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CLINICAL STUDY

Cognitive Pharmacy Services at a Pediatric Nephrology and Hypertension Clinic

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Abstract

Purpose: Pediatric patients require special attention from pediatric pharmacists. This is particularly true for pediatric patients with chronic kidney disease (CKD) as the number of their medications and the complexity of their treatment increase with disease progression. However, there is paucity of information describing pediatric cognitive pharmacy services in this setting. The objective of this study is to identify the potential roles of a clinical pharmacist as a provider in a pediatric nephrology and hypertension clinic. *Methods*: Pediatric patients (≤18 years of age) who chronically took at least one medication were consecutively enrolled at the University of North Carolina (UNC) Pediatric Nephrology and Hypertension Clinic from 1 August 2007 to 15 April 2008. Demographic information and the interventions performed during the clinic visit by a clinical pharmacist were examined. *Results*: Three hundred and seventy-four visits made in 283 participants were evaluated. The mean (SD) number of cognitive pharmacy interventions per patient was 2.3 (1.0) on the first visit, with medication counseling and verification of current medications comprising the most common activity (85%). The mean (SD) number of medications per patient was 5.7 (4.8) and of medications counseled per visit was 4.0 (3.4). Medication adherence was investigated in 141 (38%) visits. Pretransplant education on medications was performed in 3% of the patients. Discrepancies of medications were discovered in 12 of the 374 visits. *Conclusion*: Pediatric cognitive pharmacy services to patients at the UNC pediatric nephrology clinic were feasible, which improved the quality of services and promoted better outcomes for these complex patients.

Keywords: cognitive pharmacy service, pediatric, chronic kidney disease, hypertension, medication adherence, medication discrepancy, medication counseling, kidney transplantation, electronic health record, electronic medical profile, electronic medical record

INTRODUCTION

Children require special attention from pediatric pharmacists. This is particularly true for pediatric patients with chronic kidney disease (CKD) as the number of medications and the complexity of their treatment plan increase with disease progression. The pharmacokinetics and pharmacodynamics of medications in the pediatric population differ from those in the adult population.[1] Even within pediatrics, neonates and older children have different rates of absorption, metabolism, and elimination. All these factors deal with the pharmacokinetic disposition of medications. Because of these complexities and challenges, it is vital for pediatric pharmacists to be part of the medical team given their expertise in these areas of pharmacotherapy. No literature, however, exists to document the importance of clinical pharmacy services at a pediatric medical clinic.

In recent decades, pharmacists' roles have expanded from the mere dispensing of medications to a clinical role managing patients' medication therapy. This contemporary approach by pharmacists is known as cognitive pharmacy service.[2] Cognitive pharmacy

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services are defined as services provided by pharmacists related to the management of the effectiveness and appropriateness of patients' therapeutic regimens.[2] These services can be divided into two major categories: pharmaceutical care and disease-state management. Pharmaceutical care consists of evaluation of patients' pharma- cotherapy, minimization and detection of adverse medication events and drug interactions, provision of patient education on the information pertaining to medication indications and potential adverse effects with special instructions on medication administration, monitoring patients' progress on therapies, and aiding in the transition of patients' care between inpatient and outpatient settings.[2] Disease-state management, in this context, is defined as the continuous services provided by a clinician (e.g., clinical pharmacist) to manage the well-being of the patients over the course of a disease.[3] These services consist of developing and implementing efficacious and cost-effective treatment for the disease states such as asthma, diabetes, and hypertension. These services require a multidisciplinary approach, including physicians, nurses, and pharmacists.[3]

Cognitive pharmacy services in adult clinical settings have been shown to help patients control hypertension,[4] minimize the amount of sub- or supratherapeutic drug concentrations,[5] and achieve serum glucose control.[6] Pharmacists' interventions also decrease the number of adverse drug events in the outpatient setting[7–10] and help identify medication discrepancies, reported to occur in up to 60% of adult patients on hemodialysis.[11] Pharmacists can also provide medication counseling and identify potential drug interactions.[7–10] In the management of patients with CKD, a clinical pharmacist can also provide blood pressure, anemia, and hyperlipidemia management and screening for proteinuria.[12] At a community health clinic consisting of high-risk adult patients with CKD, clinical pharmacists were able to provide various therapeutic recommendations including the adjustment of antihypertensive medications, discontinuation of nonsteroidal anti-inflammatory agents, and addition of renoprotective medications.[13]

There is paucity of information describing pediatric cognitive pharmacy services. Our study describes these activities performed at the University of North Carolina Kidney Center (UNCKC) Pediatric Nephrology and Hypertension Clinic over an 8-month period. Most of these services were provided in the outpatient setting as part of the pediatric pharmacotherapy residency at the UNC Hospitals, complementing the dedicated full-time pediatric pharmacy services in the inpatient setting. The objective of this descriptive study was to identify the potential roles of a clinical pharmacist as a provider in a pediatric nephrology and hypertension clinic. To our knowledge, our study is the first study documenting cognitive pharmacy services at this pediatric setting.

MATERIALS AND METHODS

New or returning pediatric patients (≤18 years of age) who chronically took at least one medication were consecutively enrolled at the UNCKC Pediatric Nephrology and Hypertension Clinic, from 1 August 2007 to 15 April 2008. The UNCKC Pediatric Nephrology and Hypertension Clinic is a referral clinic for children and adolescents with CKD stages 1–6 and hypertension from Central and Eastern North Carolina. This study was approved by the Committee for Human Research Protection of the Institutional Review Board at UNC at Chapel Hill with waiver of informed consent.

Although most pediatric cognitive pharmacy services occurred during scheduled visits with the pediatric nephrologists in the outpatient setting, they complemented the inpatient pharmacy services provided by a dedicated pediatric clinical pharmacist.

The clinical pharmacist also provided counseling and drug education services to kidney transplant candidates (weekly or monthly) concomitant to their clinic visits with the nephrologists. Once all cognitive pharmacy services were completed, the pharmacist would discuss treatment recommendations and pharmaceutical issues with the physician before his/her medical evaluation. The physician would wait for the pharmacist to finish his encounter with the patient before going into the room to evaluate the patient. If medication changes were made during the visit, the pharmacist would see the patient again at the end to provide further counseling.

The pharmacist's clinical activities were documented in the patients' electronic health record after each visit in a concise dedicated note. This note captured (1) the number of medications that the patients were on at the beginning of the visit; (2) the number of medications updated in the patients' electronic profile; (3) medications for which patients received counseling; and (4) other cognitive pharmacy services that were provided during the clinic visits. These cognitive services were not charged to the patients' medical bill.

Demographic and medical information were collected. Patients were classified as having "glomerular," "nonglomerular" disease, and "hypertension only." Two secondary diagnoses (hypertension and anemia) were identified because these were the second and third most common clinical conditions following CKD. The interventions performed during the clinic visit by the clinical pharmacist were classified as (1) counseling and/or verification of understanding on current medications; (2) adherence assessment; (3) conveying patients' concern/issues regarding their medications to physicians; (4) provision of information to patients/parents on medications that were not prescribed by their nephrologists; (5) medication dosing/monitoring recommendations; (6) provision of drug information resource; (7) identification of medication discrepancy; (8) medication education for kidney transplant candidate;

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(9) new medication counseling; and (10) updating drug allergies. Finally, customized letters warning against pregnancy were handed to females of child-bearing age if they were on an angiotensin-converting enzyme inhibitor or angiotensin receptor antagonist.

If the patients did not bring their medications to the clinic visit and/or if the clinical pharmacist had any suspicion that the patients were not adherent (e.g., subtherapeutic drug concentration; discrepancy in reports of how they took their medications), the clinical pharmacist would call the patient's pharmacy to obtain the refill rate. We determined a patient's presumed adherence rate by a review of medical records and by contacting their pharmacy to assess medication refill frequency using a published nonadherence definition of less than 80% adherence to medication regimen.[14]

Statistical Analysis

All analyses were done with SAS™ version 9.1.3 (SAS Institute, Cary, NC, USA). Simple descriptive statistics were computed for categorical variables, such as frequencies of interventions and demographic variables. Means of continuous variables by race, sex, and diagnosis were compared by analysis of variance (ANOVA) and Turkey's multiple comparisons of means. Distribution of categorical variables by race, sex, or diagnosis was compared by chi-square tests. An α-value of less than 0.05 was considered as significant.

RESULTS

Pediatric cognitive pharmacy services were administered to 283 study participants in 374 clinic visits. Table 1 depicts the baseline characteristics of the study participants. The mean (SD) age was 10.3 (5.6) years and the mean (SD) age at diagnosis was 8.1 (5.7) years. The participants' diagnosis distribution was "nonglomerular diseases" (69.2%), "glomerular diseases" (18.4%), and "hypertension only" (12.4%).

Of the 283 participants, 32 (11%) had anemia, and hypertension (primary or secondary) was noted in 111 participants (39%) (see Table 1). More African Americans had a diagnosis of hypertension compared with participants of other ethnicities ($p = 0.004$) (Table 2). Fewer African Americans had nonglomerular disease than Caucasians or other ethnicities ($p = 0.004$), and more African Americans had glomerular diseases than both Caucasians and other ethnicities ($p = 0.02$) (Table 2). Females had more glomerular disease than males ($p = 0.04$).

The duration of pharmacy cognitive services lasted from 10 to 25 minutes and included interactions with the patients and/or their parents. The pediatric clinical pharmacist services included patient educations on medication indications (both prescribed medications and over-the-counter medications) and potential adverse effects with special considerations at the time of medication administration. Drug interactions, medication discrepancies, and potential pharmacotherapy dosing recommendations based on parameters such as drug levels, patients' weight and renal function were also conveyed to the physicians before their visit with the patient.

Table 1. Characteristics of patients who received pediatric cognitive pharmacy services at the UNCKC Pediatric Nephrology and Hypertension Clinic ($n = 283$).

Patient characteristics	Values
Age in years, mean (SD)	
Current age	10.3 (5.6)
Age at diagnosis	8.1 (5.7)
Sex, *n* (%)	
Male	151 (53)
Female	132 (47)
Ethnicity, *n* (%)	
Caucasians	121 (43)
African American	109 (39)
Other	53 (18)
Primary diagnosis, *n* (%)	
Glomerular disease	52 (18.4)
Nonglomerular disease[a]	196 (69.2)
Hypertension only	35 (12.4)
Secondary diagnosis, *n* (%)	
Hypertension[b]	76 (27)
Anemia	32 (11)
Stages of chronic kidney disease[c], *n* (%)	
Chronic kidney disease stages 1–4	22 (8)
Kidney transplantation	25 (9)
Hemodialysis	4 (1)
Peritoneal dialysis	4 (1)
Medications, mean (SD)	
Number of medications	4.4 (4.2)

Notes: University of North Carolina Kidney Center (UNCKC).
[a]Congenital urinary tract anomalies, hereditary, and tubulointerstitial conditions.
[b]Did not include "primary hypertension only."
[c]Definitions according to the KDOQI guidelines.[25]

If the patients or the parents were perceived to have inadequate understanding of their medications, the pediatric clinical pharmacist would provide follow-up services at subsequent visits until adequate understanding was acquired. This encompassed approximately 5% of the visits.

Responses to pharmacy-related questions and dosing questions posed by patients and physicians, respectively, were given in 28% of the clinic visits. Pretransplant education on medications was performed in 3% of the visits. Discrepancies between the medication history provided by the patient/family and the electronic medical record were discovered in 12 of the 374 visits (3%). Presumed adherence with medical treatment was investigated in 141 (38%) of the visits and the rate of nonadherence was around 15%. Table 3 listed the rest of the interventions by category.

The mean (SD) number of cognitive pharmacy interventions per patient was 2.3 (1.0) on the first visit, with medication counseling and verification of current medications comprising the most common

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Table 2. Distribution of diagnoses by ethnicities.

	Caucasians n = 121 (%)	African American n = 109 (%)	Other ethnicities n = 53 (%)	p-Value for difference by ethnicities
Glomerular disease	16 (13)	29 (27)	7 (13)	0.02
Nonglomerular disease	93 (77)	63 (58)	40 (75)	0.004
Hypertension only	12 (10)	17 (16)	6 (11)	0.4
Anemia	9 (7)	18 (17)	5 (9)	0.08
Hypertension (primary + secondary diagnosis)	35 (29)	56 (51)	20 (38)	0.004

Table 3. Cognitive pharmacy services by pediatric clinical pharmacist (n = 374 visits).

Services	Count	%
Counseling and/or verification of understanding on current medications	316	85
Adherence assessment	141	38
Conveying patients' concerns/issues regarding their medications to physicians	120	32
Provision of information to patients/parents on medications that were not prescribed by their nephrologists	82	22
Medication dosing/monitoring recommendations	22	6
Provision of drug information resource	21	6
Identification of medication discrepancy	12	3
Medication education for kidney transplant candidates	10	3
New medication counseling	10	3
Updating drug allergies	3	1

Table 4. Number of medication-related interactions by visits.

	Medications per patient, mean (SD)	Medications updated in electronic health record, mean (SD)	Medications counseled, mean (SD)
Visit 1 (n = 283)	4.4 (4.2)	1.1 (1.9)	3.6 (3.3)
Visit 2 (n = 58)	6.5 (4.8)	1.0 (1.4)	4.0 (4.1)
Visit 3 (n = 13)	9.5 (6.5)	1.0 (1.0)	3.7 (3.8)
Visit 4 (n = 7)	11.6 (5.6)	2.3 (2.5)	5.7 (5.3)
Visit 5 (n = 5)	8.4 (6.2)	0.6 (1.3)	0.8 (1.1)
Visit 6 (n = 2)[a]	14.5 (2.1)	2.5 (2.1)	8.5 (10.6)
Total (n = 368)	5.7 (4.8)	2.2 (1.8)	4.0 (3.4)

Notes: Each patient can have multiple visits (up to 12 visits in this cohort).
[a]Additional visits with n = 1 were not included in this summary (up to 6 visits are presented here because visits 7–12 were mainly made by few repeated patients).

Table 5. Number of medications by diagnoses and stages of chronic kidney disease.

Characteristic	Mean (SD)	p-Value for difference among categories[a]
Primary diagnosis (n = 283)		0.002
Glomerular disease	6.2 (4.9)[b]	
Nonglomerular disease	3.9 (3.9)	
Hypertension only	3.9 (4.4)	
Stages of chronic kidney diseases (n = 55)		0.01
Chronic kidney disease stages 1–4	6.2 (4.0)	
Peritoneal dialysis	8.5 (1.9)	
Hemodialysis	11.3 (2.1)	
Kidney transplantation	9.7 (4.2)[c]	
Secondary diagnosis (n = 283)		<0.0001
Anemia and hypertension	10.0 (3.9)[d]	
Anemia only	7.1 (1.5)[e]	
Hypertension only	6.2 (4.5)	
None	3.1 (3.5)	

Notes: [a]This statistical test does not directly compare groups to each other (e.g., glomerular disease vs. hypertension only). It answers the question "are all groups equal?" The followings are different tests that look at comparisons between the subgroups.
[b]Glomerular disease is higher than nonglomerular disease and hypertension only, $p < 0.05$.
[c]Kidney transplantation is higher than CKD stages 1–4, $p < 0.05$.
[d]Anemia and hypertension are higher than hypertension only or none, $p < 0.05$.
[e]Anemia is higher than none, $p < 0.05$.

activity (85%) (Table 3). The mean (SD) number of medications prescribed to each patient was 5.7 (4.8), and the mean (SD) number of medications counseled per visit was 4.0 (3.4) (see Table 4). Patients with glomerular disease had significantly more medications than those with nonglomerular disease or hypertension *only* (p = 0.002), and patients dependent on hemodialysis or kidney transplantation had significantly more medications than patients with CKD stages 1–4 ($p < 0.05$). Other significant findings related to the number of medications by secondary diagnoses are reported in Table 5. There was not a significant difference in the number of medications per patient by sex or ethnicity (p = 0.8 and p = 0.2, respectively) (data not shown).

On average, two medication updates in the patient's electronic medical profile were made during each visit (Table 4). Medications were updated in 51% of initial visits, which followed by 47% and 54% during their second and third visits, respectively (data not shown). Table 6 showed common specific interventions that were made to the cohort.

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Table 6. Common specific interventions related to pediatric nephrology patients.

1. Adjustment of calcineurin inhibitor dose based on serum concentration
2. Adjustment of erythropoiesis-stimulating agent dose based on hemoglobin levels
3. Adjustment of anti-hypertensive medications based on blood pressure measurement
4. Adjustment of vitamin D, Ca, and P-binders based on serum levels
5. Recommendation of iron therapy
6. Recommendation of different formulations of K and P supplements
7. Recommendation of pharmacotherapy for insomnia
8. Counseling on immunosuppressants
9. Provision of letters warning about ACEI or ARB fetopathy
10. Verification of erythropoiesis-stimulating dose and concentrations

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DISCUSSION

A multidisciplinary approach is vital in the management of clinical conditions such as renal diseases and hypertension in the pediatric population. Our study describes different interventions that a pediatric clinical pharmacist can provide at a pediatric nephrology and hypertension clinic and how such services may improve patients' clinical outcomes. To our knowledge, this is also the first study that documents the burden of medications in the pediatric nephrology setting.

Pediatric prescriptions are often more difficult for patients and their parents to comprehend due to the various available formulations and concentrations.[15] One example is epoetin alfa, which is commercially available in 2000, 3000, 4000, 10,000, 20,000, and 40,000 U/mL. As proven in the adult literature, patients may not be adherent if they do not have a good understanding of the indications and the directions of the medications.[16] It is established that pediatric patients are less adherent when there is a lack of parenteral supervision and appropriate drug formulations.[17] Nonadherence with medications is detrimental and may lead to short- or long-term medical consequences such as transplant loss[18] and inappropriate adjustments in medication dosages leading to subsequent toxicity, such as with tacrolimus and cyclosporine.[17] With the shortage of pediatric nephrologists and the increasing number of referrals to this subspecialty practice, pediatric pharmacists will have ample opportunities to provide cognitive pharmacy services to CKD patients in the outpatient setting. These services, however, have not been described in pediatric nephrology clinics.

Disease-state management consists of active participation by pharmacists collaborating with other health care providers in the designing and implementing of patients' pharmacotherapy.[3] These disease states include but are not limited to anemia,[20] hypertension,[4] and renal osteodystrophy.[21]

The most frequent cognitive pharmacy service provided in our study was direct counseling of patients and families regarding the medication regimen. During the time of this study, it became evident that often a family's understanding of medication indications and side effects was a major challenge. This in part may be related to the literacy level of our patient population.[22] The lack of understanding of the medications can also be related to the difficulty in interpreting medication labels.[23] Because of the below-average literacy level of our patient population, the clinical pharmacist made a concerted effort to counsel patients using metaphors. For example, if the patient takes tacrolimus, the pharmacist would describe it as the "protector" of the kidney. In addition to verbal counseling, printed literature was also provided as long as the literacy level was acceptable. Medication discrepancies, both in dispensing and prescribing, have been a major issue in the medical arena, especially in the ambulatory care setting.[11,24] Discrepancies in our setting were identified by reconciling patients' medications with the physicians' last clinic note or discharge summary. These findings are especially important in instances where medications are potentially harmful. In our study, medication discrepancies were discovered in only 3% of the clinic visits, compared with 60% in one observational study at a hemodialysis center.[11] The difference in our discrepancy rate is likely a reflection of several services already provided at the UNC Hospital System such as: (a) dedicated inpatient pediatric pharmacy services (including daily inpatient rounds with the pediatric pharmacists at the bedside); (b) medication profiles updated and consolidated at the time of discharge by our medication system within an electronic health record; and (c) the triage nurses in the outpatient clinic who update medication and drug allergy profiles. The combination of dedicated staff and integrated inpatient and outpatient electronic medical record system is vital in preventing medication-related problems in patients with end-stage renal disease.[24]

To have a pediatric pharmacist available at the clinic made it convenient for the patients to ask various medication-related questions, enhancing the patients' and their parents' knowledge. During the clinic visit, the patients or the parents would also tell the pharmacist problems or side effects that they might encounter in obtaining and taking the medications, respectively. The clinical pharmacist would in turn convey such information to the physicians and work as a team to devise a solution to the problem.

The clinical pharmacist is also a good resource to the physicians in terms of medication dosage recommendations and provision of evidence-based literature on the use of certain medications in the pediatric population. The frequency of these activities seems low in our cohort, but this observation is also a reflection of the dedicated

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inpatient pediatric pharmacy services and education at our institution, an example of great continuum of care.

One of the most involved and time-consuming tasks that the pediatric clinical pharmacist performed was to prepare kidney transplant candidates for their future medication regimen. This process is especially challenging if the patients or their parents have lower literacy skills. In the case of an English-speaking but illiterate mother of a kidney transplant candidate, weekly meetings with the pharmacist and the provision of pictorial diagrams of the medications accomplished this task. Because of these interventions, this child was finally activated in the transplant list, received a transplant, and has been rejection-free.

Medication adherence is vital in patients with hypertension and renal diseases, especially in those patients post-transplantation as pointed out by Ettenger et al.[18] The clinical pharmacist was able to contact the patients' home pharmacy if he/she deemed that the patients were not adherent based on their hesitation to answer questions or decreased blood levels of immunosuppressants. Future studies, however, should be conducted to assess the improvement of patients' adherence through the clinical pharmacist's cognitive services. The possibility of conducting pharmacist-only visits to enhance patients' understanding and knowledge of their medication regimens and aiding in medications management remains to be explored.

Even though these cognitive services provided by the clinical pharmacists were free of charge to patients, a possible cost can be calculated. In our study, 737 cognitive pharmacy interventions were made. If each intervention was for 10 minutes, then 7370 minutes or about 123 hours of pharmacist-time were consumed. These pharmacist-hours can potentially be converted to monetary value based on pharmacoeconomic data, but this discussion is beyond the scope of this article.

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CONCLUSIONS

Pediatric cognitive pharmacy services at the UNCKC Pediatric Nephrology and Hypertension Clinic provided a vast amount of clinical interventions designed to improve patients' care and their understanding on their medications, especially in patients undergoing kidney transplantation. The role that the clinical pharmacist played at the clinic was valuable as it highlighted the gaps in patient's understanding of their medication profile. The cost-effectiveness of such practice can potentially be calculated.

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