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PRN OPINION PAPER

Evidence demonstrating the pharmacist's direct impact on clinical outcomes in pediatric patients: An opinion of the pediatrics practice and research network of the American College of Clinical Pharmacy

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Abstract

The pharmacist's role in pediatric care is critical for the provision of safe medication use secondary to differences in physical development, frequent off label use of medications, need for dose calculations, and the lack of standard dosage forms. Many regulatory agencies, health care organizations, and professional societies support the pharmacist as a member of the interdisciplinary team. However, specific details showcasing how pharmacists impact the care of pediatric patients in a quantifiable and meaningful way have not been well described. The purpose of this article is to

provide a review of evidence demonstrating measurable clinical outcomes directly resulting from pharmacist participation in pediatric patient care. This report is an opinion paper of The American College of Clinical Pharmacy (ACCP) Pediatrics Practice and Research Network and has been endorsed by the Pediatric Pharmacy Association (PPA). This article represents the opinion of the Pediatrics Practice and Research Network of ACCP. It does not necessarily represent an official ACCP commentary, guideline, or statement of policy or position.

KEYWORDS

clinical pharmacist, outcomes, patient care, pediatrics, pharmacist, pharmacy

1 | INTRODUCTION

Many regulatory agencies, health care organizations, and professional societies support the integration of pharmacists into interprofessional patient care team as an essential component of the medication use process.[1-5] For example, The Joint Commission (TJC) devoted a 2008 Sentinel Event Alert on preventing pediatric medication errors.[6] TJC recommended a pediatric-trained pharmacist be assigned to any committee responsible for oversight of medication management. Most recently, a 2019 policy statement from the American Academy of Pediatrics advocated for pharmacist involvement "in all settings and as often as possible".[7]

The pharmacist's role in pediatric care is critical due to differences in patient characteristics (eg, variations in weight, body surface area, and organ maturity), high use of off-label medications, need for precise dose calculations, and the lack of standardized dosage forms.[8] These issues highlight the need for medication experts managing complex medication regimens of pediatric patients in a variety of settings.

The purpose of this article is to provide a review of evidence demonstrating measurable clinical outcomes directly resulting from pharmacist participation in pediatric patient care. This article is an opinion paper of the Pediatrics Practice and Research Network (PRN) of the American College of Clinical Pharmacy (ACCP) and is endorsed by the Pediatric Pharmacy Association (PPA).

2 | METHODS

PubMed and Ovid searches were performed with the terms pediatric(s) and pharmacist(s) from 1990 until November 2018. Upon review, 105 articles were identified; 79 studies were excluded because researchers did not address clinical outcomes resulting from care provided by one or more pharmacists. English language studies which were a comparison of clinical outcomes with vs without pharmacist participation in direct pediatric patient care were included. If the study described a pharmacist or pharmacists who were part of an interprofessional team, where independent contributions from the pharmacist could not be defined, the study was excluded. A total of 26 studies including appropriate controls were included.

3 | CLINICAL OUTCOMES

3.1 | Medication error avoidance

Studies have demonstrated that children are at an increased risk for adverse drug events (ADE) compared with adults due to weight-based dosing, customized formulations, and a child's reduced ability to communicate adverse events.[9] Several preventative strategies and general guidelines for enhancing medication safety in pediatrics have been identified.[10-15]

A prospective cohort study on medication error rates before and after unit-based clinical pharmacist integration in physician rounds and monitoring drug dispensing was conducted in three pediatric inpatient units. In the pre-intervention group, 1576 total admissions were included and in the post-intervention group, 3287 total admissions were included. In this study, National Academy of Medicine (formerly Institute of Medicine) definitions of serious errors included drug ordering, transcribing, dispensing, administering, or monitoring. The study demonstrated a serious error reduction from 29 per 1000 patient days to 6 per 1000 patient days (79%; $P < .01$).[16]

Clinical pharmacists have demonstrated improvements in medication safety in the care of children in the outpatient setting as well. A 2-month retrospective electronic medical record review was conducted in two pediatric ambulatory care clinics and 1361 prescriptions were reviewed.[9] In one clinic, dedicated pharmacists reviewed prescriptions for errors the day after the prescription was written while the other did not. The dedicated pharmacists identified the errors, notified the appropriate parties involved, presented a resolution, provided education, and made policy changes to prevent future errors. There was a significant difference in the error rates between the intervention (n = 554 prescriptions) and control clinics (n = 807 prescriptions) with 61 and 140 errors identified, respectively (11% vs 17.4%, $P = .0012$), with 10% of the errors requiring transfer to the intensive care unit. Specifically looking at prescriptions written by pediatric medical residents only, there was a larger difference in medication errors between the intervention vs the control clinic (8% vs 17.3% $P < .001$), demonstrating the importance of pharmacists' involvement in the pediatric ambulatory care setting and early in physician education and training. A comparative analysis of 900 randomly selected

electronic records from a total of 2998 patient encounters during a 3-month period revealed vaccine errors between two clinics, which were part of a pediatric health system in a large metropolitan area. The one clinic serving as a control group did not include a pharmacist in the patient care setting who reviewed charts and provided education. In the 450 records reviewed per clinic, the error rate was 2.7% in the control clinic vs 0.28% in the clinic that had clinical pharmacist involvement ($P = .0021$). The type of error most commonly identified was unnecessary vaccine administration.[17]

Pharmacists today provide a broad range of clinical services in both pediatric inpatient and outpatient settings, many of which go beyond the safe use of medications and subsequently have a positive impact on the acute and chronic clinical outcomes of patients.

3.2 | Antimicrobial stewardship

The use of antimicrobial stewardship programs that involve a clinical pharmacist within children's hospital has demonstrated an overall reduction in the use of antibiotics with no reported increase in patient's harm or antibiotic resistance. For example, Di Pentima and colleagues described the outcomes of an antimicrobial stewardship program at a children's hospital involving prospective audits conducted by an infectious disease pharmacist.[18] In the 3 years prior to and after the intervention, antibiotics were prescribed during 11 180 (44%) and 13 000 (43%) of admissions, respectively. Over 3 years following 1673 interventions, a 21% and 49% decrease in targeted and nontargeted antibiotic use, respectively, was reported ($P < 0.001$). The rates of resistance of most Gram-negative bacilli to broad-spectrum antibiotics were similar across the study periods with the susceptibility of *Enterobacter cloacae* to piperacillin-tazobactam increased from 71 to 81%. Other outcomes included statistically significant trends in prevention of adverse drug reactions, prevention of antimicrobial prescription errors, and reduced health care costs in the postprogram period.

Cies and colleagues compared a pharmacist-managed therapeutic drug monitoring service to usual care on aminoglycoside sampling in 51 pediatric patients with cystic fibrosis (CF).[19] The pharmacist-run service demonstrated a significant increase in aminoglycoside pharmacokinetic and pharmacodynamic targets over the control group (98% vs 71%; $P < .001$). Additionally, patients in the pharmacist-run group reached aminoglycoside targets 3 days sooner than those in the control group ($P < .0001$), and the average length of stay was 3 days shorter.

3.3 | Drug monitoring

Targeted clinical pharmacist interventions to improve outcomes of children receiving warfarin in an inpatient hospital setting were evaluated at a free-standing children's hospital with a large cardiac surgery center.[20] A service was developed using a series of quality improvement interventions, including a pharmacy computer system prompt for comparison of target INR and dosing. When the warfarin dose did not follow protocol, the pharmacist contacted the physician and made dosing recommendations. A total of 58 pediatric patients were evaluated, 25 pre-intervention and 33 post-intervention. The number of patients with a supratherapeutic INR values during admission decreased by over 50% ($P = .039$), and goal INR values were documented more consistently in the medical record ($P < .0001$). In another free-standing pediatric hospital, targeted pharmacist inventions to detect patients at risk for medication-induced QTc interval prolongation were conducted in 88 patients, which were compared against 42 historic controls.[21] The pharmacist recommended baseline ECG in patients receiving three or more medications known to prolong the QTc interval. Additionally, if 3 or more of these medications were administered for 5 or more days, a follow-up ECG was recommended. Pharmacist intervention improved the rate of ECG monitoring in these at risk patients from 48% to 100% ($P = .0009$).

3.4 | Opioid dependence

Pediatric patients may receive high doses of opioids for extended periods of time for pain control and sedation when mechanically ventilated. This often leads to opioid tolerance necessitating weaning protocols to prevent withdrawal.[22] Steineck and colleagues described the implementation of a pharmacist-managed methadone tapering protocol on clinical outcomes in 52 pediatric patients at a children's hospital.[23] A pre- and post-protocol evaluation was completed and demonstrated that the average taper length was decreased from 25 days to 15 days ($P = .0026$) and opioid infusions were discontinued sooner (3.3 vs 1.8 days) in the pharmacist-managed intervention group ($P = .023$). There was no difference in the withdrawal scores or number of doses of rescue opioid required; however, there was a statistically decreased hospital length of stay in the intervention group (67.3 vs 108 days; $P = .02$). In another study, the length of wean time and abstinence severity of both neonatal and pediatric patients treated with a pharmacist-managed protocol were compared with historically physician-managed patients.[24] All patients had either neonatal abstinence syndrome (NAS) or iatrogenic opioid dependence. Although the pharmacist-managed NAS patients had significantly shorter methadone wean duration compared with patients on physician managed dilute tincture of opium (DTO) (11.7 days vs 24.2 days, $P < .001$), there was no statistical difference in this group when patients were both weaned on methadone (11.7 SD ± 8.9 days vs 47 SD ± 20.8 days, $P = .101$). For patients with iatrogenic opioid dependence, there was no difference between the pharmacist and physician managed groups for either medication (DTO: 8.69 days vs 14 days, $P = .096$) (Methadone: 8.69 days vs 9.82 days, $P = .34$). There were significantly fewer consistently elevated abstinence scores in the pharmacist-managed group compared with both physician-managed DTO and methadone groups (2.89 vs 11.9, $P = .01$ and 2.89 vs 24, $P < .001$, respectively). Significantly fewer patients required an adjunct agent for the management of symptoms in the pharmacist-managed group compared with either DTO, or methadone groups managed by physicians ($P = .002$ and $P = .023$, respectively).

3.5 | Medication access

During periods of transitions of care, adherence to newly prescribed medications can be low due to a variety of factors. Filling of discharge medications has been found to prevent rehospitalization in patients with asthma,[25] and ensuring patients leave the hospital with medication "in hand" is one way to improve access to and adherence with discharge medications. In one observational study of 124 children hospitalized for asthma, children were discharged with medications in hand (n = 77) or they received usual care (n = 47) where their prescription was called into an outside pharmacy.[26] In the intervention group, a pharmacist delivered the discharge medications and provided education using the patient's dispensed medications for demonstration purposes. Seventy-five percent of families were discharged with medication in hand compared with 50% before pharmacy delivery was implemented. In addition, odds of an Emergency Department visit within 30 days were lower for those who were discharged with medication in hand vs usual care in the total of 102 patients analyzed in the study (OR 0.22, 95% CI 0.05-0.99). A similar study demonstrated an increase from 28% to 71% in patients leaving the hospital with pharmacist-facilitated discharge medications "in hand" and noted that caregiver satisfaction with receiving information about side effects increased from 50% to 88% following implementation of this process.[27]

3.6 | Pulmonology

In one of the earliest studies, Chan and colleagues described the pharmacist's role in an interprofessional program for children with asthma who were seen at a US Army Medical Center.[28] During an inpatient stay, 107 children with asthma received asthma counseling and education by the clinical pharmacist. Seventy-nine of these patients were then enrolled in an outpatient asthma management program, where the pharmacist focused on appropriate use of metered-dose inhalers with a spacer. Of the patients seen in the ambulatory setting, 90% were not rehospitalized in the 2 years after enrollment in the program. The rate of hospitalization for asthma decreased over 2 years from 3.2 to 1.9 per 1000 population (OR = 1.75, 95% CI 1.4.-2.2). Condren and Boger described an interprofessional education and management program targeting moderate to severe persistent asthma within a general pediatric clinic.[29] The pharmacist provided education about asthma, teaching on proper inhaler technique, spirometry monitoring, and telephone follow-up. After 1 year, the mean emergency department visit rate decreased from 1.33 (SD ± 1.85) to 0.25 (SD ± 0.25) per year for 52 patients with complete data, defined as 1 year of follow-up and complete survey data; the mean hospitalization rate decreased from 0.86 (SD ± 1.43) to 0.16 per year (SD ± 0.41) for 57 patients; both findings represented a statistically significant improvement ($P < .001$). In a prospective, randomized, controlled study, Almomani and colleagues evaluated the clinical pharmacist's effectiveness in providing comprehensive asthma education to caregivers and 178 patients between 7 and 18 years of age.[30] Patients in the pharmacist intervention group enrolled in face-to-face interviews and telephone follow-up at 3 and 6 months. Baseline characteristics including clinical outcome variables were similar between intervention and nonintervention groups. Compared with the nonintervention group, there were significant improvements in asthma control (80% vs 40%; $P < .001$) in the pharmacist group, which was defined as an ACT score < 20. **At baseline, emergency department visits were documented in 66.7 and 60.4% of patients in the control and intervention groups, respectively. By 6 months, these values decreased to 41.3 and 24.4% in each group ($P = .017$).[30]

Another recent study examined medication adherence, the number of pulmonary exacerbations, healthcare utilization, and costs for patients with CF who used a pharmacy-based management program within a large chain community pharmacy.[31] Specific medications were evaluated for adherence through percentage of days covered calculated from pharmacy claims data and included inhaled tobramycin, inhaled aztreonam, ivacaftor, or dornase alfa over a 1-year period. At monthly telephone visits, the pharmacist provided education on medication administration, storage/stability, side effects, adherence, and infection control education. A total of 202 matched participants identified based on medication use, age, and diagnosis were included in the analysis. Of note, age range was 6 to 46 years with a mean of 20 years; half of the patients were less than 18 years of age. Patients in the program were twice as likely to be adherent to inhaled tobramycin than matched controls (33% vs 18%: OR = 2.14, $P = .04$), had fewer mean visits to the ED (1462 vs 755 per 1000 members; IRR =0.52 [0.34, 0.78], $P < .01$), and had slightly lower ED costs (IRR =0.66, $P = .06$).

3.7 | Hematology

The impact of the pediatric clinical pharmacist was assessed in iron-overloaded ß-thalassemia major (BTM) patients seen in a pediatric hematology/oncology clinic.[32] Forty-eight children with BTM were randomly assigned to a control group receiving standard care, or an intervention group receiving standard care plus clinical-pharmacist provided services that included detection and management of drug-related problems, patient education, and provision of patient-tailored medication charts. Compared with the control group, significant improvements were seen in the intervention group for multiple clinical indicators. Serum ferritin levels were significantly lower (2632 mcg/L SD 109 vs 3713 mcg/L SD 1902; $P < .004$). The quality of life was also evaluated in these patients using the 23-item Peds-QL HRQoL questionnaire. This tool is based on a scale out of 100 and measures physical, emotional, social, and school functioning. In the intervention group, scores improved (63.5 vs 49.8, $P = .0049$); however, in the control group, there were no significant changes from baseline. The intervention group also had fewer drug-related problems compared with standard care (4 vs 64) and fewer nonadherent patients (3 vs 24).

3.8 | Immunology

A recently published study documented 7 years of pharmacist impact in a pediatric HIV clinic. This retrospective chart review analyzed 53 children over 2257 clinic visits and compared clinical indicators to clinic results prior to pharmacy services implementation. The services provided by the

TABLE 1 Summary of pharmacists' direct impact

Inpatient	Outpatient
• Decreased medication errors	• Decreased medication errors
• Decreased antibiotic use	• Decreased vaccine errors
• Shorter length of stay	• Increased access to medication
• Improved therapeutic drug monitoring targets	• Decreased emergency department visits and costs
• Improved adverse effect monitoring	• Increased medication adherence
• Shorter opioid taper schedules	• Decreased drug-related problems
• Decreased opioid withdrawal	• Increased quality of life
	• Increased vaccinations
	• Enhanced disease control

pharmacists were comprehensive and included optimizing dosages and regimens, direct patient education including adherence, prevention of medication errors, and disease state monitoring. Specifically looking at clinical endpoints, the percentage of patients with an undetectable viral load increased from 12.1% to 65.8% during the study period ($P = .0094$). The mean viral load decreased from baseline (4.37 SD 1.09 copies/mL vs 3.95 SD 1.22 copies/mL $P = .0042$) (Table 1).[33]

Another area of pharmacist involvement in the ambulatory care setting is childhood immunization. In a previously mentioned study describing two clinics, one with an integrated clinical pharmacist and the other without, there was a significant difference in the number of encounters with missed opportunities for children receiving vaccines in the pharmacist clinic group (46 vs 132 encounters; $P < .0001$) out of a total of 900 encounters.[17] In another retrospective study with similar methodologies, the clinic with integrated pharmacist participation demonstrated fewer missed vaccination opportunities in 510 patients (6.4% vs 11.1%, adjusted odds ratio = 2.14, 95% CI 1.3-3.5).[34]

3.9 | Medication adherence

Pharmacists have been successful in facilitating medication adherence with new medications when given the opportunity to interact more directly with pediatric patients and parents/caregivers. An estimated 20% of new prescriptions written for children by providers working in pediatric primary care go unfilled.[35] In one study of primary nonadherence, community pharmacists obtained patient contact information and diagnosis codes directly from a nearby pediatric primary care center for 121 patients.[36] A series of contacts were then made in 61 patients when medications were not picked up in order to assess adherence and notify primary care providers. Adherence rates were compared to 60 patients receiving usual care which consisted of automated text messaging. These methods reduced primary nonadherence by day 14 significantly compared to usual care (17.2% vs 46.7%, $P < .01$).

4 | CONCLUSIONS

Evidence supports the role of pharmacists in improving clinical outcomes for pediatric patients in the inpatient and outpatient settings. Many of these outcomes have significant societal and health benefits including reduced length of stay and the prevention of ED visits and hospitalizations. The abovementioned studies demonstrate improved patient outcomes due to pharmacist-provided care, and thus, pharmacists are a valuable member of the pediatric interprofessional team.[37-41] It should be noted that the studies identified reported only favorable results of the pharmacist-provided care, and many studies were in a single center and of limited duration (ie, less than 1 year). Available evidence and national organization recommendations support the importance of including pharmacists in the care of pediatric patients in a variety of practice settings. However, gaps in the literature on the impact of pharmacists in other settings such as primary care, ambulatory care, neonatal critical care, bone marrow transplant, emergency medicine, and solid organ transplant still exist. This indicates a critical need for research on true patient clinical outcomes by pediatric pharmacists. Studies should evaluate important and clinically relevant outcomes such as mortality, morbidity, length of stay, hospital readmission rates, along with pharmacoeconomics and other population health care indicators. However, as team-based care models advance in health care delivery, the ability to delineate the impact of individual team members may become more difficult to measure. Future investigators will have to develop accountability measures to identify contributions from pharmacist-led services. This may involve working on a larger scale than the small single-center studies presented here. National organizations should be a resource for pharmacists to collaborate and produce impactful multicenter investigations.

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CONFLICTS OF INTEREST

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