ARTICLE

Evaluation of an Intensive Pharmacist Intervention in an Inpatient Therapeutic Interchange Program

Dean Eurich, William Semchuk, Jeff Taylor, and Susan Poulin

ABSTRACT

Objective: To determine if an intensive pharmacist intervention in an automatic therapeutic interchange program affects the frequency of interchange-related problems experienced by patients upon hospital discharge.

Methods: In this nonrandomized, prospective pilot evaluation with nonparallel groups, a total of 95 patients were assigned to either the intervention or the control group. Those in the intervention group received information about the automatic therapeutic interchange program, were given the option of using their own medication, and received counselling about discharge medication. The control group received usual care. All patient follow-up was completed within 1 week of discharge. Primary outcome measures included the number of patients receiving duplicate drug therapy or no drug therapy (unintentionally) after hospital discharge. Secondary endpoints were the financial impact of the program on the patient and the Regina Health District.

Results: Eighty-six patients completed the study (36 in the intervention group and 50 in the control group). The prevalence of interchange-related problems after hospital discharge was lower in the intervention group than the control group (3% and 14% respectively). Overall, the Regina Health District experienced a modest reduction in drug acquisition costs. However, this seemed to occur at the patient's expense.

Conclusion: Several preventable interchange-related problems occurred in patients involved in this automatic therapeutic interchange program. Pharmacists should apply a patient-focused approach so as to limit the number of interchange-related problems in patients covered by such programs.

Key words: therapeutic interchange, formulary, patient outcome

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RÉSUMÉ

Objectif : Déterminer si l'intervention intensif du pharmacien dans le cadre d'un programme d'interchangeabilité thérapeutique automatique a une incidence sur la fréquence des problèmes liés à l'interchangeabilité imposée aux patients à leur sortie de l'hôpital.

Méthodes : Cette étude pilote, prospective, non randomisée avec groupes non parallèles, a évalué un total de 95 patients qui ont été répartis dans le groupe intervention ou le groupe témoin. Les patients du groupe intervention ont reçu de l'information sur le programme d'interchangeabilité thérapeutique automatique, avaient le choix d'utiliser leurs propres médicaments, et ont eu des conseils sur les médicaments qu'ils recevaient à leur sortie de l'hôpital. Les patients du groupe témoin ont reçu les soins habituels. Le suivi de tous les patients s'est terminé une semaine avant leur sortie. Les mesures primaires comprenaient le nombre de patients qui ont reçu un traitement médicamenteux en double ou qui n'ont reçu aucun traitement médicamenteux (involontairement) après leur sortie de l'hôpital. Les mesures secondaires étaient l'impact financier du programme pour le patient et pour le Regina Health District.

Résultats : En tout, 86 patients ont terminé l'étude (36 dans le groupe intervention et 50 dans le groupe témoin). La prévalence des problèmes liés à l'interchangeabilité après la sortie de l'hôpital était plus faible dans le groupe intervention que dans le groupe témoin (3 % vs 14 % respectivement). Dans l'ensemble, la réduction des coûts d'acquisition des médicaments pour le Regina Health District était modeste, ce qui toutefois avoir été réalisé au détriment du patient.

Conclusion : Plusieurs problèmes liés à l'interchangeabilité et qui étaient évitables sont survenus chez des patients qui ont pris part à ce programme d'interchangeabilité thérapeutique automatique. Les pharmaciens devraient mettre en oeuvre une démarche axée sur le patient dans le but de limiter le nombre de problèmes liés à l'interchangeabilité thérapeutique chez les patients couverts par de tels programmes.

Mots clés : interchangeabilité thérapeutique, formulaire, résultats thérapeutiques

INTRODUCTION

Development, utilization, and maintenance of a drug formulary system is integral to contemporary hospital pharmacy practice in North America.[1,2] Consequently, the major hospital pharmacy organizations in both Canada and the United States include a drug formulary system in their standards of practice.[3,4] Formularies are intended to ensure that the medications available for patient use are effective, safe, and — from a cost perspective — wise choices.

Therapeutic interchange programs represent an extension of the formulary system. In this type of program, an agent of a given therapeutic class is exchanged for a formulary product of similar, but not necessarily identical, pharmacokinetic, pharmacodynamic, and pharmacological properties. A driving force behind any therapeutic interchange program is to ensure that the most effective and economical agents are listed on the institutional formulary. Inventory control is another important reason. Although several trials have demonstrated some degree of direct inventory cost-avoidance with the implementation of a therapeutic interchange program,[5-8] there is little evidence to suggest global savings.[9-11] Complicating overall program assessment is the fact that, in these trials, professional input time has rarely been factored in as a cost and has generally been included as the pharmacist's responsibility.[10,12] Furthermore, some studies have suggested that restrictive formularies may have unintended economic effects in the form of cost shifting and increased utilization of health care resources.[13-16] However, the substantial differences in patient populations, research methodologies, and practice settings for these studies have led to corresponding controversy within the medical community as to the overall impact of a therapeutic interchange program on an institution.

Beyond the financial aspects of therapeutic interchange, there is another critical issue — the effect of interchange on the patient. To date, there are only minimal data focusing on patient outcomes under such programs.[11,17-19] However, concern is mounting that patients may be suffering from drug-related events as a result of interchange programs. Specifically, patients may become confused about their drug therapy as a result of changes to their medication regimen that occur during the hospital stay. Therapeutic interchange programs could result in inadvertent switches to agents that previously caused adverse events. As well, the therapeutic interchange may force the patient to discard costly medications upon discharge because their post-discharge therapy was altered for formulary reasons.[20]

To examine some of these concerns, a pilot study of a therapeutic interchange program was conducted, with particular attention to the impact on the patient. The objective was to evaluate whether intensive hospital pharmacist intervention in an automatic therapeutic interchange program affects the number of interchange-related problems experienced by patients upon hospital discharge. Secondary outcomes were the costs of the program to both the institution, the Regina Health District, and its clients.

METHODS

Design and Study Methods

The study was a nonrandomized prospective pilot evaluation with nonparallel groups that compared intensive pharmacist intervention in an automatic therapeutic interchange program with the usual process of therapeutic interchange within the Regina Health District. Patients were enrolled over a 4-month period in early 1999. During the first 2 months patients were enrolled into the control arm (normal pharmacy procedure) and during the latter 2 months into the intervention arm (intensive pharmacist intervention). The study was conducted in the 2 acute care sites of the Regina Health District, the Pasqua Hospital and the Regina General Hospital, in Regina, Saskatchewan. The Pasqua Hospital is a 260-bed service-oriented hospital with medical services in pediatrics, ophthalmology, gastroenterology, orthopedics, oncology, hematology, general medicine, cardiology, and general surgery. The Regina General Hospital is a 360-bed teaching hospital associated with the University of Saskatchewan; it provides a full range of medical and surgical services and serves as the major trauma centre for southern Saskatchewan. These 2 acute care hospitals serve the needs of 500 000 people in southern Saskatchewan.

Patients were identified from medication orders generated within the hospital. All medication orders with the potential to result in therapeutic interchange (nonformulary angiotensin-converting enzyme [ACE] inhibitors, ß-blockers, sedatives, inhaled corticosteroids, and histamine-2 [H_2] receptor antagonists) were identified and forwarded to the investigator (D.E.) by staff pharmacists. Patients were excluded if they had dementia or mental illness, were unable to communicate (e.g., because of a language barrier), or were unavailable for telephone follow-up.

Patients in the control arm experienced usual hospital procedures for therapeutic interchange. According to these procedures, the staff pharmacist determines if a patient receiving a medication that might be subject to therapeutic interchange has a supply of his or her own medication. The pharmacist then explains the therapeutic interchange program to the patient and discusses potential options regarding medication therapy while in hospital, including use of the patient's own medication (i.e., interchange not invoked) or a change to the interchange product. If the patient elects to use his or her own medication, this choice is documented in the patient's medical chart, and the patient continues with his or her usual medication. If the patient elects to use the hospital's therapeutically equivalent drug, the staff pharmacist must write new drug orders and document the change in the patient's medical chart as a therapeutic interchange based on the policy authority of the Medical Advisory Committee. However, depending on staff pharmacists' workload and involvement with the patient, patients may or may not be interviewed, and the therapeutic interchange protocol may be instituted automatically, without detailed patient consultation.

Patients in the intervention group experienced the same level of interaction with the staff pharmacist, but they were also interviewed by the investigator within 24 h of his receiving the medication order. The investigator ensured that the hospital procedures regarding therapeutic interchange, as outlined in the previous paragraph, were followed for every patient in the intervention group. In some instances, the information about the therapeutic interchange program was provided to the patient in duplicate, once by the staff pharmacist and once by the investigator. Thus, the major difference between the 2 arms of the study was full compliance with hospital guidelines for outlining options to the patient in the intervention group and variable compliance with the guidelines in the control group. In addition, patients in the intervention arm were counselled about discharge medication and were encouraged to ask the attending physician whether, upon discharge home, they should use the medication they were taking at the time of admission or the interchange product, if automatic interchange had been invoked.

Discharge and Follow-up Assessment

Each patient's medical chart was reviewed within 48 h of discharge to determine if the patient had been discharged on the therapeutic interchange medication or on the original medication, as indicated in either the physician's discharge letter or orders. In instances where the discharge medication was not documented, the investigator contacted the discharging physician to establish the intended discharge medication.

All patients in the study were asked to participate in a follow-up telephone survey, conducted by the investigator, within 1 week of discharge. The patients were asked a series of questions to determine if the therapeutic interchange had affected their drug therapy and to determine which agent they were actually taking.

Cost Analysis

Drug costs were based on the 1999 contract price of the Saskatchewan Health Drug Plan Formulary. Professional fees and mark-ups were not included in the cost analysis because of variability in pricing among community pharmacy dispensaries.

The potential drug costs to the Regina Health District were based on acquisition costs and were tailored to the appropriate dose strength and number of doses actually dispensed during the hospital stay. Packaging, administration, inventory carrying costs, and pharmacist's "input" time into the automatic therapeutic interchange program were excluded from the cost analysis.

The cost to patients electing to use their own medication while in hospital was based on drug acquisition cost, tailored to the appropriate dose strength and the number of doses actually used during the hospital stay. The cost to patients remaining on the therapeutic interchange medication after discharge was based on the cost associated with wastage of their original medication. This value was calculated by estimating the number of pills remaining, based on 100% compliance since the last refill date at a community pharmacy.

Outcome Measures

The primary endpoint was the number of interchange-related problems experienced on discharge, defined as follows: the number of patients taking both their original medication and the interchange medication after discharge and the number of patients not taking either medication after discharge, despite intention for maintenance of therapy.

The secondary endpoints were the financial impact of therapeutic interchange on the patient and the Regina Health District. The impact on the patient was defined as follows: cost associated with using their own medication in hospital and cost of drug wastage for patients remaining on the therapeutic interchange medication

Table 1. Patient Characteristics

Characteristic	Control (*n* = 55)	Intervention (*n* = 40)	*p* Value
Age (years)			
Mean ± SD	68.9 ± 12.9	69.3 ± 10.9	NS
Range	30–93	38–92	
Sex			
Men	35	18	NS
Women	20	22	NS
Hospital site			
PSQ	26	19	NS
RGH	29	21	NS
Length of stay (days)			
Mean ± SD	7.8 ± 5.9	7.1 ± 5.3	NS
Range	1–27	1–24	

SD = standard deviation, PSQ = Pasqua Hospital, RGH = Regina General Hospital,
NS = not significant ($p > 0.05$).

Table 2. Patient's Intended Discharge Medication

Medication	No. (and %) of Patients			
	Control (*n* = 53)		Intervention (*n* = 38)	
Patient's original medication	32	(60)	4	(11)
Therapeutic interchange medication	9	(17)	15	(39)
Information not available*	12	(23)	19	(50)

*From either the physician's discharge letter or orders.

Table 3. Medication Patient was Receiving at Follow-up

Medication	No. (and %) of Patients			
	Control (*n* = 50)		Intervention (*n* = 36)	
Patient's original medication	32	(64)	30	(83)
Therapeutic interchange medication	11	(22)	4	(11)
Both medications	3	(6)	0	(0)
Neither medication	4	(8)	2*	(6)
Interchange-related problems†	7	(14)	1	(3)‡

*One patient in the intervention group was instructed by the attending physician to discontinue her medication at discharge; this was not counted as an interchange-related problem.
†The number of interchange-related problems is the sum of the numbers of patients receiving both medications or neither medication at follow-up (except as noted otherwise).
‡Not significantly different from control ($p > 0.05$). No other comparisons were tested statistically.

after discharge. The impact on the Regina Health District was defined as follows: cost avoidance through use of the patient's own medication and cost of changing from the patient's medication to the interchange product on admission to hospital.

Statistical Analysis

All statistical calculations were performed with the SPSS Version 10 statistical package. Data are expressed as means ± standard deviation (SD), unless otherwise specified. The chi-squared test or Fisher's exact test was used to compare categorical variables. Student's *t*-test was used for comparison of continuous variables. A *p* value less than 0.05 was regarded as statistically significant.

RESULTS

Over the study period, 55 patients were enrolled in the control arm of the study and 40 in the intervention arm. The control and intervention groups were evenly matched according to age, sex, hospital site, and length of stay (Table 1). The most common drugs involved in the therapeutic interchange were ACE inhibitors (36 patients [38%]), inhaled corticosteroids (23 patients

Table 4. Breakdown of Drug Costs and Savings of Automatic Therapeutic Interchange Program for Regina Health District

Medication	Cost or Saving ($)	
	Control (*n* = 55)	Intervention (*n* = 40)
Sum of all medications		
Cost of original medication	830.60	892.40
Cost of interchange medication	573.41	512.21
Saving*	257.19	380.19
Average cost per patient ± SD		
Cost of original medication	15.10 ± 24.82	22.31 ± 32.33
Cost of interchange medication	10.43 ± 13.56	12.819 ± 15.89
Saving	4.68 ± 13.69	9.50 ± 16.90†

SD = standard deviation.
*If inhaled corticosteroids are not included in the cost analysis, the hospital had an overall net loss of $9.01 for the control group and $0.10 for the intervention group.
†Not significantly different from control ($p > 0.05$). No other comparisons were tested statistically.

Table 5. Breakdown of Drug Costs to the Patient as a Result of the Automatic Therapeutic Interchange Program

Medication	Cost or Saving ($)	
	Control (*n* = 55)	Intervention (*n* = 40)
Sum of all medications		
Cost of using own medication	65.19	64.21
Cost of discarding original medication	411.41	98.53
Total cost	476.60	162.74
Average cost per patient ± SD		
Cost of using own medication	5.43 ± 8.09	4.59 ± 4.29
Cost of discarding original medication	29.39 ± 37.94	24.63 ± 21.16
Total cost	8.67 ± 22.67	4.07 ± 9.66*

*Not significantly different from control ($p > 0.05$). No other comparisons were tested statistically.

[24%]), benzodiazepines (19 patients [20%]), and H_2 blockers (17 patients [18%]). Of the 55 patients in the control arm, 9 (16%) elected to use their own medications, 41 (75%) received the hospital interchange product, and 5 (9%) received a combination of their own medication and the interchange product. Of the 40 patients in the intervention arm, 12 (30%) chose to use their own medications, 26 (65%) chose to use the interchange product, and the remaining 2 (5%) used a combination.

Table 2 depicts the medication option intended for use upon discharge from the hospital. Two patients in each group died, which left 53 and 38 patients in the control and intervention groups, respectively.

Fifty patients from the control group and 36 from the intervention group were available for follow-up. Two control patients were excluded because of cognitive impairment, and 1 control patient and 2 patients from the intervention group were otherwise unavailable.

Table 3 details the categories of medications being taken at the time of the post-discharge interview. Three patients in the control group were taking both their original medication and the interchange medication, but no patients in the intervention arm were taking both medications. Of the 3 control patients taking both agents, 2 were using 2 inhaled corticosteroids concurrently and the third was taking 2 ACE inhibitors. In addition, 4 control patients were not taking either their original medication or the interchange medication, but only 1 patient in the intervention arm was not taking either medication. Overall, 7 patients (14%) in the control group had interchange-related problems as a result of the changes to their medications while in the hospital, whereas only 1 patient (3%) in the intervention group had an interchange-related problem. The difference in rates of interchange-related problems was not statistically significant, which is not surprising, given the small number of patients.

An important aspect of this study was the assessment of the financial impact on both the patient and the Regina Health District. The Regina Health District avoided a total cost of $257.19 for the control arm and $380.19 for the intervention arm (Table 4). This resulted in an average saving of $4.68 (SD $13.69) per patient in

the control arm and $9.50 (SD $16.90) per patient in the intervention arm. However, the Regina Health District's automatic therapeutic interchange program includes corticosteroid inhalers. The difference in acquisition cost between the 2 agents in this group is substantially greater than for other agents covered by the program. If corticosteroid inhalers are excluded from the calculation, the Regina Health District actually experienced a financial loss because of the interchange program. Furthermore, the Regina Health District uses a unit-dose system with daily cart exchange and an automatic tablet counter profile, which fills over 75% of doses. Packaging costs are therefore consistent for all medications. In addition, costs can only be extrapolated from daily costs in this study. If traditional distribution systems were in effect, the amount of drug dispensed would alter the cost figures. Tables 4 and 5 outline the various costs associated with running the therapeutic interchange program for this pilot study. A similar percentage of both patient groups (26 [47%] of the 55 control patients and 19 [48%] of the 40 intervention patients) experienced some negative financial impact because of the program, although overall patient costs were lower in the intervention arm. The costs to the patients occurred either through the direct cost of using their own medication while in the hospital or through wastage of the original medication if they were discharged on a therapeutic interchange product. For the 11 control patients discharged on an interchange medication, 6 were switched to a more expensive alternative and 5 to a cheaper alternative. Of the 4 patients in the intervention arm who were discharged on an interchange product, 1 was switched to a more expensive drug and 3 to cheaper agents. All calculations are based on data for 55 patients in the control group and 40 patients in the intervention group.

Although not an objective of the study, patients were interviewed after discharge to determine which medications they would have preferred to use during their hospital stay. Most patients in both groups (34 [68%] of the 50 control patients available for follow-up and 25 [69%] of the 36 intervention patients available for follow-up) indicated no preference. However, during their respective hospital stays, almost twice as many in the intervention group chose to use their own medications (9 [16%] of 55 control patients and 12 [30%] of 40 intervention patients). Overall, the majority of patients in both groups used the hospital's therapeutic interchange medication exclusively. A minority used both (although not concurrently). The reason for combination use was depletion of the medication the patient brought in and a subsequent switch to the interchange product. Of these patients, all were discharged with prescriptions for their original medications.

DISCUSSION

In this study, several preventable interchange-related problems occurred in patients involved in a therapeutic interchange program when normal procedure was used. Patients' lack of understanding of the discharge medication regimen may have resulted in confusion, with resultant iatrogenic drug-related problems. However, intensive involvement by a pharmacist in the therapeutic interchange process limited the number of interchange-related problems occurring in the intervention arm. This involvement included several interviews with the patient, the opportunity to use the patient's choice of therapy, and discharge counselling. To date, neither positive nor negative outcomes of a therapeutic interchange program have been published; however, there has been considerable debate about this process.[20,21]

It is possible that a patient's decision to use his or her own medication was affected by whether a staff member discussed the various options available. Despite institutional guidelines indicating that pharmacists should give patients the option of using their own medication, this option was not presented to most patients in the control group; of the 55 patients, only 5 (9%) were given such counselling, according to documentation in the physician progress notes. In the intervention group, more interaction took place. Chart documentation and patient interviews revealed that 17 of the 40 patients (43%) were informed of the interchange program by a staff pharmacist.

When interviewed, patients indicated little preference as to which agent they used, but when given the opportunity to choose, more patients in the intervention arm chose their own medication.

This study demonstrated minimal cost savings to the institution in terms of drug acquisition costs, and these minimal savings occurred at a cost to the patient. However, this program did not attempt to characterize costs based on pharmacist intervention time, as this function is part of pharmacists' daily activities. However, as staffing ratios often preclude the provision of expanded services, the time might have been better spent elsewhere.

Given the extremely modest reduction in drug acquisition cost (with the potential for increased costs if inhaled corticosteroids are excluded from the analysis) and the time necessary for development of such a

program, it is unlikely that an interchange program would provide significant benefit to hospital pharmacy budgets for long-term, low-cost medications. Where there are significant cost differences between products (as with the inhaled corticosteroids), an interchange program may be beneficial to the institution; however, the program should be accompanied by intense patient education.

Limitations

The nonrandomized, nonparallel design of this pilot study may have "softened" the information obtained. Factors other than intensive pharmacist involvement in the intervention group cannot be ruled out as contributors to the results. Despite these limitations, the results were those commonly considered by researchers questioning therapeutic interchange programs.[20]

This study was conducted as a pilot study; a longer study period would have provided better representation of how automatic therapeutic interchanges are processed within the institution and might have affected the overall results. For patients in the control arm, it was difficult to determine staff pharmacists' involvement, as there was no contact between the investigator and these patients while they remained in the hospital; staff pharmacists' involvement might therefore have been underestimated. Furthermore, pharmacist documentation of contact with the patient was defined as only those contacts recorded in the patient progress notes and did not include therapeutic interchange orders written in the order section of the chart.

The use of a more sophisticated cost-analysis strategy would have strengthened the results of this trial. Including the cost impact of staff pharmacist involvement would have affected the overall cost savings. Within the Regina Health District, considerable pharmacist time is dedicated to the proper operation of the therapeutic interchange program. The inclusion of this cost might have significantly affected the overall savings associated with the program. As well, the cost analysis was based on contract prices for medications in the 48th (1999) edition of the Saskatchewan Health Drug Plan Formulary. However, the Regina Health District has a separate contract price for many of these medications, which would also substantially affect the results of the cost analysis.

This study did not address the issue of morbidity. Seven patients in the control group and one patient in the intervention group were using their medications inappropriately after discharge. No attempt was made to quantify the effect of this inappropriate use on the patient, if any. However, it is reasonable to assume that inappropriate use of medication had the potential to increase morbidity in these patients.

Conclusions

The results of this pilot study indicate that a large-scale study is required to assess the potential negative impact of automatic therapeutic interchange programs on patients. Several preventable drug-related problems occurred as a result of this interchange program. The results also suggest that patient involvement in therapeutic interchange programs is essential to ensure that the program has no detrimental effect. Patients need to receive information about their options, the reasons for changes to their drug therapy, and clear directions about the medications to be taken on discharge. Pharmacists should apply a patient-focused care approach to patients who are candidates for therapeutic interchange.

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Dean Eurich, BSP, is a Staff Pharmacist, Regina Health District, Regina, Saskatchewan.

William Semchuk, MSc, PharmD, FCSHP, is Manager of Clinical Pharmacy Services, Regina Health District, Regina, Saskatchewan.

Jeff Taylor, PhD, is Assistant Professor, College of Pharmacy and Nutrition, University of Saskatchewan, Saskatoon, Saskatchewan.

Susan Poulin, BScPharm, is a Drug Use Evaluation/Drug Information Pharmacist, Regina Health District, Regina, Saskatchewan.

Address correspondence to:
Dr William Semchuk
Clinical Pharmacy Services
Regina Health District
1440 – 14th Avenue
Regina SK
S4P 0W5

e-mail: Bsemchuk@reginahealth.sk.ca