

The Value of Pediatricians on Pharmacy and Therapeutics Committees

Jared P. Austin, MD; Sara Gunden, PharmD, MBA; Wendy Hoffner, MD; Lana Ismail, MD; Suzanne Mendez, MD; and Francisco Alvarez, MD

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INTRODUCTION

Recent studies have highlighted the unique challenges that pharmacy and therapeutics (P&T) committees face in a rapidly changing health care environment.¹⁻⁴ To meet some of these concerns, including the move toward an increasingly specialized formulary, many articles have called for diversifying P&T committees by involving more physician specialists, primary care providers, and subspecialty committees. In particular, [Vogenberg and Gomes](#)¹ noted that the field of pediatrics could lack proper representation on P&T committees in the future. However, despite these concerns, there are no formal requirements for including pediatricians or pediatric pharmacists on these committees. In this article, we use four clinical cases to illustrate the importance of pediatrician involvement on P&T committees.

CLINICAL CASES

Case 1: A four-year-old, previously healthy male presents to a community hospital emergency department (ED) with a two-day history of fever and a right-sided limp. A magnetic resonance imaging (MRI) scan reveals osteomyelitis in his right femur. He is given a dose of intravenous (IV) vancomycin and admitted to the pediatric hospital. A basic metabolic panel drawn the next day reveals a creatinine level of 3.5 and a serum vancomycin trough of 55 ug/mL (10–20 ug/mL). Vancomycin is switched to cefazolin, and his creatinine normalizes over the next three days. A review of the medication administrative record by the P&T committee reveals that the initial dose of IV vancomycin in the ED was a standard adult dose rather than a weight-based pediatric dose. Further analysis reveals that most medications administered to pediatric patients in the hospital lack dose standardization by weight. A quality improvement initiative is launched by a pediatrician on the committee to develop dose standardization of high-risk medications for pediatric patients.

Case 2: During a procedural sedation workshop at a national meeting, a pediatric hospitalist learns about the efficacy of intranasal dexmedetomidine for use in procedural sedation and prolonged imaging studies.⁵ The medication is on the

formulary at her institution but is not approved for intranasal delivery. She submits a request to the P&T committee to allow off-label intranasal administration of dexmedetomidine to pediatric patients. The drug information pharmacist conducts a thorough review of the literature and presents the data at the next committee meeting. Because the data are compelling, the committee approves the request and a protocol is developed.

Case 3: Prompted by several pediatric deaths, the Food and Drug Administration (FDA) issues a boxed warning regarding the use of codeine in children under 12 years of age.⁶ In response, a pediatrician on the hospital P&T committee proposes that codeine be restricted to patients over 18 years of age, removing it from the pediatric formulary. The proposal passes through the committee and a hard stop is placed in the electronic medical record (EMR), preventing codeine from being prescribed to any patient under 18 years of age.

Case 4: Following extensive lobbying efforts by patient advocacy groups, a new drug for [Duchenne Muscular Dystrophy](#), Eteplirsen (Exondys 51), is approved by the FDA.^{7,8} A request is sent to the P&T committee to add the drug to the formulary. A review of the evidence by the committee's drug information pharmacist reveals several concerns: approval was based mainly on surrogate rather than clinical outcomes; clinical trials were under-powered and inadequately controlled; and annual treatment costs would be approximately \$300,000 per patient.⁹⁻¹¹ After a spirited discussion involving the requesting pediatric neurologist and the P&T committee, the committee votes against adding the drug to the formulary, pending further data.

DISCUSSION

As illustrated by the cases above, pediatricians, including generalists, hospitalists, and subspecialists, can elevate the quality of pediatric care by participating on P&T committees. This is particularly true in community hospitals where P&T policies may be focused on adult patient needs, and pediatric pharmacists may not be readily available.¹² Although the [focus and scope of the P&T committee](#) and its subcommittees may differ by institution, the committee typically oversees the following domains: maintenance of the [formulary](#), [medication safety](#), and medication delivery systems.¹³⁻¹⁵ Pediatricians can influence each of these critical areas of patient safety and care through their engagement with P&T committees.

Stewardship of the Formulary: Additions, Removals, and Restrictions of Expensive or High-Risk Therapies

Maintenance of the formulary is critical to achieving cost-effective, evidence-based care for patients.¹⁴ The P&T committee is the primary gatekeeper for ensuring that all formulary

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Dr. Austin is an Associate Professor in the Department of Pediatrics at Oregon Health & Science University in Portland, Oregon; Dr. Gunden is in the Department of Pharmacy Services at Oregon Health & Science University; Drs. Hoffner and Ismail are Assistant Professors in the Department of Pediatrics at Children's National Hospital in Washington, D.C.; Dr. Mendez is in the Division of Pediatrics and Neonatology at St. Charles Medical Center in Bend, Oregon; and Dr. Alvarez is a Clinical Associate Professor in the Department of Pediatrics at Stanford University School of Medicine in California.

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additions are properly vetted. Reviews for formulary additions should include a thorough evaluation of the available literature, focusing on efficacy, safety, cost, and comparison to other agents.¹⁶ This is especially important in pediatrics, as many medications are not adequately studied in children and must often be prescribed “off-label.”¹⁷ P&T committees require such drugs to pass a threshold of safety and efficacy before adding them to the formulary or allowing their use in children. In this way, the committees can help to hold the pharmaceutical industry accountable for conducting adequate studies in pediatric patients and providing reasonable pricing for medications.

As novel therapies emerge, P&T committees need to balance the restriction of high-cost medications with maintaining their availability to select populations who may benefit from them. For example, the IV form of acetaminophen was released in 2011 at a cost of \$11 per gram. In 2014, the price increased to \$33 per gram, a 300% increase. With few significant differences in the pharmacokinetic profile or pain control between the IV and oral formulations, P&T committees have been crucial in limiting the use of IV acetaminophen in adult populations.^{18,19} However, data are emerging that support the use of IV acetaminophen to control pain in premature infants and also for the early initiation of multimodal pain control in pediatric patients enrolled in “fast track” cardiac surgery programs.^{20,21} Having pediatric representation on P&T committees ensures that these special populations retain access to medications that may have limited application in adult patients.

Medication Safety and Delivery Systems

Medication errors are among the most common type of error that occurs in hospitalized patients.²² In the pediatric population, the rate of errors may be up to three times the rate in the adult population.^{23,24} There are multiple reasons for this, including the need for weight-based dosing, physiological differences due to age, and concentration restrictions. These differences can lead to errors in the prescribing, preparation, and administration of medications.²³ Within EDs, some of these errors may be even more common, with [studies noting](#) prescription error rates ranging from 9 to 31 per 100 orders.²⁶⁻²⁹ These errors are not limited to pediatric or adult settings but are compounded in environments that are structured around adult care practices.

Systems and structures that are built to address pediatric medication safety errors (e.g., EMR design, institutional protocols, adverse-event reporting systems) have been shown to minimize associated safety events.³⁰⁻³³ However, a 2015 survey by the [Institute for Safe Medication Practices](#) evaluating both pediatric and general hospitals noted major deficiencies in even the most common pediatric medication safety practices.³⁴ A separate survey focusing on community hospital settings found significant variation in the use of pediatric medication safety practices. In this study, only 58.7% of the hospitals had defined or documented maximum doses on orders; 50% required documentation of mg/kg dosing and 60% had specific committees to address pediatric medication safety events or concerns.¹² This further highlights the need for pediatric expertise within P&T committees to oversee and guide pediatric medication safety practices, particularly in community-centered and adult-centered hospital settings.

CONCLUSION

The cases presented and the issues discussed in this paper illustrate the important role that pediatricians can play on institutional P&T committees by promoting medication safety practices for pediatric patients. These practices, such as instituting weight-based dosing and dose standardization, and restricting the use of potentially toxic medications, serve to improve patient safety and optimize care. This paper also demonstrates the need for pediatricians to work with P&T committees to review novel therapies for safety, efficacy, and cost-effectiveness to ensure optimal care for pediatric patients in both inpatient and outpatient settings, and in community and tertiary hospitals.

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