

AMERICAN ACADEMY OF PEDIATRICS

POLICY STATEMENT

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

Committee on Drugs and Committee on Hospital Care

Prevention of Medication Errors in the Pediatric Inpatient Setting

ABSTRACT. Although medication errors in hospitals are common, medication errors that result in death or serious injury occur rarely. Even before the Institute of Medicine reported on medical errors in 1999, the American Academy of Pediatrics and its members had been committed to improving the health care system to provide the best and safest health care for infants, children, adolescents, and young adults. This commitment includes designing health care systems to prevent errors and emphasizing the pediatrician's role in this system. Human and device errors can lead to preventable morbidity and mortality. National and state legislative actions have heightened public awareness of these events. All involved persons, beginning with the physician and including every member of the health care team, must be better educated about and engaged in the several steps recommended to decrease these errors. The safe administration of medications to hospitalized infants and children requires additional specific safeguards that are above and beyond those for adult patients. Pediatricians should help hospitals develop effective programs for safely providing medications, reporting medication errors, and creating an environment of medication safety for all hospitalized pediatric patients.

ABBREVIATIONS. IOM, Institute of Medicine; ADE, adverse drug event; USP, US Pharmacopeia; CPOE, computerized physician or prescriber order entry; AAP, American Academy of Pediatrics; JCAHO, Joint Commission on Accreditation of Healthcare Organizations.

BACKGROUND

Hospitalized infants and children are subject to advantages and risks of inpatient care. Included in most medical and surgical treatment regimens for hospitalized pediatric patients is administration of medications that may be associated with undesirable as well as therapeutic effects. The Institute of Medicine (IOM)¹ defines an adverse drug event (ADE) as an injury resulting from medical intervention related to a drug, which can be attributable to preventable and nonpreventable causes. Of these, *adverse reactions* to medications include those that are usually unpredictable, such as idiosyncratic or unexpected allergic responses, and those that are predictable, such as adverse effects or toxic reactions related to the inherent pharmacologic properties of the drug. In general, the number and severity of

adverse medication reactions are directly related to the number of drugs administered to hospitalized patients.²⁻⁴ In contrast to these nonpreventable adverse drug reactions, *medication errors* occur as a result of human mistakes or system flaws. A medication error is any preventable event that occurs in the process of ordering or delivering a medication, regardless of whether an injury occurred or the potential for injury was present.^{1,5-7} The distinction between the 2 is salient; an allergic reaction to a medication can be an adverse reaction if there is no history of patient allergy, yet can be a medication error in that same case of allergic reaction if the patient did have a documented history of allergies but that medical information was not available, not consulted, or overlooked.¹ Even more important to emphasize is that medication errors can occur in the absence of injury to the patient.

Providing drug treatment in the hospital setting requires that a series of actions be performed correctly by several members of the health care team, such as the physician, the unit clerk, the hospital pharmacist, and the nurse. Errors are possible at any step of the process, from medication selection and ordering, to order transcription, to drug formulation, to drug dispensing, to drug administration. For adults, the reported incidence of errors in treatment with medications ranges from 1% to 30% of all hospital admissions,⁸ or 5% of orders written.⁵ In pediatrics, however, this number has been reported to be as high as 1 in 6.4 orders.⁹ A 1995-1999 study by the US Pharmacopeia (USP) Medication Errors Reporting Program demonstrated a significantly increased rate of medication error resulting in harm or death in pediatric patients (31%), compared with adults (13%).¹⁰ In a more recent study, ADEs occurred at a similar rate between pediatric (5.7%) and adult patients (5.3%). However, potential ADEs—those errors not causing harm—occurred in pediatric patients 3 times more often than in adults.¹¹ In adult studies, antimicrobial agents, analgesic agents, and cardiovascular drugs are most often associated with reported errors.^{2,3,12} Yet for pediatrics, intravenous fluids are the most commonly cited product involved in medication errors reported to the USP.¹⁰ In pediatric and adult populations, the most commonly reported errors include the following: inappropriate medication for the condition being treated; incorrect

dosage or frequency of administration of medication; wrong route of administration; failure to recognize drug-drug or drug-herbal/medicinal/dietary product interactions; lack of monitoring for drug adverse effects; "missed/late dose errors" with delayed drug administration; and inadequate communication between the physician, other members of the health care team, the parent or caregiver, and the patient.^{5,10} For pediatrics, incorrect dosing is the most commonly reported error, including computation errors of dosage and dosing interval.^{10,11,13,14} Many drugs lack formal US Food and Drug Administration licensing for pediatric indications and dosing guidelines,¹⁵ which increases the risk of these errors and accounts for the significant difference in the frequency of these errors in pediatrics (47% of errors) as compared with adults (28%).¹⁰ In teaching hospitals, prescribing errors decrease with each year of training; the error rate for attending physicians, however, is exceeded only by that of first-year residents.¹² Targeted education can decrease the rates of errors, but long-term retention of information is not ensured.¹⁶ Computerized physician or prescriber order entry (CPOE), standardized order forms, and alert systems have all demonstrated success in decreasing errors.^{17,18} These systems can mandate attending physician cosignature for attempted overrides of the embedded templates in the system by residents.¹⁹ For example, alert systems can assist prescribers by triggering an alert when a patient on digoxin has low potassium. In one study, such a system triggered alerts in 64 per 1000 admissions, influencing order changes that were directly attributable to the system in 29 per 1000 admissions.⁸ Templates or standardized order forms can also aid in drug choice or delivery method.¹⁹ Yet complete reliance on computer systems is not fail-safe; one third of software systems fail to trigger an alert for clinically significant drug-drug interactions.²⁰ Fortunately, fewer than 2% of erroneous medication orders reach the patient.⁹

Medication errors produce a variety of problems for patients, ranging from minor discomfort to substantial morbidity that may prolong hospitalization or lead to death.^{2,4,10,21} The 1999 IOM report implicates medication errors, at least in part, as a direct cause of up to 98 000 patient deaths annually.¹ Drug errors associated with morbidity and mortality increase inpatient health care costs by an estimated \$4700 per hospital admission, or approximately \$2.8 million annually for a 700-bed teaching hospital.¹ In addition, time spent by the health care team tracking errors, such as missed doses, can have an effect on time available for direct patient care. In a study of medical liability suits filed from January 1985 through December 2001, the Physician Insurers Association of America found medication error was the fifth most common misadventure for pediatricians. More than 30% of these cases resulted in a paid claim, with total indemnity at \$14.7 million.²² The economic burden for all areas of health care from drug misadventures exceeds \$100 billion annually in the United States alone.²³

The American Academy of Pediatrics (AAP) is

committed to decreasing medication errors in the treatment of children²⁴ and to the development of systems designed to identify and learn from errors.²⁵ Children vary in weight, body surface area, and organ system maturity, which affect their ability to metabolize and excrete medications. In addition, there are few standardized dosing regimens for children, with most medication dosing requiring body weight calculations. The causes of drug errors are multifactorial. Therefore, medication error improvement programs must focus on system improvements and team communication. The top 10 causes of pediatric errors identified by cause for the 2-year period ending December 31, 2000, by the USP are performance deficit, procedure or protocol not followed, miscommunication, inaccurate or omitted transcription, improper documentation, drug distribution system error, knowledge deficit, calculation error, computer entry error, and lack of system safeguards.¹⁰ Institutions caring for children must develop multidisciplinary programs involving active participation by physicians, nurses, pharmacists, laboratory staff, and information system specialists to significantly decrease medication errors. Involvement of the family in all areas of the medication program is also of value.^{7,26-28} These programs should be an integral part of the institutional quality assurance and quality performance activities and, when possible, incorporate computer-assisted drug ordering and monitoring. They should also be tied to laboratory and adverse event reporting systems. The AAP recognizes and supports the extensive studies and policies developed over the past decade by other organizations using nonpunitive reporting systems to decrease or eliminate drug administration errors.²⁹⁻³² Several of their recommendations and others are summarized below in a comprehensive approach to decreasing medication errors in the hospitalized pediatric patient.

Physicians who care for children in the hospital setting are encouraged to promote, if not actively develop, programs to decrease medication errors in their institutions as part of a more encompassing patient safety program.²⁵ Of particular importance to pediatric patients are weight calculations, emotional and biological developmental issues including communication ability, and patient and family involvement throughout the process. It is incumbent on hospitals to include such programs in their policies and procedures to decrease the risk of prolonged hospitalization and attendant errors associated with drug treatment. The costs for such system overhauls is significant, but a change is now being demanded by legislators and families.³³ The business community, the Medicare Payment Advisory Commission,³⁴ the Agency for Healthcare Research and Quality,³⁵ and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)⁷ acknowledge the need for system overhaul.

RECOMMENDATIONS

The following statements are actions and/or guidelines for policy, education, and communication

to assist in decreasing the rate of pediatric medication errors. Recommendations uniquely pertinent to children are noted with an asterisk (*), and more general recommendations are noted with a bullet (•).

Hospitalwide System Actions and Guidelines

- * Provide an adequate number of nursing and pharmacy staff trained to prepare, dispense, and administer medications to children.^{10,11}
- * Establish and maintain a functional pediatric formulary system with policies for drug evaluation, selection, and therapeutic use.
- * Standardize equipment throughout the institution, such as infusion pumps and weight scales.³²
- * Standardize measurement systems throughout the institution, using for example only kilograms for weight rather than pounds or kilograms in different areas within the institution.³²
- * Standardize order sheets to include areas for patient weight, old and new allergies, prescriber name, signature, and contact number.
- * Where reasonable, computerize systems to check dose and dosage schedules, drug interactions, allergies, and duplicated therapies.^{10,11,35,36} Embedded templates or clinical pathway order sets³⁷ with alert systems are examples. However, pediatric-specific templates are not yet readily available, and costs of computer system enhancements may be considerable. Implementation should be considered when templates proven for the pediatric population are available.^{8,19}
- * Develop prospective error tracking systems run on a consistent basis to target and monitor common pediatric errors. Dose range limits and sound-alike errors are examples.^{36,38} As part of this tracking system, encourage reporting of even minor errors whether or not they have been corrected or are of minimal clinical significance.
- * Develop and maintain a process for informing families of errors. This is important to provide family-centered care and commitment to quality.
- * Develop an educational program for all hospital and medical staff in calculating, prescribing, preparing, and administering medications for children.^{9,10,39–41}
- * Eliminate barriers to reporting adverse medication events^{36,42,43} and encourage a nonpunitive culture for reporting and review of adverse events.^{15,36,42,43} Ensure that all staff members understand the method for reporting and are knowledgeable in JCAHO-mandated reporting rules.⁷ Reporting systems should follow the guidelines outlined in the AAP policy statement “Principles of Patient Safety in Pediatrics,”²⁵ which focus on system error root cause analysis.
- Provide a suitable work environment for safe, effective drug preparation.¹⁰
- Establish a clearly defined system for drug ordering, dispensing, and administering that includes review of the original drug order by appropriate pharmacy and nursing staff before dispensing and before administration.¹⁰ CPOE, a computerized record for medication administration, and individual patient bar coding are examples.^{19,44,45}

- Encourage a team environment for review of orders among nurses, pharmacists, nurse practitioners, physician assistants, and physicians.
- Provide ongoing formal quality improvement of the therapeutic use of medications, including a drug-use evaluation program.
- Maintain medication profiles for inpatients and ambulatory patients receiving care at the hospital, with updated allergy histories with each encounter. This profile may include current and past-year medications lists, adverse drug reactions history, pharmacokinetics, and allergies.
- Encourage use of methodology for error and prospective data analysis and tracking, such as plan-do-check-act/plan-do-study-act format and evidence-based medicine³⁶ review.
- Communicate plans and results from plan-do-check-act studies and the pharmacy and therapeutics committee quality improvement program in a consistent manner with information systems, the medical staff, and educational committees.^{46,47}

Prescriber Actions and Guidelines

Physician prescriptions and drug orders are a means of communicating, so they must be legible, clear, and unambiguous. The following steps help ensure that medication orders communicate safely and effectively.

- * Confirm that the patient’s weight is correct for weight-based dosages. Ensure that weight-based dose does not exceed the recommended adult dose. Ensure that calculations are correct. Write weight on each order written.
- * Include dose and volume when appropriate; specify exact dosage strength to be used.
- * Write intravenous fluid orders clearly, ensuring that additives are quantified per liter and rates are noted per hour.
- Identify patient drug allergies and inquire about any changes at each encounter. Note any old and new allergies on orders.
- Write out all instructions rather than using abbreviations except for those approved by the institution.
- Avoid vague instructions (eg, “take as directed”); make instructions specific (eg, “take 1 tablet each morning”).
- Avoid use of a terminal zero to the right of the decimal point (eg, use 5 rather than 5.0) to minimize 10-fold dosing errors.
- Use a zero to the left of a dose less than 1 (eg, use 0.1 rather than .1) to avoid 10-fold dosing errors.
- Avoid abbreviations of drug names (eg, MS may mean morphine sulfate or magnesium sulfate).
- Use generic medication names rather than trade names.
- Spell out dosage units rather than using abbreviations (eg, milligram or microgram rather than mg or μ g; units rather than U).
- Ensure that prescriptions and signatures are legible, and include prescriber’s name printed next to the signature, along with a contact number.

- Avoid use of verbal orders whenever possible. If verbal orders are to be used, spell out common error words (eg, fifteen vs fifty).
- Utilize CPOE and standardized order sets when available.^{10,19,48,49}

Prescriber Education and Communication

- * Stay current and knowledgeable concerning changes in medications and treatment of pediatric conditions.
- * Utilize pharmacist consultation if available. An example is for adjustment of dose or dosing interval for neonates or for body surface area.
- Review the patient's existing drug therapy, including any over-the-counter medications or herbal or dietary supplements, and inquire about old and new allergies before prescribing medications.
- Remain familiar with individual hospital medication ordering systems.
- Ensure that drug orders are complete, clear, unambiguous, and legible. Discuss medication changes with nursing and other appropriate staff and families.¹⁰
- When possible, speak with the patient or caregiver about the medication that is prescribed and any special precautions or observations that should be noted, such as allergic or hypersensitivity reactions. Encourage patients and families to ask questions about all medications ordered.
- Report errors and encourage blame-free error reporting. Ensure that all staff members understand the method of reporting and are knowledgeable about JCAHO reporting rules.⁷
- Be aware of ongoing tracking systems and pharmacy programs and be actively involved in system development and review.

Pharmacy Actions and Guidelines

- * Recheck calculations and ensure dose ordered falls within accepted pediatric weight-based dose ranges.
- Remain available to prescribers and nurses to participate in drug therapy development and monitoring.
- Reconfirm confusing medication orders.
- Recheck drug compatibility with existing medication list, and check for current allergy history.
- Review a copy of the original written medication order before dispensing a medication, except in emergency situations. Confirm patient identity, comparing order written to information available in the pharmacy system.
- Prepare drugs in a clean and orderly work area with minimal interruptions.
- Do not store look-alike or sound-alike medications adjacent to one another.
- Dispense medication in a timely fashion using a unit-dose, ready-to-administer form whenever possible.
- Where possible, use clinical pharmacologists to review procedures and orders.^{11,50}

Pharmacy Education and Communication

- * Develop institution-specific lists of pediatric drugs for drug-use evaluation and of high-risk drugs requiring cross-checks in concert with other hospital and medical staff.
- Provide education to patients or caregivers about their medications.
- Develop institution-specific satellite areas or personnel for consistency in handling and dispensing medications. Examples include total parenteral nutrition preparation sites, oncology satellite pharmacy, and anesthesia tray preparation and dispensing.⁵¹
- Where available, integrate clinical pharmacists into patient care rounds^{50,52,53} with physicians and nurses, particularly in intensive care and oncology units.
- Develop and implement a prospective tracking system for errors and communicate consistently with information systems, the medical staff, and educational committees.
- Encourage blame-free error reporting. Ensure that all staff members understand the method of reporting and are knowledgeable about JCAHO reporting rules.⁷

Nursing Actions and Guidelines

- * Check medication calculations with another professional member of the health care team.
- * Confirm patient identity before administration of each dose.
- Be familiar with medication ordering and dispensing systems.
- Verify drug orders before medication administration.
- Unusually large or small volumes or dosage units for a single patient dose should be verified.
- When a patient or parent or caregiver questions whether a drug should be administered, listen attentively, answer questions, and double-check the medication order.
- Remain familiar with the operation of medication administration devices and the potential for errors with such devices, particularly patient-controlled analgesia or infusion pumps.

Nursing Education and Communication

- * Develop and maintain continuous education programs for nursing competencies in devices used for pediatric medication administration, particularly patient-controlled analgesia and infusion pumps.
- * Develop and maintain pediatric medications knowledge base.
- Discuss medication orders with prescriber whenever possible.
- Integrate and provide education for patient and caregiver regarding the medication regimen.
- Record and verify patient identity, weight, allergies, and previous medication use.
- Be aware of and involved in ongoing error-tracking systems and pharmacy programs. Encourage blame-free error reporting. Ensure that all staff

members understand the method of reporting and are knowledgeable about JCAHO reporting rules.⁷

Patients and Families

- * Communicate concerns and questions related to past or present medication administration to providers, including any developmental or behavioral barriers to successful medication administration.
- Inform physicians and hospital staff of any old and new allergies.
- Inform physicians and hospital staff about prescribed or over-the-counter medications the child is taking.
- Inform physicians and hospital staff about a child's use of complementary or alternative methods of health maintenance or therapeutic treatments, including herbal or dietary supplements.
- Be responsible for knowing medication names, strengths, and dosing. Ensure that dosing intervals are followed as prescribed. Ask questions to ensure understanding of medication administration. When possible, bring all current medications to the hospital for confirmation and review.
- Ensure that patient identity has been checked before medication administration.
- Ask questions about the purpose of each medication to be used.

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