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

Minimize medication-related carbohydrates when a ketogenic diet is used for seizure control

Problem: A treatment option for both pediatric and adult patients with intractable epilepsy is the ketogenic diet, which has been used since the 1920s. Although additional antiepileptic drugs are now available, 35% of patients remain refractory and there is a continued interest in the diet as a treatment option. The ketogenic diet has a high fat and low carbohydrate content. Similar to a state of fasting, it promotes the use of fats as a primary fuel source, and through catabolism of fatty acids in the liver, it produces ketone bodies resulting in a state of ketosis. There have been different theories on the exact mechanism of the diet to reduce seizures, some suggest it modifies neuronal metabolism and excitability to reduce the seizure frequency, or that the ketone bodies themselves have an anticonvulsant effect. The decision for a patient to start such a stringent diet should be in collaboration with a dietitian and neurologist.[1-3]

The success of the ketogenic diet relies on the restricted consumption of carbohydrates to promote a state of ketosis. Despite the benefits of reduced seizures that patients may experience, they may discontinue this high-fat diet because it can be unpalatable (e.g., butter, heavy whipping cream, mayonnaise, canola oil, olive oil). Adult patients particularly have difficulty maintaining the ketogenic diet because of the severe restrictions.[4] Another challenge is that patients willing to try the ketogenic diet are often already on several medications for seizure control. Practitioners must carefully evaluate each medication's dosage formulation to ensure they are providing the least amount of carbohydrates possible, avoiding the need to further restrict the limited amount of carbohydrates in the patient's diet.

Most medications contain carbohydrates, but information about the exact amount is not readily available to practitioners on the package label, in prescribing information, or in the electronic health record (EHR). Oral liquid medications (especially suspensions) and chewable tablets, typically preferred for children, often have higher amounts of carbohydrates than tablets and capsules. For example, according to the *Carbohydrate Content of Medications* table in UpToDate Lexidrug,[5] **CHILDREN'S TYLENOL** (acetaminophen) 160 mg/5 mL suspension contains less than 5 grams of carbohydrates per 5 mL, compared to **TYLENOL** (acetaminophen) 500 mg extra strength caplet which contains less than 0.125 grams of carbohydrates per caplet. However, there may be significant variations in the carbohydrate content of medications, dependent upon the varying inactive ingredients used by brand and generic manufacturers. So, practitioners often need to call each manufacturer directly, which can be time-consuming. While the exact quantity of carbohydrates that may precipitate seizures is unknown, some suggest limiting carbohydrates from medications to 1 gram per day.[6] If practitioners fail to account for the carbohydrate content of medications provided to patients on the ketogenic diet, the diet may fail (i.e., taking the patient out of ketosis) putting the patients at risk for seizures.

Even if a patient is stable on a ketogenic diet and medication regimen at home, all involved practitioners (e.g., prescribers, pharmacists, nurses, dietitians) must be made aware of dietary needs during an escalation or transition of care. For example, if a patient on a ketogenic diet is admitted for an infection, and a prescriber determines the patient requires an antibiotic and intravenous (IV) fluids, all applicable practitioners must be aware that this patient is on a ketogenic diet. Otherwise, they may prescribe, dispense, and/or administer a medication or IV fluid (e.g., amoxicillin suspension, ciprofloxacin injection in 5% dextrose, IV fluids with dextrose) that could

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SAFETY briefs

Imported glucose injection. As mentioned in our October 31, 2024 article, *Fluid shortage update—Safeguard imported products*, the US Food and Drug Administration (FDA) has temporarily approved the importation of glucose injection (anhydrous form of glucose), that is not directly interchangeable, from a concentration standpoint, with FDA-approved dextrose injection USP (hydrated form of glucose). Organizations must consider any differences between glucose and dextrose products (e.g., caloric content, pH, osmolarity) and update protocols and systems (e.g., electronic health record, automated compounding device [ACD]). Use the ISMP ***Imported Fluid Product Checklist*** to complete a gap analysis to determine potential failure points and mitigation strategies.

Review the *Dear Healthcare Professional Letters* accompanying imported glucose products, which can be found here: Baxter Resources for Products Authorized for Temporary Importation. This website also includes educational material on how to add concentrated glucose (as glucose 50% or as the equivalent of dextrose 55%) to the Baxter order entry software (Abacus) and ACD (ExactaMix). Additional information on the differences between glucose and dextrose can be found in the Webinars & Videos section which address compatibility, concentration, and energy content.

Methylene blue syringe markings could lead to dosing errors. A practitioner reported concerns with the measurement markings on a 20 mg/2 mL (1%) methylene blue injection prefilled syringe (BPI Labs, a 503B outsourcing company) label: they contain trailing zeros (**Figure 1**, page 2). Not only is it difficult to see the decimal point (e.g., a practitioner could mistake 20.0 mg as 200 mg, or 2.0 mL as 20 mL), but including both mg and mL on the label markings could contribute to errors. For example, the practitioner could mistake 5 mg for 5 mL, instead of 0.5 mL.

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take the patient out of ketosis. Similarly, the patient's outpatient pharmacy must also be aware that the patient requires a specific medication (e.g., formulation, national drug code [NDC], and/or manufacturer) or they could unknowingly dispense a formulation that could negatively affect ketosis for the patient.

Medication Errors

Below are two examples of medication safety issues reported to ISMP that involve patients on a ketogenic diet.

An infant with non-ketotic hyperglycemia and epilepsy had recently been placed on a ketogenic diet. When the infant was admitted to the hospital, a prescriber ordered 40 mg of ***CARNITOR*** *(lev****OCARN****itine) 1 g/10 mL by mouth four times a day. When completing the patient's medication history, the pharmacist noted that the patient should receive* ***CARNITOR SF*** *(sugar-free lev****OCARN****itine) which is not only sugar-free but also carbohydrate-free. The nurses administered the correct formulation while an inpatient. However, at discharge, the physician prescribed Carnitor rather than Carnitor SF and did not communicate with the outpatient pharmacy that the patient was on a ketogenic diet. The outpatient pharmacy dispensed Carnitor, which the patient's mom administered to her child. Unfortunately, the infant began to have increased seizure activity and was readmitted to the hospital, where the error was identified.*

*A pediatric patient with epilepsy and on a ketogenic diet had been stable on daily doses of felbamate 500 mg at 7 am, 500 mg at 12 pm, and 400 mg at 5 pm (1,400 mg total daily dose). When a prescriber admitted the patient, she entered separate orders for the 500 mg doses (7 am and 12 pm) and the 400 mg dose (5 pm). The felbamate products available on the hospital formulary were 400 mg and 600 mg tablets, and a 600 mg/5 mL suspension. During order verification, a pharmacist selected 600 mg tablets for the two 500 mg doses, and 400 mg tablets for the 400 mg doses, since the suspension contained a large amount of carbohydrates. For the 500 mg order, the pharmacist entered instructions in the order comments for the nurse to "crush the 600 mg tablet and mix with 6 mL of sterile water (100 mg/mL) and administer 500 mg/5 mL to the patient." Since the verification process required the pharmacist to enter free-text instructions, the hospital policy required a second pharmacist to check the calculation and transcription before order verification. When the second pharmacist did so, they modified the 500 mg order to 400 mg tablets, so that the three doses were consistent with just one tablet strength. However, the pharmacist did not update the order comments to reflect the use of a 400 mg tablet instead of a 600 mg tablet. Prior to administration, the nurse scanned the barcode on the 400 mg tablet, which did not trigger any alerts since this was the correct product linked to the 500 mg dose order. The nurse followed the original order comment instructions for manipulating the tablet and administered 5 mL (which was actually 333 mg rather than the prescribed dose of 500 mg) for 3 days. The underdose resulted in the patient experiencing breakthrough seizures that were treated with rectal diaze****PAM*** *gel.*

Safe Practice Recommendations: The complexity of medication regimens for patients on the ketogenic diet calls for a coordinated approach. Consider the following recommendations to prevent patient harm.

For Manufacturers

Specify carbohydrate content. Manufacturers should include information about the amount of carbohydrates a medication contains on the packaging/labeling and in prescribing information. This is especially important for antiseizure medications since patients with epilepsy will often require these medications while on the ketogenic diet. We encourage manufacturers to explicitly identify a product's carbohydrate content, including the exact amount, to help ensure this information is readily available to practitioners and patients. Also, drug information providers and EHR vendors

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We reached out to the BPI Labs about these concerns and to recommend updating the container label to remove trailing zeros and the mg markings. If your organization carries this product, you may want to select a different vendor to avoid the risk of dosing errors.

Figure 1. A methylene blue syringe label (BPI Labs) contains trailing zeros, along with mg and mL markings, both of which could result in dose errors.

HIGH-ALERT

DexmedeTOMIDine almost administered instead of clindamycin. A nurse in a pediatric medical-surgical unit obtained a bag of what she thought was clindamycin (300 mg/50 mL) from an automated dispensing cabinet (ADC). The nurse scanned the barcode prior to administration and identified it was actually a bag of dexmede**TOMID**ine injection (200 mcg/50 mL). A pharmacy technician mistakenly stocked the dexmede**TOMID**ine bag in the clindamycin bin in the ADC. Both products, by Baxter, come in 50 mL bags and have labels with similar colors, fonts, and designs (**Figure 1**, page 3).

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will then be able to take advantage of this information to provide enhanced clinical decision support (CDS) at the time of prescribing and pharmacist verification.

For EHR Vendors

Enhance EHR systems to support preferred formulations. Vendors should ensure systems have a method for practitioners to clearly indicate that a patient is on the ketogenic diet. If prescribers are not aware, they may order a medication that increases the patient's daily carbohydrate amount, potentially putting them at risk of a seizure. Similarly, pharmacists and nurses must be aware of the patient's ketogenic diet status otherwise they could dispense or administer a medication that is contraindicated. Vendors should also enhance the ability for practitioners to select a formulation that is ketogenic diet friendly (i.e., no or low carbohydrates) or alert users if a medication formulation is inappropriate for a patient on the ketogenic diet (e.g., drug-disease interaction checking). Without such safeguards, some organizations have implemented workarounds such as documenting dextrose as an allergy to communicate that the patient is on the ketogenic diet and cannot receive medications with dextrose. Vendors should also consider providing fields for tracking medication carbohydrate content (e.g., communication forms, carbohydrate calculator) and allow for customizable CDS such as an alert to the practitioner if an oral liquid is ordered for a patient on the ketogenic diet, or if the medication carbohydrate content exceeds the patient's recommended daily limit.

For Organizations

Evaluate ketogenic diet services. Based on your patient population (e.g., epilepsy), assess the need for establishing, modifying, and/or expanding ketogenic diet services.

Assess medications on formulary. Identify the most common medications on your formulary (e.g., antiseizure) that patients on the ketogenic diet receive. Review medication packaging/labeling and prescribing information to identify which contain carbohydrates (see below, **Avoid these inactive ingredients**) and/or contact the manufacturer to find out the carbohydrate content for each medication and formulation (e.g., liquid, tablet, infusion) on the formulary. Consider maintaining an organizational database of carbohydrate content for commonly used medications and review and update it regularly. Incorporate this as part of the review process when evaluating new drugs or formulations for formulary addition. Refer to resources such as ketodietcalculator.org and UpToDate Lexidrug *Carbohydrate Content of Medications*.[5]

Designate a preferred formulation. If your organization regularly treats patients who are on the ketogenic diet, rather than trying to maintain a separate ketogenic diet preferred formulation for a medication, purchase the medication formulation with the least amount of carbohydrates, if possible. For example, for medications that patients often require while on this diet, such as lev**OCARN**itine, consider purchasing Carnitor SF rather than Carnitor as your formulary product to reduce the risk of dispensing or administering the incorrect formulation. Practitioners will typically need to switch patients from liquid medication or chewable tablets to tablets or capsules, and carbohydrate content must always be evaluated. Remember that sugar-free does not necessarily mean carbohydrate-free!

Avoid these inactive ingredients. Medications can be a source of hidden carbohydrates due to the fillers or sweeteners that are part of the drug formulation, especially liquid and suspension formulations created for children. Below are some common carbohydrates used in prescription and over-the-counter (OTC) medications that practitioners should avoid for patients on a ketogenic diet:[7,8]

- Glycerin
- Maltodextrin
- Organic acids (e.g., ascorbic acid, citric acid, lactic acid)

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Upon investigation, the hospital found that a pharmacy technician had scanned the barcode on only one of the clindamycin bags to access and refill the clindamycin bin (following their pharmacy's restocking process to only scan one product) and then placed a dexmede**TOMID**ine bag in the clindamycin bin in error. The pharmacy had previously purchased these medications from different manufacturers and had not identified the look-alike packaging when the new products were brought into the organization. The pharmacy is now purchasing dexmede**TOMID**ine from a different manufacturer to help avoid future mix-ups.

Figure 1. Dexmede**TOMID**ine (200 mcg/ 50 mL) (left) and clindamycin (300 mg/50 mL) (right) injection bags by Baxter look nearly identical.

We have reached out to the US Food and Drug Administration (FDA) and the manufacturer to recommend differentiating these infusion bag labels. When the pharmacy receives a new product (e.g., new product added to formulary, drug shortage), conduct a review to identify potential risks with the product's design, including look-alike labeling and packaging concerns with other products in use. When the pharmacy recognizes potential risks, consider purchasing the product (or one product of a problematic pair) from a different manufacturer. Use barcode scanning technology in the pharmacy to confirm that medications chosen for distribution to the ADC match the medications listed on the ADC fill report, and ensure each individual product (e.g., each bag) is checked. Segregate and secure all medications designated for an individual ADC during transport. Those loading the ADC should use

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- Propylene glycol
- Sugars (e.g., dextrose, fructose, glucose, lactose, sucrose, sugar, palm sugar, cane syrup, cane juice, corn syrup, honey)
- Sugar alcohols (e.g., erythritol, isomalt, glycerol, mannitol, maltitol, sorbitol, xylitol)
- Starches (e.g., cornstarch, hydrogenated starch hydrolysates (HSH), pregelatinized starch, sodium starch glycolate)

Develop a policy and procedure. Develop a policy and procedure to identify patients on the ketogenic diet and an accompanying workflow to notify practitioners and ensure patients receive the appropriate medications. Some organizations use a tracking board or pager to notify practitioners when a patient on the ketogenic diet has been admitted. If your organization plans to document a patient's carbohydrate count, determine the best documentation tool (e.g., EHR form, electronic spreadsheet) to calculate daily carbohydrate content for medications ordered (include PRN orders when applicable). Since a partial dose of a tablet may be needed for pediatric patients, evaluate your workflow to determine if pharmacy can crush and mix the tablet with water prior to dispensing. When possible and if clinically appropriate, pharmacists should round the dose (e.g., nearest tablet, one-half tablet). If nurses must manipulate the tablet, develop standard order comments for the medication administration record (MAR) using a template (i.e., "Crush and mix 1 tablet [# mg] in # mL of water to make # mg/# mL. Give # mL").

Differentiate ketogenic formulations. If more than one formulation must be available (i.e., formulary product and ketogenic diet-friendly product), review storage locations and ensure the products are clearly labeled (e.g., "ketogenic diet preferred"). Consider prebuilding a designation, such as "ketogenic diet patient," on the label for patient-specific doses of medication, to warn staff to be vigilant when checking the dosage formulation (e.g., Why are we dispensing IV fluids with dextrose, if the label states this is for a ketogenic diet patient?).

Reconcile medications. Evaluate the medication reconciliation process as it relates to orders for patients on the ketogenic diet during transitions of care. Add scripting to your medication reconciliation procedures that specifically asks patients about prescription medications, OTC medications (including herbals and dietary supplements), and non-enteral medications (e.g., infusions). When documenting which medication the patient is taking, make sure to include the specific dosage formulation. Enhance the process to capture the product's NDC and/or manufacturer as this information is critical when determining the product's carbohydrate content. This may require contacting the patient's outpatient pharmacy or reviewing outpatient notes (e.g., ketogenic diet clinic, neurologist office visit) to confirm. Share this information with the dietitian so they know the amount of carbohydrates the patients are receiving from their medications.

Evaluate EHR functionality. Understand the ways that your EHR can identify that a patient is on the ketogenic diet (e.g., diagnosis, banner bar, alert). Ensure this information is readily visible for all practitioners. Consider building a ketogenic diet order set for patients with intractable epilepsy with the most common medications prescribed for this patient population. For example, since the diet typically provides only small amounts of fruits, vegetables, grains, and dairy, patients should take a low-carbohydrate multivitamin and mineral supplement daily.[1] Evaluate CDS including drug-disease interaction screening. Specific details of the medication that the prescriber ordered, and that pharmacy should dispense (e.g., dosage formulation, NDC, and/or manufacturer) must be clearly visible on all applicable screens (e.g., MAR, pharmacy verification screen).

Document and communicate. Once a patient has been identified as being on the ketogenic diet, practitioners should follow the organizational policy and procedure as it relates to ordering, dispensing, and administering medications. In some organizations, a pharmacist is automatically consulted to verify appropriate formulations are selected and to calculate and document the total daily medication carbohydrate content. If a new medication is ordered, the system must clearly

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barcode scanning to confirm the accurate placement of medications in the correct drawer or pocket. Determine if your ADC has the functionality for practitioners to scan each individual product when refilling the ADC, and consider requiring scanning each medication before placing it in the ADC. Review the ISMP ***Guidelines for the Safe Use of Automated Dispensing Cabinets*** (Core Safety Process #6). As used in this case, employ bedside barcode scanning technology to confirm that medications selected for administration match those included on the patient's medication administration record.

Does IV push equate to IV bolus? A colleague outside the United States told us the terms "intravenous (IV) push" and "IV bolus" are used synonymously in their country. However, as discussed in the ISMP ***Safe Practice Guidelines for Adult IV Push Medications***, ambiguous terminology such as IV push, IV bolus, "slow" or "fast" IV push, should be avoided because they often lead to personal interpretation, especially if the order is lacking a rate of administration. So, is there a difference between IV push and bolus? The answer is, "Yes."

IV push is a method of administration using a syringe, and should include a specific administration rate; this may include a manually administered IV bolus dose. On the other hand, IV bolus is a discrete dose of medication or a solution given rapidly over a short, defined period. Depending on the medication, a bolus dose could be prescribed and administered through alternative routes (e.g., oral bolus dose) and may precede a maintenance dose.

To avoid confusion, policies and procedures and organizational guidelines should clearly define IV push versus IV bolus. Ensure all systems (e.g., electronic health record, smart infusion pump drug library) reflect accurate terminology and include a rate of administration on the medication administration record (MAR) for all IV medication orders. Educate staff about the differences between IV push (i.e., method of administration) versus bolus (i.e., dose).

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identify the patient is on the ketogenic diet so the pharmacist is aware and selects the most appropriate formulation, documents the carbohydrate amount, and notifies the dietitian to assess for any needed diet modifications.

Monitor patients. Conduct interdisciplinary team rounding during which the team discusses the medications for each patient on the ketogenic diet. Encourage prescribers, pharmacists, and nurses to review their patients' medications (e.g., the number of times a PRN medication was administered), laboratory monitoring (e.g., ketone level, nutritional status), and seizure frequency. If a patient experiences an unanticipated seizure, consider checking if the patient is still in ketosis, and if not, consider if a medication formulation could be the culprit.

Communicate with outpatient pharmacies. When a patient is on a ketogenic diet, plan for outpatient medication management before discharge. Ask patients where they typically fill their prescriptions and collaborate with the outpatient pharmacy to ensure they understand the patient's unique needs. Check if the pharmacy has a method to "flag" patients on the ketogenic diet, or how this information will be documented/communicated. Ensure the prescription designates that the patient is on a ketogenic diet, and requires a specific medication (e.g., dosage formulation, NDC, and/or manufacturer). Consider building an outpatient ketogenic diet order set with the most common medications prescribed for this patient population. For patients that require a partial tablet dose, standardize prescription instructions for the patient using a template (i.e., "Crush and mix 1 tablet in # mL of water. Give # mL").

Educate practitioners. Provide practitioners who will be involved with ordering, dispensing, administering, and monitoring patients on a ketogenic diet with a competency assessment to complete during orientation and at least annually thereafter. Include monitoring patients for side effects of the ketogenic diet, such as:[1,2,8]

- Constipation (consider **MIRALAX** [polyethylene glycol] since it is carbohydrate-free)
- Kidney stones (side effect of both the diet and certain antiseizure medications [e.g., topiramate, zonisamide])
- Decreased bone density if on the diet long term (consider vitamin D/calcium supplementation)
- Depleted vitamin stores (consider multivitamin and mineral supplementation) and particularly carnitine stores (consider lev**OCARN**itine)
- Acidosis (may need to supplement with sodium bicarbonate)
- Hypoglycemia (consider an appropriate volume of juice or amount of dextrose)

Educate patients. Provide patients on the ketogenic diet with documentation of their medication list including the specific dosage formulation, NDC, and/or manufacturer, and encourage them to share this information with practitioners at all applicable care settings (e.g., primary care provider, hospital admission, pharmacy) as part of their medication history. Tell patients to obtain medications from a single outpatient pharmacy that is familiar with their unique needs and that can consistently stock the formulation they require. Since a partial dose of a tablet may be needed for pediatric patients, educate patients and families about how to crush and mix the tablet, and how much volume to prepare and administer using the teach-back method. Educate patients about the need for minimal carbohydrate content and how this will impact their medication regimen. Teach them to always read medication labels, including all OTC products, look for inactive ingredients to avoid, and that sugar-free does not always equate to carbohydrate-free. Teach them that they should avoid liquid medications unless they discuss this with their prescriber, pharmacist, or dietitian. Provide educational resources such as the *Charlie Foundation for Ketogenic Therapies* website.

Learn from errors. Encourage staff to report close calls as well as errors that have reached the patient. Review internally reported ketogenic diet-related errors as well as published external events.

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Tuesday, December 10, 2024

Civic Theatre – New Orleans 6:00 pm

2024 Michael R. Cohen Lifetime Achievement Award Winner

David W. Bates, MD, MSc

David W. Bates, MD, MSc, Medical Director of Clinical and Quality Analysis, Mass General Brigham; Senior Physician and Director, Center for Patient Safety Research and Practice, Brigham and Women's Hospital; Professor, Harvard Medical School and Harvard T.H. Chan School of Public Health

Join us in December for our annual Cheers Awards celebration, where we will celebrate the amazing abilities of individuals and organizations that have advanced medication safety in the past year.

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For support opportunities and/or to register for the dinner, visit: www.ismp.org/cheers

Educational Sessions with ISMP Speakers at the 2024 ASHP Midyear Clinical Meeting

Please stop by and see us in booth #1813!

Tuesday, December 10, 2024

ISMP Medication Safety Update 2024
8:00 am – 9:30 am CT
Room 272 Level 2

Get in Top Form with the 2024 Health Technology and Patient Safety Hazards
2:00 pm – 3:00 pm CT
Room 272 Level 2

The (Not So) Big Easy of Safety: Measuring Meaningfully
3:30 pm – 4:45 pm CT
Room TBD

Wednesday, December 11, 2024

Executive View: Leaders Discuss Drug Shortage Policy and IV Fluid Updates
7:45 am – 9:45 am CT
Room TBD

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