

Nurse AdviseERR®

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 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 compounding an oral suspension of chloral hydrate for pediatric sedation in both inpatient and outpatient settings.^{4,5} The raw ingredient is available from pharmaceutical supply companies. Chloral hydrate has

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Lantus overdose tied to confusing vial label. An order for 90 units of insulin glargine (LANTUS) was written for a hospitalized patient. The hospital normally used insulin pens, but the pens can only dial up to a dose of 80 units. Therefore, pharmacy dispensed a 10 mL vial of Lantus. The nurse caring for the patient was inexperienced and had only used pens before, so she was unfamiliar with drawing up doses of insulin into a syringe. When the nurse looked at the vial label, it may have been turned slightly so that all she saw was “100 units” with a “10” directly under it (Figure 1, right). This is a different label presentation than on more familiar Lantus vials (Figure 1, left). The confusing vial label represents a change that was made last year. The pictured vial (right) has a March 2019 expiration date.



Figure 1. Familiar Lantus label on the left and confusing Lantus label (more recent) on the right.

The nurse assumed the concentration was 100 units/10 mL and then proceeded to draw up 9 mL into a 10 mL syringe and injected 900 units of Lantus subcutaneously as a single 9 mL dose. (The maximum volume for a subcutaneous injection

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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). A study⁵ 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.

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 ophthalmology 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.

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is generally 2 mL.) The results could have been catastrophic. But within a couple of hours, the nurse realized her mistake and reported it. The patient was immediately given a dextrose infusion and, fortunately, did not suffer harm.

In addition to the nurse's lack of knowledge about insulin administration, safe dosing, and the maximum volume per subcutaneous injection, one of the contributing factors of this event was the formatting of the Lantus vial label. The "10" is directly beneath the "100 units." This contrasts with the formatting of the Lantus box, which has "One 10 mL Vial," so the 10 is not directly beneath the 100. Other obvious contributing factors include unfamiliarity with drawing up insulin from a vial, not understanding the meaning of a U-100 concentration, and not using a U-100 insulin syringe, which was available on the patient care unit.

All this notwithstanding, it must be said that the best way to avoid such errors is for pharmacy to prepare, label, and dispense patient-specific basal insulin doses. Also, it's surprising how many insulin-related errors reported to us reveal knowledge gaps in handling insulin. Thus, it is critical to educate staff as necessary regarding injection technique and how to measure doses with insulin syringes. We notified Sanofi and the US Food and Drug Administration (FDA) about the labeling issue that contributed to a misunderstanding of the concentration.

⚡ U-500 insulin syringes now available.

The new U-500 syringe from BD (Figure 1), previously mentioned in the September 2016 newsletter, is now available for purchase. Before the new syringe, doses of U-500 insulin had to be drawn from a vial using either a U-100 syringe or tuberculin syringe, increasing the risk of dosing er-



Figure 1. New U-500 insulin syringe from BD.

rors. Unfortunately, the new U-500 syringe does not have a safety needle to help pro-
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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 re-sedation 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 (a very small dose range that provides benefits without causing severe harm), 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

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


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tect against needlestick injuries. This may rule out use of U-500 syringes in some facilities, although the package insert for **HUMULIN R U-500** insulin notes that patients using the vials must be prescribed U-500 syringes. The **HUMULIN R U-500 KWIKPEN** is available as an alternative.

 **Should transdermal fentaNYL be stocked in the ED?** FentaNYL transdermal patch 50 mcg/hour was prescribed for an 89-year-old man in the emergency department (ED) with intractable back pain. The order for fentaNYL was continued when the patient was admitted to an inpatient unit. Unfortunately, the patient was opioid-naïve, had never used this drug previously, and did not meet product labeling requirements to be prescribed this drug. It should also be mentioned that transdermal fentaNYL is not indicated for the treatment of acute or intermittent pain and is only indicated for opioid-tolerant patients. The pharmacist contacted the admitting physician, who ordered a different analgesic. The initial order in the ED for the fentaNYL patch had been automatically verified by the computer system, thus bypassing pharmacy review. Had the patient not been admitted, he most likely would have been discharged with the patch in place, risking an opioid overdose.

Auto-verify systems, which are commonly used in EDs, can present hazards to patients since they do not require pharmacy review. This is an opportunity for system administrators to build stops or decision trees into fentaNYL patch orders requiring prescribers to verify that the patient meets prescribing criteria (opioid-tolerant patient, for chronic pain). Moreover, transdermal fentaNYL should not be stocked in the ED. Serious consideration should also be given to requiring pharmacists to verify that the patient is opioid-tolerant (e.g., checking state opioid registries) and that the dose is appropriate prior to dispensing it to the ED.

 **More on lipid rescue.** A case submitted to www.lipidrescue.org is one that sounds eerily similar to a case we wrote about in 2010. In the event we published, a 16-year-old in labor died from local anesthetic systemic toxicity caused by the accidental IV

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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 other 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 6**, by **December 30, 2016**, by entering your responses at: www.ismp.org/sc?id=2829.

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administration of fentaNYL with bupivacaine instead of the intended penicillin G (Smetzer JL, Baker C, Byrne FD, Cohen MR. Shaping systems for better behavioral choices: lessons learned from a fatal medication error. *Jt Comm J Qual Patient Saf*. 2010;36(4):152-63; www.ncbi.nlm.nih.gov/pubmed/20402372). At the time, the use of fat emulsion as an antidote for anesthetic toxicity was largely unknown. In the present case, the outcome was much different!

In the case from the website, shortly after successful epidural placement and a negative local anesthetic test dose, a healthy 21-year-old pregnant patient began experiencing perioral numbness and tinnitus followed by stupor, seizure, hypotension, and tachycardia. The puzzling factor is that nothing had been administered via the epidural space other than a test dose of 3 mL of 1.5% lidocaine, which was negative only minutes prior. It was quickly noticed that the nurse had mistakenly grabbed an epidural infusion bag (100 mL of 0.25% bupivacaine with 2 mcg/mL fentaNYL) thinking it was penicillin G, then administered all of it IV. Upon recognition of the error, fat emulsion (INTRALIPID) 20%, 150 mL, was administered via bolus IV, and the patient's blood pressure and mentation improved within 2-3 minutes. Intralipid infusion was then initiated at 0.25 mL/kg/minute for 15 minutes after return of normal systemic blood pressure. The patient experienced tachycardia and was momentarily apneic but never required cardiopulmonary resuscitation. Fetal heart rate never dropped below 130 beats per minute, and the patient delivered a healthy infant with high APGAR scores.

It was prompt recognition followed by prompt administration of fat emulsion that saved this young woman and her infant.

If you would like to subscribe to this newsletter, visit: www.ismp.org/sc?id=384



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Production of this peer-reviewed newsletter would not be possible without the assistance of a reliable and talented clinical advisory board. As 2016 nears an end, we want to

thank each of the following members of the advisory board for their dedication to making this newsletter a valuable medication safety resource for nurses.

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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 30, 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 Diazepam Ketamine Meperidine
- PENTobarbital 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)