ARTICLE

Clinical pharmacy services in a pediatric hematology/oncology clinic: A description and assessment

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ABSTRACT

Objectives: To characterize the drug-related needs of ambulatory HO patients identified by a pharmacist; describe the role of the pharmacist in a pediatric hematology/oncology (HO) clinic; assess the impact of clinical pharmacy services in a pediatric HO clinic on patient care; and make recommendations for the future provision of clinical pharmacy services to patients attending the HO clinic.

Design: Prospective descriptive study over 12 weeks.

Setting: Hematology/oncology clinic in a 411 bed tertiary/quarternary, university-affiliated pediatric hospital.

Patients: Thirty-one children who attended a clinic post-bone marrow transplant (BMT) and 27 children who attended an oncology clinic.

Methods: Actual or potential drug-related problems (DRPs) were identified or verified by patient/parent dialogue and interventions were made by the pharmacist in consultation with the responsible physician and/or patient/parent. The impact of a subset of these interventions was assessed by two physicians and two pharmacists.

Results: 165 DRPs were identified in 31 BMT and 27 ONC patients. The mean number of DRPs identified per patient was 4.8 in BMT patients and 0.6 in ONC patients. The most frequently identified DRP was "too high a dose" (35%) in BMT patients and "inappropriate medication administration" (35%) in ONC patients. 177 interventions were made by the pharmacist; 81% were accepted by the physician and/or patient/parent. The review panel deemed 83.5% of the subset of interventions to have had a positive impact.

Conclusions: Children attending the HO clinic have drug-related needs. BMT patients would benefit from dialogue with a pharmacist for assessment, prevention, and resolution of their DRPs while the primary need for newly diagnosed ONC patients is education regarding antineoplastic and supportive therapy.

Key words: pharmaceutical care, pediatrics, bone marrow transplant, oncology

RÉSUMÉ

Objectifs : Déterminer les besoins pharmacothérapeutiques des patients ambulatoires en HO (hématologie/oncologie) qu'a identifiés le pharmacien; décrire le rôle du pharmacien au sein d'une clinique d'hématologie/oncologie pour enfants; évaluer l'impact des services de pharmacie clinique dans une clinique d'HO pour enfants sur les soins apportés aux patients; et formuler des recommandations pour la planification de la fourniture des services de pharmacie clinique aux patients qui fréquent une clinique d'HO.

Plan : étude prospective de prévalence d'une durée de 12 semaines.

Milieu : clinique d'hématologie/oncologie dans un hôpital pour enfants affilié à une université, de 411 lits de soins tertiaires/quaternaires.

Patients : Trente et un enfants qui ont fréquenté une clinique après une greffe de moelle osseuse (GMO) et 27 autres enfants qui ont fréquenté une clinique d'oncologie (CO).

Méthodes : Les problèmes pharmacothérapeutiques (PP) réels ou potentiels ont été identifiés ou vérifiés au moyen d'une discussion avec le patient/parent et des interventions ont été portées par le pharmacien après consultation avec le médecin traitant et/ou le patient/parent. L'impact d'un sous-groupe de ces interventions a été évalué par deux médecins et deux pharmaciens.

Résultats : 165 PP ont été identifiés chez 31 patients GMO et 27 patients CO. Le nombre moyen de PP identifiés par patient était de 4,8 chez les patients GMO et de 0,6 chez les patients CO. Le PP qui a été le plus souvent identifié était «une dose trop élevée» (35 %) chez les patients GMO et «l'administration d'un médicament inadéquat» (35 %) chez les patients CO. Un total de177 interventions ont été réalisées par le pharmacien et 81 % de ces dernières ont été acceptées par le médecin et/ou le patient/parent. Le comité de révision a jugé que 83,5 % du sous-groupe d'interventions avait eu un impact positif.

Conclusions : Les enfants qui fréquentent une clinique d'HO ont des besoins pharmacothérapeutiques. Les patients GMO tireraient profit d'une discussion avec le pharmacien pour évaluer, prévenir et résoudre leurs PP, alors que les patients CO qui viennent d'être diagnostiqués ont d'abord un besoin d'éducation en ce qui a trait aux traitements antinéoplasiques et de soutien.

Mots clés : soins pharmaceutiques, pédiatrie, greffe de moelle osseuse, oncologie.

The current emphasis on the provision of health care in ambulatory settings has shifted patients to outpatient, day treatment and community-based services. Clinical pharmacy resources must also be transferred to these ambulatory care sites to ensure the provision of pharmaceutical care for these patients. Although clinical pharmacy services have been described in a wide variety of outpatient settings,[1–14] the provision of clinical pharmacy services or pharmaceutical care to children attending a hematology/oncology (HO) clinic has not been described to date.

This project represents the first step in the development of the role of the pharmacist in the care of children attending our HO clinics. The objectives were to: characterize the drug-related needs of ambulatory HO patients identified by a pharmacist; describe the role of the pharmacist in a pediatric HO clinic; assess the impact of clinical pharmacy services in a pediatric HO clinic on patient care; and make recommendations for the future provision of clinical pharmacy services to patients attending the HO clinic.

METHODS

Toronto's Hospital For Sick Children (HSC) is a 411-bed, tertiary/quaternary care, university-affiliated pediatric hospital. The HSC HO clinic operates Monday–Friday from 0800h–1700h. An average of 250 patients per week attend this clinic. Individual hematologists/oncologists see patients during one or more 4-hour clinic periods each week. Two 4-hour bone marrow transplant (BMT) clinics and one 4-hour oncology (ONC) clinic were selected for patient recruitment.

Patient selection criteria were adapted from Koecheler et al[15] and were designed to identify patients who were most likely to have drug-related problems (DRPs). Bone marrow transplant (BMT) patients were eligible for assessment by the pharmacist if they:

- had been transplanted within 3 months (autologous) or 9 months (allogenic) of the clinic visit;
- were receiving a drug requiring serum concentration monitoring;
- were experiencing acute or chronic graft-versus-host disease (GVHD);
- were receiving 5 or more medications or 12 or more doses per day; or
- had a history of noncompliance.

Children with cancer were eligible for pharmacist assessment if they:

- had been diagnosed with cancer within 6 months of the clinic visit;
- were receiving treatment with the HSC high-risk protocol for acute lymphocytic leukemia(ALL);
- had a concurrent, nonhematological/oncological medical condition;
- had a history of noncompliance; or
- were receiving a drug requiring serum concentration monitoring.

Patients who were referred to the pharmacist by other members of the health care team or who requested to speak to the pharmacist were also eligible for assessment.

DRPs were identified or verified by a single pharmacist. This pharmacist had completed a baccalaureate degree in pharmacy, a hospital pharmacy residency and 2 years clinical experience in pediatric oncology including BMT. The pharmacist reviewed the patient's inpatient and outpatient charts to gather background information and to identify possible DRPs. The pharmacist then interviewed the patient/parent using a structured questionnaire designed to elicit information regarding the patient's current and past drug therapy, including compliance. All patient information was reviewed for assessment of actual or potential DRPs as per Hepler and Strand.[16]

The pharmacist made one or more therapeutic interventions to resolve or prevent each DRP identified. Suggestions requiring physician approval were discussed with the physician in person or by telephone. The pharmacist summarized the findings of the patient/parent interview and subsequent recommendations in a progress note in each patient's chart. The pharmacist contacted the patient/parent after the initial interview, as needed, depending on the monitoring plan developed. The outcome of all the pharmacist's interventions was recorded and categorized into physician, patient or combined acceptance.

Fifty pharmacist's interventions which had been accepted by the physician and/or patient were randomly selected for assessment by a panel of 2 pediatric hematologists/oncologists and 2 pharmacists with experience in pediatric HO. One of the pharmacist panel members practised in an institution other than HSC. Each panel member assessed a total of 20 interventions, 10 of which were reviewed by all 4 panel members to allow calculation of the coefficient of agreement. The actual or potential impact of each intervention was rated as having either a detrimental effect, no effect, or positive (minor, moderate, or marked) effect. The reviewers then rated each intervention on its ability to have resulted in: cost savings, avoidance of adverse effects, avoidance of hospital admission, increased quality of life, a saved life or improved compliance.

The time devoted to all patient-specific, clinic-related and other activities performed by the pharmacist was collected to make recommendations regarding staffing requirements for the continued provision of clinical pharmacy services to the clinic.

Descriptive data are presented as the mean and range. The coefficient of agreement and effective reliability between the panel members reviewing the pharmacist interventions were determined using standard equations.[17] Effective reliability is defined as the reliability of the mean of the assessors' ratings. The relationship between the number of DRPs identified/patient and gender, age, number of medications prescribed, time since transplant or diagnosis, pharmacist time per patient and number of pharmacist visits was explored using correlation analysis (Statview SE+) with a level of significance of 5%.

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RESULTS

Fifty-eight patients were assessed by the pharmacist during the 12-week data collection period (July 4–October 5, 1995). Thirty-one patients (18 males) and their families were seen in the BMT clinic. They ranged in age from 0.5 to 19 years (mean 7.7 years). Most patients (21) had received an allogenic transplant. The first assessment by the pharmacist occurred, on average, 5.1 months after transplant (range 0.75– 23 months).

The pharmacist assessed 27 patients (19 males) and their families in the ONC clinic. They ranged in age from 0.7–17.5 years (mean 9.4 years). The most common diagnoses of these patients were: acute lymphoblastic leukemia (10 patients), acute non-lymphoblastic leukemia (2 patients), nonHodgkin lymphoma (2 patients) and chronic myelogenous leukemia (2 patients).

The first assessment of ONC patients by the pharmacist occurred, on average, 2.1 months after diagnosis (range 0.5–10 months). Twenty-one patients seen in the ONC clinic presented as a new diagnosis within the last 6 months; the remaining patients were either referred by team members 5 patients) were being treated with our high-risk leukemia protocol (9 patients), received treatment with a drug requiring serum concentration monitoring (1 patient) or had a concurrent non-oncological medical condition (1 patient). No BMT or ONC patient was known to be noncompliant prior to assessment by the pharmacist.

A total of 165 DRPs were identified during the study period and are summarized in Table I. The majority of these DRPs (84%) were potential problems. Ninety-nine percent of the DRPs were identified by the pharmacist. Ninety-one percent of the DRPs identified were in BMT patients. The average number of DRPs identified per BMT and ONC patient was 4.8 (range 0–16) and 0.6 (range 0–2), respectively. On average, 5.4 and 3.5 DRPs were identified per allogenic or autologous transplant patient, respectively. An average of 6.3 DRPs per patient were identified in BMT patients receiving treatment for GVHD. Oncology patients fewer than or equal to 3 months since diagnosis had an average of 0.45 DRPs per patient. Patients with ALL had an average of 0.40 DRPs per patient..

The number of DRPs identified per BMT patient positively correlated with the total time the pharmacist spent with the patient ($r=0.80$, $p<0.001$) and the number of times the patient was seen by the pharmacist ($r=0.80$, $p<0.001$). The number of DRPs identified per BMT patient correlated only weakly with the number of medications per patient ($r=0.41$, $p<0.05$) and the number of prescribed doses per day ($r=0.39$, $p<0.05$). The number of DRPs identified per BMT patient did not correlate with patient age ($r=-0.12$, $p>0.5$) or the time since transplant ($r=0.03$, $p>0.2$). On the other hand, the number of DRPs identified per ONC patient did not correlate with any patient parameter (patient age ($r=0.12$, $p>0.05$), time since diagnosis ($r=0.24$, $p>0.05$), total time the pharmacist devoted to the patient ($r=0.36$, $p>0.05$), or the number of times the patient was seen by the pharmacist ($r=0.37$, $p>0.05$)).

Table I — Summary of types of drug-related problems identified. 30 of the 165 drug related problems were described using 2 categories, and 2 were described using 3 categories. ONC=oncology clinic. BMT=bone marrow transplant clinic.

Drug related problem	Clinic ONC	Clinic BMT	Total (and %)
1 No indication	0	15	15 (7.5)
2 Drug indicated but not prescribed	2	25	27 (13.6)
3 Incorrect choice of drug/product	2	3	5 (2.5)
4 Dose too low	4	50	54 (27.1)
5 Dose too high	0	63	63 (31.7)
6 Patient not taking medications appropriately	6	17	23 (11.6)
7 Adverse drug reaction or side effect	2		5 (2.5)
8 Drug interaction	1	2	3 (1.5)
9 Other	0	4	4 (2.0)
Total	**17**	**182**	**199**

The interventions made by the pharmacist to solve or prevent DRPs are summarized in Table II. The types of medication that the pharmacist suggested be initiated for BMT patients included Pneumocystis carinii pneumonia (PCP) prophylaxis (60%); herpes, Cytomegalovirus, or general bacterial prophylaxis (16%), and electrolyte supplements (12%). ONC patients most frequently required education and/or help with compliance (50%).

The overall acceptance rate of the interventions made by the pharmacist was 81%. Physicians accepted 80% of the interventions they were asked to consider and patients accepted 91%. Six of the accepted interventions required both physician and patient approval. A further 7% of the

Table II — Summary of pharmacists' interventions to resolve a drug-related problem. 12 of the 165 drug-related problems identified required 2 interventions each. ONC=oncology clinic. BMT=bone marrow transplant clinic.

Drug related problem	Clinic ONC	Clinic BMT	Total (and %)
1 Discontinue or hold drug	0	18	18 (10.2)
2 Recommend start or restart drug	3	25	28 (15.8)
3 Recommend alternative drug/product	1	4	5 (2.8)
4 Increase dose/frequency	3	21	24 (13.6)
5 Decrease dose/frequency	1	31	32 (18.1)
6 Educate/help with compliance	10	14	24 (13.6)
7 Recommend discontinue drug/alternative therapy	0	0	0 (0.0)
8 Recommend a change in interacting drug	0	0	0 (0.0)
9 Other	2	44	46 (26.0)
Total	**20**	**127**	**177**

Table III — Reviewers' assessment of the impact on patient care of 50 interventions by pharmacists. Each panel member reviewed 20 interventions; 10 interventions were reviewed by all 4 panel members. One intervention assessment was not included in the analysis because the reviewer chose 2 impacts.

Impact	Assessments No.	%
Detrimental effect	0	0
No effect	13	16.5
Positive effect	55	83.5
Minor	30	38.0
Moderate	31	39.2
Marked	5	6.3
Total	n=79	100.0

interventions were classified as partly accepted because only a portion of the pharmacist's recommendation was implemented. Unaccepted interventions most commonly involved suggestions that antimicrobial prophylaxis be initiated and medication doses be decreased.

The results of the panel's assessment of the impact of the pharmacist's interventions are summarized in Tables III and IV. At least 1 of the 4 reviewers deemed 83.5% of the interventions to have a positive impact on patient care. One assessment was excluded from analysis because a reviewer ranked the intervention as having a potential for both a detrimental and a marked positive effect. The coefficient of agreement among reviewers was 0.42 and the effective reliability was 0.74 for the assessment of the clinical impact of the interventions (detrimental, none or positive effect). The coefficient of agreement and effective reliability between pharmacist–reviewers (0.9 and 0.95, respectively) was higher than those between the physician–reviewers (0.6 and 0.75, respectively).

Details of patient-specific workload are described in Table V. The pharmacist obtained a detailed medication history for all patients attending the BMT clinic; a compliance assessment was conducted for most BMT patients. A detailed medication history and compliance assessment were not performed for the majority of ONC patients because their medication profile consisted primarily of intravenous antineoplastics as part of their treatment protocols. The pharmacist saw each BMT patient and ONC patient 2.3 (range 0–9) and 1.3 (range 1–2) times, respectively. The pharmacist devoted an average of 8.8 hours per week to the BMT clinic and 5.7 hours per week to the ONC clinic.

Table IV — Reviewers' assessment of the impact of pharmacists' interventions on patient and health care outcomes. 80 interventions were reviewed.

Impact	n	Yes n	%	No n	%	Don't know n	%
A life-saving situation	78	5	6.4	67	85.9	6	7.7
Increased quality of life	79	45	57.0	25	31.6	9	11.4
Avoidance of adverse effects	79	35	44.3	31	39.2	13	16.5
Improved compliance	78	40	51.3	26	33.3	12	15.4
Avoidance of hospital admission	78	13	16.7	39	50.0	26	33.3
Cost saving to patient	78	18	23.1	37	47.4	23	29.5
Cost saving to clinic/hospital	77	27	35.1	25	32.5	25	32.5
Cost saving to taxpayer	77	28	36.4	24	31.1	25	32.5

DISCUSSION

A wide range of clinical pharmacy services provided in the ambulatory setting have been described.[1–14] In a survey of American acute care general hospitals,[12] patient education and pharmacokinetic consultation were identified as the most common activities of pharmacists in ambulatory clinics. Other activities included prescribing by protocol, primary care, ordering lab tests, performing physical examinations and giving medications. Evaluation of the influence of these activities on health outcomes has been hampered by difficulties in study design. Improved drug history documentation, patient compliance, and disease control have been attributed to the contribution of pharmacists to patient care.[14,18] In addition, pharmacists can decrease drug therapy costs through DRP identification.[13]

Our hospital's strategic plan includes an initiative to place greater emphasis on outpatient-based care. Prior to this study, pharmacy involvement in the HO clinic was limited to drug order audit, medication distribution, and patient consultation and drug information on demand. Conversely, the clinical pharmacy service to HO inpatients is well-established. Two pharmacist FTEs are devoted to the inpatient clinical service Monday–Friday. These pharmacists are responsible for the identification and resolution of potential and actual DRPs of patients admitted to the HO and BMT units (mean 1000 patient days/month) as well as the provision of discharge counselling to all BMT patients.

Children receiving outpatient treatment for cancer and those who have had a BMT have drug-related needs. The DRPs identified in the BMT group centred on dose adjustment based on drug concentration monitoring or renal function and physician compliance with the therapeutic protocol; those identified in the ONC group centred on a need for education. No patient descriptor can be used to reliably screen patients with the greatest drug-related needs.

Categorization of DRPs involving interpretation of drug concentrations was problematic. It was often necessary to develop a therapeutic plan based on an inappropriately timed cyclosporine blood concentration. Such situations were categorized as both a potential DRP #4(dose too low) and a potential DRP #5 (dose too high). Although it may seem reasonable to assume that the intervention made to resolve or prevent these DRPs would be to either

increase or decrease the cyclosporine dose, the pharmacist often recommended no dose change and the intervention was categorized as 'other'.

Fewer DRPs were identified in ONC patients than in BMT patients. The fact that the families of ONC patients assume less of the primary responsibility for medication administration because most of their medications are given in clinic may have contributed to this finding. Nevertheless, more ONC patients and their families were educated about their medication or their child's medication in clinic than were BMT patients. BMT patients receive intensive discharge counselling and participate in an inpatient self-medication program which may account for their reduced need for education once discharged. Nineteen ONC patients received an average of 15.8 minutes of education per patient. Experience gained from patients with other chronic diseases suggests that patient education regarding disease and medications fosters compliance.[19] Although research on compliance has seldom focused on children with cancer, compliance rates as low as 60%, with notably lower compliance rates in adolescents, have been observed.[20–22] Compliance issues have received increasing attention in cancer patients because of the important interaction between compliance and treatment outcomes such as survival. In our study, over half of the pharmacist's interventions were assessed as having a positive impact on compliance. Important treatment outcomes may well be influenced by early attention to patient/family compliance.

At the time of this project, ONC patients and their families were educated about their treatment regimen by a pediatric hematologist/oncologist and a nurse, most often immediately following disclosure of the diagnosis of cancer. It has been recommended that educational efforts not be conducted shortly after diagnosis disclosure because high levels of stress generally experienced during this time interfere with rational thought and information processing.[19] Parents of ONC patients enrolled in this study were greatly appreciative of the opportunity to discuss their child's medications in detail with the pharmacist; several parents commented that the discussion would have been more beneficial when their child was first diagnosed.

Most interventions suggested by the pharmacist were accepted by the responsible physician and/or parent. Our experience in this regard is in keeping with physician acceptance rates of pharmacists' recommendations reported by other ambulatory settings[3,4,7,8,23] and in our own institution.[24] In addition, most (84%) interventions assessed by the review panel were deemed to have had or to have the potential of having a positive impact on patient care. In fact, 5 interventions were ranked as having life-saving potential by at least one reviewer. All 5 of these interventions were made on behalf of BMT patients. Two involved compliance with prophylactic antibiotic therapy, one involved incorrect cyclosporine administration technique via a gastric tube, another involved cyclosporine dose escalation in a patient experiencing signs and symptoms of gvhd, and, in the fifth case, the pharmacist recommended an antifungal agent for a patient with signs of mucocutaneous fungal infection.

The coefficient of agreement among reviewers on the assessment of the impact of the interventions (detrimental, none or positive) was 0.42 and the effective reliability was 0.74. In other words, 2 reviewers agreed 74% of the time. Seventy-seven percent of the interventions thought to have had no effect were evaluated as such by the same physician–reviewer. The coefficient of agreement among the remaining 3 reviewers was 0.87 and the effective reliability was 0.95. There is no accepted minimum standard regarding these measures of agreement.[25] However, the effective reliability observed here indicates an acceptable level of agreement between reviewers.

Determining the potential impact of an intervention on patient and health care outcomes proved to be a difficult task for all reviewers. Approximately 50% of the interventions for the 50 DRPs were assessed as having potentially or actually increased quality of life, improved compliance or avoided side effects.

Several potential problems with the panel assessment were noted. The absence of detailed patient outcomes may have made the impact assessments more difficult. Reviewer bias may have been present; one of the pharmacist–reviewers was involved in the study

Table V — Patient-specific workload for bone marrow transplant (BMT) clinic and oncology (ONC) clinic.

	BMT clinic			ONC clinic		
		Total time/patient (min.)			Total time/patient (min.)	
Activity	n	Mean	Range	n	Mean	Range
Interview preparation	31	18.1	5.0 – 40	27	15.0	2.5 – 45
Patient interview	30	25.3	10.0 – 60	26	14.2	5.0 – 50
Post-interview data gathering	18	36.1	2.5 – 22.5	3	10.0	5.0 – 15
Documentation of interview	24	9.7	2.5 – 30	16	5.5	2.5 – 10
Miscellaneous data gathering	1	5.0		1	60.0	
Literature research	4	30.0	5.0 – 60	3	101.7	30.0 – 175
Development of pharmacy care plan	13	6.5	2.5 – 12	2	3.8	2.5 – 5
Communication with team	26	18.4	2.5 – 70	15	5.2	2.5 – 10
Communication with patient	21	10.4	5.0 – 25	9	9.4	2.5 – 20
Patient education	2	7.7	5.0 – 15	17	15.8	5.0 – 30
Chart documentation	30	15.2	5.0 – 65	25	6.7	2.5 – 15
Miscellaneous DRP resolution	10	31.5	5.0 – 105	25	24.0	5.0 – 40
Total time	31	113.4	5.0 – 325	27	75.0	20.0 – 297

development and one of the physician–reviewers interacted extensively with the pharmacist during the study.

The information gathered during this study regarding the needs of patients attending the BMT and ONC clinics at HSC has been used to support a proposal to create a pharmacist position to:

- provide intensive medication counselling to all families of children with cancer shortly after diagnosis;
- identify, prevent, and resolve DRPs in children discharged postBMT; and
- identify, prevent, and resolve DRPs in children receiving outpatient treatment for cancer on a consultation basis.

SUMMARY

Children attending the HO clinic at HSC have substantial drug-related needs although the needs of children receiving treatment for cancer differ from those being followed postBMT. BMT patients would benefit from a structured interview with a pharmacist to identify actual and potential DRPs; ONC patients would likely benefit from education regarding the medication included in their treatment protocols. This education could take place in either the inpatient or outpatient setting shortly after diagnosis. Selection of BMT patients for an interview based on the number of medications prescribed and the presence of gvhd may be reasonable if time restrictions preclude dialogue with all patients.

Pharmacists should expect to actively follow BMT patients for at least one year post-transplant to assess each patient's care plan and suggest modifications when necessary. Active follow-up of most ONC patients would not likely be required but the pharmacist should be available for consultation.

Further research is necessary to evaluate the pharmacist's contribution to patient compliance and long-term health outcomes.

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