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THE ROLE OF THE CLINICAL PHARMACIST IN PEDIATRIC CARE: A COMPREHENSIVE REVIEW

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Abstract:
Pediatric care undoubtedly represents one of the most complex and sophisticated fields in modern-day clinical pharmacy practice.[1,25] Being a young patient implies numerous physiological and pharmacological differences which can have a significant impact on proper drug choice, dosage, and form.[3,4] Clinical pharmacists working with pediatric teams are patient safety experts who are involved at every stage of the medicines use process from dose selection and management to therapy monitoring and adverse effects identification.[1,12] The present paper gives a concise overview of current scientific evidence to highlight the important aspects of the clinical pharmacist's work within pediatric departments including roles and responsibilities, problems associated with pediatric pharmacology, and the positive influence of pharmacists' work on treatment results. It should be noted that scientific data proves that providing clinical pharmacist services to pediatric patients significantly decreases the number of medication-related mistakes, lowers hospitalization periods, promotes rational use of antibiotics, and positively affects the satisfaction of patients' families.[1,6,7] Thus, enhancing pharmacists' work in pediatric health care is crucial for further improvement of medicines use in this field.[18,21]

Keywords: *clinical pharmacist, pediatric pharmacy, medication safety, pharmacokinetics in children, antimicrobial stewardship, therapeutic drug monitoring, neonatal pharmacy, multidisciplinary care*

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INTRODUCTION:

Taking care of kids inside the hospital environment involves a high level of professionalism along with a high degree of compassion.[25] Different from adults, kids are covered by a wide variety of physiology, ranging from a very young child at 24 weeks who weighs only 500 grams to an almost grown-up adolescent kid at 17 years old.[4,5] There are specific patterns when it comes to medication and each phase requires a specific kind of method that may not work on another phase, thus rendering it ineffective or even risky.[3,20]

During most of the twentieth century, medicines intended for adults were prescribed for children using dose formulas derived from weight proportions of adult therapies, and there was no information on the safety of pediatric use published in the literature.[2,18] It is due to the awareness of the orphan drug phenomenon among children that has led to regulatory reforms worldwide, such as the Pediatric Research Equity Act in the USA and the European Paediatric Regulation, which require the conduction of clinical pediatric trials for many new drugs being developed.[18] However, many of the drugs used in pediatrics are either unapproved or labeled for off-label use.[2,19]

The involvement of the clinical pharmacist within the field of pediatrics has changed immensely over the past few decades.[12,21] From being involved primarily in the process of dispensing medications, the role of the clinical pharmacist now covers numerous areas of clinical activity: ward round attendance and multidisciplinary meetings, pharmacokinetic consultations tailored to each individual patient, antibiotic stewardship programs, medication reconciliation, pain management advice, nutrition-focused pharmacotherapy, and education of both clinicians and patients' relatives.[16,21]

Developmental Pharmacology: Why Children Are Different

Pharmacokinetic Considerations Across Age Groups

A foundational principle of pediatric pharmacotherapy is that pharmacokinetic parameters are not static — they change continuously as children grow.[3,25] Understanding these changes is essential to safe drug prescribing, and the clinical pharmacist is typically the team member best equipped to translate this knowledge into practical dosing decisions.[5,16]

Absorption: In neonates and young infants, gastric pH is higher than in older children and adults, which affects the ionization and solubility of orally administered drugs.[3,4] Gastric emptying is slower and irregular, leading to delayed and sometimes unpredictable peak drug concentrations.[4,20] Transdermal absorption is enhanced in neonates owing to thinner, more hydrated skin — a double-edged sword that can lead to toxicity if topical products designed for adults are used inappropriately.[4,22]

Distribution: The volume of distribution of many drugs is increased in neonates and infants because of increased total body water as compared to body weight.[3,20] In newborns, the percentage of body water is around 80%, whereas in adults, it is roughly 60%.[3] Therefore, water-soluble drugs like aminoglycosides need larger dosing in young infants than adults to reach therapeutic drug concentration.[4,16] Moreover, low concentrations of plasma proteins and albumin with decreased binding capacity for many drugs result in an increase in the unbound fraction in neonates.[3,4]

Metabolism: Cytochrome P450 enzymes involved in the metabolism of a wide range of drugs develop in a gradual fashion after birth.[3,25] For instance, cytochrome P450 3A7 decreases after birth and converts into CYP3A4 within the first year of life.[3,20] Other enzymes of the P450 family including 1A2, 2C9, and 2D6 are present in immature form at birth, so the same dose of medication that results in toxicity in infants may be eliminated quickly in toddlers.[3,25]

Drug Elimination via Kidney: The GFR of neonates is significantly lower than that of older infants, even when accounting for body surface area differences, and does not reach adult levels until about the age of one or two years.[4,20] Hence, renal clearance drugs like vancomycin, aminoglycosides, and various beta-lactams must be closely monitored in neonates.[16,4] Pharmacists commonly undertake pharmacokinetic calculations for personalized medication dosages in their daily practice.[16]

Off-Label and Unlicensed Drug Use

One of the key challenges in pediatric clinical pharmacy is the widespread practice of prescribing unlicensed and off-label medications.[2,19] Several studies conducted across different countries have shown that anywhere from 50 to 90 percent of the medicines dispensed in pediatric wards and up to 100 percent in neonatal intensive care units are prescribed either off-label or in doses that are unapproved for children.[2,17] While using such medications does not necessarily mean doing harm, there may be insufficient evidence to prove that such medications are safe and effective.[17,19]

The task of assessing whether it is safe to prescribe off-label drugs falls squarely to the clinical pharmacist.[12,19] In addition to reviewing the

evidence available and determining the best dose of a medication from pharmacokinetic information, the clinical pharmacist must convey the risks and benefits of off-label drug administration to physicians as well as parents or legal guardians.[19,24] Another key responsibility of pharmacy services in children's hospitals is maintaining an updated pharmaceutical formulary for off-label drug use.[23]

Core Clinical Roles of the Pediatric Pharmacist

Medication Safety and Error Prevention

Consequences of medication errors for children tend to be far more severe than for adults.[1,10] Since dosages for pediatric patients are determined based on their weight, the potential for a ten-fold miscalculation exists — a commonly documented issue — leading to either an excessive or deficient dosage.[1,11] Overdosage of medication has been shown to result in conditions such as renal failure, hepatotoxicity, cardiac arrhythmias, or even fatality, while significant under-dosage leads to inadequate treatment.[10,22]

Pharmacists working clinically are well-equipped to intervene at several stages in the drug utilization process.[12] Research from pediatric inpatient environments has documented incidences where pharmacist order reviews detected clinically significant drug-related errors in 1–5% of orders, with the rate increasing substantially when pharmacists are present at the bedside.[1,9] A groundbreaking study in *Pediatrics* found the involvement of pharmacists in pediatric rounds resulted in a 66% reduction in preventable adverse drug events.[1]

Even though clinical decision support integrated CPOE systems have been successful in decreasing errors in certain groups of prescriptions, they are not the ultimate solution.[3,11] Weight-based dosage checking requires precise and up-to-date information regarding patient body weight, and alert fatigue makes the success rate low.[11] The pharmacist acts as another line of defense in the prescription process without substituting the role of technology.[12]

Therapeutic Drug Monitoring (TDM)

Therapeutic drug monitoring is perhaps the most tangible contribution that the clinical pharmacist can make to pediatric care.[16] Drugs with narrow therapeutic indices such as aminoglycosides, vancomycin, anticonvulsants, tacrolimus, digoxin, and some chemotherapy drugs necessitate periodic drug level determination to optimize therapeutic outcome while minimizing toxicity.[16,5] Given the marked variation in pharmacokinetic profiles within different pediatric age classes owing to renal function, organ development, concomitant medications, and disease state, population-based dosage charts fall short.[4,5,24]

Clinical pharmacokinetic specialists utilize Bayesian statistical analysis and population pharmacokinetics to determine dosages based on drug levels.[16,24] Specialized pharmacy TDM services have proven effective in decreasing nephrotoxic effects of vancomycin therapy and increasing target achievement with aminoglycoside therapy in multiple pediatric studies.[5,16]

Antimicrobial Stewardship

Antimicrobial resistance poses one of the biggest challenges to public health across the world, and the misuse of antibiotics among children contributes to antimicrobial resistance in both patients and populations.[7,15] Pharmacists are important members of antimicrobial stewardship programs (ASPs), working alongside physicians, microbiologists, and infection control nurses in pediatric hospitals.[7]

Stewardship interventions carried out by pharmacists include prospective audits and feedback on antibiotic prescribing, managing formularies, dose adjustments, intravenous-to-oral switching programs, and educating clinicians about antibiotic use.[7,15] A systematic review provides evidence of reduced antibiotic use, shorter treatment periods, fewer cases of *Clostridioides difficile* infection, and decreased health care costs through ASPs without any harm to patients.[7,8]

Pediatric practice presents challenges to stewardship due to the prevalence of empiric antibiotic therapy in children who are suffering from fever but whose conditions end up being viral infections.[8,15] The role of pharmacists here includes formulating evidence-based guidelines for the empiric use of antibiotics, balancing promptness and safety.[7]

Participation in Multidisciplinary Rounds

The transition to multidisciplinary ward rounds within pediatric inpatient departments provides a perfect opening for clinical pharmacists to shape care during the decision-making process.[12,21] Pharmacists can contribute expertise concerning medication choice, dosing, drug interactions, and patient monitoring as part of the multidisciplinary team, preventing errors from happening.[1,12]

Several studies in pediatric inpatient wards and intensive care units showed that the presence of pharmacists during ward rounds resulted in significant benefits such as appropriate antimicrobial therapy, faster dose adjustments, more consistent adherence to clinical guidelines, and improved documentation for off-label drug use.[1,6,7]

Medication Reconciliation and Care Transitions
Medication transitions such as admission, transfer within the hospital, and discharge pose a significant risk for medication errors.[9,11] Medication reconciliation entails a systematic comparison of current medication orders against all medications the patient has been on prior to transition, ensuring discrepancies are discovered and corrected.[9]

There are a number of challenges in conducting medication reconciliation in the pediatric population: medications may come in liquid form with unconventional dosing instructions, there may be complicated regimens that parents manage at home, and patients attending schools may be receiving medications that parents do not mention.[9,11] A clinical pharmacist is the best professional to conduct thorough medication histories and interact with community pharmacists and physicians.[12,21]

Discharge counseling is another important function that should be carried out.[12] Research shows that pharmacist discharge counseling can help prevent readmission and visits to the emergency room because of drug issues.[9,12]

Specialty Areas of Pediatric Clinical Pharmacy

Neonatal Pharmacy
The NICU is potentially the most pharmacologically intricate setting within pediatrics.[4,9] The patients consist of extreme prematurity babies as well as full-term neonates with various congenital malformations, hypoxic ischemic brain damage, and sepsis.[4,13] The medication regimens utilized in the NICU are complicated, the therapeutic indices are tight, and the risks associated with medication mistakes are tremendous.[9,16]

The Neonatal Clinical Pharmacist plays an essential role every day to ensure the safe and efficacious use of medications in the NICU setting — including participating in daily ward rounds, calculating infusion concentrations, supervising therapeutic hypothermia, advising parents on medication safety during breast feeding, and supervising parenteral nutrition.[4,9,16] The Neonatal Clinical Pharmacist also acts as a consultant for inquiries concerning excipients such as benzyl alcohol, propylene glycol, and ethanol, which can lead to severe toxicity when given to neonates.[4,18]

Pediatric Oncology Pharmacy
Pediatric oncology is an example of a field in medicine where very complicated and risky pharmacological therapy exists.[5] The regimen of chemotherapy for childhood cancers involves a number of cytostatics and is delivered over a relatively long period based on specific protocols.[5] Oncology pharmacists operate as key members of the interdisciplinary team in charge of developing treatment protocols, pre-chemotherapy evaluation of kidney and liver function, preparation of chemotherapy in dedicated isolators, administration of supportive treatment medications, and surveillance of late effects among survivors.[5,8] On top of the care directly provided to patients, oncology pharmacists help with quality control and error reporting in order to create more reliable institutions over time.[5]

Pediatric Critical Care Pharmacy
Integrating the challenges of critical illness with the highly variable pharmacokinetics of pediatric patients makes for a formidable combination.[6,13] Severely ill pediatric patients can experience alterations in their drug absorption because of gut hypoperfusion, high renal clearance rates during early sepsis, or dramatically decreased clearance due to multi-organ dysfunction syndrome.[6,13] Simultaneous management of sedatives, analgesic agents, vasopressors, anticoagulants, anti-epileptics, and complex antibiotic protocols necessitates an extraordinary degree of pharmacologic sophistication.[6]

PICU pharmacy services have proven themselves to be highly effective in reducing drug-related adverse reactions, helping to ensure adherence to evidence-based guidelines, and assisting in safe transition from intensive care units.[6] Pharmacists are especially useful for managing pain and sedation protocols, including designing customized withdrawal programs for patients given prolonged infusions of opiates and benzodiazepines.[6,10]

Pediatric Pain Management
Effective pain relief in children is necessary both clinically and ethically; however, it is often substandard in many healthcare institutions.[10] The barriers in effective pain relief include difficulties in evaluating pain in non-verbal children, fears of opioid side effects and dependency, and insufficient literature to support some analgesics in particular age ranges.[10,22] Pharmacists offer assistance in pain management by suggesting appropriate analgesics and dosages, providing surveillance of side effects, facilitating conversion from intravenous to oral analgesics, and educating parents on safe pain management practices at home.[10,12]

Education, Training, and Competencies
The expertise necessary for pediatric clinical pharmacy practice is quite extensive, and the training needed should therefore account for this

reality.[14,21] In several countries, those involved in pediatric pharmacy practice participate in postgraduate training through residencies or fellowships that offer structured learning opportunities in developmental pharmacology, pharmacokinetics, and clinical skills.[14] Specialist organizations such as the Pediatric Pharmacy Association (PPA) of the US have developed board certification programs in pediatric pharmacy (BCPPS).[14]

The pediatric clinical pharmacist is also responsible for the education of future professionals in the field.[21] Several children's hospitals act as educational centers, where pharmacists play a crucial role in the teaching of pharmacy residents, intern physicians, and nurses.[21] Continuous learning becomes necessary in a profession in which there is constant new information and new medication available; pediatric pharmacists frequently attend conferences and work in national and international networks which share best practice guidelines.[21,23]

Impact of Clinical Pharmacy Services: Evidence Summary

The evidence base demonstrating the benefits of clinical pharmacy practice within pediatrics has greatly increased during the last two decades.[1,6,7,9,10,12] Below is a summary of the most significant findings from representative studies highlighting the scope of advantages gained from clinical pharmacy interventions in pediatrics.

Study / Author	Setting	Intervention	Key Finding
Kaushal et al. (2001) [1]	Pediatric Inpatient	Pharmacist participation in ward rounds	66% reduction in preventable ADEs
Cowley et al. (2019) [6]	PICU	Pharmacist-led medication review	Significant reduction in medication errors & costs
Bourgeois et al. (2010) [11]	General Pediatric Ward	CPOE + Pharmacist Review	Improved error detection vs. CPOE alone
Newland et al. (2012) [7]	Pediatric Hospital ASP	Antimicrobial Stewardship Program	22% reduction in broad-spectrum antibiotic use
Hess et al. (2010) [5]	Pediatric Oncology	Pharmacy TDM consultation	Reduced methotrexate toxicity; shorter stays
Abdel-Qader et al. (2010) [9]	Neonatal ICU	Clinical pharmacist integration	Identified errors in ~3.5% of all orders
Le et al. (2018) [10]	PICU	Pharmacist-led opioid weaning protocol	Reduced iatrogenic withdrawal incidence

Table 1: Summary of selected evidence for pharmacist impact in pediatric settings. ADE = adverse drug event; TDM = therapeutic drug monitoring; ASP = antimicrobial stewardship programme; PICU = pediatric intensive care unit; CPOE = computerised physician order entry.

Challenges and Future Directions

Despite the abundance of positive information, there are still issues concerning clinical pharmacy services for pediatrics.[18,21] There is an evident problem with the shortage of workforce, especially in developing countries, where the number of specialized pediatric pharmacists may not be enough to accommodate the growing population of complicated inpatient cases.[18]

Technologies such as electronic prescriptions, clinical decision support systems, artificial intelligence, and telepharmacy can contribute to the development of pediatric pharmacy; however, these innovations should be carefully validated to ensure proper results.[11,21] The global inequalities that exist regarding access to pediatric clinical pharmacy should be discussed openly, and the solution requires investing in training programs, establishing proper policies, and strengthening health care systems.[18]

From a future perspective, advancements in precision medicine and pharmacogenomics can help achieve personalized treatments in children.[25] Genetic differences in drug metabolism enzymes such as CYP2D6 and CYP2C19 impact the dosing of drugs including codeine and selective serotonin reuptake inhibitors (SSRIs) in pediatric patients.[25] Codeine should no longer be prescribed to children

because of the risk that a child may be an ultra-metabolizer of the drug.[22,25]

CONCLUSION:

Clinical pharmacy practice plays an exceptionally critical role in pediatric care teams.[1,12] With specialized expertise in pediatric pharmacodynamics and pharmacokinetics, and extensive knowledge about the evidence for drug treatment in childhood, the pediatric clinical pharmacist becomes a safety buffer, educator, clinician, and patient advocate.[5,16,25]

The findings of this review make clear that the participation of the clinical pharmacist results in better patient care outcomes in many different settings and specialties, including reductions in medication errors, improvements in antibiotic stewardship goals, better drug monitoring processes, and greater preparedness among parents in managing pediatric drug therapy upon discharge from hospitals.[1,6,7,9,12] This is not merely an incremental improvement; in a pediatric population where dosage mistakes can have fatal consequences, this represents a significant enhancement in patient safety.[1,10]

The task at hand for health care systems, hospital management, and policy makers is to apply these findings toward sustainable staffing and professional models that integrate the practice of clinical pharmacy within the delivery of care for children.[18,21] This is not just a matter of improving patient safety; it is a commitment to ensuring that the children and families relying on these health care systems feel secure.[18]

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