

Pediatric Pharmacy Advocacy Group - Comments on ASHP Guidelines on Providing Pediatric Pharmaceutical Services

The Pediatric Pharmacy Advocacy Group supports this guidance document with suggestions for the following modifications:

Background

General comments: This section does not adequately explain the need for this guidance. The importance of the structure of children's hospitals (e.g. standalone children's hospital vs. "hospital within a hospital") needs to be emphasized as the majority of hospitals designed to provide care for adults are struggling to provide optimal pharmaceutical care for pediatric patients. The guidance could be much stronger to support institutions that are trying to enhance their services for pediatric patients. Many institutions are unable to convince administration to support many of the services necessary, which are often standard for adults) to provide safe and effective pharmaceutical care for children. If ASHP were to put forth a statement with specific recommendations, many hospitals would be able to use it as a means of obtaining the support for personnel, systems, etc to support pediatric drug therapy.

Specific comments:

8 - **Add:** "and outcomes of these services"

8 - **Add:** "While, many children's hospitals are designed and organized to provide excellent pediatric pharmaceutical services, other organized systems may not provide pharmaceutical services to pediatric patients that measure up to adult care standards. In addition, the pediatric patient population poses a higher risk for medication errors; pediatric patients are three times more likely to suffer from a medication error. Thus, stronger vigilance in the pediatric patient population is warranted." [Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA*.2001; 285 :2114 –2120.]

10 - **Modify to include:** These challenges include..."providing pharmaceutical care to a patient population that undergoes constant changes resulting in age-related differences in pharmacokinetic and pharmacodynamic parameters,..."

General Principles

General Comments:

PPAG is contacted by many institutions attempting to justify the need for pediatric trained personnel to assist them in providing services for children. Recommendations from ASHP or PPAG that would have a significant impact on care include:

- personnel requirements (? Pediatric trained pharmacist for institutions which provide services to a certain number of pediatric beds),
- training or experience of pediatric clinical specialists (a pediatric specialist should be recommended to have formal postgraduate training or extensive work experience with the pediatric population); all personnel should complete standard competencies on an annual basis
- there is a need for schools of pharmacy to better prepare graduates in the provision of pediatric pharmaceutical care

- pharmacy system requirements,
- and the establishment of satellite vs. central pharmacy services for children.

In reality, the services provided for pediatrics vs. adults is often substandard – and should not be.

Specific Comments:

20 - **Modify:** "...direction of a competent pediatric pharmacist with adequate training to provide pharmaceutical care to pediatric patients."

28 - **update name of PPAG** from "Pediatric Pharmacy Administrative Group" to "Pediatric Pharmacy Advocacy Group"

Add: Qualifications of Pediatric Pharmacists

Add: "All personnel providing pharmaceutical care services to the pediatric population must possess the necessary education and training to fulfill their responsibilities. Recruitment and selection of personnel should be based on job-related qualifications and prior performance. Pediatric clinical pharmacists should have received postgraduate training in pediatric pharmacy practice via a pediatric specialty residency, a pharmacy practice residency with emphasis in pediatrics, or extensive working experience with the pediatric patient population."

Orientation and Training

32 - Participation in staff development programs to maintain competency should be required of all personnel." [ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals pp. 325-330]

32-35 - Orientation, training, and staff development programs for pharmacists providing services to pediatric patients should emphasize dosage calculations...**ADD** "terminology common to pediatrics, dosing by age vs. weight vs. body surface area, drug additives/preservatives which are problematic in children (which ages), appropriate references/resources for pediatric drug info, IV drug administration devices and techniques and their limitations (syringe pumps, microbore tubing, catheters, access issues in children). All personnel should complete a standard competency exam annually to be deemed competent in pediatric pharmacy practice. The assessment tool may be facility-specific or a general standardized pediatric age-related competency exam published by ASHP and/or PPAG."

Page 2

Inpatient Services

General Comments:

The practice standards for providing pharmaceutical services for pediatric patients should be the same as that of adults as outlined in the ASHP Guidelines on a Standardized Method for Pharmaceutical Care [pp. 195-7]. Principal elements of pharmaceutical care provided should include medication related, including decision making regarding the appropriateness of medications for each individual patient, care directly provided to pediatric patients with the goal of improving the individual patient's outcomes and quality of life, and accountability of the personnel providing pharmaceutical services. [ASHP Statement on Pharmaceutical Care pp. 189-191] In addition, monitoring of adverse drug

reactions and prevention of medication errors should be included in the pharmaceutical services provided. Another important aspect of medication use and administration applicable to ambulatory and hospitalized patients is minimization or prevention of pain and discomfort associated with injectable medications. The fear of receiving an injectable medication (a "shot") is often paramount on a young child's mind when seen in a clinic setting or upon hospital admission. When possible (i.e., nonemergent), the potential for this discomfort should be addressed with the patient and caregivers. Medication products (local anesthetics) are available for this use. These products should be readily available and offered to children and caregivers. Nondrug methods to reduce discomfort and anxiety may also be helpful (e.g., help of Child Life Specialist), and they should additionally be offered to children and caregivers when feasible.

Specific Comments:

5 - Perhaps include a statement recommending that, if available, commercially available products should be employed (rather than pharmacies cutting costs by attempting to compound or dilute medications . . . especially for IV agents).

Add: "If possible, 24 - hour pharmaceutical services should be provided. In the absence of a 24-hour pharmacy, a pharmacist familiar with pediatrics should be available for consultation in emergency situations." [ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals pp. 325-330]

Add: At least one clinical pharmacist should be available to make rounds with the various health care teams in any organized health-system, especially in the critical care units, or to respond to pharmacotherapeutic consultations requests, including reporting of medication errors.⁴ Completion of a pediatric specialty residency or a pharmacy practice residency with an emphasis in pediatrics is strongly recommended. Alternatively, equivalent experience in pediatric pharmacy practice should be considered for competency purposes.

Unit Dose System

It is acknowledged that providing unit dose systems to children is inherently more labor intensive and thus requires greater staffing ratios, particularly a greater technician to pharmacist ratio. As noted earlier, hospitals often have difficulty justifying their requests for pediatric personnel to administration and this document would be helpful in that regard. The standard of care delivered to children should be the same as that delivered to adults.

I.V. Admixture Service - Recommend encouraging readers to follow USP 797 guidelines, which addresses all these issues.

More specific information is requested.

- Continuous infusions – standard concentrations, prepared in pharmacy, expirations
- Large volume IVF – expirations for IVF in which pharmacy adds agents
- Double check systems in pharmacy for drugs with low therapeutic indexes?
- Quality controls – describe what types should be employed

- Batch preparation – state that even dilutions of meds should be prepared and assigned a lot #

Ambulatory Care Services

No comments

Drug Information - Suggest ASHP or PPAG write an accompanying article to recommend references at time of publication.

Page 3

2 - **Add:** "Examples of references include, but not limited to the Nelson Textbook of Pediatrics, Neonatology Pathophysiology and Management of the Newborn, the Neofax, the Pediatric Dosage Handbook, the Harriet Lane Handbook, the Teddy Bear Book: Pediatric Injectable Drugs, and Drugs in Pregnancy and Lactation."

3 - **Modify:** "**Access to** literature supporting..."

Therapeutic Drug Monitoring/Pharmacokinetic Services

A recommendation for minimal expectations for clinical services – statement assumes that these exist for all pediatric pharmacy services, however PPAG is contacted frequently regarding what our position is on this. PPAG would like ASHP to recommend that a clinical pharmacist trained in pediatrics should be employed to provide such services? At least available for consults? Attendance at pediatric codes? Perhaps refer to the general guidelines for adults [ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals pp. 325-330]. See also recommendation under "Inpatient Services."

Patient and Caregiver Education

40 - **Modify:** Every effort should be made to include the pediatric patient in the education session. Helpful tips regarding language, length of session, and overcoming barriers when communicating with children have been published. [Sleath B, Bush PJ, Prudel FG. Communicating with children about medicines: a pharmacist's perspective. Am J Health Syst Pharm. 2003;60:604-607.] Education pamphlets in the appropriate language should be provided.

Medication Errors

General Comments

Recommend referring to the ISMP guidelines for preventing medication errors in children and PPAG's Guidelines for preventing medication errors in pediatrics [J Pediatr Pharmacol Ther 2001;6:426-42]. It should be stated that these guidelines be employed by all organized health care systems.

Specific Comments

Page 4, line 5

Add: " Preferential use of preservative-free agents should be employed for infants and young children, especially during times of shortages of these products."

Adverse Drug Reactions

The statement “Pediatric patients frequently have the same adverse drug reactions that adults have . . . “ should be modified to read: "Pediatric patients may have similar types of adverse drug reactions that adults have, but these may occur at a higher frequency in pediatric patients than adults." A specific recommendation or guidance on how to monitor new agents within institutions would be helpful.

Drug-Use Evaluation

No comments

ADD:

"Formulary Considerations

Formulary recommendations/therapeutic substitution recommendations should take into consideration the pediatric patient; unilateral decisions may put pediatric patients at risk. In some instances, exceptions may be necessary for children of certain ages. Many institutions do not take these issues into consideration when P & T decisions are made. A pediatric pharmacist should sit on P&T to address needs of the population. Exceptions may need to be made for this patient population."

Research

No comments

References may need to be updated depending on whether the guidelines have been updated and republished.

PPAG Advocacy Members (2004-2005): Catherine Tom (chair), Sherry Luedtke (board liaison), Margaret Campbell, Sheryl Drawdy, Cindy Dusik, Helen Fiechtner, Larry Gatlin, Alison Grisso, Tina Hatzopoulos, Ginger Hearnburg, Shannon Holland, Kristin Klein, Kitty Kline, Cathy Leaders, Kelley Norris, Leslie Patatanian, Amy Potts, Joan Reilly, Kathleen Reilly, Cherie Robertson, Pam Smith, Tara Smith, Katie Thompson, and Ellen Worlund.

ACKNOWLEDGEMENTS: The Pediatric Pharmacy Advocacy Group would like to thank Dr. Rita Jew for her expert review and helpful suggestions.

Submitted on June 15, 2005.