



# Preventing Home Medication Administration Errors

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Medication administration errors that take place in the home are common, especially when liquid preparations are used and complex medication schedules with multiple medications are involved; children with chronic conditions are disproportionately affected. Parents and other caregivers with low health literacy and/or limited English proficiency are at higher risk for making errors in administering medications to children in their care. Recommended strategies to reduce home medication errors relate to provider prescribing practices; health literacy–informed verbal counseling strategies (eg, teachback and showback) and written patient education materials (eg, pictographic information) for patients and/or caregivers across settings (inpatient, outpatient, emergency care, pharmacy); dosing-tool provision for liquid medication measurement; review of medication lists with patients and/or caregivers (medication reconciliation) that includes prescription and over-the-counter medications, as well as vitamins and supplements; leveraging the medical home; engaging adolescents and their adult caregivers; training of providers; safe disposal of medications; regulations related to medication dosing tools, labeling, packaging, and informational materials; use of electronic health records and other technologies; and research to identify novel ways to support safe home medication administration.

## BACKGROUND

Errors in pediatric medication administration in the home environment are common<sup>1–3</sup> and can result in serious consequences.<sup>4–6</sup> These errors include dosing mistakes (both underdosing and overdosing), errors in frequency or duration of dosing (including missed doses), administration of incorrect medications or formulations, wrong route of administration, incorrect preparation or storage, and use of expired medications.<sup>2–4,7–9</sup> Many root causes have been identified that may contribute to errors,

## abstract

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including provider prescribing practices,<sup>10-12</sup> pharmacy dispensing practices,<sup>6,13</sup> confusing measurement units and dosing tools for liquid medications,<sup>14-19</sup> involvement of more than one caregiver,<sup>5,9</sup> and health literacy and language barriers.<sup>17,20-24</sup> This policy statement reviews this information and recommends strategies to reduce the incidence of pediatric medication administration errors at home, including those involving prescription and over-the-counter (OTC) medications, as well as vitamins and supplements.

### STATEMENT OF PROBLEM

More than half of children in the United States take 1 medication or more each week,<sup>25</sup> and caregivers commonly make errors in administering medications to children.<sup>2,3,19,26</sup> One study showed that nearly half of caregivers gave a dose of medication that deviated more than 20% from what was prescribed after their child was discharged from the emergency department of a public hospital; 1 in 4 caregivers gave a dose that deviated by more than 40%.<sup>3</sup> A second study in a similar setting found comparable rates.<sup>19</sup> In another study, more than half of caregivers gave doses of OTC medications outside of the recommended range for their child.<sup>26</sup> Although for the majority of commonly used medications, a single dosing error is unlikely to cause a clinically significant injury, persistent errors across multiple doses raise concerns for harm. OTC medications as well as vitamins and supplements are widely used and are perceived to be safe by many caregivers<sup>25,27-32</sup> but may cause serious harm when used incorrectly.<sup>5,33-36</sup> Regimen-related factors, involving multiple medications<sup>37-39</sup> or requirements for more frequent administration (eg, 3 times a day instead of 1 time

a day), are associated with more errors.<sup>40,41</sup> Regimens in which acetaminophen and ibuprofen are given continuously in an alternating fashion are also difficult to follow and prone to error,<sup>42-44</sup> unless explicit instructions and/or charts are clearly provided to support understanding. Other regimen-related factors that place children at risk for errors include scenarios involving liquid medications or other special preparations (eg, granules that need to be mixed with food),<sup>1,45</sup> situations in which a combination of single and multiple ingredient prescription and OTC medications are given (in which confusion between generic and brand names may result in families being unaware that a child is being given medications with overlapping active ingredients),<sup>22,46,47</sup> when medications are available in more than one concentration and/or formulation,<sup>22,48,49</sup> or when medications with narrow therapeutic windows are involved.<sup>50-52</sup> Home medication errors are of particular concern in the management of children with chronic conditions and special needs, such as cancer, sickle cell disease, epilepsy, and autism, as these children are often prescribed multiple medications or medications that have complex administration instructions, and there is an increased potential for harm when errors occur.<sup>9,53-58</sup> Medication administration in pediatrics is also challenging as more than one caregiver may be involved in the care of a child and more than one child in a family may be taking medications.<sup>9,59</sup> Confusion about whether a medication has already been given can lead to double dosing or missed doses of medicines; miscommunication between caregivers has contributed to cases of significant pediatric morbidity.<sup>5</sup> Adolescents with less caregiver supervision may also have

more frequent home medication errors, particularly when their prescriptions are for conditions treated confidentially, without caregiver knowledge, such as sexually transmitted infections.<sup>59-63</sup> In the outpatient pediatric setting, medication administration errors are believed to account for the majority of preventable pediatric adverse drug events.<sup>37,64</sup>

### IMPACT OF HEALTH CARE PROVIDER PRESCRIBING AND PHARMACY DISPENSING PRACTICES

Health care provider prescribing practices contribute to medication errors; providers can prescribe in ways that can make medication administration by caregivers and patients easier or more complex. Missing or unclear information (eg, related to route, frequency, duration, indication) can affect the understandability of medication instructions.<sup>10,65</sup> In addition, providers may not follow safe prescribing practices recommended by The Joint Commission, resulting in caregiver confusion; The Joint Commission standards apply to both inpatient and outpatient settings and recommend inclusion of leading zeros (eg, 0.X), avoidance of trailing zeros (eg, X.0), and avoidance of confusing abbreviations that may not be familiar to families, such as U (unit) and QD (daily), when prescriptions are ordered.<sup>66</sup> Because pediatric providers often rely on weight-based dosing and may prescribe in milligrams (mg), which may lead to complex dose amounts (eg, 4.8 mL) prescribed when milligrams are converted to milliliters, rather than simpler and easier-to-measure doses rounded to a whole number (eg, 5 mL).<sup>67,68</sup> Pediatric providers may also use multiple units of measurement in their instructions<sup>18,19</sup> and may believe that caregivers are more comfortable with instructions using teaspoon or tablespoon terms.<sup>69</sup>

Limitations in the functionality of electronic health record (EHR) systems may further contribute to these issues by not allowing rounding or by defaulting to instructions that use multiple units.<sup>67,70,71</sup> Providers who have not performed a thorough medication review or reconciliation process may also not be aware of all the medications a child is taking and whether caregivers are administering medications correctly, including avoiding giving medications that interact; the medical home model seeks to prevent this by having a coordinating health care provider with oversight over all medications for an individual patient.<sup>72</sup> Providers can simplify medication regimens by avoiding prescribing medications that are not essential as well as deprescribing, or discontinuing, unnecessary medications.<sup>73</sup>

Pharmacist dispensing practices may also contribute to incorrect medication administration, because dispensing practices can affect the clarity of instructions given to caregivers.<sup>6,13</sup> Several studies have shown that units of measurement included on prescriptions were frequently changed in the pharmacy setting (eg, one unit switched to another unit or additional unit of measure added), which can become a source of caregiver confusion, particularly if the units used as part of instructions are different from the units mentioned during medication counseling in the clinical setting.<sup>18,19</sup> State pharmacy regulations also allow pharmacists to fill a prescription using a different strength and/or concentration of medication than prescribed, as long as the dose in milligrams is equivalent; if pharmacists do not inform caregivers of this change, this practice can contribute to confusion.<sup>13,74</sup> Like providers,

pharmacists also can alter the display of doses involving decimals.<sup>13,75</sup> Pharmacy dispensing errors have contributed to cases of significant pediatric morbidity (eg, related to changing units of measurement).<sup>6,13</sup> Use of pharmacy software to support safe pharmacist dispensing practices and use of a universal formulary that limits the number of medication concentrations available (including for medications requiring compounding) have been suggested as ways to decrease the potential for pharmacist dispensing error as well as caregiver administration error.<sup>13,76</sup> The US Food and Drug Administration (FDA)-funded Standardize 4 Safety initiative, led by the American Society of Health-System Pharmacists, seeks to create national standards around medication concentrations for intravenous and oral medications to reduce the risk of medication errors.<sup>76</sup>

#### **ROLE OF HEALTH LITERACY AND LIMITED ENGLISH PROFICIENCY**

For caregivers, the task of understanding how to correctly administer medications to children may be challenging from a health-literacy perspective, and advanced health-literacy skills may be required to manage complex medication regimens. Health literacy refers to an individual's ability to read, understand, and process health information for informed decision-making regarding health issues and includes the ability to navigate the health care system.<sup>77,78</sup> Nearly 30% of parents in the United States, or approximately 21 million US parents, have low health literacy,<sup>79</sup> placing them at increased risk of making medication administration errors.<sup>17,41,79,80</sup> Notably, only 15% of parents are considered to have proficient levels of health literacy, indicating that the majority of caregivers struggle with some

health-literacy challenges.<sup>79</sup> Caregivers with low health literacy have greater difficulty understanding prescription and OTC labels and are more likely to use nonstandard kitchen spoons, to misunderstand active ingredient information, and to be unaware of weight-based dosing.<sup>23,47,79-84</sup> Among caregivers, limited health literacy has been linked to an increased odds of liquid medication dosing errors by 1.5-fold to 2.5-fold.<sup>17,24,82,83</sup>

Approximately 12% of US adults have limited English proficiency.<sup>85,86</sup> Patients with limited English proficiency are at increased risk for misunderstanding instructions and making errors, especially when the information provided is not in the language of their preference and the quality of translated instructions is poor.<sup>21,37,86-91</sup> Cultural factors may also affect adherence to medication regimens<sup>22,92,93</sup>; assessing culturally based health beliefs related to medication use can help providers understand issues that may have significant implications for how caregivers or patients understand and will act on the instructions provided. Provision of instructions in the caregiver's and/or patient's native or preferred language is considered to be an essential first step to achieving understanding of medication instructions; use of trained interpreters and certified translation experts is necessary to facilitate high-quality translation and interpretation.<sup>94,95</sup> Suboptimal access to high-quality medical interpretation and pharmacy label translations is common and can have important clinical consequences.<sup>88,96-98</sup> Notably, those with limited English proficiency are disproportionately affected by low health literacy.<sup>24</sup> Compared with those with low health literacy or limited English proficiency alone, caregivers with both low health literacy and limited English

proficiency are at even greater risk of medication errors.<sup>24</sup>

### **CHALLENGES FOR EFFECTIVE PROVIDER-PATIENT AND CAREGIVER COMMUNICATION IN CLINICAL AND PHARMACY SETTINGS**

Communication obstacles in the clinical setting can be challenging for caregivers and patients regardless of literacy level and English proficiency, but these issues are especially difficult for those with low health literacy and limited English proficiency.<sup>20,77,79,87,99–101</sup> Provider counseling may be incomplete, leaving out key information, such as indication, dose, route, frequency, and duration, or may not address side effects or drug interactions.<sup>102,103</sup> Provider counseling may also not be explicit enough (eg, medication instructions say to give “twice a day” instead of “in the morning” and “in the afternoon”) or may not be accurate (eg, “give every 8 hours” leads to the impression that a child would need to be woken up from sleep when this may not be true)<sup>13,22</sup>; it is best if these more explicit instructions are verbally presented to families by the provider and conveyed to the pharmacist for inclusion on the prescription. Use of a Universal Medication Schedule (UMS) approach, in which frequency information is presented by using 4 specific times of day (eg, “morning,” “noon,” “evening,” and “bedtime” instead of as number of times per day) has been associated with improved patient understanding of medication instructions.<sup>104,105</sup> Lack of explicit provider counseling regarding route of administration may lead to medications inadvertently being put in the wrong location (eg, oral antibiotic for an ear infection placed in the ear canal instead of in the mouth), resulting in treatment failure.<sup>2,22</sup>

Confusion may also result from the language used on the prescription (eg, for the instruction “once a day,” Spanish-speaking families may misinterpret “once” to be “11,” resulting in a serious overdose).<sup>77,106</sup> EHRs could be leveraged to facilitate provision of complete instructions (eg, hard stops unless information on dose, frequency, route, and duration are included) and can support provision of explicit standard dosing intervals (eg, Universal Medication Schedule [UMS] approach) as well as appropriate language translations.<sup>104,107</sup>

The majority of pediatric providers do not routinely use health literacy-informed “advanced counseling” strategies,<sup>108,109</sup> such as demonstration, drawings/pictures, or teachback/showback, even though use of these strategies has been associated with reduced caregiver dosing errors and improved understanding of medication instructions,<sup>3,109,110</sup> with benefits observed for families across literacy levels.<sup>111</sup> For patients who are being discharged from the hospital with complex medication regimens, emphasis on demonstration and showback, as part of a rooming-in process, may be beneficial for a safe transition to home.<sup>112</sup> Use of simulation may also be helpful for caregivers and providers to learn important aspects of medication administration and effective counseling strategies, respectively.<sup>113–115</sup>

Although use of written information as part of counseling has been found to be beneficial in reducing cognitive load,<sup>116,117</sup> health care providers often do not use written information to supplement provider verbal medication counseling.<sup>108,118</sup> Plain-language written instructions can give clinicians a framework for low-literacy counseling, helping to

provide an easy-to-understand “script,” as well as ensuring that key concepts are covered; optimally, these patient- and regimen-specific instructions would be given to families to take home and share with other caregivers.<sup>3,119</sup> Provision of a pictographic dosing diagram as part of written instructions, which visually illustrates the amount of medication to provide within a recommended dosing tool, has been found to be a promising strategy to enhance caregiver understanding of the appropriate dose, with benefits observed across health-literacy levels<sup>82,120</sup>; in 1 study, researchers found a more than fivefold reduction in dosing errors with prescribed daily dose medications with the use of a pictographic medication instruction sheet-based intervention to supplement provider verbal counseling.<sup>3</sup> Use of the intervention, which included a pictographic printed log to help caregivers track medication use, was also associated with an increased likelihood of families completing  $\geq 80\%$  of the recommended medication course.<sup>3</sup> Technological advances represent a promising avenue for promoting provider adoption of such tools.<sup>67,121,122</sup> For example, incorporation of tools into the EHR workflow could allow providers to quickly generate pictographic patient- and medication-specific low-literacy instruction sheets at the point of prescribing. Providing families with a printout of the after-visit summary allows them to have a tangible resource to refer to when they have questions about how to take medications at home; families may not be able to access this information online from home.

There are many ways EHRs could support the provision of tailored written medication instructions for pediatric patients.<sup>67,122</sup> For example, a typical precaution for a

drug that causes sedation is “do not drive a car or operate heavy machinery,” which might be disregarded by a caregiver of a young child who would then overlook the potential risk of sedation. EHRs could automatically adjust messaging based on the age of the patient; for example, a child-focused precaution for a drug that causes sedation could be “watch your child when he or she is riding a bike, climbing stairs, or doing other activities where being awake and alert is important.” In addition, EHRs could provide pediatric-centric information about the frequency or severity of adverse reactions in children because this information may differ from information targeted for adult patients.

Use of other visual modalities, as well as online and mobile technology resources, can also help support safe medication administration. Linkages to online pediatric information, as well as apps,<sup>123</sup> could be made more easily accessible to families seen in health care settings. Videos can also help support adherence to medication instructions.<sup>123</sup> Use of text messaging could also be leveraged to support caregivers in administering medications to children,<sup>124,125</sup> but text messaging of protected health information must comply with the Health Insurance Portability and Accountability Act of 1996.<sup>126,127</sup>

Because all patients and families benefit from simple, clear instructions, a “universal precautions” communications approach is generally recommended.<sup>100,101,128,129</sup> There is growing acceptance of the concept that health literacy is a fluid state that can be affected by stress, anxiety, and context, rather than a fixed trait.<sup>77,129,130</sup> It is, therefore, best to use health literacy-informed communication with all individuals.

In the pharmacy setting, caregivers often do not receive or opt out of verbal counseling from staff.<sup>131</sup>

Prescription bottle labels may not be designed in a patient-centered manner<sup>132–134</sup> and may not incorporate health-literacy principles. For example, although prescription labels that include a pictographic dosing diagram have been found to be beneficial, especially for reducing large dosing errors (in 1 study, researchers found a twofold decreased odds of error with the use of text-plus-pictographic dosing instructions compared with text-only instruction<sup>82</sup>), use of pictographic diagrams on medication labels has not been adopted as part of standard care. Finally, written materials provided to families at the time of medication dispensing are often written at a ninth-grade reading level or higher<sup>16,135,136</sup>; experts recommend a sixth- to eighth- grade reading level for the average person and a fifth-grade level or below for people with low literacy.<sup>137–139</sup>

Empowering families during clinical and pharmacy encounters can help reduce the risk of home medication errors.<sup>140–144</sup> Health care providers, including pharmacists, can encourage caregivers to ask questions when they are unsure of how to give medications at home by increasing awareness that caregiver difficulty with administering medications is common and that questions are expected (eg, “It is common for caregivers to have questions about how to give these medications. What questions do you have for me?”).<sup>142,145–147</sup> Caregiver awareness that both prescribers and pharmacists are responsible for providing information on how to administer medications safely to their child may prompt them to ask questions when they are confused.<sup>142</sup>

## ROLE OF LIQUID FORMULATIONS IN HOME MEDICATION ERRORS IN CHILDREN

Liquid formulations of medications, on which pediatric providers rely, especially for young children and children who have feeding tubes,<sup>13,148,149</sup> are involved in more than 80% of pediatric home medication errors.<sup>1</sup> For children with feeding tubes, care is further complicated by the need to give a water flush after medication dosing to facilitate removal of any remaining medication in the tube.<sup>148</sup> Compared with tablets and capsules, liquid medications may be more complex to administer<sup>1,150</sup>; in certain contexts, switching from liquid to tablets or chewable formulation may simplify therapeutic regimens and promote adherence.<sup>151,152</sup> Dosing errors are easier to make with liquid formulations compared with solid-form medications, with confusion related to the measurement of liquids resulting in wide variation in dosing, ranging from large multifold overdoses to significant underdosing.<sup>13,19,83</sup> Overdosing medications is problematic given concerns related to drug toxicity and side effects, but underdosing can also have serious implications, including lack of therapeutic effect and symptom relief as well as potential contributions to antibiotic drug resistance.<sup>2,4,8,80,83,153,154</sup>

Many caregivers are unaware that use of nonstandard kitchen spoons for dose measurement should be avoided because kitchen spoons vary widely in size and shape.<sup>14,23,155,156</sup> Caregiver use of kitchen spoons is associated with higher rates of dosing errors<sup>50,155,157,158</sup>; although a teaspoon is considered to be equivalent to 5 mL, kitchen teaspoons have been found to measure between 2 and 9 mL.<sup>159</sup> The American Academy of Pediatrics

(AAP) has long recommended that liquid medications be measured using standard dosing tools.<sup>14,160</sup> A wide range of tools with standard measurement markings are available, including oral syringes, cups, dosing spoons, droppers, and measuring spoons<sup>17</sup>; these standard tools have calibrated markings that can be used to help caregivers measure doses accurately.<sup>156,158,160</sup> The FDA has recommended inclusion of a dosing tool with standard measurement markings (also called a standard dosing tool) for all OTC liquid medications.<sup>161–163</sup> Despite these recommendations, it is not standard practice for dosing tools to be provided in the clinical or pharmacy setting.<sup>3,109,164</sup> Use of health literacy–informed advanced counseling strategies (such as teachback, showback, and demonstration) has been found to be especially effective when conducted in conjunction with provision of a standard dosing tool.<sup>109</sup>

With prescription and OTC products, it is recommended that only the tool provided with the medication be used for administering that medication<sup>15,162,165</sup>; caregivers can be counseled to ask for a dosing tool at the time of medication purchase if they are not given one.<sup>166</sup> Colocation of dosing tools with their associated medications and storing the tool with the medication up, away, and out of sight of children can promote caregiver use of the correct tool and prevent unintentional medication ingestions.<sup>166–169</sup> The quality of dosing tool used has implications for correct medication measurement; some dosing tools that are designed for single or limited use have markings that rub off. Repeated use of such tools can result in hard-to-read markings that make it difficult for caregivers and/or patients to determine the right level to which to fill the tool; the US Pharmacopeia

recommends the use of dosing tools with indelible markings.<sup>170</sup>

Caregivers vary in their ability to dose accurately with different types of standard dosing tools.<sup>17,82,83,171,172</sup> Dosing cups may be especially difficult to measure with; caregivers may confuse the entire cup as the dose, may not place the cup on a level surface when measuring, or may not look at the markings at eye level; markings on devices may also not be printed clearly (eg, etched versus printed).<sup>17,166,173</sup> Dosing cups have been associated with a more than threefold increased odds of error compared with oral syringes,<sup>17,80,83</sup> and the potential for multifold errors with cups is especially high with small-dose volumes.<sup>80,82,83</sup> Oral syringes are typically preferred by health care providers for increased accuracy in dose measurement and are generally recommended when dosing accuracy is essential<sup>14,83</sup>; this is especially important with medications that have a narrow therapeutic window.<sup>50,83</sup> Oral syringes are typically recommended for administering medication to young children, especially when small doses are involved.<sup>83</sup> To determine the optimal dosing tool to give to families, it is also important for providers to consider the relationship between the size of the dosing tool and the prescribed dose amount.<sup>80,82,83</sup> Dispensing a tool that is too large for a dose (eg, a 10-mL syringe for a 1-mL dose) increases the risk of multifold errors because there is a large amount of extra space that can be filled, resulting in overdosing.<sup>82,173</sup> Dispensing a tool that is too small for a dose (eg, 5-mL syringe for a 7.5-mL dose) results in the need to fill a tool multiple times, requiring the use of numeracy skills (eg,  $5 + 2.5 = 7.5$  mL).<sup>16,82,120</sup> Dosing cups may be adequate for larger doses (eg, >10 mL), particularly for lower-risk medications with wide therapeutic margins.<sup>82</sup> With the growing use of

electronic prescribing,<sup>174,175</sup> information on optimal dosing tools for prescribed medications could be automatically generated at the point of prescribing in the EHR or at the point of dispensing within pharmacy software systems, providing information to clinicians and pharmacists about which tool is best to use based on the recommended dose amount.

Confusion about units of measurement also contributes to dosing errors with liquid medicines.<sup>13–15,19,81,176</sup> A variety of terms, such as milliliter, teaspoon, and tablespoon, and their associated abbreviations (mL, tsp, TBSP, respectively) may be used interchangeably as part of verbal and written communication of dosing instructions and associated dosing tools; milligram (mg) may also be used.<sup>13,15,18,19,177</sup> Variability in the use of units is common; in 1 study, researchers found that in more than one-third of cases, medication bottle labels did not contain the same units found on the prescription,<sup>19</sup> and in another study, researchers found that labels and associated dosing tools included with top-selling OTC liquid medications frequently did not use consistent text for unit terms.<sup>15</sup> Confusion between volumetric unit terms increases the risk of multifold errors by caregivers and providers (eg, teaspoon confused for milliliter can lead to a fivefold under or overdose)<sup>13</sup>; confusion between volumetric and nonvolumetric terms (eg, milliliter and milligram) can also lead to confusion.<sup>18,177</sup> Spoon-based terms inadvertently endorse the use of nonstandard dosing tools; in 1 study, caregivers had a fourfold increased odds of choosing a kitchen spoon (ie, kitchen teaspoon or tablespoon) when teaspoon units were present on the medication label.<sup>81</sup> Dosing in milliliters has been associated with fewer

caregiver errors compared with dosing using spoon-based terms.<sup>82,83</sup> Concerns about unit-of-measurement-related errors has led the Centers for Disease Control and Prevention, via its PROTECT (Prevention of Overdoses and Treatment Errors in Children Taskforce) Initiative, to recommend milliliter-only dosing and elimination of spoon-based terms.<sup>178</sup> As a member of this initiative, the AAP has endorsed milliliter-only dosing, joining groups such as the American Academy of Family Physicians, American Pharmacists Association, American Association of Poison Control Centers, US Pharmacopeia, the Institute for Safe Medication Practices, and the Pediatric Pharmacy Advocacy Group.<sup>13,14,179–181</sup> Although people with low health literacy may especially benefit from a simpler, milliliter-only dosing system, those with low health literacy are more likely to prefer teaspoon units and perceive that a move to a milliliter-only unit system will be difficult.<sup>182</sup> EHR systems can be leveraged to support milliliter-only dosing (eg, limiting unit choices and defaulting to milliliter-only dosing).<sup>14,69</sup>

## OTC MEDICATIONS

Caregivers and patients often do not receive guidance from health care providers on the use of OTC products<sup>20</sup>; they may not be aware that pharmacists are trained to counsel families about how to select and use OTC products and are available for consultation.<sup>183</sup> Caregivers and patients, therefore, often rely on their own health-literacy skills or those of family members to determine which medications to purchase and how to appropriately administer them.<sup>20,84</sup> Nearly 60% of US caregivers report difficulty understanding OTC labels, with 1 in 3 reporting “great” or “moderate” difficulty.<sup>79</sup> Many caregivers struggle to appropriately

select medications, including distinguishing between different formulations or strengths, and recognizing that 2 or more medications with the same active ingredient should not be given at the same time (to avoid double dosing).<sup>4,7,47,184</sup> Caregivers also struggle to navigate dosing charts to determine the correct amount of medication to give to their child and fail to recognize that dosing should generally be based on child weight rather than age.<sup>23,26,185</sup> This issue may be especially confusing for caregivers of children who are overweight or obese.<sup>186,187</sup> In addition, caregivers may confuse the child’s weight in kilograms versus pounds; consistent provider use and communication of weight in kilograms could reduce inadvertent caregiver dosing errors.<sup>187,188</sup> Dosing charts also may not include dosing information for the youngest children; for example, for children younger than 2 years, the dosing chart for acetaminophen states “ask your doctor,”<sup>189,190</sup> contributing to caregiver confusion.

Caregivers are frequently confused about how to correctly administer OTC cough/cold products.<sup>84,191,192</sup> Several issues have been specifically identified that contribute to caregiver errors with OTC cough/cold products, including confusion with age restriction information, difficulty recognizing that some cough cold medications contain multiple active ingredients (and may include an antipyretic), and confusion interpreting dosing charts.<sup>47,192,193</sup>

In 2008, the FDA, spurred by cases of fatalities in young children, several of which involved home administration errors by caregivers,<sup>194–196</sup> issued a public health advisory recommending that cough/cold products not be used in children younger than 2 years<sup>191</sup>; this recommendation was later

voluntarily extended to children 4 years and younger by manufacturers of OTC cough/cold products.<sup>197</sup> Although rates of adverse events related to cough/cold medication in children have decreased after these efforts, caregivers of young children continue to use these products.<sup>8,28,192</sup>

## MEDICATION RECONCILIATION AND THE MEDICAL HOME

Because children are often taking a combination of medications, which may include both single and multi-ingredient prescription and OTC products, as well as vitamins and other supplements, a medication reconciliation process is recommended at all relevant clinical encounters, such as when a new provider is taking over the care of a patient, when there has been a long gap between clinical encounters, or when a new medication is being prescribed.<sup>198–201</sup> Caregivers may not realize that 2 medications interact or may not realize that 2 medications their child is taking contain the same active ingredients, leading to a multifold overdose.<sup>28,47</sup> For children with special health care needs, in particular, having a medical home with a primary care provider responsible for coordinating care among all providers is helpful for promoting a safe home medication-use environment.<sup>72</sup>

Review of each medication a patient is taking (to determine if the medication is being administered correctly, if the medication is still necessary, and if the administration instructions need to be updated [eg, dose adjusted to account for weight gain]) is considered an important safety practice.<sup>100,101,202</sup> EHRs could be used to generate medication lists for families to review and bring to provider visits to support the medication reconciliation process.<sup>199,203</sup> Encouraging

caregivers to bring in medications to provider visits and describe how medications are being administered can also be helpful in identifying potential errors in medication use.<sup>100,101,198</sup>

## MEDICATION DISPOSAL

Caregivers often keep medications in their homes even after medications are expired or are no longer in use.<sup>204,205</sup> Having medications in the home that are no longer in use may increase the likelihood that these medications will be confused with medications in use and may lead to inadvertent administration of the wrong medication to the child that the medication was intended for or another person in the home<sup>206</sup>; with unused opioids in the home, there are also concerns about the abuse and diversion potential for adolescents and other adults in the home.<sup>207</sup> Saving leftover medicine prescribed for an acute illness for a later illness episode may lead to ineffective treatment of a child's illness because there may not be sufficient medication remaining to properly treat a subsequent illness and medication potency may be reduced for expired medications.<sup>206,208</sup>

Recommendations exist about how to safely dispose of medications.<sup>209,210</sup> Recent federal guidelines state that prescription or OTC medications are not to be flushed down the toilet or poured down a sink unless patient information material specifically states that it is safe to do so. If no disposal instructions are given as part of the medication labeling information, FDA guidelines recommend the following actions:

- Taking advantage of programs that allow the public to take unused drugs to a central location for proper disposal. Local law enforcement agencies may

sponsor medicine take-back programs. City or county government household trash and recycling services may also have specific medication disposal options and guidelines.

- Transferring unused medicines to collectors registered with the Drug Enforcement Administration (DEA). The DEA website has information on how to find an authorized collector ([http://www.deadiversion.usdoj.gov/drug\\_disposal/index.html](http://www.deadiversion.usdoj.gov/drug_disposal/index.html)).<sup>211</sup>

Pharmacies may also have drug disposal kits available for safe medication disposal in the trash or drop-off kiosks where families can dispose of unused medications.<sup>210</sup>

If there are no disposal instructions given on the drug label and no take-back program or disposal kits are available, medications can be thrown out in the household trash. Before throwing out medications, removal of medications from their original containers and mixing them with an undesirable substance, such as used coffee grounds, dirt, or kitty litter, is recommended (this makes the drug less appealing to children and pets and unrecognizable to people who may intentionally go through the trash seeking drugs).<sup>210</sup> Placement of the mixture in a sealable bag, empty can, or other container will prevent the drug from leaking or breaking out of a garbage bag.<sup>209</sup>

## RECOMMENDATIONS

The following actions can reduce home medication administration errors:

1. Improve communication to caregivers and patients (Table 1):
  - Make medication regimens as simple as possible (eg, avoid prescribing unnecessary medications, reduce number of medications prescribed, discontinue

medications when possible, reduce administration frequency, and avoid unnecessary multiingredient combination products).

- Use appropriate dosing units (eg, use mL-only and avoid spoon-based or nonmetric units; avoid nonvolumetric units [eg, mg] in describing the dose amount).
- Use only kilograms (kg) for child weight to reduce inadvertent mix-ups (with pounds) and potential for error.
- Learn and use health literacy-informed verbal counseling strategies (eg, plain language, pictures/drawings, and teachback/showback) for use in clinical and pharmacy settings, including as part of hospital discharge.
- Provide verbal counseling in the language of caregiver/patient preference, using a trained interpreter if the provider does not have fluency in the patient's preferred language.
- Provide written patient education materials on medication use appropriate for the literacy level and languages spoken by patients and caregivers.
- Provide a printout of the after-visit summary for families to take home and refer to for information about their medication instructions.
- Make an extra effort to verify caregiver/patient understanding in cases involving specific higher-risk medication regimens or at-risk populations (Table 2). This includes the following:
  - Counseling caregivers about OTC medications and addressing common sources of caregiver confusion with

**TABLE 1** Recommended Provider Counseling Practices to Promote Safe Home Administration of Pediatric Medications

Recommended Practice	Explanation
Provide straightforward and actionable instructions	<p>Medication counseling conveys key instructions, including:</p> <ul style="list-style-type: none"> <li>● Medication name</li> <li>● Medication purpose (indication)</li> <li>● Dose amount</li> <li>● Frequency</li> <li>● Duration</li> <li>● Route of administration</li> <li>● Side effects</li> </ul> <p>Provide dose amount using milliliter units only, using the abbreviation “mL.”</p> <ul style="list-style-type: none"> <li>● Avoid spoon-based units (eg, teaspoon [tsp] and tablespoon [TBSP])</li> <li>● Avoid dosing in cubic centimeters (ie, cc)</li> <li>● Use mL units consistently in verbal and written communication</li> </ul> <p>Provide dose amounts that are easy to measure: avoid fraction or decimal amounts when possible (use whole number amounts); include leading zeros if decimal amounts are used (eg, 0.X); avoid trailing zeros (eg, X.0); and avoid confusing abbreviations, such as U (unit) and QD (daily) (eg, for insulin dosing, spell out the word “unit”).</p> <ul style="list-style-type: none"> <li>● Avoid fraction or decimal amounts when possible (use whole number amounts)</li> <li>● Include leading zeros if decimal amounts are used (eg, 0.X)</li> <li>● Avoid trailing zeros (eg, X.0)</li> <li>● Avoid confusing abbreviations, such as U (unit) and QD (daily) (eg, for insulin dosing, spell out the word “unit”)</li> </ul> <p>Give explicit instructions regarding timing:</p> <ul style="list-style-type: none"> <li>● Provide information on time of day (eg, in the morning and in the evening) instead of providing only frequency information (eg, 2 times a day)</li> <li>● Include information on explicit timing on prescriptions</li> </ul>
Incorporate health literacy–informed counseling strategies and educational materials for caregivers as part of care provided in inpatient, outpatient, emergency care, and pharmacy settings	<p>Use a universal precautions approach to counseling (perspective that all patients would benefit from receiving evidence-based, health literacy–informed communication strategies)</p> <p>Use the following health literacy–informed verbal communication strategies:</p> <ul style="list-style-type: none"> <li>● Plain, “living room” language</li> <li>● Demonstration (eg, for liquid medications, consider using an oral syringe to demonstrate the amount of medication the caregivers should measure out; for asthma, consider having a staff member demonstrate how to use the spacer with inhaler)</li> <li>● Teachback: ask caregivers to say in their own words how they will give the medication (eg, “I want to make sure I did a good job explaining to you how much medication you should give. Can you tell me how much medication you will give to Jennifer each time?”)</li> <li>● Showback (eg, have caregiver demonstrate how much medication they plan to give each time using an oral syringe).</li> </ul> <p>Provide patient- and regimen-specific written instructions that can be taken home and shared with family members:</p> <ul style="list-style-type: none"> <li>● Incorporate written instructions into verbal counseling to reduce cognitive load</li> <li>● Use pictures and/or drawings to supplement counseling (eg, for liquid medications, provide a pictographic dosing diagram which visually shows the right amount of medication to give within a standard dosing tool)</li> <li>● Provide a log for caregivers to keep track of medications given and help promote adherence to the full course of medication</li> <li>● Written information recommended to be at a sixth- to eighth-grade reading level for the general population and a ≤5th grade reading level for patients with low literacy.</li> </ul>
For liquid medications, promote caregiver use of standard dosing tools	<ul style="list-style-type: none"> <li>● Counsel caregivers to use standard dosing tools (eg, tools with standard measurement markings, such as oral syringes, cups, dosing spoons, and droppers) and avoid the use of nonstandard kitchen spoons.</li> <li>● For prescribed medications, it is recommended that health care providers or pharmacists provide a standard dosing tool to caregivers to take home if no tool is provided as part of packaging (in particular, providers dispensing the medication are responsible for making sure that families have an appropriate tool to use to measure the prescribed medication). <ul style="list-style-type: none"> <li>○ Provide oral syringes when dosing accuracy is important, especially when smaller doses are recommended (eg, &lt;5 mL).</li> <li>○ Provide tool with the smallest size to fit the dose without the need to fill the tool multiple times for a single dose.</li> </ul> </li> <li>● Warn caregivers regarding potential known pitfalls of dosing cup use.</li> </ul>

**TABLE 1** Continued

Recommended Practice	Explanation
	<ul style="list-style-type: none"> <li>◦ Avoid cups for smaller doses (eg, &lt;5 mL).</li> <li>◦ Place cups on a level surface when measuring; look at markings at eye level when measuring.</li> <li>● Promote dosing-tool best practices.               <ul style="list-style-type: none"> <li>◦ For prescription medications, use tool provided by health care provider or pharmacy for specific medication prescribed.</li> <li>◦ For OTC medications, use dosing tool included in packaging.</li> <li>◦ Colocation of dosing tool with prescribed medication.</li> </ul> </li> </ul>
Provide language concordant care	<p>Verbal counseling and written information should be provided in the language of patient and/or family preference.</p> <ul style="list-style-type: none"> <li>● High-quality translations should be provided.</li> <li>● Trained/certified professional interpreters should be used.</li> </ul>
Empower caregivers to engage in care	<ul style="list-style-type: none"> <li>● Empower caregivers to ask questions.               <ul style="list-style-type: none"> <li>◦ Acknowledge that many caregivers have difficulty with administering medications and that questions are expected (eg, “I just gave you a lot of information. It is common for caregivers to have questions about how to give these medications. What questions do you have for me?”)</li> </ul> </li> <li>● Encourage caregivers to request a dosing tool if one is not provided.</li> </ul>
Reconcile medications at each relevant patient encounter	<p>Conduct regular reviews of medication lists with patients and caregivers.</p> <ul style="list-style-type: none"> <li>● Systematically review each medication taken (eg, name, strength, indication, dose, frequency, and expected duration)</li> <li>● OTC medications, and vitamins and/or supplements, should be included.</li> </ul>

OTC medications, including age restrictions, active ingredient information, and dosing instructions (eg, prioritization of weight versus age).

- Providing anticipatory guidance for adolescent patients to address their

evolving responsibility in managing their own health care, including the responsible use of medications and review of their medication use with adult caregivers.

- Encouraging families with multiple caregivers to

develop a communication strategy about medication administration to prevent overdoses and maintain correct dosing intervals.

- Encouraging families to avoid use of products that have “do not use” statements on the label that apply to their child, such as for OTC

**TABLE 2** Scenarios Involving Increased Risk for Medication Error

<p>Regimens involving:</p> <ul style="list-style-type: none"> <li>● Medications with a narrow therapeutic window, including warfarin and tacrolimus</li> <li>● “High-alert” medications (see Institute for Safe Medication Practices’ High-Alert ambulatory list: <a href="https://www.ismp.org/recommendations/high-alert-medications-community-ambulatory-list">https://www.ismp.org/recommendations/high-alert-medications-community-ambulatory-list</a>)</li> <li>● Complex instructions (eg, multiple medications, multiple administrations in a day, nonwhole number doses, or more than one unit of measurement used), including medications that require compounding in which standard concentrations may not exist</li> <li>● Medications requiring special preparation (eg, mixing and diluting)</li> <li>● OTC medications (eg, caregiver confusion related to age restrictions, active ingredient information, and dosing chart interpretation)</li> <li>● Regimens involving alternating acetaminophen/ibuprofen dosing</li> <li>● Cough/cold medications, especially in young children</li> </ul> <p>Populations at risk:</p> <ul style="list-style-type: none"> <li>● Children with chronic health conditions and special needs</li> <li>● Multiple caregivers are involved</li> <li>● More than one child in the family is taking the same medication</li> <li>● Adolescents</li> <li>● Caregivers/patients with low health literacy</li> <li>● Caregivers/patients with limited English proficiency</li> </ul>
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cough/cold medications.

2. Encourage the use of a standardized dosing tool with all liquid medications. This may be already included in packaging or provided by the pediatric clinician or pharmacist.
  - Provide oral syringes when dosing accuracy is essential, especially when smaller doses are recommended (eg, <5 mL) and when medications are for young children.
3. Provide a dosing tool with the smallest size to fit the dose without the need for filling the instrument multiple times for a single dose.
4. Demonstrate the prescribed dose of medication by using a dosing tool and have the patient/caregiver teachback/showback the dose.
5. Counsel caregivers about collocation of dosing tool for ease of access of the tool when medications are administered; store dosing tools with medications safely (eg, up, away, and out of sight).
6. Encourage caregivers to ask for a dosing tool with all prescribed medications and to use their medication-specific tool each time.
7. If a dosing tool comes packaged with a medication, caregivers should use that tool to measure that medication.
8. On all prescriptions, it is best to do the following:
  - Include patient weight so that pharmacists can double check the dose.
9. Include indications so that pharmacists can provide a second check on the dose (some medications are dosed differently on the basis of indication or may be used off-label), except in cases that involve sensitive issues, such as psychiatric or substance use disorders.
10. Reconcile medications at all relevant patient encounters (such as when a new provider is taking over the care of a patient, when there has been a long gap between clinical encounters, or when a new medication is being prescribed) by systematically reviewing each medication being taken (eg, name, strength, indication, dose, frequency, and expected duration); OTC medications, and vitamins and supplements, should be included in this review.
  - Medication information provided to families, including at the time of discharge from both inpatient units and emergency departments, needs to include key administration information, such as medication dose, route, frequency, and duration.
11. Providers involved in discharge, from both inpatient units and emergency departments, are responsible for giving information to the patient's primary care provider such that the medication plan initiated in the hospital is appropriately executed at home. For chronic medications, information about whether the medication needs to be adjusted for weight is considered an essential piece of information.
12. Encourage caregivers to bring for review their actual medications, or a list of medications, to provider visits.
13. Providers should access educational modules and other resources for safe prescribing practices (including mL-only dosing), health literacy-informed patient education and counseling, and safe storage and administration of home medications (Table 3).
14. Professional organizations should make educational modules and other resources to promote safe home medication administration available to providers and incorporate them as part of continuing medical education and maintenance-of-certification opportunities.
15. To avoid unintentional ingestions and use of expired prescription medications, promote safe disposal of unused medications after course completion. Common household OTC medications should also be safely disposed of when expired.
16. Encourage governmental agencies and industry to adopt measures to promote home medication safety, including the following:
  - Standardization of dosing units.
17. Ensuring that appropriate dosing tools are packaged with oral liquid medications.
18. Optimization of medication labels and packaging to decrease caregiver confusion.
19. Standardization of formulations to reduce confusion between infant versus children's formulations of medications.
20. Provision of health literacy-informed patient information materials in the language of patient and/or family preference.
21. Removal of "ask your doctor" from OTC medication labels and replacement with more precise instructions when possible (eg, acetaminophen for children aged <2 years).
22. Promotion of EHR functionality that supports safe pediatric medication use (eg, automatic rounding to whole numbers for liquid medications, limitation or default to mL-only dosing, limitation to one concentration of medication, default standard dosing based on weight, explicit standard dosing intervals [eg, morning and night versus twice a day], hard stops to facilitate acquisition of a complete set of information [eg, dose, frequency, and duration], prompts about drug interactions, and provision of

**TABLE 3** Helpful Resources

	Resources
Safe prescribing practices	AAP Policy Statement: “Metric Units and the Preferred Dosing of Orally Administered Liquid Medications” (April 2015) <sup>14</sup> : <a href="http://pediatrics.aappublications.org/content/135/4/784/">http://pediatrics.aappublications.org/content/135/4/784/</a> The Joint Commission “Do not use” list <sup>66</sup> : <a href="https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/patient-safety/do_not_use_list_9_14_18.pdf">https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/patient-safety/do_not_use_list_9_14_18.pdf</a>
Health literacy–informed counseling strategies	American Board of Pediatrics Safe Prescribing Performance Improvement Module <sup>212</sup> : <a href="https://pim.abp.org/rxwriting/faq/">https://pim.abp.org/rxwriting/faq/</a> American Board of Pediatrics Performance Improvement Module on Health Literacy <sup>213</sup> : <a href="https://pim.abp.org/health_literacy/faq/">https://pim.abp.org/health_literacy/faq/</a> AHRQ Universal Precautions Toolkit (includes information on verbal and written communication strategies, medication reconciliation) <sup>100,101</sup> : <a href="https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/index.html">https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/index.html</a> and <a href="https://www.ahrq.gov/sites/default/files/publications/files/healthlittoolkit2_3.pdf">https://www.ahrq.gov/sites/default/files/publications/files/healthlittoolkit2_3.pdf</a> AHRQ How to Create a Pill Card <sup>214</sup> : <a href="https://www.ahrq.gov/sites/default/files/wysiwyg/patients-consumers/diagnosis-treatment/treatments/pillcard/pillcard.pdf">https://www.ahrq.gov/sites/default/files/wysiwyg/patients-consumers/diagnosis-treatment/treatments/pillcard/pillcard.pdf</a> Plain language pediatrics: Health Literacy Strategies and Communication Resources for Common Pediatric Topics. Abrams MA, Dreyer BP, eds. Elk Grove Village, IL: Elk Grove, IL: American Academy of Pediatrics; 2008 <sup>22</sup> : <a href="https://ebooks.aappublications.org/content/plain-language-pediatrics">https://ebooks.aappublications.org/content/plain-language-pediatrics</a> HELPIX Pictographic Medication Instruction Sheets <sup>215</sup> : <a href="https://med.nyu.edu/helpix/helpix-intervention/instructions-providers">https://med.nyu.edu/helpix/helpix-intervention/instructions-providers</a> and <a href="https://www.helpix-program.org">https://www.helpix-program.org</a> Universal Medication Schedule White Paper <sup>104</sup> : <a href="https://ncpdp.org/NCPDP/media/pdf/WhitePaper/NCPDP-UMS-WhitePaper201304.pdf">https://ncpdp.org/NCPDP/media/pdf/WhitePaper/NCPDP-UMS-WhitePaper201304.pdf</a>
Safe disposal recommendations/resources	Where and How to Dispose of Unused Medicines (FDA) <sup>209</sup> : <a href="https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm">https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm</a> Disposal of Unused Medicines: What You Should Know (FDA) <sup>210</sup> : <a href="https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know">https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know</a> Drug Disposal Information (US Department of Justice and DEA) <sup>211</sup> : <a href="http://www.dea diversion.usdoj.gov/drug_disposal/index.html">http://www.dea diversion.usdoj.gov/drug_disposal/index.html</a>

AHRQ, Agency for Healthcare Research and Quality.

information in the patient’s preferred language).

23. Continued support for child-proof packaging.
24. Encourage research funding for novel ways to support safe home medication administration, including identifying strategies to evaluate and support appropriate dosing, and improve medication tracking and feedback to support caregiver and patient adherence to instructions.

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## ABBREVIATIONS

AAP: American Academy of Pediatrics  
DEA: Drug Enforcement Administration  
EHR: electronic health record  
FDA: Food and Drug Administration  
mg: milligram  
mL: milliliter  
OTC: over-the-counter  
TBSP: tablespoon  
tsp: teaspoon  
UMS: Universal Medication Schedule

**POTENTIAL CONFLICT OF INTEREST:** Dr Yin reports a National Institutes of Health/*Eunice Kennedy Shriver* National Institute of Child Health and Human Development research relationship; Dr Paul reports an expert panel relationship with Denver Health, advisory board relationships with Pfizer, Consumer Healthcare Produce Association, and Johnson & Johnson, and a consulting relationship with Merck and Evidera; and Dr Neuspiel has indicated he has no potential conflicts of interest to disclose.

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