

# ASHP Guidelines for Providing Pediatric Pharmaceutical Services in Organized Health Care Systems

Patient care consists of integrated domains of care, including medical care, nursing care, and pharmaceutical care. The provision of pharmaceutical care involves not only medication therapy but decisions about medication selection, dosages, routes and methods of administration, medication therapy monitoring, and the provision of medication-related information and counseling to individual patients.<sup>1</sup> The pediatric patient population poses some unique challenges to the pharmaceutical care provider in terms of these medication-related activities. These challenges include the lack of published information on the therapeutic uses and monitoring of drugs in pediatric patients; the lack of appropriate commercially available dosage forms and concentrations of many drugs for pediatric patients; and the resulting need to develop innovative ways of ensuring that the patient receives the drug in a manner that allows the intended therapeutic effect to be realized.<sup>2</sup> These guidelines are intended to assist pharmacists in meeting the special needs of the pediatric patient in any organized health care setting.

## General Principles

The pharmacy service should be organized in accordance with the principles of good management. It should be under the direction of a pharmacist and be provided with sufficient physical facilities, personnel, and equipment to meet the pharmaceutical care needs of the pediatric population. Resources necessary for compounding and testing alternative doses and dosage forms of commercially available products are essential. The pharmacy should comply with all applicable federal, state, and local laws, codes, statutes, and regulations.<sup>3</sup> The setting should meet applicable accreditation criteria of the Joint Commission on Accreditation of Healthcare Organizations. Organizations such as the National Association of Children's Hospitals and Related Institutions, the American Academy of Pediatrics, and the Pediatric Pharmacy Administrative Group are useful sources of further information on pediatric health care services.

## Orientation and Training Programs

Orientation, training, and staff development programs for pharmacists providing services to pediatric patients should emphasize dosage calculations, dosage-form selection appropriate to the patient's age and condition, and specialized drug preparation and administration techniques. Pharmacists should be familiar with the pharmacokinetic and pharmacodynamic changes that occur with age (e.g., in volume of distribution, protein binding, renal elimination, metabolism, muscle mass, and fluid requirements) and with disease-specific conditions that might affect drug choice or administration (e.g., short-gut syndrome, lactose intolerance). A sensitivity to the nature, frequency, and severity of medication-related errors in the pediatric population is important for all pharmacy personnel.<sup>4</sup>

## Inpatient Services

A lack of availability of commercially prepared dosage forms, combined with the documented risk of calculation errors, requires the use of comprehensive unit dose drug distribution systems and intravenous (i.v.) admixture services for pediatric patients. Appropriate dosage standardization in both oral and parenteral drug distribution systems may facilitate the provision of these services.

**Unit Dose System.** The pediatric unit dose system must meet the original intent of these systems, which is to minimize errors and provide drugs to the patient care areas in ready-to-administer form. Multidose containers and stock medications should be avoided. An extemporaneous preparation service should facilitate the preparation and packaging of medications according to sound compounding principles.

**I.V. Admixture Service.** The drugs provided by the i.v. admixture service should include all i.v. push, i.v. minibag, intramuscular, and subcutaneous doses; large-volume injections; antineoplastic agents; parenteral nutrient fluids; ophthalmic products; peritoneal dialysis solutions; and irrigation fluids. Knowledge of pediatric fluid requirements and limitations, drug administration techniques and devices, and acceptable volumes for intramuscular injection is critical. Care should be taken when making dilutions to maximize concentrations of drug products (when safe to do so) for fluid-sensitive patients, as well as to minimize hyperosmolar solutions that might lead to destruction of vasculature or, in the neonate, intraventricular hemorrhage. Quality controls for both manually prepared and computer-driven preparation should exist to ensure that each product contains the ingredients ordered and that they are properly labeled. Knowledge of products that contain benzyl alcohol and the risks of this substance in neonates is essential in a pediatric i.v. admixture service.

The labels of all products should be evaluated for legibility, clarity of expression, and their potential for leading to a medication error.<sup>5</sup> Labels should include the drug name; the drug concentration; the route of administration; the expiration date or time; appropriate instructions for administration, additional preparation, and storage; and the lot number (if a batch-prepared product).<sup>6</sup>

## Ambulatory Care Services

Ambulatory care pharmacy services should be attentive to the unique drug needs of the pediatric patient. These include the need for special dosage forms (e.g., liquids and chewable tablets), measuring devices, and detailed counseling on drug administration. When product stability is a problem, caregivers may have to be taught how to prepare an appropriate dosage form in the home. Consideration must be given to taste and the need for an extra prescription container to

be taken to school or daycare. Children should be included whenever possible in discussions concerning their medications. In the ambulatory care setting, the pharmacist is well positioned to play a role in preventive health care, including poison prevention and immunization.<sup>7</sup>

### **Drug Information**

Drug information services should provide the pharmacist practicing in the pediatric setting with information unique to the pediatric population. References should include pediatric medical texts and current information on pediatric dosages, extemporaneous formulations, drug compatibilities and stability, poison control, and drug effects during pregnancy and lactation. Drug information should be available in areas where decisions are being made about drug therapy. Literature supporting the use of drugs for unlabeled uses in pediatric patients should also be available.<sup>8</sup> Pharmacists should provide other health care professionals with information on new and investigational drugs, adverse effects of and contraindications to drug therapy, compatibility and stability information, dosage computations, pharmacokinetics, and drug interactions. This may be accomplished through educational presentations, seeing patients in conjunction with other caregivers (“rounding”), and printed materials (e.g., newsletters).

### **Therapeutic Drug Monitoring**

Therapeutic drug monitoring enables assessment of therapeutic outcomes and recognition at the earliest moment of an undesirable response to a drug. Both desired and undesired effects should be documented. The person performing therapeutic drug monitoring should take into consideration the age-related differences in dosage when recommending or reviewing drug therapy.

### **Pharmacokinetic Services**

For both oral and injectable drugs, pharmacokinetic services should ensure that the drug has been administered appropriately before samples are taken for the measurement of serum drug concentrations. The frequency and timing of sampling should also be monitored to avoid excessive and traumatic sampling in children. Knowledge of age-related differences in absorption, distribution, metabolism, and elimination is essential for the pharmacist who is involved in pharmacokinetic services for pediatric patients. The collection and publication of accurate pharmacokinetic data on the pediatric population are encouraged.

### **Patient and Caregiver Education**

Pharmacists should counsel and educate patients and caregivers about their medications, including the purpose of each medication, dosage instructions, potential drug interactions, potential adverse effects, and any specific age-related issues (e.g., compounding and diluting techniques, measuring and administration instructions). Caregivers should be informed of any drug products for which crushing, chewing, dividing, or diluting should be avoided. Suggestions about masking the taste of an unpleasant medication should also be provided. Administration of products, including ophthalmics,otics, inhalers, and injectables, should be demonstrated.

The prevention of accidental ingestion of medications should also be emphasized. The benefits of educational programs are best realized when a cooperative multidisciplinary approach is used. Sharing of pertinent information by all participants is fundamental to the success of patient education services.<sup>9</sup>

### **Medication Errors**

Systems for the recognition, documentation, and prevention of medication errors are essential for the pediatric population. Pharmacist participation in quality-improvement committees and the participation of pharmacists, nurses, physicians, and risk managers are important in minimizing medication errors in pediatric patients. The development and enforcement of policies and procedures for minimizing medication errors are essential. Pediatric patients are especially vulnerable to errors caused by mistakes in calculations. Pharmacists should recognize that since some commercially available products are available in strengths that can be potentially toxic to a pediatric patient, special scrutiny of these products is necessary.<sup>5</sup>

### **Adverse Drug Reactions**

Pediatric patients frequently have the same kinds of adverse drug reactions that adults have, but adverse reactions in the pediatric population may be harder to recognize or of greater or lesser intensity. The lack of literature on newly introduced therapeutic agents makes it imperative to monitor experience with new drugs initially used in the pediatric population. Comprehensive adverse drug reaction monitoring and reporting programs are important in reducing the occurrence of these reactions in pediatric patients.<sup>10</sup>

### **Drug-Use Evaluation**

Drug-use evaluation should be directed at drugs with a low therapeutic index that require extensive monitoring, those that are responsible for serious medication errors in the institution, and those that are found to be associated with high frequency of preventable adverse drug reactions. Cost-related issues may also become important in the evaluations, since many expensive drugs are not available in package sizes appropriate for the pediatric patient.

### **Research**

Pediatric patients have long been recognized as “therapeutic orphans” because of a relative absence of therapeutic trials in this patient population. The reasons for this are numerous and include ethical issues, potential adverse publicity, possible litigation, methodological hurdles, and an inability to justify such studies for economic reasons. Nonetheless, the need for timely and effective research on medication safety, efficacy, and practical application in the pediatric population is compelling. The paucity of pediatric drug information, the impact of new drug delivery systems, the expansion of adult diseases (such as AIDS) into the pediatric population, and expanded applications of new and established therapeutic agents are all areas warranting additional research. The pediatric pharmacist can be directly involved in collaboration with other health care providers in conducting pediatric

research. Examples of pediatric research topics include, but are not limited to, the following:

- Safety and efficacy of drug products in pediatric patients;
- Pharmacokinetics and pharmacodynamics of new medications;
- Stability, safety, and efficacy of extemporaneously compounded sterile and nonsterile drug products;
- Safety and efficacy of administration techniques;
- Comparative evaluations of medications addressing treatment regimens, outcomes of therapy, and their relative costs;
- Behavioral and socioeconomic compliance issues in pediatric pharmaceutical care; and
- New and existing pharmacy drug distribution systems and services for pediatric patients.

Examples of direct involvement include

- Serving as a member of an institutional review board;
- Maintenance, oversight, and dissemination of all information on investigational drug studies and comparative trials involving medications in the pediatric population; and
- Maintenance, coordination, and oversight of policies and procedures involving investigational drug studies and comparative trials involving medications in the pediatric population.

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