THE CLINICAL PHARMACY SERVICES STUDY

A Study of Clinical Services Provided by Pharmacists in Ontario Hospitals

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EXECUTIVE SUMMARY

The Clinical Pharmacy Services Study was a comparative study of pharmacist recommendations on the drug therapy of acute, medical in-patients in 17 Ontario hospitals providing three different levels of patient pharmacotherapy monitoring (PPM).

Interventions were recorded by pharmacists providing Drug Order Review (DOR), Basic Patient Pharmacotherapy Monitoring (B-PPM), or Concurrent PPM (C-PPM). Drug Order Review was defined as the regular screening of drug orders for general accuracy. The review of a patient for the purposes of evaluating specific drug therapy was called B-PPM, while C-PPM was defined as the on-going monitoring of patients, their drug therapy and response to therapy.

During a five-week period, 132 pharmacists provided 3747 hours of monitoring services to 1570 acute medical beds and recorded a total of 3373 cases with 4559 recommendations. Pharmacists providing C-PPM averaged 11.9 minutes of patient monitoring per patient-day compared to 4.0 minutes per patient-day for B-PPM, and 2.2 minutes per patient day for DOR.

Pharmacists in hospitals with higher levels of PPM identified more pharmacotherapy issues and made more recommendations regarding patient's drug therapy.

Pharmacists in C-PPM sites reported nine times as many cases and recommendations per patient-day compared to DOR sites and three times as many as in B-PPM sites.

Recommendations were more often made pro-actively, were of a more clinical (less technical or procedural) nature, and were solicited by other health professionals more frequently in hospitals providing higher levels of PPM services. Pharmacists in C-PPM sites were located in the patient care area at the time of the recommendation in 93.3% of cases compared to 40.1% and 1.3% in B-PPM and DOR sites, respectively. One in four C-PPM cases involved pro-active participation by the pharmacist in drug decision-making compared to 11.4% for B-PPM and 4.2% for DOR sites. Drug regimen changes were more common in C-PPM sites (42% vs 27% for B-PPM and 27% for DOR) while DOR recommendations most often involved drug distribution (40% vs 26% for B-PPM and 14% for C-PPM).

Drug product cost changes resulting from pharmacists' recommendations demonstrated the influence pharmacists can have on drug expenditures when making recommendations for changes in drug therapy. All sites reduced unnecessary drug costs with savings from 21-96% depending on the recommendation and level of service. In some cases, costs rose as pharmacists made changes to improve therapy.

At higher levels of PPM, the focus of pharmacist recommendations shifted from the drug product being dispensed to the individual patient receiving medical care. Similarly, a shift occurred in pharmacists' assessments of their recommendations towards improved therapeutic effect and risk reduction for patients, in addition to decreasing unnecessary drug costs. Physicians' assessments tended to affirm pharmacists' opinions of impact. Pharmacists in C-PPM sites also provided follow-up monitoring to determine patient response to their recommendations more often than those providing less intensive levels of PPM.

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Increased PPM services to patients required more resources. Hospitals with more acute care beds, more pharmacist and pharmacy technician staff compared to numbers of patients, more pharmacists with hospital residency and advanced training, and more service hours per patient-day provided higher intensities of PPM.

Changes in the provision of pharmacy services with C-PPM observed in this study are consistent with the philosophy of pharmacy practice embodied in Pharmaceutical Care. The provision of Pharmaceutical Care requires an investment in resources (staff and technology), education and training of pharmacists, reorganization of resources to maximize a pharmacist's time for patient monitoring, and organization of service delivery so pharmacists have unlimited access to patients.

Pharmacists provided services that were assessed to have increased the quality of patient care, reduced drug costs and/or improved drug prescribing to varying degrees depending on the level of PPM service.

INTRODUCTION

Background Information

Since the early 1960s, a key development in hospital pharmacy practice has been the emergence of clinical pharmacy services.[1] Clinical pharmacy has been defined as the provision of structured services by pharmacists to meet the drug-related needs of patients, physicians, and nurses in a commitment to the optimization of drug therapy. In doing so, pharmacists exercise professional judgment and accept responsibility for the quality of drug-related patient care outcomes.[2] Developments in clinical pharmacy have taken place internationally and have received impetus from recognition of the potentially serious problems for patients associated with inappropriate drug use,[3-5] escalating drug costs,[5,6] and the need for adequate measures to promote optimal drug use.[7,8]

Pharmacists acknowledge the necessity of caring for the drug-related needs of patients and have accepted this as their professional mandate.[1] The mission for pharmacy as stated by the Canadian Society of Hospital Pharmacists is: "to improve the quality of life of individual patients through activities which ensure individual patients are receiving drug therapy to achieve desired outcomes."[9]

Reports from the United States, Canada, United Kingdom, and the World Health Organization reiterate the importance of clinical pharmacy practice in hospitals.[1,10-19] The development of reliable research models that demonstrate the value of clinical services is a difficult process. However, with the support of policy makers, clinical practice development and investigation have been possible. A number of clinical pharmacy practices have been advocated to improve patient care as cited in the reports of the Pharmaceutical Inquiry of Ontario (the Lowy Inquiry)[20] and the British Columbia Royal Commission on Health Care.[21]

Despite recent information supporting the contribution of clinical pharmacy, there has been somewhat of a lag in the development of such services in Canada. While many pharmacy practitioners provide valuable clinical services to patients in their institutions, the advances in clinical practice have occurred more frequently in the larger teaching hospitals and the extent of development varies from institution to institution.[16,22-27]

A survey in 1989 by Einarson and Mann illustrated the variability in clinical pharmacy services in Canada.[27] Central review of a patient's medication profile prior to dispensing for >90% of drug orders was reported in 97 (75%) of the 130 responding hospitals. In contrast, review and monitoring of patients at the ward level was being performed for 90% of patients in only 8 (6.2%) hospitals. Appropriateness of drug therapy for an individual patient can usually only take place at the ward level, where the pharmacist has access to the patient, medical team, and pertinent clinical information.[28] Consequently, location is an important constraint on the pharmacists' contributions to optimal drug use for patients.

Despite evidence that time spent clinically with patients can provide up to a 20-fold return on dollars invested, a survey by the Ontario Hospital Association demonstrated that approximately 50% of the pharmacist's time is spent on non-clinical activities.[29]

In response to the need to further develop clinical pharmacy services, the Clinical Pharmacy Advisory Committee (CPAC) of the Canadian Society of Hospital Pharmacists released a working paper in 1990 called "A White Paper on the Establishment and Elaboration of Clinical Pharmacy Services". This document outlined a patient-oriented philosophy of pharmacy practice, a management model and a practice model for clinical services to assist pharmacy directors and hospital administrators in prioritizing the use of staff and resources to implement and expand clinical programs.[30]

The Pharmaceutical Care model developed by Helper and Strand and the White Paper both emphasize the importance of making patients the central focus of all services pharmacists provide.[30,31] One major difference between the two models; however, is acknowledgment in the White Paper that current pharmacist practices and pharmacy department organization cannot change overnight. The CPAC proposed development of patient-oriented services in an incremental fashion with each pharmacy department's present structure and operation as the starting point.[30]

It was stated by CPAC that the most practical and feasible clinical pharmacy activity offering the most

benefit to patient care was drug therapy monitoring or Patient Pharmacotherapy Monitoring (PPM).[30] From this statement flowed the recommendation that PPM be given the highest priority in the development of clinical services based on patient care impact and cost benefit expectations.[30] The systematic review of drug therapy and patient response and recommendations when appropriate to ensure safe, efficacious and economic drug use for each patient would be required.

While the incremental approach to the development of pharmacy services advocated by the CPAC is feasible, the benefits of this approach need to be identified. Information is needed to assist hospital pharmacy directors in strategic planning and hospital administrators in determining pharmacy resource requirements in the current era of fiscal restraint.[27]

As the first step towards establishing a policy for future development, the decision was made to conduct a comparative, descriptive study of different levels of clinical pharmacy services based on definitions in the White Paper.[30] Most previous studies have been limited to a particular aspect of clinical pharmacy service in one hospital.[32,33] Ontario hospitals provided an ideal population for study since there was variation in hospital size, type and level of pharmacy service, yet common legislation and overall policy.

Research Goals and Objectives

The overall objective of the Clinical Pharmacy Services Study was to compare different levels of PPM adapted from the White Paper on the Establishment and Elaboration of Clinical Pharmacy Services.[30] Hospitals at different stages of development of their PPM services created a natural environment for a comparative study of pharmacist recommendations on the drug therapy of acute, medical, in-patients in Ontario hospitals.

The expectation was that the quantity, nature, and impact of recommendations made by pharmacists differed in hospitals providing different levels (intensities) of PPM. As well, the level of PPM would be related to the number of pharmacy staff employed in relation to the number of patient beds in each hospital. The institutions with more staff per bed would be expected to provide more services.

Specific objectives were to:

1) determine the ratio of acute care beds to the number of pharmacy staff serving acute beds in study sites and compare results among the three levels of PPM;
2) describe the frequency of issues and recommendations reported during the data collection period and compare results among the three levels of PPM;
3) describe the types of issues and recommendations and compare results among the various levels of PPM;
4) evaluate the pharmacists' and physicians' assessments of the impact of the recommendations and compare results among the levels of PPM; and,
5) measure the financial consequences of pharmacists' recommendations in terms of changes in drug product costs in a sample of cases and compare results among the PPM levels.

METHODS

General Approach

During a five-week study period, pharmacists providing PPM services to patients in designated medical, acute care patient areas (study areas) within each hospital were asked to record all patient-specific recommendations on each day services were provided. Pharmacists also provided assessment on the perceived impact of their recommendations. Physicians who received the recommendations were surveyed to determine their assessment of the impact of the recommendation. Drug product cost changes were calculated for a sample of cases.

Study Sample

Ninety-six public, general hospitals located in the province of Ontario were surveyed to obtain a description of the potential study hospitals. Of 81 responses, 19 were ineligible for consideration as study sites (three sites had fewer than 100 acute beds and two sites were specialty pediatric hospitals, ten sites did not meet minimum DOR service requirements and four sites provided unclearly defined services). The remaining 62 hospitals were stratified by level of pharmacy monitoring service and constituted the sampling framework for the study. For the purpose of our study, the following definitions were used:

1) Drug Order Review (DOR): The regular screening of drug orders for general accuracy and completeness as described in the White Paper.[30]

2) Basic Patient Pharmacotherapy Monitoring (B-PPM): The review of patient information for the purposes of evaluating specific drug therapy with access to patient specific information. This encompasses both Selective PPM and Comprehensive / Universal PPM as described in the White Paper since, although the selection of which patients received PPM differed, the intensity of monitoring provided to an individual patient was the same.[30]

3) Concurrent Patient Pharmacotherapy Monitoring (C-PPM): The routine (usually daily) on-going monitoring of patients, their drug therapy and their response to therapy, usually aided by the development and implementation of a patient-specific therapeutic plan.

Criteria used to categorize hospitals into service levels are shown in Appendix A. Based on time and resource limitations, the possibility of drop-outs, and results from

a pilot study in three British Columbia hospitals, a sample of 17 sites was taken. (Appendix B)

Data Collection

Designated study areas were selected from each study hospital (acute care, medical, in-patient areas) where the most developed PPM services were consistently provided. Data collection occurred over a five-week period in September and October 1992. Pharmacists received training on data collection including verbal instructions, an orientation manual, sample cases and cases for practice prior to the start of the study. Each site had one or more designated study coordinators responsible for organization and study administration.

Data Collection Form

A data collection form was designed specifically for use in this study (Appendix C). The form was extensively field tested, revised and re-tested in the pilot study prior to use in this study.

The form was organized into three parts to be completed by the pharmacist each time a recommendation was made.

Part One: Background information was recorded including date, time, location, study site, pharmacist identification, and patient descriptive information.

Part Two: The pharmacotherapy issue and recommendations made were described to create a written record of the work done by the pharmacist while providing monitoring services.

Part Three: The results of the recommendation, including pharmacist assessment, whether it was accepted by the responsible physician and any follow-up of patient response resulting from the recommendation were documented.

Pharmacists were asked to record all names, doses, dosage forms, and dosing schedules for drugs involved with the issues and recommendations.

The purpose of the data collection form was to:

- describe the pharmacotherapy issue identified (or solicited) during patient monitoring that prompted the pharmacist to make a recommendation;
- describe the pharmacist's recommendation(s) in response to the issue;
- identify the information that was available to the pharmacist at the time the recommendation was made;
- measure acceptance and patient follow-up rate after the recommendation (cases were followed for patient response when the pharmacist deemed follow-up was required and/or in circumstances when follow-up was feasible (e.g., patient still on ward, monitoring time available) for up to seven days.); and,
- delineate the pharmacists' self-assessment of impact of their recommendation(s).

In order to reduce ambiguity, the following definitions were used in the study:

Pharmacotherapy issue: A situation arising in conjunction with drug therapy monitoring where the pharmacist was asked to contribute, or the pharmacist independently deemed input was required in order to ensure optimal drug therapy and/or minimize drug-related problems for a specific patient.

Optimal drug therapy: The most appropriate, safe, efficacious, and economical drug use in a specific patient based on the characteristics of the patient, the patient's response to therapy, and the desired therapeutic outcomes for the patient.

Drug-related problem: An actual or potentially inappropriate response to drug therapy including insufficient response (e.g., because dose too low), excessive response (e.g., toxicity, therapeutic duplication), unexpected response (e.g., allergy), or different response (e.g., adverse effect, drug interaction, wrong drug selection).

Pharmacist recommendation: The response by the pharmacist in the form of a recommendation as to what should be done for the specific patient in order to resolve the pharmacotherapy issue. One pharmacotherapy issue may result in more than one pharmacist recommendation. Recommendations were further categorized as follows:

1) Drug Selection – the choice of which drug should be given to a patient.
2) Drug Regimen - the decision of what form and the dosage of a chosen drug which should be given to a patient.
3) Drug Distribution - the technical requirements of accuracy and conformity for a drug order (including formulary status) before it is dispensed to the patient.
4) Monitoring - the use of laboratory or other tests to follow the progress of treatment for a patient.
5) Other - all remaining areas of concern regarding drug therapy for patients.

Pharmacist Time Log

Each study pharmacist recorded on a time log the number of hours they spent each study day providing DOR and/or PPM services to patients in the study areas. Drug order review time was the number of hours the pharmacist spent reviewing drug orders for patients located in the study areas. Drug order review usually took place within the pharmacy but also occurred on the study ward if the orders were screened there by a pharmacist prior to being filled in the dispensary.

If DOR time for the study areas could not be separated from the total time spent servicing the entire hospital, the time to service the study areas was estimated. For example, in a 500 acute bed hospital with 100 beds (1/5 of all beds) designated as being in the study, if a pharmacist spent five hours providing DOR services to all acute beds then 1/5 of the time (one hour) was spent serving the study areas.

Patient pharmacotherapy monitoring time was the number of hours spent by pharmacists monitoring patients and their drug therapy while located in the study areas. Time spent on medical and nursing rounds could be included as part of PPM time if the pharmacist was an active participant in the rounds.

Activities that were not recorded as study time included: administrative duties/meetings, lunch and coffee breaks, departmental projects, inventory/technical distributive functions, and attending/presenting in-service education.

The pharmacist time log was an indicator of the actual number of hours pharmacists had available to provide the service being measured in this study. All time was interpreted as reported by the pharmacist, except in the case of pharmacy residents. It was assumed that residents spent approximately half of their time working as a member of the pharmacy department and half of their time studying. Therefore, all PPM time reported by pharmacy residents was halved before inclusion in the time total for each study site.

A time-out day was a contingency allowed in the study to enable a data collection day to be removed if the usual level of service to the study area was compromised in any way. The entries pharmacists made in their time logs for each "time-out" day were zero hours, since, for the purposes of the study, no hours of service were provided where data could be generated.

Site Physician Assessment

Once recorded, pharmacists' recommendations were sorted by the site coordinator and those targeted to a physician (medical resident, intern, or attending physician) were sent to that individual for assessment of the impact of the recommendation. This assessment did not require any additional chart review on the part of the physician since a description of the issue and recommendation were recorded on the form (see Appendix C). A maximum of five randomly chosen assessment requests per physician per twice-weekly mailing was set based on an informal workload survey of attending physicians and residents at the Ottawa General Hospital.

Background Information

Descriptive information about the study hospital and study areas was provided by the pharmacy director from each site. A demographic and professional profile was also obtained from each pharmacist submitting data.

Drug Cost Assessment

Each issue and recommendation description was reviewed and coded to identify cases for the evaluation of drug costs. Cases were excluded from the drug cost study if the drugs involved were used on an "as needed" or "PRN" basis since the frequency of drug administration per 24-hour period could not be determined. Cases were also excluded if the drug name was missing, no direct drug cost changes occurred (e.g., allergy verification), or costs could not be assigned to drug orders as written (e.g., due to drug order errors).

The costs to provide 24 hours of drugs in the dose, form and schedule described in the issue and recommendation sections of each case in the sample were calculated. The Ontario Hospital Association Hospital Purchasing Plan Contract Prices (1992), the Ontario Drug Benefit Formulary (Best Available Price), or the List Price from the manufacturer were used as sources for prices paid by Ontario hospitals for a specific drug.

Drug product cost changes per 24-hour period were calculated as the difference between the costs of relevant drug products used for therapy during the 24-hour period before the recommendation was made (described in the pharmacotherapy issue), and the 24-hour period after the recommendation was made (described in the recommendation). Drug product costs did not include the time or supply costs of drug preparation or administration nor the costs of wastage or the costs of drug products not involved with the issue or recommendation. The cost of one intravenous minibag was included in the cost of each dose that was to be administered by that route.

DATA PROCESSING AND ANALYSIS

Confirmation of Study Groups

Study sites were grouped into one of the three PPM service levels based on the anticipated intensity of monitoring to the study areas. The groups were established using results from the initial Ontario hospital survey and on-site interviews. This grouping was then evaluated using a cluster analysis of baseline data collected during the study. The baseline indicator of

the actual intensity of service during the study was PPM time per patient-day and reflected the allocation of pharmacy resources to provide PPM services to that specific area. The higher this value, the more pharmacist time was spent monitoring patients relative to the numbers of patients present during the study period. By definition, DOR sites were not expected to report any PPM time on the wards, whereas C-PPM sites would have higher values than B-PPM sites because of the greater intensity of monitoring provided in C-PPM sites.

Data Processing

All information from the data collection forms and physician assessment surveys were manually edited and coded, then entered into a computer using SPSS/Data Entry II^{R}. All editing and coding was completed by the research coordinator. Patient morbidity data were coded using the International Classification of Diseases Codes (ICD-9). Editing was checked during data entry, which was contracted to The Statistical Consulting Centre at Carleton University, Ottawa, Ontario. Data entry was 100% verified. Descriptive and statistical analyses were performed using SPSS/PC+^{R}, Version 5.0.[34]

Data were interpreted in a multiple response format. Each study hospital was considered as one subject with all cases collected from the site viewed as multiple responses that, when combined, described the level of PPM provided during the study. The cases from each hospital were compiled to create a summary value for each variable.

Data Analysis

Summary values for key variables were used in a comparative analysis across the three different service levels examined. In preparation for analysis, data were tested for normality of distribution and consistency of variances using the Lilliefors Test.[34] Any data that were normally distributed or could be made normal through transformation by log10(x+1) were reported as mean (± SD) and analyzed using One-way Analysis of Variance (ANOVA) and Duncan's Multiple Range Test (MRT) for inter-group comparisons. If transformation did not normalize the data, median data were reported and the non-parametric Kruskal-Wallis ANOVA and Dunn's Test for multiple comparisons were used.

RESULTS

All seventeen sites completed the entire study. Sites were grouped by level of service - six sites provided DOR services, five sites provided B-PPM and six were C-PPM sites. A total of 3373 cases with 4559 recommendations were submitted by 132 pharmacists providing a total of 3747 hours of monitoring services for patients in the study areas.

STRUCTURE OF THE SERVICES

Hospitals

Study hospitals are described in Table I. All DOR hospitals were non-teaching facilities. One B-PPM site was a teaching hospital and the other four sites were community hospitals. All C-PPM hospitals were university-affiliated teaching hospitals.

Larger hospitals employed a greater number of pharmacists. The number of pharmacy staff compared to the number of patient beds was also related to the level of PPM as described in Table II. The acute bed: acute care pharmacist ratio differed significantly among all three levels of service.

Table I: Description of Hospitals
mean (standard deviation)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Total beds	281 (73)	327 (188)	620 (322)
Acute care beds	207 (39)	294 (144)	585 (343)
Acute (in-patient) admissions[1]	9845 (2692)	12,503 (6383)	23,471 (11,099)
Acute occupancy rate[1] (%)	82.0 (5.9)	85.3 (8.3)	83.5 (6.6)
Acute (in-patient) pharmacist FTE (resident= 0.5 FTE)	4.1 (0.9)	8.2 (4.4)	30.6 (19.9)
Acute (in-patient) technician FTE	4.7 (1.6)	8.2 (4.3)	28.4 (14.2)

1 For time period April 1991 - March 1992
FTE = Full-Time-Equivalents

Table II: Ratio of Acute Beds : Pharmacy Staff[1]
mean (standard deviation)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Acute care bed : pharmacist FTE*	51 (4)	38 (9)	20 (3)
Acute care bed : technician FTE**	48 (12)	40 (19)	20 (4)
Acute care bed : Pharmacist + technician FTE**	24 (4)	19 (7)	10 (1)

1 excluding staff serving non-acute care areas (e.g., out-patient, chronic care)
FTE = Full-Time-Equivalent
* $p<0.05$ (One-way ANOVA). Differences between all three service levels are significant (Duncan's Multiple Range Test).
** $p<0.05$ (One-way ANOVA). Differences between DOR and C-PPM sites, and between B-PPM and C-PPM sites are significant (Duncan's Multiple Range Test).

Designated Study Areas

Study areas are described in Table III. During the five weeks, the actual number of days of data collection varied because of "time-out" days. In hospitals with B- or C-PPM services, "time-out" days usually occurred on weekends when pharmacy staff was at a minimum and services were reduced to DOR only. Drug Order Review sites were usually able to maintain their weekday level of service on weekends.

The pharmacists' time spent providing services was dependent on the number of beds served, the number of days the beds were served and ultimately, the number of patients in the study beds on each study day (patient-day). Pharmacist time per patient-day was considered to be the best baseline representation of time spent. It allowed for exclusion of beds that were empty on a particular day and comparisons between hospitals with study areas of different sizes. Monitoring time was reported as the total time required to provide all monitoring services to patients in the study areas (total pharmacist time) and the time spent monitoring patients specifically on the wards (PPM time).

Approximately twice as much total pharmacist time per patient-day was spent providing B-PPM services compared to DOR. Hospitals providing C-PPM services reported spending approximately three times as much total time per patient-day as did pharmacists providing B-PPM services. Drug Order Review sites did not report any time spent monitoring patients on the wards. Sites with C-PPM services provided a mean of 7.3 minutes of ward-based patient monitoring per patient-day which was significantly higher than the 1.8 minutes per day in B-PPM sites.

Data Collection Pharmacists

A greater number of pharmacists participated in data collection at C-PPM sites compared to other service levels. Examination of pharmacist demographics also revealed differences among pharmacists from the different service levels (Table IV).

Pharmacists in hospitals with C-PPM services were more recent graduates than pharmacists from other sites. Significantly more C-PPM pharmacists had completed a hospital residency, compared to pharmacists from B-PPM and DOR sites. A higher percentage had also received post-baccalaureate training. All C-PPM hospitals in the study had established pharmacy residency training programs, whereas a program was offered in only one B-PPM site and no DOR sites.

Patients Involved in the Study

Descriptive data provided by the pharmacists were used to give a general overview of the patients receiving pharmacist recommendations. Patients ranged in age from 16 to 100 years with a mean age of 64 (±17) years with females making up 52% of patient subjects. Excluding patients who remained hospitalized longer than 30 days, the median length of stay per site was nine days with a range of six to 11 days.

The most frequently cited reasons for admission among all service levels were circulatory-cardiovascular disorders, respiratory disorders, neoplasms and ill-defined

Table III: Description of Study Areas mean (standard deviation)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Acute care beds	71 (11)	92 (32)	114 (52)
Study days[1]	31 (4)	27 (4)	25 (1)
Patient–days[2]	2015 (413)	2082 (731)	2405 (1225)
Total pharmacist time (hours)[3]	76 (55)	135 (55)	436 (112)
PPM time (hours)[4]	0 (0)	64 (39)	272 (99)
Total pharmacist time per patient– day* (minutes)	2.2 (1.6)	4.0 (1.4)	11.9 (3.3)
PPM time per patient–day* (minutes)	0 (0)	1.8 (1.1)	7.3 (2.4)

1 Number of days data were collected
2 Total of number of patients in study beds on each study day
3 Drug Order Review Hours + Pharmacist PPM Hours + 1/2 (Pharmacy Resident PPM Hours)
4 Pharmacist PPM Hours + 1/2(Pharmacy Resident PPM Hours)
* $p<0.05$ (One-way ANOVA). Differences between DOR and C-PPM sites, and between B-PPM and C-PPM sites are significant (Duncan's Multiple Range Test).

Table IV: Pharmacist Demographics

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Pharmacists submitting data	25	42	65
Year of pharmacy graduation* [mean (SD)]	1976 (8)	1981 (8)	1984 (6)
Hospital residency (%)**	16	26	52
Advanced degree (%)	0	5	11
Years in hospital practice*** [mean (SD)]	11.2 (8.8)	8.2 (5.4)	6.3 (5.5)
Years in current position* [mean (SD)]	7.4 (7.4)	4.5 (4.4)	3.0 (2.2)

* $p<.05$ (one-way ANOVA). Differences between DOR and B-PPM sites, and between DOR and C-PPM sites are significant (Duncan's Multiple Range Test).
** $p<.05$ (Kruskal-Wallis non-parametric ANOVA). Differences between DOR and C-PPM sites, and between B-PPM and C-PPM sites are significant (Dunn's Test).
*** $p<.05$ (one-way ANOVA). Difference between DOR and C-PPM sites is significant (Duncan's Multiple Range Test).

symptoms (e.g, syncope, nausea not yet diagnosed). In those cases where concurrent medical problems were known and reported by the pharmacist, the most frequently mentioned conditions were endocrine and metabolic disorders, genitourinary disorders, mental disorders, sequelae of previous injuries, and prosthetics.

Number of Cases and Recommendations

The number of cases (i.e., the number of pharmacotherapy issues) and recommendations submitted by the study sites was influenced by many variables including the number of hours pharmacists provided services and the number of patient-days. Results are summarized in Table V.

Table V - Cases and Recommendations

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Number of cases submitted [mean (SD)]	53 (30)	123 (50)	415 (100)
Number of recommendations per site [mean (SD)]	45 (26)	153 (73)	580 (176)
Cases per hour of total pharmacists time[1] [median (range)]	0.58 (0.45– 0.97)	0.87 (0.70–1.27)	0.92 (0.78–1.36)
Recommendations per hour of total pharmacist time[1]* [median (range)]	0.67 (0.53– 1.22)	0.98 (0.88–1.38)	1.22 (1.01–2.17)
Cases per patient day[2]** [mean (SD)]	0.02 (0.01)	0.06 (0.02)	0.19 (0.08)
Recommendations per patient– day[2]** [mean (SD)]	0.03 (0.01)	0.08 (0.04)	0.27 (0.13)

SD= Standard Deviation
1 Drug Order Review Hours + Pharmacist PPM Hours + 1/2 (Pharmacy Resident PPM Hours).
2 Total of number of patients in study beds on each study day
* $p<0.05$ (One-way ANOVA). Difference between DOR and C-PPM sites is significant (Duncan's Multiple Range Test).
** $p<0.05$ (One-way ANOVA). Differences between DOR and C-PPM sites, and between B-PPM and C-PPM sites are significant (Duncan's Multiple Range Test)

Table VI: Pharmacist Involvement With the Case median (range)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Number of recommendations	40(21–102)	145(50–255))	525(393–825))
Recommendation made before initial drug order written (%)*	4.2 (0–6.5)	11.4 (8.6–18.9)	24.5 (19.9–38.1)
Recommendation solicited by non–pharmacy personnel (%)**	4.2 (0–15.8)	8.5 (7.9–24.6)	14.0 (11.4–25.7)
Pharmacist in patient–care area at time of recommendation (%)*	1.3 (0–3.2)	40.1 (34.3–46.0)	93.3 (70.5–99.4)
Recommendation documented in the patient's chart (%)	65.9 (17.2– 72.4)	28.2 (7.5–59.7)	18.7 (1.1–95.9)

* $p<0.05$ (One-way ANOVA). Differences among all service levels are significant (Duncan's Multiple Range Test).
** $p<0.05$ (One-way ANOVA). Difference between DOR and C-PPM sites significant (Duncan's Multiple Range Test).

Pharmacists in C-PPM sites reported nine times as many cases and recommendations per patient-day compared to pharmacists in DOR sites, and more than three times as many as pharmacists providing B-PPM services. Reported rates per patient-day were statistically different amongst all three service levels. For example, using a hypothetical ward with 33 beds at 100% occupancy, pharmacists providing C-PPM services reported nine recommendations per day compared to B-PPM or DOR pharmacists reporting 2.6 and 1 per day, respectively.

How the Pharmacist Became Involved with the Case

Details of how the pharmacist got involved with making a therapeutic recommendation for a patient are provided in Table VI. When the pharmacist made a recommendation prior to a drug order being written, he or she pro-actively contributed to patient care independent of the DOR process. This pro-active participation was reported more frequently in C-PPM sites than B-PPM or DOR sites. More cases from C-PPM sites were reported as being initiated by a request from another health professional than in DOR sites.

The pharmacist was more likely to be located in the patient care area at the time of recommendation as the intensity of monitoring service increased from DOR to B-PPM to C-PPM. In all sites, 80-90% of pharmacist recommendations were targeted to physicians (staff, residents, interns, or clinical clerks) or nurses.

The proportion of cases in which pharmacist recommendations were documented in the patient's chart varied widely within service levels such that differences across the levels were not statistically significant. Pharmacists making recommendations to change drug orders usually had authority to re-write orders that were then co-signed by the prescriber and put in the chart, thus creating a record of their actions. Pharmacists monitoring patients on the wards had permission to write their impressions in the form of a consultation report in the patient's chart in some hospitals while others had a specific portion of the chart allocated for pharmacy records. In some sites, pharmacists were not permitted to write in the patient's medical record.

OUTCOMES OF THE SERVICES

Pharmacotherapy Recommendations Made by Pharmacists by Categories

Pharmacists recorded pharmacotherapy recommendations on the data collection form in narrative form and also by category. The categories of recommendations are shown in Table VII. The majority of DOR site cases involved recommendations about the technical aspects of drug distribution such as correcting errors, clarifying the intent of an order, and enforcing prescribing guidelines according to the hospital formulary. Sites with more intense service levels reported a significantly smaller proportion of recommendations dedicated to these problems. Conversely, the majority of C-PPM site cases described recommendations involving changes to patient's drug regimens. Drug regimen changes, including increasing the dose, decreasing the dose, changing the dosing schedule and changing the route of administration were aimed at providing specific drug therapy to better fit a patient's needs or reduce unnecessary drug costs.

All three service levels reported similar proportions of recommendations involving drug selection and other recommendations, although B-PPM sites reported a higher proportion of recommendations pertaining to laboratory and serum drug level monitoring tests.

Key Issues and Recommendations

Categories of recommendations based on the issues identified were reported to a greater extent by one service level than the others. This is summarized in Table VIII.

Recommendations with greater frequency in DOR sites were those involving the general accuracy of a drug order. Examples include: conformity with a hospital formulary, compatibility with a patient's allergy status indicated on the patient's profile, and consistency with general manufacturer's drug dosing guidelines. Sites providing B-PPM services had the highest proportion of recommendations involving serum drug level/laboratory test monitoring and patient counselling. This observation is likely due to the selection of patients to receive B-PPM based on high-risk situations such as drugs with a narrow therapeutic index (where monitoring utilizes laboratory assessments), or complex therapeutic regimens (where patient counselling programs are targeted).

Recommendation categories reported by C-PPM sites with significantly greater frequency than other sites involved drug selection, dosing duration, and dosing schedule issues which would require the pharmacist to have an on-going knowledge of a patient's medical progress.

Table VII: Categories of Recommendations Made by Pharmacists median (range)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Number of recommendations per site	40 (21–102)	145 (50–255)	525 (393–825)
Drug Selection (%) (e.g., add drug, stop drug, change drug)	19 (5–38)	19 (16–26)	26 (16–34)
Drug Regimen (%)* (e.g., increase/decrease dose, change route)	27 (8–33)	27 (21–38)	42 (34–45)
Drug Distribution (%)* (e.g., clarify/correct drug order, change to formulary drug)	40 (32–51)	26 (14–44)	14 (5–26)
Patient Monitoring (%)** (e.g., request serum drug level, cancel lab tests)	1 (0–6)	10 (4–17)	7 (5–17)
Other (%) (e.g., patient counselling, verify allergy, drug information)	9 (0–25)	10 (4–31)	11 (4–17)

* $p<0.05$ (One-way ANOVA). Difference between DOR and C-PPM sites.
** $p<0.05$ (One-way ANOVA). Differences between DOR and B-PPM sites, and between DOR and C-PPM sites.

Table VIII: Key Recommendation Categories[1] median (range)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Number of recommendations per site	40 (21-102)	145 (50-255)	525 (393–825)
Categories:			
Add Drug (%)*	0 (0–3)	4 (1–8)	9 (4–10)
Suggest Starting Dose (%)*	3 (0–5)	2 (1–8)	9 (6–11)
Change Route of Administration (%)**	0 (0–3)	1 (0–12)	3 (2–5)
Change Order to Formulary Drug (%)***	32 (8–36)	12 (3–24)	4 (2–6)
Request Serum Drug Level (%)†	0 (0–3)	6 (1–14)	4 (2–10)
Provide Patient-Specific Education (%)***	0 (0)	6 (0–16)	3 (1–3)
Verify Patient Allergy Status (%)**	1 (0–5)	1 (0–1)	0 (0–1)

1 expressed as the percent of all recommendations per site
* $p<0.05$ (Kruskal-Wallis One-way ANOVA). Difference between DOR and C–PPM and B–PPM and C–PPM. (Dunn's Test).
** $p<0.05$ (Kruskal–Wallis One–way ANOVA). Difference between DOR and C–PPM. (Dunn's Test).
*** $p<0.05$ (Kruskal–Wallis One–way ANOVA). Difference between all levels. (Dunn's Test).
† $p<0.05$ (Kruskal–Wallis One–way ANOVA). Difference between DOR and B–PPM and DOR and C–PPM. (Dunn's Test).

Relationship Between Issues and Recommendations

When the issues and resultant recommendations are examined on a case-by-case basis, one observes that the issues leading to certain pharmacist recommendations vary across the three levels of service (Table IX). Drug Order Review sites rarely requested a new drug be added to a patient's regimen whereas other sites did make "add drug" recommendations. The most frequent issues resulting in an "add drug" recommendation were "drug needed but not ordered" or "drug selection needed".

When a recommendation to stop a drug or order for a patient was made, the reason for the request in DOR sites was most often because the drug ordered was a therapeutic duplication of a second drug. In B-PPM, the "stop drug" request was made because of therapeutic duplication, excessive duration of treatment or the drug interacted adversely with another. Concurrent PPM sites requested drugs be stopped most often due to therapeutic duplications, excessive duration of treatment, or cases where no treatment was needed.

A request to change a drug (to a different agent in the same therapeutic class) was made in DOR sites most often because an allergy or drug interaction was detected on review of the patient profile, whereas, for B-PPM and C-PPM sites, the most common reasons were the availability of less costly, less toxic or more effective alternatives.

Finally, although recommendations involving dose adjustments were observed in all sites, 79% of the dose adjustment issues for DOR sites were requests secondary to an error in the original drug order, whereas, only 39% and 17% of dose adjustment issues were because of drug order errors in B-PPM nd C-PPM sites, respectively. The remaining recommendations for dose adjustments were based on pharmacist judgment of dose adjustments needed.

Table IX: Selected Drug Recommendations by Issue Category

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Number of "Add drug" recommendations	4	25	281
Issue category:			
drug needed but not ordered (%)	50	68	78
drug selection needed (%)	25	32	18
drug allergy detected (%)	25	0	<1
more effective drug available (%)	0	0	3
Number of "Stop drug" recommendations	39	80	439
Issue category:			
therapeutic duplication (%)	82	37	33
drug allergy detected (%)	13	3	1
drug ordered but not needed (%)	3	9	13
drug interaction detected (%)	3	9	4
duration adjustment needed (%)	0	35	37
adverse drug reaction detected (%)	0	3	4
Number of "Change drug" recommendations	16	24	119
Issue category:			
allergy detected (%)	38	17	9
drug interaction detected (%)	19	4	3
more effective drug available (%)	13	21	38
drug order error detected (%)	13	0	0
less costly alternative available (%)	6	29	24
less toxic alternative available (%)	6	25	24
Number of "Dose adjustment" recommendations	33	48	326
Issue category:			
drug order error detected (%)	79	39	17

Drugs Mentioned in Issues and Recommendations

Of the 3373 cases submitted, 1462 cases (43%) identified the specific drug therapy in the description of the issue and recommendations. The remaining cases contained either descriptions where the drug name was missing or no specific drug product was involved. The majority of the drugs named were from the following four therapeutic classes as defined by the American Hospital Formulary Service: anti-infective agents (33%), gastrointestinal agents (17%), central nervous system agents (15%), and cardiovascular agents (11%). Other therapeutic categories represented less than 5% of drugs mentioned. The most frequently reported individual drug from all three service levels was gentamicin.

Drug Product Cost Changes

A random sample of cases was assessed to enable costs to be assigned. Sampling was proportionately larger from DOR and B-PPM cases than C-PPM cases to account for the disproportionately lower numbers submitted from these service levels. Of the 552 cases in the sample, 89 (16%) were from DOR sites, 140 (26%) were from B-PPM sites and the remaining 323 (58%) were from C-PPM sites. These cases were examined in detail for the cost analysis. Results are summarized by recommendation category in Table X, Overall, the average drug product cost change per recommendation resulted in a 40% reduction in drug costs, equivalent to a mean of $4.75 savings per 24 hours of drug therapy. Other factors such as the cost of pharmacy preparation time, nursing administration time, and laboratory tests were not quantified but would also have been avoided.

The cost reduction per recommendation was the greatest from DOR sites. However, DOR sites made the fewest recommendations that resulted in increased costs (e.g., add drug or increase daily dose). The direction and magnitude of cost changes observed depended on the category of the recommendation made. The recommendations "add drug" and "increase daily dose" resulted in cost increases with the intent at ensuring that patients received the needed drug therapy.

Table X: Drug Product Cost Changes*

Recommended Category	Service Level	N	Average Net % Change*	$/case per 24 hours mean (SD)
All categories	All	552	– 40	– $4.75 (20.67)
	DOR	89	– 50	– $5.84 (25.39)
	B–PPM	140	– 39	– $4.59 (13.67)
	C–PPM	323	– 38	– $4.52 (21.75)
Change of Route Administration	All	35	– 87	– $15.90 (15.34)
	DOR	0	N/A	N/A
	B–PPM	6	– 96	– $16.93 (14.26)
	C–PPM	29	– 86	– $15.79 (15.79)
Decrease Daily Dose	All	90	– 52	– $14.02 (32.81)
	DOR	6	– 66	– $46.31 (83.99)
	B–PPM	17	– 44	– $10.50 (17.52)
	C–PPM	67	– 51	– $12.02 (27.22)
Change Drug (same therapeutic class)	All	44	– 48	– $11.96 (11.96)
	DOR	9	– 30	– $3.64 (10.42)
	B–PPM	11	– 39	– $6.94 (31.77)
	C–PPM	24	– 52	– $17.39 (41.55)
Stop Drug	All	137	N/A	– $5.89 (14.62)
	DOR	19	N/A	– $6.28 (16.32)
	B–PPM	33	N/A	– $6.88 (19.27)
	C–PPM	85	N/A	– $5.42 (12.12)
Change Dosage Form	All	23	– 68	– $2.50 (4.63)
	DOR	5	– 31	– $1.51 (4.25)
	B–PPM	5	– 95	– $5.60 (5.28)
	C–PPM	13	– 70	– $1.69 (4.33)
Change to Formulary Drug	All	83	– 34	– $1.66 (7.30)
	DOR	39	– 39	– $2.94 (10.47)
	B–PPM	23	– 22	– $0.60 (1.38)
	C–PPM	21	– 21	– $1.43 (0.43)
Increase Daily Dose	All	44	+ 73	+5.75 (13.95)
	DOR	5	+ 82	+ $6.69 (8.90)
	B–PPM	5	+ 125	+ $7.71 (14.82)
	C–PPM	34	+ 65	+ $5.32 (14.72)
Add Drug	All	59	N/A	+ $7.48 (19.46)
	DOR	1	N/A	+ $7.48 (N/A)
	B–PPM	6	N/A	+ $2.20 (2.36)
	C–PPM	52	N/A	+ $8.22 (20.62)

* cost change = (cost for 24 hours of drug before pharmacist recommendation) - (cost for 24 hours of drug after recommendation)
N indicates the number of cases with this recommendation present
% change for all cases related to the recommendation

Concurrent PPM sites reported more recommendations to add a drug than other sites and this was reflected in the number of "add drug" recommendations in the costing sample. Not only did C-PPM sites recommend drugs be added to patient regimens more often, but the average cost was also higher per recommendation.

Drug Order Review pharmacists saved an average of $2.94 per 24 hours when recommending an order change to a formulary drug, whereas, the same recommendation in the other sites generated less savings ($0.60 and $1.43) for B- and C-PPM sites, respectively. Other recommendation categories with large cost differences among service levels included "change a drug within the same therapeutic class", and "decrease daily dose".

The percent and dollar savings were variable within a recommendation category and depended on which drug was involved in a particular case. Although cost data are skewed, results are reported as a means to include the impact of extreme costs or savings.

Acceptance Rate for Pharmacist Recommendations

Overall the mean acceptance rate by physicians of pharmacist recommendations was high with over 88% of the recommendations being accepted unconditionally or accepted in principle with modifications. Results are summarized in Table XI.

Table XI - Acceptance Rate mean (standard deviation)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)	Overall (N=17)
Number of recommendations	53 (30)	153 (73)	580 (176)	268 (263)
Accepted (%)	84 (7)	82 (6)	84 (8)	83 (7)
Rejected (%)	5 (3)	8 (3)	6 (4)	6 (3)
Modified and accepted (%)	6 (5)	5 (2)	4 (1)	5 (3)
Unknown (5)*	5	5	6	6

* Those cases in which the pharmacist was unable to determine if the recommendation was accepted or rejected.

Pharmacist Follow-up Monitoring of Patient Response

After a recommendation was implemented, pharmacists were asked to record any follow-up monitoring they provided pertaining to their recommendation. Results are shown in Table XII.

Cases were eligible for follow-up data recording if the recommendation was accepted, modified and accepted, or if the subsequent action was documented as being unknown. For these cases, DOR sites were unable to provide follow-up monitoring. Pharmacists in B-PPM sites provided follow-up monitoring in a median of 19% of eligible cases, whereas, C-PPM sites reported a median follow-up rate of 35%. The differences in the follow-up rate among the groups was statistically significant.

Table XII: Follow-up of Patient Response median (range)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Number of cases eligible for follow-up	32 (17–77)	110 (31–155)	359 (235–495)
Number of cases with follow-up provided(%)*	0 (0–7.7)	19 (7.3–50.3	35 (20–58.8)
Observed patient response:			
Monitoring parameters improved(%)	N/A	30 (12.5–40.6)	37.8 (31.7–56.8)
Monitoring parameters worsened(%)	N/A	0 (0–21.9)	3.2 (2.2–8)
Parameters unchanged(%)	N/A	25 (15.4–50)	25.7 (10.2–43.8)
No parameters present (%)	N/A	16.7 (9.4–50)	27.9 (6.3–42.6)
Response unknown or missing (%)	N/A	5.1 (0–12.5)	1.6 (0–5.6)
Reason why monitoring of patient response ended:			
Desired response observed(%)	N/A	35 (11.5–5.50)	19.4 (11.2–48.4)
Patient lost to follow–up (moved)(%)	N/A	37.5 (16.7–57.7)	38.2 (28.1–47.7)
7 days of monitoring completed(%)	N/A	16.7 (9.25)	22.2 (14.8–41.6)
Reason unknown or missing(%)	N/A	16.7 (0–25)	13 (1.6–22.7)

* $p<0.05$ (Kruskal-Wallis One–way ANOVA) Significant differences among all three comparisons. (Dunn's Test)

In those cases with follow-up reported, monitoring parameters most often improved or remained unchanged. Less often parameters worsened or no parameters were available to provide an intermediate measure of patient response. In over half the cases, patients were lost to follow-up because they were moved to another ward, were discharged home, or were treated for conditions requiring greater than seven days for a therapeutic response to be observed.

ASSESSMENT OF IMPACT OF PHARMACIST RECOMMENDATIONS

At the time a recommendation was made, the pharmacist provided a self-assessment of the perceived impact of the recommendation on the patient and patient care. These assessments were made prior to any clinical response exhibited by the patient, and provided insight into what factors were motivating the pharmacist to make the recommendation in the first place.

Pharmacist Assessment of the Impact of Recommendations

The results of pharmacist self-assessments of therapeutic effect, risk change, and drug cost at the time the recommendations were made are provided in Table XIII. Pharmacists in DOR hospitals estimated a higher median percentage of cases with no therapeutic effect or no impact on risk compared to other service levels. Conversely, pharmacists reported higher median percentages of cases with some beneficial therapeutic effect and/or risk reduction in B-PPM and C-PPM sites, although differences did not reach statistical significance.

The overall focus of pharmacist recommendations was different across service levels. Drug Order Review sites were more often providing recommendations with the aim of decreasing drug costs than influencing the quality or level of risk of drug therapy the patient was receiving. Basic PPM and C- PPM sites had higher proportions of cases with beneficial therapeutic and risk reduction effects with a higher proportion of cases perceived as resulting in cost increases.

Site Physician Assessment of the Impact of Recommendations

Cases were sent to physicians involved in the case as described in the Methods. The response rate was above 50% in all but two C-PPM sites where difficulties arose in following up with medical residents who had a rotation change during the study. Physicians were asked to give their assessment of the perceived impact of the pharmacists' recommendations on patient care. These assessments provided insight into the rationale for the physician's response to the recommendation. Neither physicians nor pharmacists were aware of the opinions of the other party at the time their own opinions were provided.

Table XIII: Pharmacist Assessment of Impact Median (range)

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Number of Recommendations	35 (18–87)	132 (40– 177)	403 (305– 544)
Pharmacists' opinion of impact on therapeutic effect of the recommendation:			
Beneficial effect (%)	36 (22–90)	50 (42–86)	64 (50–76)
No effect (%)	61 (10–78)	45 (14–57)	36 (24–50)
Detrimental effect (%)	2 (0–4)	1 (0–3)	1 (0–1)
Pharmacists' opinion of impact on patient risk:			
Reduced risk (%)	3 (26–66)	56 (41–77)	44 (21–58)
No change in risk (%)	67 (32–72)	42 (22–56)	48 (40–67
Increased risk (%)	1 (0–2)	1 (1–5)	5 (1–12)
Pharmacists' opinion of impact on drug costs:			
Reduced costs (%)	46 (26–55)	42 (27–51)	34 (16–40)
No change in costs (%)	52 (35–61)	46 (38–72)	49 (36–74)
Increased costs (%)	7 (0–13)	11 (1–14)	15 (10–28)

The frequencies of therapeutic effect, risk, and cost opinion responses for physicians across the service levels are summarized in Table XIV. Physicians in DOR hospitals perceived that a higher median percentage of cases had no therapeutic effect and a lower percentage of cases had positive therapeutic effects compared to physician assessments from other service levels. No significant differences in opinions were observed between B-PPM and C-PPM physician responses. Overall, physician assessments reinforced the observed differences in the focus of pharmacist recommendations across service levels.

Recommendations from DOR sites were more often perceived to be of no effect in terms of the risk reduction from recommended changes. Basic PPM and C-PPM sites had a higher percentage of cases with moderate beneficial therapeutic improvement and moderate risk reduction, and fewer cases with no effect than DOR (not shown) ($p<.05$). No differences between B-PPM and C-PPM sites were observed. Opinions on the degree of cost changes resulting from the recommendations were evenly distributed among service levels.

Comparison of Pharmacist and Physician Assessments

Of those cases with both pharmacist and physician assessments provided, levels of agreement are summarized for each assessment category in Table XV. The proportion of cases with agreement between assessments on the presence or absence of a therapeutic effect increased as the pharmacy monitoring service increased. Conversely, the proportion of cases with costing assessment agreement decreased as the level of pharmacist monitoring increased. As the health professional working most closely with drug products, pharmacists would be expected to know the cost of drugs, perhaps more accurately than prescribers. Agreement on the opinions of changes in risk to the patient was the lowest of the three opinion categories evaluated.

An additional phase of the research is currently underway to assess the perceived impact of a random sample of cases using an external panel of expert pharmacist and physician clinicians. The results of this study will be used to validate the perceived outcomes reported by pharmacists and physicians during the study.

DISCUSSION

The quantity, nature and impact of recommendations made by pharmacists differed in hospitals providing different levels of PPM.

At higher service levels, the issues and recommendations were more often of a clinical, as opposed to a technical, nature. Similar results have been reported

Table XIV : Physician Assessment of Impact

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Response rate (%)	73	76	59
Mean (SD)	(14)	(6)	(19)
Number of cases with physician assessment.	15	32	124
Median (range)	(8–31)	(16–81)	(98–142)
Physicians' opinion of therapeutic effect of the recommendation:			
Median (range)			
Beneficial effect (%)*	48 (11-54)	59 (33-81)	68 (55-75)
No effect (%)*	53 (47-78)	34 (19-60)	31 (26-41)
Detrimental effect (%)	0 (0-13)	0 (0-7)	2 (0-7)
Physicians' opinion of Patient Risk from the recommendation:			
Median (range)			
Reduced risk (%)*	11 (0-33)	32 (32-47)	7 (27-43)
No change in risk (%)*	89 (63-92)	56 (53-65)	58 (55-67)
Increased risk (%)	2 (0-12)	5 (0-12)	6 (3-8)
Physicians' opinion of impact on drug costs from the recommendation:			
Median (range)			
Reduced cost (%)	34 (23-49)	43 (31-47)	41 (29-52)
No change in cost (%)	56 (43-77)	51 (36-63)	49 (26-55)
Increased cost (%)	7 (0-14)	13 (6-18)	15 (8-23)

* $p<0.05$ (Kruskal-Wallis One–way ANOVA). Differences between DOR and B–PPM and DOR and C–PPM (Dunn's Test).

Table XV: Pharmacist and Physician Assessment Agreement[1]

	DOR (N=6)	B-PPM (N=5)	C-PPM (N=6)
Therapeutic Effect agreement (%)	57 (N=91)	67 (N=179)	68 (N=707)
Risk agreement (%)	54 (N=90)	55 (N=179)	61 (N=708)
Drug Cost agreement (%)	74 (N=86)	72 (N=176)	66 (N=687)

1 percent of cases with the same pharmacist and physician opinions
N indicates the number of cases with both pharmacist and physician opinions present

elsewhere. Pharmacists reviewing drug orders in the central pharmacy tend to detect mainly technical problems with the way drug orders are written.[33,36,37] Pharmacists monitoring patients on the wards report not only more problems identified, but also more clinically-oriented cases involving drug therapy selection, drug regimen adjustments, and the use of laboratory tests.[27,32,38-41] It follows that technical issues surrounding drug distribution should be handled by pharmacy technicians or the appropriate technology so that pharmacists can focus on providing clinically-oriented care to patients.

Pharmacists' assessments of the impact of their recommendations demonstrate the driving forces behind their recommendations to be both quality of care and cost containment. Pharmacists in B-PPM and C-PPM hospitals were more likely to make recommendations with perceived clinical impact than in DOR hospitals. The changing trend in pharmacist opinions is clinically important as the focus of the pharmacists' efforts changes from drug costs to quality of care plus cost considerations or quality alone. Similar patterns emphasizing quality of care in pharmacist assessments were reported by Hatoum et al. In this study, a panel of pharmacist assessors concluded that 41.7% of the recommendations made by pharmacists providing clinical services on the wards reduced drug costs and 83.9% improved the quality of care for patients.[19]

The high acceptance rate of pharmacists' recommendations reported in all three service levels during the study indicates that other health professionals within the institution agree with suggested changes. This acceptance is a strong endorsement of the positive work pharmacists do while providing monitoring services.

Drug product cost changes demonstrated the influence pharmacists can have on drug expenditures when making recommendations for changes to a patient's drug therapy. The magnitude and direction of drug product changes in the sample of cases depended on the type of recommendation. The majority of recommendations, including stopping drugs, changing to different drugs, changing routes of administration and dosage forms all reduced drug product costs, regardless of the level of service. Some recommendations that typically resulted in increased costs were more common in hospitals with ward-based monitoring services where the decision to change therapy was based on patient needs and not reducing costs (e.g., add a drug that was needed but not ordered). The other major recommendation category where drug costs rose was increasing a dose that was too low. Regardless of whether doses were increased to correct a drug order error or because of inadequate patient response, the patient's need for adequate therapy was more important than the increased drug product costs. Although not quantified, overall health care costs would be expected to rise due to inadequate treatment which would be greater than the increased drug product costs required to correct the situation.

Drug product costs are only a portion of the costs involved with delivering drug therapy to the patient, but have been used as a measure of the value of pharmacist interventions.[42] As health care costs have risen in recent years, these studies have been used to justify present and future pharmacy staffing requests.[43-45] Other studies have attempted to analyze more completely the costs associated with drug therapy but these efforts also have limitations.[22,26] In particular, the drug and administration costs are counter-balanced by the costs of providing pharmacist monitoring services, which in turn are offset by costs from the clinical consequences of not having pharmacist recommendations in the first place. Given the wide variety of clinical scenarios in which pharmacists make recommendations, estimating and interpreting the indirect costs per recommendation is difficult.

Some researchers have avoided the problems of determining cost changes for individual recommendations by studying the overall changes in drug costs, drug charges and patient length of stay for groups of patients who did and did not receive clinical pharmacy services during their hospitalization.[16,18,46] Patients who received clinical pharmacy services had lower pharmacy costs and charges compared to control groups. Study patients also had shorter hospital stays, which were used as a proxy-measure of quality of care and clinical outcome. In Canada, systems are being developed to enable pharmacy billings by individual patients, but results of studies using this information for economic analysis are not yet available.

One Canadian study incorporated factors such as morbidity secondary to inappropriate drug therapy, risk attributable to drug therapy, and other indirect costs in their outcome analysis using a panel of physician assessors to predict changes in patient length of stay due to pharmacist recommendations.[25] Using a standard per diem rate of $600, researchers estimated that 15 selected interventions by pharmacists resulted in a total cost avoidance of $17,760.

Results of a survey of Ontario hospitals indicated that therapeutic intervention programs more than pay for themselves in terms of costs saved or avoided.[47] Data from 53 hospitals showed an average of 29 minutes of a pharmacist's time to intervene and resolve a drug therapy problem. Data from 10 hospitals showed a cost savings or avoidance of $49.34 per intervention. Using an hourly wage of $25.00, each intervention cost $12.08 in a pharmacist's time and produced a four–fold return on investment in cost savings/avoidance.[47]

In the present research, the use of drug product cost changes per 24-hour period reduced the assumptions

required when estimating costs. For example, no supposition is made of the number of days' treatment that would have been consumed by a patient if the pharmacist had not changed the therapy. One major limitation is the lack of inclusion of related costs such as pharmacist and nursing time, laboratory tests, and other monitoring procedures. The costs associated with patient outcome, quality of life and the value of patient satisfaction have also not been quantified.

A study from the United States demonstrated the beneficial effects of pharmacists on in-patient health care outcomes.[16] Patients receiving care from a health care team including a ward-based clinical pharmacist had significantly shorter lengths of stay than patients in control groups (7.6 days vs 8.2 days). Re-admission rates were also higher in the control groups which, although clinically important, did not reach statistical significance. Drug costs were marginally lower in the study group but the major difference in costs was in the total cost per admission, where study patients averaged US$377 less than their control group counterparts. When the cost to provide pharmacy monitoring services was considered, the authors concluded the presence of pharmacists on the health care team was not only important for patient outcomes, but also cost effective.[16] These results confirm similar findings reported in other studies.[18,38,46]

A key difference between hospitals providing different levels of PPM to patients in this study was the number of pharmacists on staff relative to the numbers of beds being served. As the level of PPM intensified, so did the relative number of pharmacists employed by the hospital. Similar results were observed in the survey by Einarson and Mann where almost twice as many pharmacists per bed were employed in sites with decentralized patient monitoring compared to sites with central drug order editing services.[27] Data from the 1993 Lilly Canada Hospital Pharmacy Survey support these trends.[35]

Clearly, a prerequisite for the provision of advanced PPM is sufficient pharmacist staff. Technical support including pharmacy technicians, computers, and a drug distribution system that frees the pharmacist from technical functions is also important. The pharmacy department must be organized to allow pharmacists sufficient time to make patient monitoring a priority. One problem, identified in sites with B-PPM and C-PPM, is the lack of continuity of patient monitoring services on weekends and holidays. Patients still require services during these times and pharmacists must be prepared to provide them consistently to retain the credibility of the service.

Pharmacists in sites with higher levels of PPM had less experience but more training than pharmacists in other sites. This may reflect changes in undergraduate curricula where clinical training is emphasized more than in previous years. Clinical services also require a degree of specialization achieved by residency training. All C-PPM hospitals in the study had established pharmacy residency training programs, whereas, a residency program was offered in only one B-PPM site and no DOR sites. This may have influenced the proportion of participants with residency training since many institutions hire their residents after their year of study is completed.

Expansion of higher levels of PPM requires pharmacists with more clinical training.[27] Support is needed for pharmacists to receive advanced training, including continuing education programs for staff pharmacists and residency training opportunities. With recent cut-backs in hospital funding, money for pharmacy residencies has been lost. This is bound to have a negative effect on clinical pharmacy since residents were active contributors to patient care and pharmacy development through residency projects.

Pharmacist monitoring time per patient day increased with the service level. This reflected the increased input required to provide more intensive PPM. The location of the pharmacist during the time of monitoring was also important. Pharmacists located in the patient care area were able to detect and act on drug therapy issues (problems) in a more timely, proactive manner than pharmacists located in the central pharmacy. As well, pharmacists in the central dispensary generally had little knowledge of drug problems for patients. Even pharmacists providing B-PPM were limited in their scope of monitoring because of the way their target patients were identified, which was often through drug order screening for problems in the dispensary. Pharmacists' presence on the wards was a regular reminder to other staff that they were active members of the health care team. This was exemplified by the increased proportion of cases in C-PPM sites where pharmacists were asked to help resolve a drug-related issue for a patient. Pharmacists need to work in the patient care areas if they are to make their maximum contribution to patient care.

In spite of devoting much of their time to monitoring patients, the majority of pharmacists providing C-PPM did not document their recommendations in the patient's chart as a written record of their clinical contributions. Pharmacists need to document their work in continuing care for recognition and credibility. As pharmacists get more involved in direct patient care, this documentation assumes even more importance as an official record of pharmacist contributions should they be held accountable and liable for a patient's clinical outcome.

Quality of care is a critical issue that many health care providers feel has been neglected in today's era of fiscal restraint.[48] Health care is neither economical nor effective if hospitalized patients receive minimal care or are prematurely discharged back into the community. Costs to individual patients and society as a whole due to compromises in the quality of institutional care are potentially enormous.

An important issue is the identification and resolution of drug therapy problems for all patients. Although we were unable to test for similarity of patients from the standpoint of disease intensity, patient mix did not appear to be markedly different between sites or service levels. Therefore, it is a concern that, if many more drug issues are being identified and resolved in sites with higher levels of PPM, then there may be many unresolved drug issues for patients in hospitals with lesser PPM services. The extent and costs associated with patient morbidity due to unresolved drug problems deserves further study.

Although the present research provides an overview of differences between levels of PPM, other research questions still need to be addressed. A longitudinal study to measure outcomes of patient care with and without PPM is needed to answer the ultimate question on the impact of PPM. A cost impact analysis of PPM services using case costing methods would also be valuable for assessing a pharmacist's impact on indirect health care costs as well as direct drug costs.

Pharmacist and physician opinions on therapeutic effect, risk reduction, and drug cost changes resulting from pharmacist recommendations need to be validated. Biases may have been present in the opinions of those individuals directly involved in the patient cases reported during the study. To address this issue, an additional arm of the study has been developed whereby panels of pharmacist and physician clinicians are independently evaluating a random sample of study cases. Results of this validation study will be reported at a later date.

Practice models for C-PPM are needed to enable pharmacists to reorganize their workload to focus on PPM and the resolution of pharmacotherapeutic issues for patients. Tools for reporting pharmacists' work and maintaining quality assurance are also required. Results from the Clinical Pharmacy Services Study can be viewed as a reference point of where the profession of pharmacy is and where the profession is going as pharmacy services evolve to meet the needs of patients.

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APPENDIX A

CRITERIA FOR CATEGORIZING CLINICAL PHARMACY SERVICES INTO DIFFERENT LEVELS OF PATIENT PHARMACOTHERAPY MONITORING

DEFINITIONS

ALL PATIENTS - for the purposes of this study, all patients means 100% of acute care medical in-patients who have been identified as study subjects. Study subjects are determined by the level of pharmacy monitoring (DOR or PPM) they receive.

ALL DRUG ORDERS - refers to >90% of drug orders written for a patient. This standard allows for consideration of drug orders written when the pharmacist is not available (eg. orders written prior to a patient being transferred to a patient care area)

PATIENT PHARMACOTHERAPY MONITORING – refers to all those activities involved in a pharmacist's effort to optimize a patient's drug therapy. This involves the regular, systematic review of drug therapy and patient response to ensure appropriate, safe, efficacious and economic drug use for each patient.

Three levels of monitoring have been identified as the levels of service to be compared in this study. These levels have been adapted from the levels originally described in the working paper entitled, "A White Paper on the Establishment and Elaboration of Clinical Pharmacy Services".[30]

CENTRAL DRUG ORDER REVIEW

Process Criteria

All drug orders for acute care in-patients are routinely reviewed for general accuracy. The pharmacist will intervene on behalf of the patient if problems/discrepancies are detected.

Central drug order review involves screening for the following:

* recommended usual drug dose, dosing interval and duration of therapy;
* potential allergies;
* drug duplications/therapeutic duplications;
* potential drug interactions;
* technical requirements for drug orders (e.g., physician signature, completeness of instructions); and,
* formulary requirements.

Structural Criteria

1) Drug order review occurs primarily in the central pharmacy or satellite.
2) Drug order review occurs with the use of a patient medication profile (manual or computerized).
3) The pharmacist reviews drug orders after the drug order is written (ie. retrospectively).
4) The pharmacist has minimal, if any, face-to-face interaction with patients who receive drug order review services.
5) The focus of drug order review is on the specific drug ordered. Drug order review is unable to ensure that the prescribed drug is the best choice for a specific patient's needs.

BASIC PATIENT PHARMACOTHERAPY MONITORING

Process Criteria

Individual patients are monitored with the aim of minimizing or avoiding drug-related problems. Drug therapy is monitored with the use of patient-specific information. The pharmacist will intervene on behalf of the patient if problems/discrepancies are detected or anticipated, or opportunities for improving therapy are identified.

Basic PPM involves monitoring for the following:

* all DOR criteria;
* rational drug dose, dosing interval and duration of therapy for the individual patient's needs;
* appropriate indication;
* optimal dosage form and method of administration for the individual patient's needs;
* contraindications/precautions related to patient characteristics and/or disease state; and,
* adverse drug reactions.

APPENDIX A (continued)

Structural Criteria

1) Basic PPM usually occurs on the patient ward.
2) The pharmacist has access to health record, laboratory data and profiles.
3) Most drug orders are written without the input from a pharmacist. The pharmacist usually becomes involved in the drug decision-making process retrospectively.
4) The pharmacist has face-to-face interaction with patients receiving B-PPM services when needed.
5) The focus of B–PPM is the drug with consideration given to characteristics and needs of the patient who will be receiving the drug.

CONCURRENT PATIENT PHARMACOTHERAPY MONITORING

Process Criteria

Individual patients are automatically followed by a pharmacist from admission to discharge on as frequent a basis as is warranted for their condition(s) and drug therapy (minimally once daily) to optimize the overall outcomes of therapy and improve the patient's quality of life. Concurrent PPM involves the following:

* all DOR and B-PPM criteria;
* designing a patient-specific therapeutic plan including desired outcomes of drug therapy;
* implementing the therapeutic plan by recommending the most appropriate drug, dose, dosing interval and duration of therapy for the individual patient;
* following a series of clinical parameters to monitor patient response to therapy;
* providing recommendations to the health team for changes in therapy based on regular assessments of patient response; and,
* sharing the responsibility for the drug selection process and outcome of drug use through documentation of recommendations in the patient's chart and the provision of after-hours on-call pharmacist coverage.

Structural Criteria

1) Decentralized concurrent monitoring of patient pharmacotherapy occurs primarily on the patient ward.
2) The pharmacist has access to health records, laboratory data and profiles.
3) The pharmacist provides input as part of the health care team both before and after the drug order is written (i.e., prospectively and retrospectively).
4) The pharmacist has face-to-face interaction with patients receiving C-PPM services as frequently as needed, usually daily (excluding times when the department may not be providing these services - e.g., weekends).
5) The focus of C-PPM is the outcome of therapy and overall health care for a patient.

APPENDIX B

LIST OF STUDY PARTICIPANTS

Pilot Study Hospitals
Burnaby Hospital, Burnaby, B.C.
Lion's Gate Hospital, North Vancouver, B.C.
Richmond Hospital, Richmond, B.C.

Study Participants
Belleville General Hospital, Belleville, Ontario
Joseph Brant Memorial Hospital, Burlington, Ontario
St. Joseph's Hospital, Hamilton, Ontario
Kingston General Hospital, Kingston, Ontario
Victoria Hospital Corporation, London, Ontario
Queensway-Carleton Hospital, Nepean, Ontario
Greater Niagara General Hospital, Niagara Falls, Ontario
Ottawa General Hospital, Ottawa, Ontario
Salvation Army Grace General Hospital, Ottawa, Ontario
Hotel Dieu Hospital, St. Catharines, Ontario
Scarborough General Hospital, Scarborough, Ontario
Northwestern General Hospital, Toronto, Ontario
St. Joseph's Health Centre, Toronto, Ontario
The Toronto Hospital, Toronto, Ontario
Women's College Hospital, Toronto, Ontario
Welland County General Hospital, Welland, Ontario
Woodstock General Hospital, Woodstock, Ontario

APPENDIX C
DATA COLLECTION FORM - ONTARIO STUDY

Name - Last: _____ _____

First: _____

Bed: _____

Clinical Pharmacy Services Study

Part II

4987

Date (d/m/y): ___/___/___

PHARMACOTHERAPY ISSUE:

Description: _____

_____

_____

DRUG SELECTION

more effective drug available	
less toxic drug available	
therapeutic duplication	
less expensive drug available	
drug selection needed	
drug needed but not ordered	
drug ordered but not needed	

DRUG REGIMEN

starting dose recommendation needed	
dose adjustment needed	
change of route/form needed	
duration adjustment needed	
frequency/schedule adjustment needed	

DRUG DISTRIBUTION

non-formulary/restricted drug	
IND/emergency release drug	
drug order error	
order clarification	

MONITORING / OTHER

monitoring tests needed	
monitoring tests not needed	
test interpretation needed	
allergy	
drug interaction	
adverse drug reaction	
incompatibility/instability	
patient education needed	
drug information needed	

BACKGROUND INFORMATION AT TIME OF RECOMMENDATION:

Access to FUNCTIONAL STATUS:

Yes		No	

If YES, indicate RELEVANT status: (↑ N ↓)

renal	
hepatic	
immune	
GI	
cardiac	

Access to LABORATORY VALUES:

Yes		No	

If YES, indicate RELEVANT values: (↑ N ↓) (↑ N ↓)

WBC		Na	
HGB		K	
PLT		Cl	
PT		CO2	
PTT		BUN	
ALB		CRE	
		BGLU	

Part II (continued)

Treatment stage:

order not yet written	
<24 hours after order written	
>24 hours after order written	

Number of active drug orders:

regular	
PRN	

RECOMMENDATION:

Initiation:

solicited outside pharmacy		self-initiated	
solicited within pharmacy			

Location:

in pharmacy		with medical team	
on patient ward			

Description: _____

_____

_____

DRUG SELECTION

add drug	
stop/hold drug	
change drug	
change vehicle	
no changes	

DRUG REGIMEN

starting/stat dose	
increase dose	
decrease dose	
increase interval	
decrease interval	
change schedule	
change route	
change dose form	
increase duration	
decrease duration	
no changes	

DRUG DISTRIBUTION

formulary change	
use protocol	
correct error	
clarify order	

MONITORING / OTHER

add test	
stop/hold test	
change test	
monitor patient	
give information	
give counselling	

RECOMMENDATION MADE TO:

Position:

staff physician		RN/RNA	
medical resident/intern			

Name (*if patient, leave blank*): _____

Recommendation documented in patient's chart:

yes		no	

_____

Was recommendation a pharmacy policy?

yes		no	

Was recommendation withdrawn or rejected?

yes		no	

Part III **PERCEIVED IMPACT:**

Do you think this recommendation(s) is likely to have an impact in terms of:

* **THERAPEUTIC EFFECT for the patient?** yes ☐ no ☐

If YES, rate your perception of the degree of impact:	1	2	3	4	5	6
	marked benefit	moderate benefit	mild benefit	mild detriment	moderate detriment	marked detriment

* **RISK for the patient?** yes ☐ no ☐

If YES, rate your perception of the degree of impact:	1	2	3	4	5	6
	marked decrease	moderate decrease	mild decrease	mild increase	moderate increase	marked increase

* **COSTS of drug therapy?** yes ☐ no ☐

If YES, rate your perception of the degree of impact:	1	2	3	4	5	6
	marked decrease	moderate decrease	mild decrease	mild increase	moderate increase	marked increase

SUBSEQUENT ACTION (*within 48 working hours*):

Recommendation was:

accepted	☐	modified and accepted	☐
accepted by policy	☐	withdrawn	☐
rejected	☐	action unknown	☐

Description of modification, reason for withdrawal or reason for rejection:

_____

_____

PATIENT RESPONSE (*complete only if recommendation implemented*):

Patient monitored after recommendation(s) made: yes ☐ no ☐

If NO, why?

not required	☐	not feasible	☐	☐	☐

If YES, describe patient response: _____

_____

monitoring parameter(s) improved	☐	monitoring parameter(s) unchanged	☐
monitoring parameter(s) worsened	☐	no specific monitoring parameters	☐
unable to determine	☐		

Other factors that could have influenced patient response:

yes	☐	no	☐	unable to determine	☐

If YES, specify: _____

Monitoring continued until:

appropriate time for therapeutic response	☐
discharge/transfer	☐
a maximum of 7 days	☐

Date monitoring stopped:

____/____/____
d/ m/ y

Clinical Pharmacy Services Study

Part I

Name - Last: _____

First: _____

Bed: _____

Study site: _____

Study ward: _____

Patient number: _____

Pharmacist:	**Date (d/m/y):**	**Time (24H):**
_____	____/____/____	_____
_____	____/____/____	_____
_____	____/____/____	_____

PATIENT INFORMATION (*to be completed once per patient*):

Admission date (d/m/y) ____/____/____

[Discharge date (d/m/y) ____/____/____]

Birth date (d/m/y) ____/____/____

Gender (M/F) _____

Reason for present admission:

information available to pharmacy	☐
information not available to pharmacy	☐

If available, specify: _____

_____

_____

_____

Other medical problems (*of possible relevance to the present admission*):

information available to pharmacy	☐
information not available to pharmacy	☐

If available, specify: _____

_____

_____

_____