The assessors used data collected in the baseline and follow-up HMHs to compare the use of prescribed and non-prescribed drugs, the presence or absence of symptoms, and symptom frequency or severity between the two interview times to determine whether drug-related issues were resolved, partially resolved, not resolved or "outcome unknown."

Physician opinion was requested through a mailed survey accompanying the pharmacist's letter which included a self addressed, stamped envelope. The survey consisted of three questions: "In the letter regarding your patient, Mr/s X, we proposed N suggestions/informative comments. (1) How many recommendations did you agree with? (2) How many recommendations resulted in a change to the drug regimen? and (3) In general, what is your opinion of this pharmacy consultation service (very useful, somewhat useful, neutral opinion, waste of time)?" Repeated mailings and telephone follow-ups were conducted with non-responders to encourage completion of the survey.

The sample size was calculated using medication adherence as the primary endpoint. A sample size of 100 test drugs and 100 control drugs was required to detect at least a 20 per cent change with 80 per cent certainty and a two-tailed significance level set at  $\alpha=0.05$ . Data were coded for computer entry using SAS-FS.<sup>23</sup> Chi-square analysis and McNemar's test for correlated proportions were used for bivariate comparisons of categorical variables and Student's t-tests for continuous variables. Mantel-Haenszel  $\chi^2$  and repeated measures analysis of variance were used, respectively, for comparisons involving changes in baseline versus follow-up between test and control groups in frequencies and means.

## Results

Of 190 clients referred to the pharmacist consultant between May 27, 1993, and April 27, 1995, 139 (73 per cent) completed the home medication history (HMH). Data on four clients were excluded (one client was less than 65 years old, one client did not sign the consent form, and

**Table 1: Demographic data on test and control subjects**

Variable	Test n=69	Control n=66	P value
Gender: female	52 (75%)	55 (83%)	0.254
Age: mean $\pm$ SD	76.9 $\pm$ 8.4	77.2 $\pm$ 8.8	0.786
Race: Caucasian	69 (100%)	66 (100%)	1.000
Education			
< 9th grade	17	14	0.712
grades 9-12	33	29	
some college	12	12	
college graduate	7	11	
Housing status			
lives alone	42 (61%)	51 (77%)	0.018
Annual income			
<\$15,000	28	36	0.259
\$15-30,000	19	15	
>\$30,000	10	4	
not available	12	11	
Financial hardship	11 (16%)	18 (27%)	0.119

two control clients were withdrawn because of potentially life-threatening drug-related issues). Demographic data on the remaining 69 test and 66 control clients are presented in Table 1. Between baseline and follow-up HMH, there were an additional 21 withdrawals (13 test, eight control). Fifteen clients withdrew (10 test, five control), four clients died (two test, two control), one client was transferred to a nursing home and one client could not be contacted for a follow-up interview.

The pharmacist was able to fully evaluate and make recommendations on 66 of the 69 baseline test clients (one death, one transfer to nursing home, and one withdrawal). All of the 66 test clients had at least one drug-related issue and a mean of  $14.4 \pm 4.6$  potential or actual issues were identified (range 5-27). The frequency of direct and associated drug-related issues identified in the 66 test clients and the frequency of their resolution in the 56 test clients available for follow-up are listed in Table 2. Common issues included adverse drug reactions, need for prevention strategy (for example immunisation, osteoporosis prevention), and improper storage of medication. Partial or complete resolution was noted for 230 (29 per cent) of the 794 pharmacist recommendations made.

Fifty-seven doctors were sent letters regarding 66 clients and a response was received regarding 35 (53 per cent) clients. Of the 35 physician responses, 33 (94 per cent) agreed with at least one recommendation. These 33 physicians agreed with 118 of 158 (75 per cent) recommendations. Additionally, 29 out of 35 (83 per cent) rated the services as somewhat or very useful and 23 (66 per cent) indicated that at least one change would be made to the drug regimen.

Table 3 presents comparisons between test and control groups for number and cost of prescribed medications as derived from the provincial prescription claims database. Costs were also estimated from the baseline and follow-up HMHs and were not different between groups. There was no difference noted between groups at base-

**Table 2: Drug-related issues requiring intervention and their resolution**

	Direct issues		Associated issues		
	Baseline: Frequency (% total)*	Follow up: Resolution† (% issue)‡	Baseline: Frequency (% total)*	Follow up: Resolution† (% issue)‡	
Adverse drug reactions	197 (21)	45/173 (26)	Need for primary prevention strategy	138 (14)	16/110 (15)
Improper drug selection	67 (7)	19/60 (32)	Improper storage of medications	76 (8)	42/68 (62)
Untreated indication	65 (7)	19/56 (34)	Sensory/physical/cognitive limitations	53 (6)	5/44 (11)
Drug use without indication	65 (7)	15/44 (34)	Inadequate knowledge	40 (4)	15/31 (48)
Drug interactions	53 (6)	11/48 (23)	Outdated label	27 (3)	11/26 (42)
Suboptimal dosing regimen	46 (5)	11/36 (31)	Cheaper alternatives available/financial hardship	19 (2)	0/15 (0)
Overdosage	32 (3)	5/25 (20)	Multiple physicians or pharmacists	13 (1)	3/11 (27)
Intentional/unintentional non-adherence	27 (3)	8/22 (36)	Poor communication with health care professionals	8 (1)	2/6 (33)
Subtherapeutic dose	26 (3)	3/19 (16)			
<b>Subtotal</b>	<b>578</b>	<b>136/483 (28)</b>	<b>Subtotal</b>	<b>374</b>	<b>94/311 (30)</b>

\* A total of 952 potential or actual drug-related issues were identified, at baseline, in the 66 test clients

† Issue determined to be fully or partially resolved at follow-up

‡ The number of issues (denominator) was fewer than at baseline for each category since only 56 test clients were available for follow-up

line compared with follow-up on the endpoints measured. A subanalysis on the group of test clients whose physicians agreed with the pharmacist recommendations and indicated that they would make at least one change to the medication regimen also found no difference in endpoints.

Table 4 compares the test group against controls for measures which related to self-medication behaviour and knowledge of drug purpose, as well as number of reported symptoms (within previous month).

At baseline, control subjects were using a greater mean number of home remedies

**Table 3: Changes in number and cost of prescribed medications**

Variable	Test		Control		P value
	Baseline	Follow-up	Baseline	Follow-up	
<i>Prescribed drug products</i>					
	n=69	n=56	n=66	n=58	
Number (%) taking	69 (100)	56 (100)	63 (95)	54 (93)	0.119
Mean ± SD	5.9±3.1	5.9±3.5	6.5±3.4	6.7±3.7	0.760
Number discontinued		1.3±1.7		1.2±1.3	0.568
<i>Estimated annual prescription drug costs (\$) per client*</i>					
	n=61	n=61	n=60	n=58	
Mean ± SD	881±650	809±578	944±687	874±754	0.971

\* Given that 66 of the 69 test clients reached the point of intervention, attempts were made to obtain Manitoba Health medication costs for all 135 eligible clients (69 test and 66 control) unless clients requested full withdrawal from the study

**Table 4: Changes in self-medication taking behaviour and knowledge**

Variable	Test		Control		P value
	Baseline n=69	Follow-up n=56	Baseline n=66	Follow-up n=58	
<i>Non-prescribed drugs*</i>					
Number (%) taking	69 (100)	55 (98)	65 (98)	57 (98)	0.575
Mean ± SD†	7.2±4.1	6.8±3.4	5.9±3.8	5.8±3.2	0.130
Number discontinued‡		3.3±3.0		2.3±2.2	0.033
<i>Home remedies</i>					
Number (%) taking	24/68 (35)	18/54 (33)	20/65 (31)	14/57 (25)	0.277
Mean ± SD‡§	1.0±0.2	1.1±0.3	1.4±0.6	1.1±0.4	0.160
<i>Hoarded drugs</i>					
Number (%)	41/67 (61)	25/55 (45)	43/65 (66)	23/54 (43)	0.821
Mean ± SD¶	3.0±2.9	1.8±1.2	2.7±2.2	2.0±2.0	0.018
<i>Prescribed drugs</i>					
Knows purpose	n=403 368/402 (92)	n=329 304/327 (93)	n=412 379/412 (92)	n=374 335/373 (90)	0.397
<i>Symptoms reported</i>					
Mean ± SD	7.2±3.7	7.9±4.1	7.5±3.5	7.2±3.7	0.089
<i>Medication adherence (by drug)</i>					
Mean ± SD	n=252 95.0±79.4	n=309 86.7±46.0	n=230 95.5±56.7	n=280 85.1±41.1	0.895

\* Includes herbal remedies. At baseline 33 per cent of test clients and 17 per cent of controls were using herbal remedies

† Mean number includes users only

‡ More discontinued drugs for test group ( $P < 0.04$ )

§ Users in the control group took more home remedies at baseline ( $P < 0.02$ )

¶ Both test and controls decreased at follow up ( $P < 0.02$ )

( $P < 0.02$ ). At follow-up, a greater mean number of non-prescribed drugs were discontinued in the test group ( $P < 0.04$ ) and the mean number of hoarded drugs decreased for both test and control groups ( $P < 0.02$ ).

## Discussion

This report describes one of the few prospective, randomised controlled studies evaluating the impact of a pharmaceutical care model for non-institutionalised elderly. Previous research on the benefits of pharmacists' interventions has rarely focused on the elderly, especially in the community setting.<sup>19,24,25</sup> A recent critical analysis of the pharmaceutical care research literature determined that most published studies are deficient in their research design and many studies mislabel the term "pharmaceutical care" for such pharmacy services as patient counselling, pharmacokinetic services or drug utilisation review.<sup>19</sup>

In this study, a pharmacist's comprehensive intervention strategy resulted in the identification of a large number of drug-related issues. All of the test clients had at least one drug-related issue. Of note was the low resolution rate of these issues despite relatively positive survey responses by physicians. Physicians were made aware of this study by way of the provincial association newsletter and recommendations to physicians were made primarily in writing. The lack of verbal communication with physicians might explain the low acceptance rate. Rees *et al*, in a similar community-based study, also found a low implementation rate (17 per cent of recommendations) by physicians, despite an independent review panel assessing most of the recommendations as either beneficial or even life-saving.<sup>26</sup> In contrast, high acceptance rates of over 80 per cent have been noted in studies conducted in the hospital, clinic and family practice settings, where physicians and pharmacists have developed close working relationships.<sup>5</sup>

Several barriers to a successful working relationship between community pharmacists and physicians have been identified including limited direct contact between professionals, physician "territoriality", and a lack of understanding of pharmacists' extended role by physicians.<sup>27</sup> Reebye *et al* proposed a "pharmacist-patient-physician" communication triangle model and suggested that improved interactions between the pharmacist and the physician could enhance patient care.<sup>27</sup> Based on their survey of 36 Canadian and 36 Dutch community pharmacists, four strategies to improve patient care were identified: (1) increased professional interaction; (2) developing a mutual understanding of roles; (3) participating in joint initiatives; and (4) holding structured meetings between physicians and pharmacists.

The Canadian Pharmaceutical Association and the Canadian Medical Association joint state-

ment "Approaches to enhancing the quality of drug therapy"<sup>28</sup> recognises the importance of the client, the pharmacist and the physician working in close collaboration and partnership to achieve optimal outcomes from drug therapy. It is notable that the "pharmacist's responsibilities in drug therapy" outlined in the document supports the practice of pharmaceutical care.

Although more non-prescription drugs were discontinued in the intervention group, the pharmacist was not able to favourably impact on the mean number or costs of prescribed medications, even for the group of test clients whose physicians were willing to make some changes to the medication regimen. These findings were similar to two other randomised control trials of non-institutionalised elderly, where the pharmacists were also unable to impact on the number of prescribed drugs.<sup>25,29</sup> A reduction in the number of prescribed drugs in the elderly is clearly a desirable endpoint given the strong predictive power of this variable on the rate of drug-related morbidity.<sup>4,13</sup> However, it is probably not an appropriate quality of care measure for comprehensive geriatric pharmaceutical care. This assumption seems reasonable, given that only 35 per cent of the 952 drug-related issues identified in our test sample had the potential to reduce costs or numbers of medications (ie, adverse drug reactions, drug interactions, drug use without indication, and cheaper alternatives available.) The remaining 61 per cent of issues might have either increased or had no effect on number and cost of medications. The finding that not all significant interventions result in reduced number or cost of drugs was previously reported and underscores the importance of selecting quality of care measures which are responsive to a given intervention.<sup>30</sup> Especially in a group as heterogeneous as the elderly, there is wide variability in what constitutes a positive effect; for optimal health outcomes, some older persons may require a higher number or more costly medications.

Two separate studies have developed criteria for "medication appropriateness" and were able to demonstrate a beneficial effect of pharmacy services provided to the elderly by this measure.<sup>6,29</sup> Consideration might also be given to an adaptation of Goal Attainment Scaling, involving a system of goal setting and measurement of goal attainment, in future pharmaceutical care research involving the elderly.<sup>31</sup> The measurement of patient satisfaction or quality of life might have also been more responsive to the patient-focused pharmacy services provided, although studies using these endpoints in the elderly have produced inconsistent results.<sup>25,29</sup>

The study had a number of limitations. Since a pharmacist addressed control clients' immediate concerns, this may have contaminated the control group. A physician may have had patients from both control and intervention groups, raising the possibility of cross contamination.

The study accepted patients taking two or more medications, a criterion much lower than most previous studies. While this may have weakened the ability to detect the effects of pharmaceutical care, it improved the "external validity" or generalisability of our findings. Since the sample size was calculated with medication adherence as the primary outcome, the study may be underpowered for the other outcomes measured. Subjects included in this study might not have been representative of the elderly population at large. Clients recruited for the study were drawn either from a self-presenting, highly motivated and relatively well elderly population or from a referred, frail elderly population requiring extensive support (which may have included review or supervision of medication). Since baseline-adherence in these samples was high, it would have been difficult to see any change in this outcome. Categorisation of outcomes was a challenge for the health care professionals involved in this process. Given the nature of the drug-related issues as either potential or actual, outcomes had the potential to be theoretical rather than actual.

In summary, using a randomised, controlled study design, a pharmaceutical care model for the non-institutionalised elderly did not impact significantly on outcome measures including number of prescribed medications, adherence to therapy, knowledge of the purpose of medication, cost of medication, and number of symptoms reported. Collaboration between physicians, patients and pharmacists will need to improve before the full benefits of pharmaceutical care are realised.

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