A Pilot Project for Clinical Pharmacy Services in a Clinic for Children With Medical Complexity

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OBJECTIVE The primary objective of the project was to assess the impact of clinical pharmacy services in a clinic for children with medical complexity. Secondary objectives were to identify and characterize the drug-related needs of these patients and to describe and develop the role of a pharmacist in the clinic.

METHODS This was a prospective descriptive study in which a clinical pharmacist staffed the clinic for children with medical complexity for 11 weeks, from January to March 2011. This allowed for the collection of baseline data, such as patient characteristics and measurements of pharmacist workload and assessment (eg, types of drug therapy problems, medication reconciliation, medication teaching).

RESULTS A pharmacist participated in 46 clinic visits with 43 patients, identifying a total of 42 drug therapy problems. Of the 42 problems, 35 actual and 7 potential drug problems were identified, resulting in approximately 1 problem per patient. The most common actual problems included “dose too small” (37.1%) and “patient requires a medication for untreated condition” (20%). Common potential problems included “drug interactions” (43%) and “adverse effects” (57%).

CONCLUSIONS The pilot study demonstrates that children with medical complexity are at high risk for drug therapy problems and the presence of a clinic pharmacist is beneficial in the identification, prevention, and resolution of drug therapy problems, while helping ensure continuity of care in this population.

ABBREVIATION IQR, interquartile range

KEYWORDS ambulatory care; children; clinic; complex; medical; pharmacy

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Introduction

The Institute of Medicine has identified children with special health care needs as a population whose health care requirements are great and complex and who require special attention.¹ These children have been defined as “those who have or at increased risk for a chronic, physical, developmental, behavioral or emotional condition and who also require health and related services of a type or amount beyond that required by children generally.”² A smaller subset of children with special health care needs has been identified in the literature as children with medical complexity.³ These children require a level of care that may include: 1) need for intensive hospital- and/or community-based service; 2) dependence on multiple medications, technology, and/or home care to maintain a basic quality of life; 3) risk of frequent and prolonged hospitalizations; and 4) a need for care coordination.^{2,3}

Although medication errors commonly occur in children, these errors are more prevalent in children with urgent and complex medical conditions.^{4,5} Children with complex medical issues are on numerous chronic medications (eg, bronchodilators, anti-sialagogues, an-

ticonvulsants, antacids, gastric motility agents); hence, there is high risk for potential and actual drug therapy problems. Pharmacists are uniquely suited to assess, identify, prevent, and resolve medication problems because they are able to provide effective medication use management to medically complex individuals. This is further emphasized by recent research, which demonstrated that a cutoff of ≥ 4 prescription medications is a very sensitive screening tool for identifying patients at risk for clinically significant medication-related problems.^{6,7} Examples of problems that might be seen include: inappropriate indication for medication, drug required for untreated indication, inappropriate dosage formulation or dose, patient non-compliance with medication or medication teaching required for patients and/or families, monitoring for adverse effects, and screening for drug-drug interactions. In addition, the risk of medication errors in children is generally increased because of the need for dosage calculations, the use of “off-label” medications, and the need to use age-specific pharmacokinetic data to optimize drug therapy.⁴ Pharmacists possess the knowledge, skills, and training required to identify medication issues. Likewise, they are well suited to conduct medication

histories and perform medication reconciliation, which are both helpful in minimizing the occurrence of drug problems. In fact, a study on medication reconciliation noted that pharmacist-obtained medication histories were more accurate and complete than physician-conducted medication histories.⁶⁻⁹ Furthermore, unresolved drug problems can lead to suboptimal care and compromised patient safety, resulting in poor health outcomes.

Two systematic reviews have assessed the impact of pharmacists in the adult community or ambulatory care settings and the interventions of hospital pharmacists in improving pediatric drug regimens (inpatient and outpatient); the description and/or assessment of pharmacist-staffed pediatric clinics in the literature is limited to 5 studies.¹⁰⁻¹⁶ Although both systematic reviews and the small handful of studies supported the role of pharmacists in identifying, preventing, and treating medication problems, there was a lot of heterogeneity in the study objectives, settings, design, duration, size, methodology, and outcomes. Of these studies, only one compared pharmacist interventions to those made by other health care professionals. Furthermore, the provision of these services to a clinic specializing in the care of children with medically complex needs has not been previously described. As a result, research is required to evaluate the impact of an ambulatory pharmacist, given the complexity of the medication regimens in this pediatric population.

SickKids is a 370-bed, tertiary/quaternary care, teaching pediatric hospital, the largest one in Canada. The Complex Care Program, formerly called the Norman Saunders Complex Care Initiative, is an innovative program at SickKids that provides children with medical complexity a community-wide model of care. The program provides these children and their families with continuity and coordination of care throughout inpatient, outpatient, and community-based services. It currently consists of approximately 328 patients across 5 sites (SickKids and 4 community clinics) in southern Ontario.¹⁷ The program (including community clinics) encompasses 21 part-time and full-time physicians, 4 nurse practitioners, and an array of allied health care professionals, including pharmacists, dietitians, occupational therapists, physiotherapists, and social workers, as well as research support staff (SickKids Complex Care website: <http://www.sickkids.ca/PaediatricMedicine/What-we-do/Complex-Care-Program/Index.html>).

These children are also provided inpatient care via a consult team consisting of a physician and a nurse practitioner and outpatient care through a weekly clinic staffed by a pediatrician, nurse practitioner, and selected allied health professionals. The consult team serves as support for the pediatric medicine inpatient unit teams in the care of patients enrolled in the program. Currently clinical pharmacist services are funded

by the Department of Pharmacy to support and provide pharmaceutical care to pediatric medicine inpatients, which encompasses complex care patients admitted for acute care. Currently, hospital funding is not allocated to support pharmacy services in the outpatient Complex Care Clinic servicing the identical population.

The focus of health care delivery continues to shift to the ambulatory setting, facilitating the need to ensure optimal continuity of safe patient care. This shift, coupled with the increased emphasis on medication safety and errors, has underscored the need to extend provision of clinical pharmacy services to this population in the ambulatory setting.

In 2011, the Department of Pharmacy made the decision to temporarily allow a pharmacist to staff the clinic for children with medical complexity for a period of 11 weeks. This arrangement allowed for the collection of preliminary baseline data, including characterizing the drug-related needs of this population, and pharmacist-initiated interventions in the form of a pilot study. The primary objective of the descriptive pilot was to assess the impact of clinical pharmacy services in a clinic for children with medical complexity. Secondary pilot objectives were to identify and characterize the drug-related needs of these patients and to describe and develop the role of a pharmacist in this clinic environment.

Materials and Methods

This prospective descriptive study was conducted in the Complex Care clinic at SickKids where a clinical pharmacist was included in the roster of Complex Care clinic staff, for a period of 11 weeks, from January to March 2011. This clinic runs weekly on Tuesday afternoons. Typically, physicians and nurse practitioners see each patient while selected allied health care professionals meet with patients/families who require their area of expertise. At the time of the pilot, there were 5 pediatric medicine clinical pharmacists who saw hospitalized patients, all of whom also rotated through the outpatient clinic during the pilot period. A clinical pharmacist was assigned to the outpatient clinic for the day, with time spent that morning screening the clinic list of patients and working them up for medication-related problems using the pharmaceutical care model developed by Hepler and Strand.¹⁸ The model is the basis for clinical pharmacy practice at our institution and involves: 1) identifying potential and actual drug-related problems; 2) resolving actual drug-related problems; and 3) preventing potential drug-related problems.

After conducting the workup day of clinic, the pharmacist would then see the patient and the patient's family with the physician and the nurse practitioner. If no drug therapy problems were identified during the workup, the pharmacist would communicate this to the team and not see the clinic patient. Clinic-related drug information questions on non-clinic days during

Table 1. Data Collected**Patient Characteristics**

Age

Number of medications per patient

Number of conditions per patient

Pharmacist Workload and Assessment

Pharmacist preparation time (eg, working up patients, checking laboratory values)

Answering drug access questions (eg, Does patient's family have private drug plan? Is medication approved in Canada?)

Answering drug information questions (eg, verbal, phone, email)

Identifying drug therapy problems

- Drug interaction
- Non-compliance/medication administration issues
- Adverse effects
- Ineffective drug
- Drug dose too large
- Drug dose too small
- Patient requires a medication for untreated condition
- Patient on a medication without indication

Preparing medication calendars

Medication reconciliation

Medication teaching with families

Therapeutic drug monitoring/pharmacokinetic consults

Clinical documentation

the week were answered by the scheduled clinic pharmacist for that week.

In addition to providing care to clinic patients, pharmacists prospectively collected data related to patient demographics and pharmacist workload and assessment. These types of data are outlined in Table 1 and were further categorized by type. Each type of drug-related problem was analyzed separately. Information was logged daily into an Excel spreadsheet. Data and calculations were reviewed at the end of the pilot period and are summarized as numeric values, as a percentage and median values with interquartile range (IQR). The pilot did not meet criteria for research; however, institutional approval through the departments of pediatric medicine and pharmacy were obtained. Institutional policies on data privacy and security were followed.

Results

Clinical pharmacists were involved in 46 patient visits in the clinic for children with medical complexity. Of these, 43 were different patients. These patients were on a total of 322 medications (including duplication of medications). With respect to baseline patient demographics, the median age of the patients was 4.29 years (IQR, 2.35, 6.91) and the median numbers of medical conditions and medications per patient were 7 (IQR, 6, 9) and 8 (IQR, 6, 10), respectively. Examples of medical conditions include: seizure disorders, metabolic and genetic disorders, chronic respiratory issues, severe

Figure. Summary of types of drug therapy problems seen in complex care clinic patients by pharmacist (as number and percentage).

gastroesophageal reflux, and long-standing feeding difficulty. A total number of 35 actual and 7 potential medication problems were identified (Figure), resulting in approximately 1 drug therapy problem per patient or a combined 42 medication interventions out of 322 opportunities for drug-related problems. The most common actual problems included “small dose” (13 of 35; 37.1%) and “patient requires a medication for untreated condition” (7 of 35; 20%). Common potential problems included “drug interactions” (3 of 7; 43%) and “adverse effects” (4 of 7; 57%).

Throughout the pilot, data on activities requiring pharmacist intervention were collected (Table 2). These included medication teaching, medication reconciliation, development of medication administration calendars, answering drug information questions outside the weekly clinic day, and addressing drug access queries. Drug access was collectively defined by pharmacists involved in the pilot project as either commercial availability of a drug (eg, is the drug approved in Canada or available under Health Canada's Special Access Program), or whether the drug was covered by a public or private insurance plan. The development of calendars was especially important to patients and families because the average patient was on 8 medications, and some of the families conveyed to us the calendars were useful. A total of 33 distinct activities were captured. Medication reconciliation comprised most activities (22 of 46; 47.8%), which at the time was not a hospital accreditation standard for outpatients. The average time for completion of medication reconciliation was 12.6 minutes (range, 2–20 minutes).

A total of 38 drug information questions and 12 drug access questions were addressed during the 11-week pilot. These were further broken down into questions

Table 2. Activities Requiring Pharmacist Interventions

Type of Intervention	Interventions, n (%)
Medication teaching*	4 (8.7)
Medication reconciliation*	22 (47.8)
Medication administration calendar*	7 (15.2)
Drug information	38
Drug access	12

*46 patients.

pertaining to patients visiting the clinic that day, and those who were not physically in the clinic but were still part of the Complex Care Program. For example, of the 38 drug information questions, 30 were related to patients seen in clinic that day, and 8 were related to patients who were not. Of the 12 drug access questions, 9 were related to patients seen in clinic and 3 were related to patients who were not. The average time to answer a clinic-related drug information question was 11.3 minutes (range, 2–35 minutes) and the average time for a clinic-related drug access question was 9.1 minutes (range, 2–30 minutes).

Discussion

Our project focused on assessing the impact of clinical pharmacy services in a clinic for children with medical complexity, which has not been previously described in the literature. Given the level of medical issues in these patients, the heavy medication burden in this patient population, and the increased focus on medication safety and errors, these patients are at high risk for medication-related problems and medication errors.

The pilot study findings showed that in 46 patient clinic visits involving 43 different patients, pharmacists identified 42 drug-related problems (35 actual and 7 potential) or approximately 1 pharmacist intervention per patient. However, because of logistical reasons, such as limited time to conduct the pilot and available staffing (i.e., need to staff inpatient areas and dispensary), a more robust study design was not feasible. For example, the study did not feature a preintervention or comparator arm (i.e., assessment of drug-related interventions by physician and/or nurse practitioner) to more accurately compare the impact of drug-related interventions made by pharmacists. In addition—again because of limited time to conduct the pilot—the study did not assess the impact of pharmacist interventions. The study conducted by Taylor et al¹² used an independent committee for this purpose.¹² Nevertheless, the pilot data demonstrate that this patient population is at high risk for medication discrepancies because the patients were each on an average of 8 medications, which is greater than the cutoff of 4 medications used

to identify patients at high risk for significant medication discrepancies.

The amount of information describing the role of a pharmacist in a pediatric ambulatory setting is limited to 5 published studies. The prospective descriptive single-center study by Taylor et al¹² assessing clinical pharmacy services in a pediatric hematology-oncology clinic identified 165 medication-related problems in a total of 58 bone marrow transplant patients (mean of 4.8 per patient) and oncology pediatric patients (mean of 0.6 per patient), with a physicians and pharmacists review panel assessing 83.5% of a subset of pharmacist interventions had a positive impact. A study assessing clinical pharmacy services at a pediatric nephrology and hypertension clinic reviewed clinical pharmacy interventions from 374 visits in 283 participants and found that the mean number of clinical pharmacy interventions per patient was 2.3 on the first visit, with medication counseling and verification of current medications accounting for 85% of common activities.¹³ In contrast, our study identified about 1 intervention per patient; this may be partly attributed to different pediatric patient populations and complex medication regimens, the smaller sample size, and duration of the pilot. Because of the lack of literature describing the complexity of their multiple medications and the increased risk of medication-related problems, we feel the contributions and impact of drug-related interventions made by pharmacists in this pediatric patient population can be better highlighted through publishing methodologically sound studies.

In light of no previously published studies about pharmacist involvement in this pediatric population, our pilot study demonstrates that children with medical complexity are at increased risk for medication-related problems and that the presence of a clinic pharmacist is beneficial in the identification, prevention, and resolution of these issues, while helping ensure continuity of care in this pediatric population.

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