PHARMACY & THERAPEUTICS
UPDATE

METHODIST

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Critical Drug Shortages

On-going shortages and strategies to minimize the impact to patient care for drugs with limited availability

Shortage:	***Dextrose 50% vials***
Action:	*glucagon*
Shortage:	***Pantoprazole injectable***
Action:	*injectable famotidine, oral pantoprazole*
Shortage:	***Morphine, Hydromorphone PCA***
Action:	*oral alternatives, intermittent dosing*
Shortage:	***Injectable Opiates***
Action:	*Oral alternatives if possible*
Shortage:	***Diazepam Injection***
Action:	*oral alternatives, lorazepam*
Shortage:	***Lidocaine, Bupivacaine injection with and without epinephrine***
Action:	*alternative concentrations, sizes*

In this Issue

If you have any questions or concerns, please contact the NMH Pharmacy Purchasing Department: 402-354-4337

FDA Warning: Abrupt Discontinuation of Opioids

The U.S. Food and Drug Administration (FDA) issued a warning regarding serious harm occurring in patients who are physically dependent on opioid pain medicines if medications are discontinued abruptly or when rapidly reducing the dose. Adverse events include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide. The FDA will require package labeling be modified to include guidance on safely discontinuing or tapering the opioid.

Health care professionals are urged to consider a variety of factors when the decision is to discontinue or reduce opioids including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. No standard opioid tapering schedule exists that is suitable for all patients. Providers are urged to create a patient-specific plan to gradually taper the dose of the opioid and ensure ongoing monitoring and support, as needed, to avoid serious withdrawal symptoms, worsening of the patient's pain, or psychological distress. The FDA warning offered the following information to consider when tapering doses:

- In general, for patients who are physically dependent on opioids, taper by an increment of no more than 10 percent to 25 percent every 2 to 4 weeks.
- Patients who have been taking opioids for shorter time periods may tolerate a more rapid taper.
- Tapering may be paused or returned to the previous dose if patient experiences increased pain or serious withdrawal symptoms; once stable, proceed with a more gradual taper.
- Ensure multimodal approach to pain management is initiated, including mental health support if needed prior to tapering, especially for patients on high opioid doses or long-term treatment.
- Frequent follow-up with patients is important to reassess/manage pain, withdrawal symptoms, suicidal thoughts, use of other substances, or changes in mood.
- When opioid analgesics are being discontinued due to a suspected substance use disorder, evaluate and treat the patient, or refer him/her for evaluation and treatment of the substance use disorder.

https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes

Pantoprazole Injection Shortage – Automatic Interchange & Prescribing Restrictions

There have been several instances over the past year where national shortages of injectable pantoprazole and other injectable proton pump inhibitors have occurred, the most recent beginning in May. In order to conserve supply of pantoprazole, the Medical Executive Committee has approved the following initiatives:

- Routine Stress Ulcer Prophylaxis – No history of GI diagnosis: pharmacists will interchange injectable pantoprazole orders to injectable famotidine 20mg IV q12h.
- Stress Ulcer Prophylaxis – History of GI diagnosis: pharmacy will notify provider to discuss alternative therapies based on available supply
- Pantoprazole Continuous Infusion - orders will be limited to GI specialty based on available supply
    - Providers are encouraged to consider intermittent pantoprazole therapy (q12h) in lieu of a continuous infusion or beginning intermittent therapy and consulting GI to evaluate the need for a continuous infusion.
- Injectable to Oral conversion: as previously approved, pharmacy may convert intermittent injectable pantoprazole when patient is taking oral meds/oral diet

If you have any questions, please contact pharmacy at 402-354-4334.

AHA, ACC Guidelines on Cholesterol Management

In order to reduce the lifetime risk for atherosclerotic cardiovascular disease and improve upon the 2013 guidelines, the American Heart Association (AHA) and the American College of Cardiology (ACC) released updated clinical guidelines regarding cholesterol management in November 2018. These new guidelines personalize the risk and add treatment recommendations to the previously existing guidelines.

The 2018 guidelines expand its population focus of a heart-healthy lifestyle by emphasizing the importance of starting assessments during childhood in order to decrease the lifetime ASCVD risk. Though there is lack of evidence in the younger population, the guidelines suggest screening children as young as two years of age who have a family history of heart disease or high cholesterol. In addition, the update includes spotlighting ethnic groups and estimated risk due to country of origin, socioeconomic factors, and cultural factors.

The 2018 update divides individuals into four groups based off of estimated spectrum of risk of cardiovascular events in the next ten years:

- Low risk: less than 5%
- Borderline risk: 5-<7.5%
- Intermediate risk: 7.5-<20%
- High risk: 20%+

Similar to the previous guidelines, the new guidelines continue to focus on the four statin-benefitting groups:

- Those with clinical ASCVD
- Those with LDL-C ≥ 190 mg/dL
- Those with diabetes mellitus, 40-75 years old, with LDL-C ≥ 70 mg/dL
- Those with no diabetes, but with LDL-C ≥ 70 mg/dL and ≥ 7.5% ASCVD risk

A significant change in the guidelines is the emphasis on LDL percentage reduction treatment goals and focus on long-term monitoring of therapeutic efficacy.

For secondary prevention, the guidelines recommend considering the addition of non-statin medications in addition to statin therapy for patients at very high risk. Since 2013, randomized clinical trial evidence has emerged, supporting the usage of adjunct therapies. When statins alone are ineffective in reducing risk, the 2018 update recommends adding ezetimibe (Zetia) to the regimen. For patients at high ASCVD risk with a maximally tolerated statin dose and ezetimibe, consider adding a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (alirocumab or evolucumab) when the LDL-C is 70 mg/dL or greater.

https://www.acc.org/latest-in-cardiology/articles/2018/11/07/15/19/sat-1130am-guideline-on-the-management-of-blood-cholesterol; https://utswmed.org/medblog/high-cholesterol-guidelines-update/; https://www.acc.org/latest-in-cardiology/articles/2018/11/14/10/48/was-the-juice-worth-the-squeeze; https://annals.org/aim/fullarticle/2734785/2018-cholesterol-clinical-practice-guidelines-synopsis-2018-american-heart-association