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Ethanol Content of Medications and Its Effect on Blood Alcohol Concentration in Pediatric Patients

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OBJECTIVE Ethanol is a common excipient used in liquid medications to enhance solubility and inhibit bacterial growth. While the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) have released guidance for how much ethanol is acceptable in medicines, many medications contain more than the recommended amount. The objective of this study was to determine what effect these medications would have on blood alcohol concentration (BAC) for pediatric patients, defined as those medications that would increase the BAC by ≥2.5 mg/dL.

METHODS A list of medications dispensed to pediatric patients from a single hospital over a period of 4 months was obtained. The package inserts of these medications were reviewed to determine ethanol content. Typical doses were used to determine the amount of ethanol pediatric patients weighing 10, 20, and 40 kg would receive. The theoretical BAC was then calculated for each medication containing ethanol.

RESULTS Seven hundred ninety-six medications were dispensed for pediatric patients during the study period, of which 33 contained ethanol. Seven medications would be projected to increase the BAC above 2.5 mg/dL with a normal pediatric dose.

CONCLUSION While most medications do not contain ethanol, we found 7 that contained enough ethanol to potentially raise the BAC above 2.5 mg/dL. Health care practitioners should consider the ethanol content of medications prior to recommending them in children and when assessing overdoses.

ABBREVIATIONS BAC, blood alcohol concentration; CYP, cytochrome P450; EMA, European Medicines Agency; FDA, US Food and Drug Administration; IV, intravenous; KIDs List, Key Potentially Inappropriate Drugs in Pediatrics List; NDC, National Drug Code; PI, package insert; Vd, volume of distribution

KEYWORDS dosage forms; ethanol; patient safety

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Introduction

The use of excipients for pediatric patients requires careful examination of their safety in this population. Seven excipients are included in the Key Potentially Inappropriate Drugs in Pediatrics List (KIDs List)[1] as being potentially inappropriate: benzyl alcohol, ethanol/ethyl alcohol, isopropyl alcohol, methylparaben/propylparaben, phenylalanine, polysorbate 80, and propylene glycol. Some of these, such as benzyl alcohol and polysorbate 80, have high-quality evidence that demonstrates their risk and the doses known to be hazardous. Less is known about the risks and potentially dangerous doses of ethanol.

Ethanol has been used as an excipient in medications for decades; it is used as a solvent to keep active ingredients in solution and also functions as a preservative. The amount contained in medications is usually small and unlikely to approach concentrations where it may have an effect similar to consuming alcoholic beverages, but even the small amount contained in medications may pose a risk to infants and young children. Toxicity following the accidental exposure to an ethanol-containing acetaminophen elixir has been reported in an 18-month-old female.[2]

Metabolism of ethanol changes drastically throughout growth and development. The major enzymes responsible for its metabolism, alcohol dehydrogenase and cytochrome P450 (CYP) 2E1, are present in reduced concentrations in the pediatric population when compared with those seen in adults. Alcohol dehydrogenase concentrations in neonates are less than 20% of those in adults, with adult values not reached until about age 5 years,[3] and CYP 2E1 concentrations reach only 30% to 40% of adult concentrations during the first year of life.[4]

In 1984, the American Academy of Pediatrics' Committee on Drugs released a recommendation that the amount of alcohol in over-the-counter products intended for use in children be limited to 5%.[5] Further, they stated that it would be ideal if medications for

children contained no alcohol. No regulation exists for prescription products. In 2020 the Pediatric Pharmacy Association published the KIDs List, which also recommended that alcohol content be limited to less than 5%.[1] The European Medicines Agency (EMA) has also released guidance for package leaflet information on the ethanol content of medications.[6] Current US Food and Drug Administration (FDA) guidance limits alcohol content of over-the-counter products to 10% for products intended for adults and children 12 years and older, 5% for products developed for children 6 to 12 years of age, and 0.5% for products used in children younger than 6 years.[7]

In our study we aimed to report the percentage alcohol of commonly used medications in the pediatric population and approximate the blood alcohol concentration (BAC) that could arise from administration of normal doses.

Materials and Methods

To evaluate the presence of ethanol in pediatric medications, a list of medications was generated from institutional dispensing records for the pediatric intensive care unit and general pediatrics unit from a single hospital during March–June 2021. The hospital in the study is a 597-bed tertiary care center that treats both adult and pediatric patients. The list generated included all medications dispensed to the units, irrespective of patient age. This list was screened to allow preliminary exclusion of all dosage forms not likely to contribute to a systemic ethanol concentration (e.g., tablets, capsules, topical products, "swish and spit" liquids, eye/ear drops, transdermal patches, and nasal sprays), as well as compounded intravenous (IV) syringes, IV fluids, vaccinations, and other nonrelevant medical orders. The remaining medications were evaluated for ethanol content by using individual product package inserts (PIs). Medications found not to contain ethanol were excluded from further assessment. Package inserts were obtained primarily through the National Library of Medicine's DailyMed database, and independently reviewed by 1 investigator for all manufacturers or packagers of each drug product. Repackaged labels and duplicate package inserts were not evaluated. If a product PI was not able to be found in DailyMed, the PI was instead obtained through the internet or hospital inventory. Any products that were still unable to be found following this second search were excluded from the study. The final list of products eligible for BAC analysis included those with at least 1 formulation found to contain ethanol.

The theoretical rise in BAC following a single dose for patients weighing 10 kg, 20 kg, and 40 kg was calculated for each medication containing ethanol. This allowed for theoretical correlation to a 1-, 5-, or 12-year-old child, respectively. The primary endpoint was to identify medications with potentially significant effects on BAC in pediatric populations. Following EMA recommendations,[5] the significant point of ethanol exposure was defined as ≥15 mg/kg/dose, which would cause a rise in BAC of ≥2.5 mg/dL. This is approximately equivalent to the BAC increase that an adult would experience after drinking 10 mL of wine (for reference, a standard serving size of wine is about 150 mL).

Calculation of BAC:

$$BAC\left(mg/dL\right) = \frac{Ethanol\left(g\right)}{Vd\left(L/kg\right)*BW\left(kg\right)} * 100$$

For the purposes of this study, volume of distribution (Vd) was assumed to be 0.6 L/kg as recommended by EMA guidance (BW, body weight.[6] While real-life Vd can vary greatly by age and sex, the EMA justifies the use of 0.6 L/kg to allow for overestimation of calculated BAC values as a precautionary measure for young children.[6] All calculations assumed regular renal and hepatic function with the exception of medications indicated solely for patients receiving hemodialysis. It should be noted that this formula is intended to reflect changes in BAC after oral ingestion of alcohol. Consequently, results may be over- or underestimated when the BAC calculation is applied to medications with other routes of administration (i.e., rectal, inhalation, or IV dosage forms).

Results

Of 796 medications obtained from dispensing records, 467 medications of nonrelevant dosage forms were excluded during preliminary screening (see Supplemental Figure). The remaining 329 medications were reviewed for ethanol content via independent PI evaluation. A total of 33 medications (4.1%) were found to have at least 1 formulation containing ethanol (Table 1). The distribution of dosage forms among these final medications included 19 oral solutions, 8 parenteral injections, 3 inhalations, and 3 rectal formulations. Six of the 33 medications identified ethanol as an excipient but did not specify the amount of ethanol contained therein. Consequently, these medications were not evaluated for ethanol exposure and BAC.

Certain medications were found to contain different amounts of ethanol depending on the manufacturer, such as phenobarbital oral solution, which is available as a 13.5%, 14.25%, or 15% ethanol formulation. For these medications, ethanol exposure and BAC were calculated for each available ethanol concentration. Sirolimus oral solution was another notable medication, as it is stated to contain "1.5% to 2.5% ethanol" on manufacturer labels. To account for product variability, calculations for ethanol exposure and BAC were performed by using 1.5% ethanol as the minimum exposure and 2.5% ethanol as the maximum exposure.

Following calculation of ethanol exposure and predicted rise in BAC, it was found that 7 of the

Table 1. Medications Dispensed From Pediatric Units at a Single Hospital During a 4-Month Period With at Least 1 Market Formulation Found to Contain Ethanol

Product	Dosage Form	Ethanol Content in Medication Formulation(s), % w/v	Commercially Available Alcohol-Free Alternatives
Glass of wine (comparison)	—	10%	—
Acetaminophen-codeine 120 mg/5 mL	Oral solution	7%	No
Albuterol 90 mcg	Inhaler	Not specified by manufacturer	No
Beclomethasone 40 mcg	Inhaler	Not specified by manufacturer	No
Beclomethasone 80 mcg	Inhaler	Not specified by manufacturer	No
Cannabidiol (Epidiolex) 100 mg/1 mL	Oral solution	7.9%	No
Chlorothiazide 250 mg/5 mL	Oral solution	0.4%	No
Citric Acid-Sodium Citrate (ORACIT) 30 mL	Oral solution	0.25%	Yes
Cyclophosphamide 2 g/100 mL	Injection	Not specified by manufacturer	No
Cyproheptadine 2 mg/5 mL	Oral solution	5%	No
Diazepam 2.5 mg	Rectal	10%	No
Diazepam 10 mg	Rectal	10%	No
Diazepam 20 mg	Rectal	10%	No
Diazepam 10 mg/2 mL	Injection	8%*	No
Diphenhydramine 12.5 mg/5 mL	Oral solution	14%	Yes
Hydroxyzine 10 mg/5 mL	Oral solution	0.4%*	Yes
Ketorolac 15 mg/1 mL	Injection	10%	No
Ketorolac 30 mg/1 mL	Injection	10%	No
Mycophenolate mofetil 500 mg/15 mL	Injection	Not specified by manufacturer	No
Nystatin 500,000 units/5 mL	Oral solution	≤0.8%*	Yes
Oxcarbazepine 300 mg/5 mL	Oral solution	Not specified	Yes
Oxycodone 5 mg/5 mL	Oral solution	0.04%*	Yes
Paricalcitol 2 mcg/1 mL	Injection	16%*, 28%*, 32%*	No
Phenobarbital 20 mg/5 mL	Oral solution	13.5%, 14.25%, 15%	No
Phenobarbital 65 mg/1 mL	Injection	8%*	No
Phenytoin 100 mg/2 mL	Injection	8%*	No
Phenytoin 100 mg/4 mL	Oral solution	0.35%, ≤0.6%	Yes
Prednisolone 15 mg/5 mL	Oral solution	1.8%, 5%	Yes
Propranolol 20 mg/5 mL	Oral solution	0.48%*	No
Sirolimus 1 mg/1 mL	Oral solution	1.5-2.5%	No
Sodium polystyrene sulfonate 15 g/60 mL	Oral solution	0.24%*	No
Sulfamethoxazole-trimethoprim 200 mg–40 mg/5 mL	Oral solution	0.03%, 0.04%, 0.26%, ≤0.5%	No
Sulfamethoxazole-trimethoprim 800 mg–160 mg/20 mL	Oral solution	≤0.5%	No
Valproic acid 250 mg/5 mL	Oral solution	≤0.05%	Yes

* Indicates a conversion from v/v to w/v (All concentrations were assumed to be w/v unless otherwise stated on medication labeling).

33 medications (21%) would be projected to cause significant ethanol exposure (≥15 mg/kg/dose, ≥2.5 mg/dL in theoretical BACincrease) for pediatric patients (Table 2). All were oral solutions except for one, which was an IV solution. Of note, only 2 of these medications had commercially available alcohol-free alternatives on the market. Phenobarbital had the most potential to increase BAC, by as much as 31.3 mg/dL.

Discussion

Clinical manifestations of acute ethanol exposure in pediatric patients include respiratory depression, central nervous system depression (ranging from lethargy to coma), and seizures.[9–12] In children younger than 5 years the most common manifestation is hypoglycemia.[8,13] Hypoglycemia develops secondary to the metabolism of ethanol, which increases the cellular redox ratio favoring the conversion of pyruvate to lactate.[14,15] Because pyruvate is diverted from being a substrate for gluconeogenesis, individuals with diminished glycogen stores are more likely to develop hypoglycemia. Children are at particularly high risk of becoming hypoglycemic following exposure to ethanol owing to their reduced liver size and resultant low glycogen stores. Multiple reports of hypoglycemia following ethanol intoxication have been reported.[2,12,16–20] In one retrospective case series, there was a 22% incidence of hypoglycemia in children with a documented exposure to ethanol.[21] A fatality attributed to hypoglycemia has been reported in a 4-year-old male following the ingestion of 12 ounces of mouthwash containing 10% ethanol.[16]

While the minimum lethal exposure of ethanol via the oral route in a child is 3 g/kg (~3.8 mL/kg) body weight,[22] a dose of 0.5-mL/kg absolute ethanol can cause significant toxicity in a child. One method to assess the clinical relevance of alcohol content of medications is to calculate the theoretical BAC that consumption of a dose of medication would cause. An estimated BAC of 50 to 75 mg/dL would result from the ingestion of 0.5-mL/kg absolute ethanol. BACs are correlated with effects in older children and adolescents; a BAC of 50 to 75 mg/dL would cause impaired judgement and coordination.[23] A BAC of 100 to 150 mg/dL would cause difficulty with gait and balance, and 150 to 250 mg/dL would cause lethargy and difficulty standing up.[23] Death from ethanol intoxication is usually associated with BAC greater than 400 mg/dL, but has been reported with concentrations as low as 250 mg/dL.[24–25] The maximum survived BAC reported in a pediatric patient is 740 mg/dL.[26]

Ethanol content in medications has long been an area of contention amongst pediatric practitioners. Its usefulness as an excipient to enhance solubility has led to its use in many medications, and a clear relationship between use of these medications and toxicity has not been found. While many organizations and publications have expressed the opinion that its use should be avoided if at all possible, it remains in several medications that are commonly used in children. We attempted to quantify the probable exposure that patients would receive with usual doses by calculating the estimated BAC in the hopes that this would allow practitioners to have a more tangible idea of the effects of alcohol in these medications. It is also our hope that regulations will add more guidance for acceptable amounts of ethanol for prescription medications and that manufacturers will be encouraged to produce more ethanol-free options.

While we only found 7 medications that met our definition of significantly increasing the BAC, some of these medications are commonly used in pediatric patients, such as phenobarbital in premature infants. Others had an alcohol-free alternative, such as diphenhydramine. After this study was completed, our hospital switched to the alcohol-free diphenhydramine product for our formulary.

One observation throughout the study was that reporting ethanol as an ingredient and its quantity in the medication was inconsistent. Many medications did not report the amount of ethanol under the "inactive ingredients" section on the DailyMed website, meaning that it often had to be found through other means (e.g., box images, warnings, or drug description). A more consistent layout and content of PIs will assist health care providers in making clinical decisions about these medications.

It should be noted that many of these medications are used chronically and thus the alcohol exposure may occur daily for months to years; in fact the medication with the largest potential to cause an increase in BAC—phenobarbital—is used chronically, and often in our most vulnerable population—premature infants. The clinical significance of this chronic exposure is unknown, and given other confounding variables in this population, its full effects may never be fully elucidated. Given the unclear nature of its chronic effects, an alcohol-free phenobarbital preparation would be very useful; in fact many pharmacies compound an ethanol-free oral phenobarbital suspension—for which a recipe exists—to avoid the ethanol exposure.[27]

A limitation of this evaluation was that some medications neglected to report ethanol concentration entirely. When thinking beyond a therapeutic dose, the absence of this information introduces a major gap in the assessment of potential toxicity following an overdose. Contacting one's regional poison control center in this situation is critical to ensure the risk of toxicity from both the medication and its ethanol excipient is considered. Poison control centers in the United States leverage the Micromedex POISINDEX System (Truven Health Analytics) as a major resource. In this system a list of a product's ingredients, specific to a distinct National Drug Code (NDC), is available for both active ingredients and excipients. Despite ethanol being listed as an

Table 2. Medications With Potentially Significant Effect on BAC (Ethanol Exposure ≥15 mg/kg/dose)

Product	Manufacturer(s)	Ethanol Content, % w/v	Alcohol-Free Alt.	10-kg Patient			20-kg Patient			40-kg Patient		
				Single Dose	Ethanol Exposure, mg/kg	Rise in BAC, mg/dL‡	Single Dose	Ethanol Exposure, mg/kg	Rise in BAC, mg/dL‡	Single Dose	Ethanol Exposure, mg/kg	Rise in BAC, mg/dL‡
Acetaminophen-codeine 120 mg–12 mg/5 mL oral solution	Hi-Tech Pharmacal Co, Inc; Pharmaceutical Associates, Inc	7%	No	50/5 mg–100/10 mg	15–29	2.4–4.9	100/10 mg–200/20 mg	15–29	2.4–4.9	200/20 mg–400/40 mg	15–29	2.4–4.9
Citric Acid-Sodium Citrate (ORACIT) oral solution 1 mEq/mL	CMP Pharma, Inc	0.25%	Yes	6.7 mEq–66.7 mEq	1.7–16.7	0.28–2.8	13 mEq–133 mEq	1.7–16.7	0.28–2.8	27 mEq–267 mEq	1.7–16.7	0.28–2.8
Cyproheptadine 2 mg/5 mL oral solution	Lannett Company, Inc; Patrin Pharma; Rising Pharmaceuticals, Inc; VistaPharm, Inc.	5%	No	N/A	N/A	N/A	2.5 mg–6 mg	16–38	2.6 – 6.25	5 mg–8 mg	16–25	2.6–4.2
Diphenhydramine 12.5 mg/5 mL oral solution	Pharmaceutical Associates, Inc	14%	Yes	12.5 mg	70	11.7	25 mg	70	11.7	50 mg	70	11.7
Phenobarbital 20 mg/5 mL oral solution	Pharmaceutical Associates, Inc; Quagen Pharmaceuticals LLC; Rising Pharmaceuticals, Inc	13.5%	No	30 mg–50 mg	101–169	16.9–28.1	60 mg–100 mg	101–169	16.9–28.1	120 mg–200 mg	101–169	16.9–28.1
	Pharmaceutical Associates, Inc	14.25%			107–178	17.8–29.7		107–169	17.8–29.7		107–178	17.88–29.7
	BioRamo, LLC; e5 Pharma, LLC; Par Pharmaceutical Inc; Westminster Pharmaceuticals	15%			112.5–188	18.8–31.3		112.5–188	18.8–31.3		112.5–188	18.8–31.3
Phenobarbital 65 mg/1 mL IV solution*	Cameron Pharmaceuticals; West-Ward Pharmaceuticals Corp	8%	No	15 mg–200 mg	1.8–24.6	0.31–4.1	30 mg–400 mg	1.8–24.6	0.31–4.1	60 mg–800 mg	1.8–24.6	0.31–4.1
Sirolimus 1 mg/1 mL oral solution†	Amneal Pharmaceuticals LLC; Apotex Corp; Greenstone LLC; VistaPharm, Inc	1.5%–2.5%	No	0.7 mg–40 mg	1.1–100	0.175 – 16.7	1.2 mg–40 mg	0.9–50	0.146–8.3	2 mg–40 mg	0.75–25	0.125–4.2

Alt, alternative; BAC, blood alcohol concentration; IV, intravenous; N/A, not applicable

* Note that projected changes in BAC for phenobarbital IV solution may be an underestimation of actual exposure, because the BAC formula is intended for oral substances and not IV injections.

† Sirolimus oral solution is stated to contain "1.5% to 2.5% ethanol" according to manufacturer labeling. To account for product variability, projected ethanol exposure was calculated by using 1.5% ethanol (minimum exposure) and 2.5% ethanol (maximum exposure).

active ingredient or excipient for each of the 7 medications assessed in Table 2, a link for the management of ethanol toxicity was listed only for 11 of the 23 NDC numbers for those 7 medications. This means that anyone determining management for an overdose of these medications would not necessarily be aware of the contribution of ethanol to the overall toxicity.

Another limitation of this study was the method of collecting drug names dispensed from a single hospital. Our hospital does not have pediatric oncology or pediatric cardiothoracic services, thus we may have missed some medications that contain significant quantities of ethanol. Digoxin elixir, for example, is 10% ethanol. At a dose of 35 mcg/kg for a 10-kg child, the BAC would be expected to rise by approximately 11.7 mg/dL. Digoxin is also a chronic medication, and as stated previously, the effects of chronic exposure to ethanol are unknown.

Additionally, dexamethasone oral elixir, which is 5% to 5.1% ethanol, was not captured by our study, as it is not used at our hospital because of its ethanol content. Because this elixir is 0.5 mg/5 mL (0.1 mg/mL), a typical dose of 0.6 mg/kg for a 10-kg child (6 mg) would be 60 mL and this would be projected to raise the BAC by 5 mg/dL. The IV solution is 10 mg/mL and this is used at our hospital because of its high concentration (and thus low dose volume) and lack of ethanol. Dexamethasone oral elixir is an example of a medication with a relatively low concentration of ethanol (<5%) with an expected large effect on BAC because of its dilute concentration. Finally, clinicians should remember that BAC calculations are approximations, as the Vd of alcohol varies by age, sex, and other factors.

Pharmacists, pediatricians, and poison control centers should be aware of medications that have the potential to cause significant BACs in their patients, and alcohol-free preparations should be chosen if available. As more pediatric-friendly dosage forms enter the marketplace, alcohol-free preparations would help improve the safety of these medications for children.

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