

Drug-Related Problems Identified and Resolved Using Pharmaceutical Care Versus Traditional Clinical Monitoring

Stephen Shalansky, Robert Nakagawa and Annabel Wee

ABSTRACT

Many hospital pharmacy departments are implementing pharmaceutical care (PC); however, time limitations are making this transition difficult. Unfortunately, with the current economic climate, increased staffing is unlikely in the foreseeable future. With this in mind, we designed a study to assess the impact of PC versus traditional clinical pharmacy monitoring on the number of drug-related problems (DRPs) identified and resolved without changing staffing levels or time allocated to clinical practice. Data collection was prospectively carried out during two eight-week periods on two general medicine wards (64 beds total) staffed by 1.5 full time equivalent clinical pharmacists. The same pharmacists were involved in both arms of the trial. The two data collection periods were separated by four months during which the clinical pharmacists learned and practiced PC. The two phases were similar in terms of the number of monitoring shifts (73 vs. 73), mean hours of monitoring per shift (3.9 ± 1.3 vs. 3.9 ± 1.5), mean ward census (29.3 ± 2.5 vs. 29.8 ± 2.2), mean patient age (67.1 ± 18.1 vs. 68.4 ± 16.0), and diagnoses. There were fewer patients monitored per shift during the PC phase (8.6 ± 3.2 vs. 14.1 ± 5.8), yet there were significantly more DRPs per shift identified (6.75 ± 5.25 vs. 8.63 ± 5.69 , $p=0.04$) and resolved (5.92 ± 4.74 vs. 7.79 ± 5.29 , $p=0.025$). There was no obvious advantage of either approach in terms of drug-related cost avoidance. In conclusion, despite caring for fewer patients using PC, more DRPs can be identified and resolved. Further study is required to assess whether implementing PC will result in improved patient outcomes.

Key Words: clinical services, drug-related problems, patient monitoring, pharmaceutical care, pharmacotherapy monitoring

RÉSUMÉ

De nombreux services de pharmacies d'hôpitaux passent des soins traditionnels aux soins pharmaceutiques (SP). Toutefois, les contraintes de temps rendent cette transition difficile et la situation économique actuelle ne laisse pas entrevoir d'accroissement d'effectif dans un proche avenir. C'est dans cet esprit que nous avons conçu une étude visant à évaluer l'impact des SP comparativement à celui du monitoring pharmacothérapeutique clinique traditionnelle, sur le nombre de problèmes pharmacothérapeutiques (PP) qui ont été identifiés et résolus sans allouer plus de personnel ou de temps

à la pratique clinique. Les données ont été recueillies prospectivement au cours de deux périodes de huit semaines, dans deux services de médecine générale (64 lits au total) dotés de 1,5 pharmaciens cliniciens équivalents. Les mêmes pharmaciens cliniciens ont fait l'objet des deux phases de l'étude. Les deux périodes de collecte des données étaient séparées par un intervalle de quatre mois durant lequel les pharmaciens cliniciens ont appris et prodigué les soins pharmaceutiques. Les deux phases de l'étude étaient semblables en terme de nombre de quarts de surveillance pharmacothérapeutique (73 c. 73), d'heures moyennes de monitoring pharmacothérapeutique par quart ($3,9 \pm 1,3$ c. $3,9 \pm 1,5$), de recensements par service ($29,3 \pm 2,5$ c. $29,8 \pm 2,2$), d'âge moyen des patients ($67,1 \pm 18,1$ c. $68,4 \pm 16,0$), et de diagnostics. On a observé un nombre inférieur de patients ayant fait l'objet d'une monitoring pharmacothérapeutique par quart durant la phase des SP ($8,6 \pm 3,2$ c. $14,1 \pm 5,8$); malgré ce fait, un nombre significativement plus élevé de PP par quart ont été identifiés ($6,75 \pm 5,25$ c. $8,63 \pm 5,69$; $p = 0,04$) et résolus ($5,92 \pm 4,74$ c. $7,79 \pm 5,29$; $p = 0,025$). Aucun avantage en terme de réduction des coûts en médicaments n'a été noté avec l'une ou l'autre approche. Bien qu'un moins grand nombre de patients puissent recevoir des soins avec la méthode des SP, un nombre supérieur de PP peuvent cependant être identifiés et résolus. D'autres études

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sont nécessaires pour évaluer si oui ou non la mise en oeuvre des SP se traduira par des résultats thérapeutiques plus favorables pour le patient.

Mots clés : monitoring des patients, monitoring pharmacothérapeutique, problèmes pharmacothérapeutiques, services cliniques, soins pharmaceutiques

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INTRODUCTION

Since Helper and Strand published their landmark paper in 1990,¹ pharmaceutical care (PC) has quickly become the focus of future direction for the pharmacy profession. It is endorsed by the Canadian Society of Hospital Pharmacists,² the American Society of Hospital Pharmacists, as well as several other pharmacy organizations.³ Many hospitals in Canada and the United States are investigating this approach or are in the process of implementing PC. Unfortunately, there has been very little work studying the potential impact of PC versus traditional clinical pharmacy monitoring on hospital pharmacy practice and patient care.

It is important to determine the impact of PC on patient outcomes. As identified by Strand, positive patient outcomes that result from appropriate drug therapy include cure of the disease, reduction or elimination of the patient's symptoms, the arrest or slowing of the disease process, and the prevention of disease or symptoms. Unfortunately, these outcomes are very broad and the contributions of the pharmacist-provider of PC cannot be isolated from that of physicians, nurses and other health professionals.⁴ PC, thus, focuses on identification and resolution of drug-related problems (DRPs) as the pharmacist's contribution to patient care. As stated by Strand et al, "The absence or presence of potential drug-related problems serves as a pharmacotherapeutic outcome for the purpose of identifying the pharmacist's contribution."⁴

Traditional clinical monitoring, that described by the Canadian Society of Hospital Pharmacists as level I to III patient pharmacotherapy monitoring (PPM), tends to result in drug or task-specific interventions without specifically attempting to resolve all DRPs in each patient.⁵ The patient-specific approach of PC will require more pharmacist time per patient than traditional patient monitoring.⁶ Therefore, hospital-wide implementation of PC will require reorganization and possibly increased clinical staffing in order to meet these demands. With the current state of health care funding in Canada, additional staffing is unlikely. Furthermore, many departments are already understaffed making additional clinical time with existing staff difficult to justify. Without an increase in the number of clinical pharmacists or the time devoted

to clinical activities, implementation of PC will result in fewer patients monitored per day.

With this in mind, we designed a trial to study the impact of PC versus traditional clinical pharmacy monitoring on the identification and resolution of DRPs on two general medicine wards. In order to assess the result of implementing PC without increasing staff, the number of hours devoted to clinical monitoring was kept constant between the two phases of the study.

METHODS

This trial was carried out at Lions Gate Hospital (LGH), a 350-bed community hospital serving a population of approximately 170,000 in North and West Vancouver. The Pharmacy Department consists of 30.4 full time equivalent (FTE) staff including 14.2 FTE staff pharmacists and two pharmacy residents.

Data collection was divided into two eight-week phases: a control and a PC phase. Three pharmacists, 1.5 FTEs dedicated to clinical monitoring, participated in the study. Each of these pharmacists had at least four years of clinical experience at this institution and were involved in both phases. Two general medicine and surgery wards totaling 64 beds were chosen as the study site. There was no medical resident or intern program at LGH; therefore, the physicians involved in caring for patients on the study wards were consistent between study phases.

During the control phase, a drug or problem-specific monitoring approach was used. Problems were identified through review of the medication profile, serum drug levels reported by the laboratory (aminoglycosides, vancomycin, theophylline), and by a computer generated "clinical investigation report". This report included a list of patients whose entered medication profile contained drug - drug interactions, drug - allergy conflicts, flagged drugs (e.g., aminoglycosides, salbutamol nebulizer orders), or comments regarding potential problems identified by the dispensary pharmacist. Time was prioritized based on resolving the problems identified by this system, without specifically attempting to identify all DRPs in each patient seen.

The phases were separated by a four-month period during which the study pharmacists learned and practiced PC. This included a series of readings, lectures delivered by individuals with PC experience, and a three-week visitation at an institution with an established PC program. During the visitation, pharmacists were closely followed to ensure that the principles of PC were being employed. After the visitation, pharmacists were scheduled for several additional weeks of patient care at LGH to practice the PC approach on the study wards before the study PC phase began.

During the PC phase, the PC approach described by Hepler and Strand^{1,4} was employed. That is, the pharmacist employed a patient-specific approach in an effort to thoroughly identify and resolve all existing or potential drug-related problems in each patient seen. A pharmacist-patient relationship was established to ensure that the patient's opinions were included in the therapeutic plan. Selection of patients to be followed was left to the discretion of the pharmacist which included consideration of the problem lists described for the control phase, admitting diagnosis (i.e., high priority if drug-related), age, number of medications prescribed, and nurse or physician referrals.

The monitoring forms utilized during the study enabled the pharmacists to prospectively collect the following data: the number of hours spent monitoring patients each day, the number of patients monitored per day, a brief description of each DRP identified, whether the problem was resolved, unresolved or resolved without intervention, and a description of the resolution. The decision as to whether or not a DRP was resolved was made after the necessary follow-up and was at the discretion of the clinical pharmacist. Problems resolved without intervention of the pharmacist were not included in the analysis. An independent observer not otherwise involved in the trial (same individual in both phases) assigned each DRP a category as described by Strand et al⁷ and a severity rating as described by Chase et al.⁸ The severity rating was designed to reflect the potential for harm to the patient if unresolved: 1 = no apparent harm, 2 = potential harm, 3 = harmful.

One hundred resolved problems were randomly selected from each phase for a cost-avoidance analysis. Cost calculations were based on estimated differences between original drug regimens and those changed according to a pharmacist's intervention. This included analysis of drug acquisition, labour, and equipment costs. Drug costs were the 1994 drug acquisitions costs based on the group purchasing contract prices for LGH. Labour costs were based on the Guidelines for Management Information Systems in Canadian Health Care Facilities⁹ and best estimates for procedures not listed. The duration of therapy for discontinued regimens was calculated based on an estimate of the number of doses the patient would have received had the pharmacist not intervened: that is, the shorter of hospital stop order policies or the date of transfer or discharge. Equipment costs included acquisition costs for minibags, diluent, syringes, secondary lines, alcohol swabs, and venting needles. Laboratory costs and the costs of drug-related adverse effects were not included in the analysis.

Statistical Analysis

All data were analyzed in consultation with a professional statistician using SPSS[®] for Windows[™] release 6.1.3

statistical software. The duration of each data collection phase (eight weeks) was established to enable detection of a 15% difference in the number of DRPs identified and resolved (alpha = 0.05, power = 0.80) based on previous clinical data from the study wards. The primary outcome parameters were set *a priori* as the number of DRPs identified and resolved per shift. These were analyzed using a two-tailed t-test for independent samples with a p value of 0.05 considered statistically significant. All other data was analyzed using descriptive statistics.

RESULTS

The time devoted to patient care was essentially identical in both phases: 73 shifts in both cases, 3.9 ± 1.3 hours/shift in the control phase versus 3.9 ± 1.5 hours/shift in the PC phase. However, there were fewer patients followed per shift in the PC phase (8.6 ± 3.2 versus 14.1 ± 5.8) despite similar mean ward censuses (29.8 ± 2.2 versus 29.3 ± 2.4).

The characteristics of the patients cared for are listed in Table I, along with the characteristics of all patients admitted to the study wards during the two study periods (ward populations). In the PC phase, pharmacists selected patients with longer hospital stays and those prescribed more medications. The distribution of diagnoses was similar between the two phases with the

Table I: Patient Demographics

	Control Phase		PC Phase	
	monitored patients	ward population	monitored patients	ward population
number of patients	183	438	128	368
percent female	58.0	56.8	56.3	49.2
mean age	67.1	61.7	68.4	62.8
mean length of stay	18.1	7.5	23.0	8.6
mean number of medications per admission:				
regularly scheduled	15.0	7.0	18.6	7.7
as required	7.9	5.1	9.6	5.7
diagnosis (%)				
gastrointestinal	32.8	46.3	23.4	40.2
cardiac	21.9	13.5	20.3	14.7
respiratory	16.4	12.1	16.4	14.9
hematological/ oncological	12.0	3.2	18.8	4.1
musculoskeletal	8.2	9.4	10.2	8.2
genitourinary	3.3	3.9	2.3	3.8
neurological	1.6	1.6	3.1	5.7
psychiatric	1.6	1.4	3.1	1.6
ear/eyes/nose/throat	1.1	6.8	1.6	6.0
endocrine	1.1	1.8	0.8	0.8

exception of more patients with gastrointestinal diagnoses in the control phase and more patients with hematological or oncological diagnoses in the PC phase. In both cases this reflected the ward populations from which the monitored patients were selected.

There were more problems identified (626 versus 492) and resolved (565 versus 431) in the PC phase. The number of problems identified per shift was significantly higher in the PC phase (8.63 ± 5.96 versus 6.75 ± 5.25 , $p=0.04$) as was the number of problems resolved (7.79 ± 5.29 versus 5.92 ± 4.74 , $p=0.025$). In the PC phase 90.3% of the identified problems were resolved, versus 87.7% in the control phase.

The severity rating and category of each problem identified in both phases are listed in Table II. The additional problems identified in the PC phase appeared to be of lowest severity and included many patient counselling issues. Problems involving "untreated indications" were also more common in the PC phase. Such problems were often detected during patient interviews when it was discovered that medications taken as an outpatient had not been prescribed on admission to hospital.

Table II: Number (%) of Identified Drug-related Problems by Severity Index and Category

	Control Phase	PC Phase
total number identified	492	626
severity index^a		
1	207 (42.1)	345 (55.1)
2	252 (51.2)	245 (39.1)
3	33 (6.7)	36 (5.8)
category		
inappropriate drug or formulation	83 (16.9)	84 (13.4)
untreated indication	74 (15.2)	101 (16.1)
drug use without indication	51 (10.4)	42 (6.7)
overdose	47 (9.6)	45 (7.2)
failure to receive drug	40 (8.1)	22 (3.5)
adverse drug reaction	36 (7.3)	37 (5.9)
subtherapeutic dose	34 (6.9)	31 (5.0)
drug interaction	25 (5.1)	15 (2.4)
miscellaneous		
patient counselling	25 (5.1)	125 (20)
scheduling	19 (3.9)	9 (1.4)
order/discontinue drug	10 (2.0)	22 (3.5)
drug information	8 (1.6)	29 (4.6)
allergy assessment	8 (1.6)	5 (0.8)
more appropriate formulation	8 (1.6)	7 (1.1)
non-formulary	7 (1.4)	2 (0.3)
order clarification	7 (1.4)	14 (2.2)
medication history	2 (0.4)	2 (0.3)
other	7 (1.4)	34 (5.4)

a - reflects potential for harm to the patient if unresolved: 1 = no apparent harm, 2 = potential harm, 3 = harmful

The results of the cost avoidance analysis are illustrated in Figure 1. In both phases, the selected DRPs most often had no measurable impact on drug-related costs. There were a larger number of resolved DRPs which did influence expenses in the control phase (33 control versus 25 PC associated with added expense, 22 control versus 12 PC associated with cost savings). However, the mean cost avoidance was larger during the PC phase ($\$14.07 \pm \100.71 versus $\$5.51 \pm \43.92). The large standard deviations associated with these figures precludes further statistical analysis.

DISCUSSION

In the 1980s pharmacy was described by some as "a profession in search of a role".¹ Therefore, when PC was first popularized by Hepler and Strand in 1990, pharmacy departments throughout North America embraced the concept with particular enthusiasm. It has been described as "pharmacy's mandate for the twenty-first century",¹ or "the change agent we have been waiting for".¹⁰

"Research within the practice setting that scientifically supports the value of pharmaceutical care" is considered to be extremely important for the profession according to a recent American Society of Hospital Pharmacists survey.¹¹ However, PC is being implemented in many institutions without any scientific data supporting its benefit. While there have been a wealth of articles published on the philosophy behind the PC concept, there have been very few trials studying its impact on patient care. The trials that have been published generally compare the provision of PC to no clinical pharmacy involvement.^{12,13}

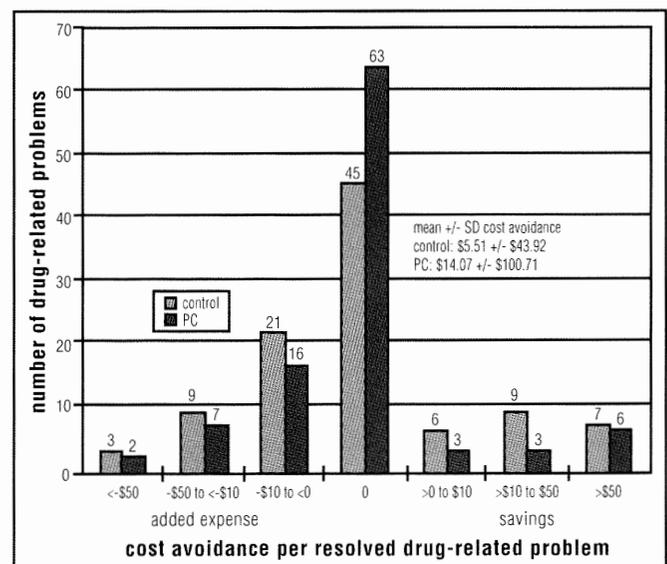


Figure 1: Cost Avoidance Associated with 100 Resolved Drug-related Problems Randomly Selected from Each Phase.

There have been two studies published comparing PC to traditional clinical pharmacy monitoring; however, both were small pilot trials conducted in specialty areas.^{14,15} The first was a pilot trial for the study described in this report, conducted in the LGH Intensive Care Unit.¹⁴ The second such trial was carried out in palliative care patients and included extensive education on palliative care pharmacotherapy between the control and PC phases making it difficult to isolate the impact of the PC approach itself.¹⁵

In this study, there were significantly more DRPs identified and resolved per shift using the PC approach than a traditional problem-specific monitoring system. This is consistent with the results of the pilot trial.¹⁴ There were approximately the same number of DRPs assigned a moderate or high severity rating in both phases (285 in control phase versus 281 in PC phase), but a larger number of DRPs of low severity in the PC phase (345 versus 207).

It is assumed that the difference in identified and resolved DRPs resulted from the different patient care approaches and not differences in patient populations. That is, we believe that the same number of DRPs existed in the study populations, whether detected or not, in both arms of the study. Table I outlines the ward population during each arm of the trial. There are no obvious differences between the phases which would suggest a discrepancy between the number of DRPs available for pharmacists to detect. Although there were fewer patients admitted to the study wards during the PC phase, these patients had a slightly longer mean length of stay and thus were prescribed a slightly higher number of medications during their stay. There was a similar mix of diagnoses on the study wards during each phase.

The additional problems identified in PC patients largely involved patient counselling issues. These issues typically involved medications with a high potential for problems (e.g., warfarin) or misuse (e.g., inhalers), or patients on complex regimens. Many of these counselling interventions were initiated at the request of the patient. Although such actions may not involve problems with immediate potential for harm to the patient, they do have an unmeasurable impact on prevention of DRPs. These types of activities are also likely to improve patient satisfaction with pharmacy services. Patient satisfaction was not assessed in this study. However, a recent survey at the training site revealed an overwhelming patient preference for the service provided under a PC system compared to more task-specific clinical monitoring (unpublished data. Chee C, Kim-Sing A. St Paul's Hospital, Vancouver, B.C.). Clearly, if the pharmacist can provide individualized PC and involve the patient in their own care plan, the patient will better understand and appre-

ciate pharmacy services than if a more traditional clinical approach is used.

A cost-avoidance analysis was conducted in an effort to analyze the impact of these two monitoring approaches on drug-related costs. It should be kept in mind that the labour expenses associated with pharmacist monitoring were constant between the two phases. The nature and scope of this trial did not include a comparison of costs associated with drug-related morbidity. The wide variety of DRPs analyzed resulted in a broad range of calculated costs. Although there were more DRPs resolved in the PC phase and the mean cost savings associated with each DRP was larger than in the control phase, the large standard deviations associated with the mean cost avoidance figures limit examination to descriptive analysis. In both phases, resolving DRPs usually had no impact on costs suggesting that neither approach had any obvious advantage in terms of drug-related cost avoidance.

There are several issues which can be raised regarding the design of this trial. Traditional outcome parameters were not measured and therefore it cannot be concluded, based on this data, that PC improves total health status or quality of life. Identification and resolution of DRPs were chosen as primary outcome parameters since they are clearly goals of PC and other more direct measurements of effect are difficult to isolate from the contributions of the other health professionals.⁴ In addition, the large range of disease states encountered would have been difficult to predict making *a priori* disease-specific outcome parameters impossible to develop. While identification and resolution of DRPs may not be direct assessments of health status, they are measurable outcomes which reflect the pharmacists' contribution to disease management and resolution.

In an effort to simulate routine clinical practice as closely as possible, pharmacists determined which patients would be monitored. This introduces selection bias. For example, the fact that patients in the PC phase had a longer length of stay most likely reflected selection based on a higher perceived potential for DRPs, rather than a negative effect of PC on this outcome parameter. Similarly, pharmacists selected patients who were prescribed a larger number of medications during the PC phase.

Self-reporting of data, in this case DRPs, also introduces potential for bias. It may be argued that pharmacists were more likely to report DRPs under the PC system. In an attempt to limit such inconsistency the methodology included an independent observer to assign each problem a category and severity rating. Although the study pharmacists were primarily responsible for reporting the number of DRPs, the observer was involved in deciding whether an issue warranted classification as a problem. During the pilot trial, an attempt

was made to retrospectively assess each DRP in a blinded fashion. It became evident that extensive information was often required to accurately determine whether or not an identified DRP was actually a problem, whether the DRP was resolved, and which category and severity rating should be assigned. Even after a full chart review, these questions were sometimes not answered. Therefore, we included an independent observer, consistent between phases, to prospectively carry out these decisions. While this process was not blinded, it was accurate and; therefore, felt to be more valuable than a blinded, retrospective process.

There is a plausible explanation for improved efficiency in identification of DRPs in the PC phase. By looking at fewer patients, pharmacists were less often required to review background information necessary for finding and resolving problems. Under the traditional approach, pharmacists were more likely to move on to another patient after a problem was addressed, rather than using the background of a familiar patient to identify and address further problems.

Spending more time with each patient in the PC phase resulted in a higher number of identified problems with low potential for harm. It is conceivable that problems of lower severity would be more difficult to detect. Therefore, more thoroughly reviewing each patient enabled the pharmacist to detect less obvious problems which may have otherwise been overlooked. While this result may be expected, a more interesting finding was that the PC approach did not compromise the number of DRPs identified with moderate or high potential for harm to the patient despite resulting in fewer patients monitored. This suggests that significant attention is required to detect all important DRPs in each patient. Although fewer patients may be monitored using the PC approach, problems are more thoroughly identified. DRPs that could potentially harm the patient may be overlooked even in patients seen under a more traditional, task-specific system.

The traditional clinical system studied in this trial had been utilized for over five years before this trial began. Therefore, comparing it to a PC approach which the study pharmacists had been exposed to for only a few months is less than ideal. It is possible that the difference in DRP identification and resolution would be even greater as the pharmacists became more efficient PC practitioners. A follow-up assessment conducted a few years after PC implementation would be worthwhile.

The pharmacists involved in this trial agreed that their visitation to an institution with an established PC program was the most important step in the education process. The experience gained during preparation and data collection has provided our Department with thor-

oughly trained PC clinicians to aid with the planned department-wide implementation of PC.

This trial was conceived during department strategic planning sessions when it was realized that there was nothing in the literature which would help predict the impact of implementing PC. There was a fear that significant DRPs would be missed in those patients who were not seen under the more thorough PC approach. While it is true that DRPs will be missed under any system unless all patients can be thoroughly monitored, these results suggest that pharmacists can take the time necessary for provision of individualized care in select patients without compromising the overall efficiency of DRP identification and resolution. As a result, our department has adopted PC as the patient care approach of choice for the restructuring of our clinical system. Wards are currently being selected for PC services with the plan of providing problem-specific "trouble shooting" to those patients not followed using the PC approach.

It appears that pharmacy departments need not dwell on those problems they may miss if PC is adopted, but rather concentrate on providing comprehensive patient-specific care whenever possible. The PC provided to these select patients will likely be noticed and appreciated by patients and health care workers. Perhaps their reaction and data such as that presented in this study will provide the necessary incentive for expanding clinical pharmacy services so that PC can be provided to a wider range of hospitalized patients. Further research assessing the impact of PC on patient outcomes is warranted. ☒

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