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Acute Care ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Chloral hydrate: Is it still being used? Are there safer alternatives?

In early 2017, ISMP plans to update its list of high-alert medications to correspond with the release of a new **ISMP Medication Safety Self Assessment® for High-Alert Medications**. The new assessment tool, funded by the US Food and Drug Administration (FDA), will allow hospitals and outpatient facilities to evaluate their level of implementation of error-prevention strategies for 11 high-alert medications or categories. One of the high-alert medication categories included in the new self assessment is minimal and moderate sedation agents, including agents used to sedate pediatric patients for diagnostic tests or procedures in various settings, such as radiology, electrocardiography, neurologic testing labs, dentistry, the emergency department (ED), and the operating room. Sedation of pediatric patients for even painless diagnostic procedures is common because its use has been linked to higher quality studies and reduced diagnostic errors.[1]

The pediatric oral sedation agent provided as an example on our current ***ISMP List of High-Alert Medications in Acute Care Settings*** (www.ismp.org/sc?id=2820) is oral chloral hydrate, a sedative-hypnotic used for more than 100 years.[2] Chloral hydrate liquid for pediatric sedation is also a specific medication on the ***ISMP List of High-Alert Medications in Community/Ambulatory Healthcare*** (www.ismp.org/sc?id=2821).

Older chloral hydrate adverse events

Between 1996 and 2009, ISMP published dozens of errors about chloral hydrate used for sedation involving mostly dosing errors, oversedation, and administration of the oral liquid by the IV route. The events we published included 8 that resulted in death. In two of the cases, technical support personnel who were unauthorized to administer the drug failed to recognize they were administering an overdose. In a third fatality, a dentist ordered a weight-based dose of 6,000 mg for a 13-year-old child that led to respiratory arrest. In three more cases, the drug was administered to the child by a parent at home prior to a procedure. In two of these cases, the drug was prescribed by volume alone, and a higher concentration of the commercial product than intended by the prescriber was dispensed by the pharmacy (500 mg/5 mL instead of 250 mg/5 mL), leading to overdoses. In the other case, the pharmacy dispensed a 10-fold overdose. The seventh case involved a 4-year-old boy who was given chloral hydrate before a procedure and strapped onto a papoose board without proper positioning of his head to protect his airway. The final fatality was caused by repeated "5 mL prn" doses that led to respiratory arrest.

Compounded chloral hydrate

Since 2010, ISMP has not received additional reports of errors involving pediatric sedation with chloral hydrate, which we assumed was due in large part to the 2012 discontinuation of the only remaining commercially available chloral hydrate products (oral solution by Pharmaceutical Associates, oral capsules by Breckenridge) in the US, for business reasons.[3] However, some ambulatory and hospital pharmacies are still compounding an oral suspension of chloral hydrate from crystals or powder for pediatric sedation in both inpatient

continued on page 2—Chloral hydrate >

SAFETY briefs

Don't give Zurampic without allopurinol. ZURAMPIC (lesinurad) is indicated for hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone, such as allopurinol or febuxostat. The drug carries a boxed warning about the risk for acute renal failure when used without a xanthine oxidase inhibitor. Patients taking this medication alone during clinical trials experienced renal failure at a rate of 9.3% compared to about 1% when taken in combination with

continued on page 2—SAFETY briefs >

In deepest sympathy…

We were saddened to learn of the cancer-related death on October 22nd of one of the most respected medication safety researchers of our time, **Betsy Allan Flynn**. Dr. Flynn worked closely with Dr. Kenneth Barker at Auburn University (AU). Together they furthered methods for prospective monitoring of medication systems in hospitals and community pharmacies. They developed AU MEDS, which was later commercialized and adopted by a number of hospitals to help proactively identify flaws in their medication safety systems. Dr. Flynn was a co-investigator on over $5 million of research, and conducted studies in over 250 sites in the US, France, the United Kingdom, and Italy. She published or presented more than 125 papers. She is a former recipient of the ISMP Cheers Award, among many other honors and recognitions. She also served on the Institute of Medicine's Committee on Identifying and Preventing Medication Errors and the US Pharmacopeia Safe Medication Use Expert Committee.

> Chloral hydrate—continued from page 1

and outpatient settings.[4,5] The raw ingredient is available from pharmaceutical supply companies. A study[5] comparing the previously available commercial formulation of chloral hydrate to the compounded formulation used for pediatric sedation during echocardiographic examination showed that the compounded drug resulted in a shorter duration of sedation, more frequent need for the use of a secondary sedation agent (increasing the risk of an adverse event[4,6]), and more frequent sedation failure.

There are no FDA-approved drug products that contain chloral hydrate. As mentioned above, the firms commercially manufacturing and distributing drug products containing chloral hydrate without FDA-approval voluntarily removed their products from the market in 2012. We were thinking about removing chloral hydrate from our lists of high-alert medications but have not done so given the unknown frequency of prescribing and compounding the drug. There have also been worrisome, more recent adverse events associated with the drug as reported in the news media and professional literature. Chloral hydrate has a US Pharmacopeial Convention (USP) monograph so pharmacists can compound it under section 503A (individual prescription) of the Federal Food, Drug, and Cosmetic (FD&C Act), but it can't be compounded under 503B (outsourcing facilities) because it is not on FDA's list of bulk drug substances (www.ismp.org/sc?id=2831).

More recent chloral hydrate adverse events

In June 2014, Nordt et al. published three cases of pediatric chloral hydrate overdoses, one a fatality, that occurred in the outpatient setting following procedural sedation.[2] These patients were all seen in the ED within a 4-month period, alerting the authors to a potential public safety issue.

The first case involved a 4-year-old girl for whom a dentist had prescribed 900 mg (70 mg/kg) of chloral hydrate prior to a dental extraction. The child was sedated upon arrival at the office, and the procedure was completed without further sedation. After an hour, the patient remained somnolent but arousable and was discharged. The child's mother called 6 hours later to report ongoing somnolence and was reassured that the effects of sedation would decrease over time. Several minutes later, the child suffered a respiratory arrest and the mother called emergency medical services. Resuscitation efforts prehospital and in the ED were extensive, with an initial return of spontaneous circulation. But the child arrested again and died.

The next event involved a 3-year-old boy for whom a dentist had prescribed 500 mg (50 mg/kg) of chloral hydrate to be administered at home prior to arrival in the office for a dental procedure. (Only healthcare professionals should administer sedatives to children prior to a procedure *after* they have arrived at the facility to ensure proper supervision, monitoring, and access to resuscitation equipment and other medications if needed.) The dentist had anticipated repeat visits and prescribed 60 mL of chloral hydrate (100 mg/mL). The child's mother could speak Spanish and English, but could read only Spanish, so she asked a family member to read the label. That person misdirected her to give the child the entire 60 mL (6,000 mg) bottle. The child became somnolent within 10 minutes and unresponsive once in the dental office. The mother alerted the office staff, who called emergency medical services. The child vomited on the way to the ED, where he was intubated and treated with an esmolol infusion for life-threatening cardiac dysrhythmias. He was admitted to a pediatric intensive care unit and discharged 24 hours later without sequelae.

The third event involved a 15-month-old child with a history of severe neurodevelopmental deficits who was given 1,200 mg of chloral hydrate (100 mg/kg) at an outpatient ophthal-

continued on page 3—Chloral hydrate >

> SAFETY briefs

cont'd from page 1

a xanthine oxidase inhibitor. Given this risk, a pharmacist reported that it seemed odd that the drug was approved as a single entity tablet rather than a combination product with allopurinol.

AstraZeneca, the manufacturer, told us the company plans to submit a fixed-dose product containing both lesinurad and allopurinol to the US Food and Drug Administration (FDA) later this year. Given the lack of a combination tablet, it would be a good idea to develop an order set that requires both drugs to be used and to place reminders in computer systems and on auxiliary labels.

Does CLARISPRAY look familiar? **CLARISPRAY** is fluticasone propionate, a corticosteroid nasal spray that is generically equivalent to **FLONASE ALLERGY RELIEF**. In the upper right hand corner of the CLARISPRAY package label (**Figure 1**), Bayer, the distributor of the product, notes that it is "from the Makers of Claritin." **CLARITIN** is loratadine, an antihistamine. With this

Figure 1. CLARISPRAY (L) is labeled "from the Makers of Claritin," but it doesn't contain loratadine (R).

product association, the similar package colors and graphics, and since each name starts with "CLARI-," it's possible that some patients may think that CLARISPRAY is a spray form of loratadine. No cases of confusion have been reported yet, but keep this in mind if you have these products in your ambulatory care pharmacy. Consumers and pharmacists need to be aware of the differences between these products.

Highly concentrated potassium chloride injection. You may have noticed that, while most premixed IV solutions list the medication and vehicle, concentrated potassium chloride in sterile water (in premixed minibags) is an exception. We re-

continued on page 3—SAFETY briefs >

> Chloral hydrate—continued from page 2

mology clinic prior to evaluation. Within 25 minutes of receiving the drug, the child vomited, became obtunded, and developed stridor, periods of apnea, and cyanosis. The child improved after an oral airway was established and oxygen was administered. She was transferred to the ED, monitored for 12 hours, and then discharged.

Other issues with chloral hydrate

In addition to the risk of respiratory depression associated with most sedatives used for pediatric sedation, chloral hydrate carries several other risks worthy of mention:

Resedation after discharge. Chloral hydrate can result in prolonged sedation or resedation with effects persisting beyond 24 hours in children of all ages, including those who have demonstrated resolution of sedation prior to discharge.[2,4,7] This appears to have played a role in the fatality of the 4-year-old girl described previously. Chloral hydrate is rapidly converted to an active metabolite (trichloroethanol) responsible for its sedative properties, which has a half-life at therapeutic doses of up to 66 hours in neonates, 28-40 hours in infants, 8-12 hours in children, and much longer following an overdose.[2,7]

No reversal agent. If respiratory depression occurs or the patient becomes obtunded, no specific agent is available to reverse the effects of chloral hydrate.[2]

Narrow therapeutic index. Chloral hydrate has a relatively narrow therapeutic index, which can increase the risk of adverse effects when higher therapeutic doses or overdoses are administered.[2]

Cardiac toxicity and hypotension. Ventricular dysrhythmias and severe hypotension leading to some fatalities from chloral hydrate toxicity have been reported. This has been seen mostly after large doses or overdoses since this effect is dose dependent.[2,8]

Irritating gastric effects. Nordt et al. notes that chloral hydrate is more rapidly absorbed with food; fasting before a procedure where chloral hydrate is used for sedation is not recommended since it can delay the drug's onset, leading to sedation failures.[2] However, gastric irritation has led to vomiting, which can result in aspiration of the stomach contents.

Large volume per dose. Chloral hydrate is very bitter tasting and requires a large volume per dose. Poor palatability has necessitated administration via a nasogastric tube at times.[9] In addition, compounded chloral hydrate is difficult to concentrate, leading to even larger volumes per dose than the previously available commercial formulation.[5] This can lead to vomiting or spitting out of unquantifiable amounts of the dose.

Comparison to other pediatric sedation agents

Chloral hydrate has been a drug of choice for pediatric sedation in some facilities due to its low cost.[5] However, in regards to efficacy, there are conflicting studies regarding which sedation agent is best. Numerous studies suggest there are many other effective sedative agents with more predictable pharmacokinetic profiles than chloral hydrate, including oral or intranasal midazolam.[6,7,10-12] Other studies have shown that chloral hydrate resulted in more effective sedation of pediatric patients than other agents,[9,13-15] and recommendations for its continued use for certain procedures exist in the literature, particularly for painless diagnostic procedures such as neurologic imaging,[13,16] echocardiography,[5] and auditory brainstem response testing.[17]

continued on page 4—Chloral hydrate >

> SAFETY briefs

cont'd from page 2

cently received a call from a physician whose patient had hypernatremia, and he wanted to make sure that sodium chloride was not in the potassium chloride solution. While B. Braun and Hospira mention in label text that their potassium chloride injection is mixed in sterile water, Baxter does not list the vehicle. According to United States Pharmacopeia (USP) Chapter <7>, if the vehicle is water for injection, it need not be named. Please let all healthcare practitioners know about this issue. We also informed the US Food and Drug Administration (FDA).

Look-alike generic names. A hospital reported a mix-up between linaclotide (**LINZESS**) and linagliptin (**TRADJENTA**) after a technician and pharmacist incorrectly dispensed linagliptin instead of linaclotide for patient A, and linaclotide instead of linagliptin for patient B. Fortunately, bedside barcode scanning identified both errors prior to administration. Both drugs were nonformulary medications and were not available in unit-dose packaging, so the pharmacy had to prepare unit-dose packages, which contributed to their look-alike appearance. Linaclotide, available in bottles of 145 mcg and 290 mcg capsules, is indicated for irritable bowel syndrome with constipation and chronic idiopathic constipation. Linagliptin is available as 5 mg tablets in 30 and 90 tablet bottles or unit-dose blisters. The drug is a dipeptidyl peptidase-4 (DPP-4) inhibitor used to improve glycemic control in patients with type 2 diabetes. Since both drugs share the same first four letter characters of their generic drug names, the risk of selection errors when choosing either drug using their generic name from a pull-down list or reading labels is increased.

Using tall man letters (lina**GLIP**tin and lina**CLO**tide) may be helpful in preventing mix-ups, as would looking up drugs in order entry systems by their first 4 or 5 letters and their strength, and including the indication along with the dosing instructions (constipation for linaclotide and diabetes

continued on page 4—SAFETY briefs >

> Chloral hydrate—continued from page 3

Nevertheless, numerous studies have also shown that other sedation agents, such as midazolam, produce less severe adverse effects. For example, Costa et al. studied pediatric patients who received a high dose of either oral chloral hydrate (70-100 mg/kg) or oral midazolam (1-1.5 mg/kg) during outpatient dental treatment. They found that the chance of an adverse event, including post-discharge, was significantly lower among children who received midazolam than those who received chloral hydrate.[7] Cote et al. found that, among 118 cases of serious (neurologic injury) or fatal outcomes reported to FDA, most (65%) of the children had been sedated with chloral hydrate.[6]

Seeking your input

The risks of adverse events and the potential for compounding errors associated with chloral hydrate are concerning. Thus, the literature is replete with recommendations to use a safer alternative agent instead of chloral hydrate when sedating pediatric patients.[2,4,6,7,10-12,18-19] However, the evidence regarding efficacy of chloral hydrate and alternative sedatives is conflicting. Before ISMP takes a position on the issue in our **ISMP Medication Safety Self Assessment® for High-Alert Medications**, we would appreciate your participation in a **short survey** on the topic, which should take less than 15 minutes to complete, even less if you do not use chloral hydrate for pediatric sedation. Either way, we need your input on this important issue and would sincerely appreciate your encouragement of participation by healthcare providers working in both inpatient and outpatient settings! Please include radiology, dentistry, or other areas that may use chloral hydrate and complete the survey, which appears on **page 5**, by **December 16, 2016**, by entering your responses at: www.ismp.org/sc?id=2829.

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> SAFETY briefs

cont'd from page 3

for linagliptin) with all orders. Another option is to prescribe these drugs using the brand names, which are very different, and including brand names when the drug names appear on computer screens.

Standardize 4 Safety: Fewer choices, fewer errors. The American Society of Health-System Pharmacists (ASHP) announced availability of the first list of recommended concentrations for adult intravenous (IV) continuous infusions as part of their US Food and Drug Administration (FDA)-funded initiative, *Standardize 4 Safety* (www.ismp.org/sc?id=2830). Standardizing IV drug concentrations helps in reducing certain error-prone processes such as selecting the proper solution from a computer drop-down list. It can reduce the risk of someone using an incorrect concentration for a specific dose and can also help reduce extemporaneous compounding errors within hospitals. It makes standardizing smart pump libraries easier and, on a national and even international level, can provide the demand necessary for manufacturers to offer more commercially prepared standard solutions (if not already available). We hope that every hospital will take the time to consider how they might be able to conform to the new ASHP standards.

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

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ISMP Survey on Oral Chloral Hydrate for Pediatric Procedural Sedation

ISMP is conducting a short survey on oral chloral hydrate use to learn whether inpatient and outpatient facilities are still using it for pediatric procedural sedation, details regarding its use and adverse effects experienced by patients, and professional opinions regarding its continued role in pediatric procedural sedation. The article in this week's newsletter can help provide background on the subject. We encourage healthcare professionals who work in either inpatient or outpatient settings to participate in the survey by submitting responses to ISMP by **December 16, 2016**, by visiting: www.ismp.org/sc?id=2829. Please ask all healthcare practitioners, including prescribers, to answer this survey.

1 Since distribution of commercial chloral hydrate was discontinued in late 2012, has your organization continued to use or see the use of oral chloral hydrate for sedation for any inpatient or outpatient pediatric procedures?

☐ No **(skip to question # 7)** ☐ Don't know ☐ Yes

In which setting(s) is oral chloral hydrate used? (select one)
☐ Inpatient ☐ Outpatient ☐ Both inpatient and outpatient ☐ Don't know

2 What are the primary reasons for continued use of oral chloral hydrate for pediatric procedural sedation? (select all that apply)

☐ Low cost ☐ Efficacy ☐ As safe as other alternatives ☐ Inadequate alternatives
☐ Less frequent sedation failures than alternatives ☐ Lack of availability of anesthesia professionals
☐ Experience with positive outcomes ☐ Other (please specify) ☐ Don't know

3 Where is the oral chloral hydrate product obtained for use? (select all that apply)

☐ Hospital pharmacy compounds the drug ☐ Ambulatory pharmacy compounds the drug
☐ Compounding pharmacy provides the drug ☐ Other source (please specify) ☐ Don't know

4 Is oral chloral hydrate used in combination with another sedative for procedural sedation?

☐ No, never ☐ Only when sedation failures with chloral hydrate occur ☐ Don't know
☐ Yes, sometimes or always, as part of the initial sedation plan

Which are the most common additional sedatives used in combination with oral chloral hydrate? (select all that apply)
☐ Oral midazolam ☐ Intranasal midazolam ☐ Diaze**PAM** ☐ Ketamine ☐ Meperidine
☐ **PENT**obarbital ☐ Nitrous oxide and oxygen ☐ Don't know ☐ Other (please specify)

5 Have your patients experienced any of the following serious adverse events or effects within the past 3 years while using oral chloral hydrate for pediatric procedural sedation? (select all that apply)

☐ Hypoxia or hypercapnia ☐ Respiratory depression ☐ Airway obstruction ☐ Respiratory arrest
☐ Cardiopulmonary arrest ☐ Permanent neurologic injury ☐ Hypotension ☐ Cardiac dysrhythmia
☐ Prolonged sedation ☐ Post-discharge sedation ☐ Excessive somnolence or obtundation ☐ Other (please specify)
☐ Refusal of medication (spitting out dose) or vomiting ☐ Sedation failure or inability to complete the procedure ☐ Don't know

6 Have you seen any pediatric patients in your hospital emergency department for evaluation and treatment of adverse events or adverse effects of oral chloral hydrate administered for procedural sedation outside the hospital, such as at home?

☐ No ☐ Not Applicable (no emergency department in my organization) ☐ Yes (please explain) ☐ Don't know

7 Do you believe oral chloral hydrate still has a role in oral pediatric sedation for procedures?

☐ No ☐ Don't know ☐ Yes

For which procedures? (select all that apply)
☐ Any procedure ☐ Dental procedures ☐ Minor surgical procedures ☐ Pulmonary function tests
☐ Premedication for surgical procedures ☐ Radiology imaging ☐ Neuroimaging
☐ Electrocardiography testing ☐ Emergency department procedures (e.g., suturing)
☐ Auditory brainstem response test ☐ Electroencephalogram ☐ Other (please specify)

8 Please select the category that best describes your practice setting and profession. (select one for each topic)

Practice Setting
☐ Hospital
☐ Ambulatory pharmacy
☐ Dental office
☐ Medical office
☐ Ambulatory surgery center
☐ Ambulatory diagnostic center
☐ Clinic
☐ Other (please specify)

Profession
☐ Registered Nurse
☐ Licensed Practical Nurse
☐ Advanced Practice Nurse
☐ Pharmacist
☐ Physician or Dentist
☐ Other Prescriber
☐ Pharmacy Technician
☐ Other (please specify)

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Breakfast 9:00 AM – 9:30 AM
Symposium 9:30 AM – 11:00 AM
North Convention Center, South Pacific F

MONDAY, DECEMBER 5

From the Front Line: Improving Sterile Compounding Safety

11:30 AM – 1:00 PM
North Convention Center, South Pacific J

TUESDAY, DECEMBER 6

Error Prevention in Chemotherapy: Building Safer Medication Use Systems

11:30 AM – 1:00 PM
North Convention Center, South Pacific H

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Educational Sessions with ISMP Speakers

SUNDAY, DECEMBER 4

The 2016 ISMP Medication Safety Assessment and Strategies for Antithrombotic Therapy in Hospitals

3:00 PM – 4:30 PM
Oceanside C, Level 2

TUESDAY, DECEMBER 6

Current Considerations for Conducting Root Cause Analysis: Developing Your Plan

2:00 PM – 3:30 PM
South Seas F, Level 3

WEDNESDAY, DECEMBER 7

An ISMP Update for 2017

8:00 AM – 9:45 AM
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Implementing ISMP's Targeted Medication Safety Best Practices

9:00 AM – 11:00 AM
Mandalay Bay L, Level 2

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