Establishing a Unique Medication Administration System for Pediatric Patients at the Point of Care

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Abstract

Children require a dedicated medication utilization system tailored specifically to their needs. This necessity arises because their integration into an adult-oriented prescription processing system creates problematic risk factors and necessitates unconventional solutions. In its 2014 policy statement regarding off-label medication use in children, the American Academy of Pediatrics (AAP) asserted that federal legislation aimed at enhancing drug testing in children has yielded positive results, with "over 500 pediatric-specific labeling changes" being implemented. However, the AAP's stance has remained largely unchanged since its initial 2002 policy statement. Furthermore, it is noteworthy that various other healthcare professionals, their associations, or affiliated practice-based research network (PBRNs) mechanisms have continued to be disregarded, excluded from cooperation, or even neglected in acknowledgments.

It is important to highlight that the majority of the 500 labeling modifications made since 1997 have primarily focused on the scientific validity of indications for medication use in the pediatric population, without addressing issues related to medication formulation or monitoring. Consequently, medication usage among children remains associated with an unacceptably high incidence of adverse events, morbidity, and even fatalities.

Keywords: Medication-use system • Off-label • Pediatrics • Pharmacotherapy

Introduction

The Committee on Drugs of the American Academy of Pediatrics (AAP) issued a policy statement addressing the utilization of drugs in children that are not specifically indicated on their official labels With in this statement, the AAP put forth five supplementary recommendations outlining their proposed framework for the administration of medications in children. The Committee provided a definition for "off-label" use, characterizing it as the utilization of a drug in a manner not specified in the officially approved labeling provided by government authorities. They also elucidated the dual role of the United States Food and Drug Administration (US-FDA)concerning children: first, as the arbiter responsible for drug labeling, and second, as the entity overseeing post-market drug monitoring.

In the context of therapeutic decision-making, the Committee reiterated that off-label use should not be viewed as experimentation or research, and as such, it does not necessitate special consent or review procedures. In summary, the AAP asserted that federal legislation aimed at enhancing drug testing in children has proven effective, leading to more than 500 changes in drug labeling specific to pediatric use.

Fundamentally, the AAP's recently updated policy statement on pediatric drug use remains largely consistent with its initial stance from 2002. This updated statement continues to emphasize that ensuring the safety and effective use of medications for children should primarily be a top-down process, primarily involving the relationship between the AAP and the US-FDA. It does not involve other healthcare professionals, their associations, or affiliated Practice-Based Research Networks (PBRNs).

In this paper, we delineate several unaddressed issues within the AAP's policy statement and illustrate how the perpetuation of the existing pharmacotherapy system in the pediatric population needlessly exposes children to the risks of drug-related health problems and fatalities.

How secure is the use of Medications in children throughout the care spectrum?

A brief examination of the existing literature indicates that the use of medication in children has been linked to an alarmingly high incidence of adverse events, illnesses, and even fatalities. While some of these occurrences may be attributed to the lack of validated drug labeling, recent reviews on medication errors have revealed that issues related to drug therapy in non-hospital settings are underreported and lack consistent definitions. Research has demonstrated that the implementation of Computerized Provider Order Entry Systems (CPOE) in hospitals can reduce the likelihood of certain errors in pediatric patients by up to 50%. Limited studies focusing on the identification and summary of pharmacotherapy problems and medication errors in children living at home have unveiled an overall error rate of 70.2 errors per 100 patients, with a median rate of Preventable Adverse Drug Events (PADEs) at 16.5%.

In a study conducted by Zed and colleagues, the natural course of pediatric Emergency Department (ED) visits was examined, revealing that medication-related ED visits and subsequent hospital admissions were both frequent and often preventable in pediatric patients, resulting in significant utilization of healthcare resources . Unfortunately, the current healthcare advisory services appear to have limited effectiveness in preventing medication administration errors.

Off-label drug use

In the context of the term "off-label," the meaning of drug use pertains to the utilization of a medication in a manner that is not explicitly specified on the product's label. Pediatricians may consider this type of drug use necessary and justifiable in certain patients based on their medical needs. However, when examining the labeling of any product following the US-FDA Modernization Act of 1997, it becomes apparent that "indication" is just one of the 20 components on the label.

For instance, when changes were made to support a pediatric indication for palonosetron, a 5-hydroxytriptamine 3 inhibitor, as an anti-emetic for children experiencing nausea and vomiting due to chemotherapy or post-surgical procedures, it resulted in three modifications to the label: (1) indication, (2) dosing, and (3) warnings and precautions. Notably, only the dosing information, which established a weight-based dosing regimen for children, specifically pertained to the pediatric population. The indication and safety information remained general and did not address the unique considerations of the pediatric population.

Furthermore, since the US-FDA did not mandate the company to include information about the preparation of palonosetron dosages in the label change, the company did not incorporate such compounding details in its submission. In essence, although the US-FDA required assurance from the company regarding the reliable compounding of both intravenous and oral palonosetron doses by pharmacies, it left the addition of information on dose preparation in the product's labeling as an optional measure.

Consequently, the inclusion of the fixed weight-based dosing information in the label modification sufficed. However, even though palonosetron now possesses an approved usage indication, rendering it no longer an "off-label" medication, pediatricians still lack specific instructions for dose preparation when consulting with pharmacists. Additionally, a pharmacist may still categorize the use of palonosetron in the pediatric population as "off-label" because there is no mention of how to formulate a dose for a child anywhere in the drug's labeling. It is essential to note that the label does not provide monitoring parameters tailored to children for ensuring safety and effectiveness, which can be of concern to both nurses and parents.

In summary, it becomes evident that the concept of an "approved drug use" is more comprehensive and encompasses more elements than what the AAP advocates. A substantial alteration to drug labeling should encompass much more than merely establishing an approved use indication, which is necessary not only for medical justification but also for third-party insurance reimbursement. Adding a label change related to the indication without including the necessary means for its implementation, such as dose preparation and stability, lacks both logical and ethical justification.

Is the distinction between innovative practice and research artificial?

The AAP's Committee on drugs makes a statement of utmost significance: "Off-label use is not incorrect or investigational if it is grounded in solid scientific evidence, expert medical judgment, or published literature". Consequently, in many cases, off-label use can be seen as an innovative practice, and this concept extends beyond the field of pediatrics. The AAP's policy statement would offer greater value if it furnished a clear definition of "innovative practice," the strategies for its implementation, and the role of Practice-Based Research Networks (PBRNs) in the context of practical research.

Since the late 1990s, the Agency for Healthcare Quality and Research (AHRQ) has been actively promoting the establishment and operation of Practice-Based Research Networks (PBRNs) under the framework of the Healthcare Research and Quality Act. It's noteworthy to observe that within both the realms of government and medicine, the American Academy of Pediatrics (AAP) appears to have overlooked the significance of these networks in its endeavors to foster the creation of scientific evidence to support more effective medication usage in children.

Distinct medication-use system

From the moment a healthcare provider assesses a pediatric patient's requirement for drug therapy, each potential option may be associated with uncertainty and ambiguity. The prevalence of off-label drug use in children has been estimated to be as high as 80%, depending on factors such as how off-label use is defined, the legal jurisdiction, the healthcare setting, and the perspective of the particular study.

Regrettably, resources allocated by governments, professional alliances, and pharmaceutical companies for research and development have predominantly concentrated on the pharmacokinetics and pharmacodynamics of injectable drugs within limited subsets of the pediatric population. In fact, over the past two decades, there have been only sporadic scientific endeavors aimed at creating distinct oral non-sterile dosage forms with the potential for mass production and standardization, which could effectively meet the needs of pediatric patients with chronic illnesses who are below the age of four.

Hence, there is a need for a multi-phased, systematic approach to pediatric pharmacotherapy that would encompass the following key elements:

1. The integration of assessments for both safety and effectiveness at the point-of-care.
2. The inclusion of information-sharing requirements throughout the entire continuum of care.
3. The pursuit of formulation standardization to enhance therapeutic results.

This comprehensive system would also involve organized and timely follow-up processes and feedback mechanisms to validate anticipated outcomes. Additionally, point-of-care assessments would be conducted by healthcare professionals who possess the necessary training and credentials, such as board-certified pediatric or clinical pharmacists.

We propose the development of two distinct and separate age-based medication utilization systems: one tailored for individuals aged 17 and older, and the other designed for those below 17 years of age. Given that the current approach adopted by the US-FDA and AAP primarily focuses on validating medication indications, a new system is imperative, one that places children's unique requirements at the forefront and addresses four additional aspects of system design:

1. Exploration, validation, and dissemination of novel and improved methods for extemporaneous formulation or reformulation.
2. Strengthening the infrastructure for computer informatics, this includes scientifically validated extemporaneous and mass-produced products, and allows for the bidirectional flow of comprehensive information from prescription initiation to fulfillment.
3. Establishment of collaborative practices between pediatricians and board-certified pediatric clinical pharmacists to systematically assess, gather, and transmit outcomes data to a central repository using a pediatric-specific minimum data set.
4. Implementation of pragmatic clinical trials, enabling teams of healthcare professionals to pose and answer crucial outcomes-oriented inquiries.

To effectively oversee this child-specific medication utilization system, it is essential to provide specialized training and certification for clinical pharmacists, who should be consistently employed at the point of care to complement and enhance the clinical practices of pediatricians.

The rationale behind AAP's omission of PBRNs as a viable system for acquiring, synthesizing, and disseminating knowledge is a matter for readers to contemplate. Nevertheless, it is worth emphasizing that thesocial and Congressional mandate of the US Food and Drug Administration (US-FDA) as the ultimate authority on pharmaceutical facts remains incomplete without a systematic, comprehensive, and exclusive focus on ensuring medication safety for children.

Specifically, delving into the role of PBRNs in generating evidence-based data collection, objective analysis, and the dissemination of knowledge would provide valuable guidance to clinician-researchers and pharmacists interested in establishing networks for child-specific knowledge. Indeed, numerous professional groups, such as the Children's Oncology Group and the Pediatric Trials Network, are structured as PBRNs with the objective of facilitating engagement among clinician-researchers in standardizing and harmonizing treatment practices.

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