TDMHSAS BEST PRACTICE GUIDELINES

Medication Safety

There are several issues surrounding medication safety for children and adolescents. One obvious issue relates to how medications, including vitamins, are stored in homes or facilities where children reside and/or visit. A less talked about, but equally important, issue is the difficulty that parents and/or other caregivers have in accurately measuring medication dosages for young children, in particular ("Errors put infants", 2011).

Storage Considerations

Often homes with young children do not do a good job of safely storing medications (Asti, Jones, & Bridge, 2012). This lack of attention to proper medication storage leaves the door open for children, especially young children, to inappropriately access medications, the result of which could be a call to the poison center, a trip to the emergency room, or worse. Baker & Mickalide (2012) say that the number of children seen in emergency departments (ED) on a daily basis can fill nearly four school buses.

- 95 percent of ED visits involving children younger than five years of age are associated with unsupervised accidental intake of medications.
- For two-year-olds, one in 150 go to the ED due to unintentional medication overdose.
- Calls to poison control centers indicate that sedatives, analgesics, and antihistamines are the primary culprits in 50 percent of all poison-related deaths among young children (Baker & Mickalide, 2012).

A group of researchers in Ohio conducted a pilot study to explore medication storage patterns and the presence of expired medications in the home using direct observation (Asti, Jones, & Bridge, 2012). Children in the homes ranged in age from two to six years. "Unsafe storage" meant that either medications were stored at less than five feet, i.e., adult "eye' level, or that when stored at less than five feet, the medications were not in a locked container/entity. This study differed from previous studies on storage patterns in that storage was directly observed in the home and not based on self report. Though the sample size was small (N = 24 families) and selected based on availability rather than using random selection, the results offer useful information on how medications in homes with children are really stored.

- Most medications tend to be stored in the kitchen, with the bathroom being the second most common storage location.
- Slightly more than 20 percent of medications were stored in an unsafe manner.

- Only seven percent of medications were stored in a locked container, a finding much lower than observed in previous research. However, the findings are based on direct observation compared to self report (Asti, Jones, & Bridge, 2012).

Storage Solutions

Store medications in locked receptacles. This is a recommendation of the American Academy of Pediatrics (AAP). Childproof caps and packages are not as effective in keeping medications out of the reach of children as locked containers. Many children can open the "childproofed" medications better than adults. Thus, "childproofed" medications still leave children at high risk of unintentional poisoning and/or death (Baker & Mickalide, 2012; Asti, Jones, & Bridge, 2012). Storing medications in locked containers will reduce that risk.

Store medications in locations that are not easily accessible by children. In this context, children include the parent's own children, children for whom a caregiver is responsible, and/or any child that is visiting the home and/or facility. Every reasonable effort should be made to store medications 'up and away', out of sight of children. The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) have several resources to assist providers, parents, caregivers, and youth in adhering to proper storage of medications.

- Tips for Safe Medicine Storage can be retrieved from http://www.upandaway.org/pdf/Travel_Tips.pdf. This is a one-page document that can serve as a reminder on appropriate medicine storage when traveling.

- Under no circumstances should you refer to medications as candy (Baker & Mickalide, 2012).

- An "Up and Away" coloring book for younger children is available through the PROTECT initiative in partnership with CDC. The coloring book can be downloaded at http://www.upandaway.org/pdf/Up_and_Away_Downloadable_Coloring_Pages_508.pdf.

Older youth, parents, caregivers, providers, or anyone serious about medication safety for children should take the following pledge.

- **I pledge to:**

    - Pick a place high up and out of sight that my child cannot reach where I can safely store my medicines and vitamins.
    - Always put every medicine and vitamin away every time I use it, including those I use every day.
    - Always re-lock the safety cap on a medicine bottle.
    - If the medicine has a locking cap that turns, I will twist it until I hear the click.
    - Teach my children about medicine safety.
    - Tell guests, friends and family about medicine safety and ask when they visit my home to keep their medicines up and away and out of sight.
    - Program my Poison Help center's number in my phone: 800.222.1222 (upandaway.org, 2012).

- Two online videos are available through the FDA at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm204457.htm. The videos are titled "Medicines in My Home: The Over-the-Counter Drug Facts Label" and "Lock It Up: Medicine Safety in Your Home".

Expiration Considerations

Keeping medicines longer than their expiration date also lead to bad outcomes for children and adolescents. Research has shown that many homes where children reside and/or visit keep at least one medication that has reached its expiration date. Medications with expired dates tend to lose their potency and may cause harm due to a breakdown of the chemicals. Actually, without laboratory test, the extent of deterioration in expired medications is unknown.

The pilot research study of researchers from Ohio showed the following about expired medications as found in observed homes:

- Close to 30 percent of all medications—prescription and over-the-counter (OTC)—were past their expiration date.
- On average, there were nine expired medications per home.
- One "outlier" home had 31 expired medications (Asti, Jones, & Bridge, 2012).

Expiration Date Solution

Dispose of medications that are no longer needed and/or have not been used (Asti, Jones, & Bridge, 2012). Medications that have past their expiration date meet these criteria. If the child or adolescent takes expired medication, he/she may not be receiving the required dosage, which sometimes can be as harmful as receiving too much medication. It is also possible that the chemical structure of the expired medication has changed, which would make it extremely difficult to assess its interaction with other medicines or foods.

Dosing Considerations

Lack of parent/caregiver knowledge about selecting and dispensing medications for young people, especially those under five years of age, has been identified as a potential medication safety hazard. Researchers in Australia found that dosing errors and inappropriate use of medicines, including OTC medications, led to a dramatic upswing in the number of calls to poison centers and visits to emergency rooms involving youth. Doses for children are typically small so the risk of making an error in measurement is greatly increased. In 2008, 48 percent of more than 100,000 calls to poison centers were concerned with accidental overdoses in children. Fifteen percent of those children had to be hospitalized. More than 85 percent of the calls involved children younger than five years of age, with nearly 80 percent of the incidents involving children younger than three years old ("Widespread parental misuse", 2010).

It is especially important that parents and/or caregivers that give young children prescription painkillers take extra care in making sure they give just the right dose. There is some concern that, without taking into consideration the age, gender, and weight of the child, the pharmacy dosage could be too high. University of South Carolina researchers found evidence of an overdose amount, with greater incidence of overdose amounts for the younger children ("Errors put infants", 2011).

Dosage Solution

Domestic spoons should never be used to dispense medications to children. There are significant differences in the capacity of spoons, with some holding up to three times as much as others. This differential in capacity could result in too little or too much medication for the child (Falagas, Vouloumanou, Plessa, Peppas, & Rafailidis, 2010;"Using domestic spoons", 2010).

Providers should strive for accurate prescribing and pharmacists should aim for accurate dispensing. Prescribers must consider factors such as body-weight, body-surface, gender, age of the child, or some combination when preparing the prescription. Pharmacists should ensure that the prescription is appropriately and accurately filled. To accomplish this, contact with the prescriber may be necessary ("Errors put infants", 2011).

How Psychiatric Medications Are Determined as Safe for Use with Children and Adolescents

Until recently, most psychotropic medications prescribed for youth were "off label". This means that the appropriate scientific studies have not yet been conducted with children and adolescents. Off-labeling, however, is typical and consistent with general clinical practice involving pediatric populations (APA & AACAP, n.d.). Dr. Phillip Janicak (2007) says that the lack of regulation essentially mandates that clinicians should follow a consistent standard of care. His recommendations for a standard of care for off-label prescribing include:

- Tell the patient or his/her representatives why the off-label medication is their best option BEFORE prescribing it.
- Inform the patient and/or his/her representatives about other treatment options, and do NOT proceed with off-label prescribing until you have the consent of the patient or his/her representatives.
- Document the process and note that a discussion has taken place with the patient and/or his/her representatives regarding the off-label prescribing.
- Stay vigilant for any unexpected adverse events, particularly in the early stages of treatment (Janicak, 2007).

The U.S. Food and Drug Administration (FDA) currently requires that researchers include young people in studies for approval of medications for their population (APA&AACAP, n.d.; healthyplace.com, 2001). The process often begins when psychiatrists describe their successes in single cases. If the outcome is positive, the next step is the ***gold standard***, a double blind, placebo controlled study. In this design, neither physicians nor patients know if the patient is receiving the active medication or a placebo (a look-alike for the drug under study). The final test is to be able to repeat the double blind study in other settings and to obtain similar positive outcomes (Klee, 2001).

The FDA's role is to determine whether research sponsored by pharmaceutical companies indicates that a medication is safe and effective for the indications in which it has been studied. The agency has the additional responsibility of ensuring that information on the approved product labeling is accurate. As a result, the FDA limits the manufacturer's marketing to the information contained in the approved labeling. ***The FDA does not, however, limit the manner in which psychiatrists and other prescribing professionals prescribe an approved drug***. Prescribing professionals should continue to use the available evidence, expert opinion, and their own clinical experience in decisions related to what is the best medication for each individual patient (Texas Department of Family and Protective Services and the University of Texas at Austin College of Pharmacy, 2010).

"Black Box" Warnings

The FDA required makers of all antidepressant medications to update the existing warning on the product labeling for antidepressants and include additional warnings about increased risks of suicidal behavior and thinking in young adults (ages 18-24) during initial treatment. Initial treatment was defined as the first one to two months (FDA, 2007a).

Moreover, the FDA (2007b) revised its Medication Guide that deals with the risk of suicidal actions and thoughts in antidepressant medicines. The Guide was designed to answer the question: What is the most important information to know about antidepressant medicines, depression and/or other serious mental illnesses, and suicidal actions or thoughts? **First and foremost**, though, the Guide tells the reader to talk to his/her or a family member's healthcare provider.

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