

PHARMACY AND THERAPEUTICS NEWSLETTER

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http://www.tarzanacme.com/pharmacy_newsletter.aspx

P&T COMMITTEE ACTIONS

FORMULARY

Deletion: Chloral Hydrate – discontinued by the sole manufacturer

DRUG SHORTAGE!!

The American Systems Healthcare Pharmacist (ASHP) Drug Shortage [link is available for review on the new PTMC intranet](#). Refer to the "QuickLinks" on the front page of the site, which has up-to-date information about drug shortages, including reasons for the shortage and likely duration.

Current Shortages Impacting PTMC

- Acyclovir (Zovirax®) IV
- Propofol (Diprivan®) IV
- Multivitamin IV
- Nitroglycerin 2% Ointment

POLICY UPDATE

Warfarin Policy

The policy has been revised to incorporate the ACCP 2012 Antithrombotic Guidelines. The recommendations for DVT/PE treatment are:

- Begin with parenteral anticoagulants
- Start warfarin (Coumadin®) the same day as parenteral anticoagulation; delay is not advised
- Continue parenteral anticoagulation for at least 5 days, regardless of INR. This guideline change reflects the action of

warfarin, where the increase in INR after starting the therapy reflects factor VII depletion rather than true systemic anticoagulation. Depletion of factor II and X is a more accurate indication of warfarin's antithrombotic effect, which takes about days.

TPN Pharmacist Consult Policy

An appendix was added to this policy and provides the basis for which pharmacists formulate TPN. All pharmacy policies, including this one, can be found: PTMC intranet → Resource → Document Central → Policy and Procedure → Pharmacy.

Insulin IV Columnar Protocol Pilot

The Diabetes and P&T committee recommended adopting the "Providence System IV Insulin Columnar protocol". **As a pilot, this protocol started at PTMC on November 14, 2012 in the ICU and CVIUC as staffing allowed.** The standard insulin IV infusion concentration changed to 1 unit/mL and will be the same at all Providence ministries.

MEDICATION SAFETY

Fentanyl (Duragesic) Patch

Despite warnings from the FDA, fentanyl patches (Duragesic®) continue to cause harm to patients nationwide. The FDA reports a 78 year old male admitted to an ED with lethargy and dizziness. He was under treatment for chronic pain and was given a prescription for a fentanyl patch, 25 mcg/hr. During the examination in the ED he was found with total of 6 patches on his body. Interviewed, the patient stated that the directions said to apply a patch every 72 hours. There were no directions to remove the patches. Similar findings were reported at PTMC this year.

A thorough physical examination, and medication history, may prevent this type of adverse event.

Are New Oral Anticoagulants Safe and Effective?

Dabigatran (Pradaxa®)

The ISMP (Institute for Safe medication Practice) monitors all serious adverse drug events reported to the FDA.

The ISMP identified dabigatran (Pradaxa®) and warfarin (Coumadin®) as the two leading medications reported to the FDA with serious adverse events in the year 2011.

Dabigatran is an oral direct thrombin inhibitor anticoagulant approved for the prevention of stroke in patients with atrial fibrillation. Dabigatran accounted for 3,781 serious adverse events in 2011, including 62% (2,367) from hemorrhage and 14% (542) deaths. In comparison, warfarin accounted for 1106 serious adverse events in 2011, including 66% (1,106) from hemorrhage and 7% (72) deaths².

Dabigatran appears simpler to use than warfarin because of less monitoring and fewer drug interactions. However, dabigatran does not have a reversal agent, like Vitamin K for warfarin. During clinical trials with dabigatran, there was a trend towards higher incidence of major bleeding when compared to warfarin for patients older than 75 years of age. Many of the post marketing bleeding events have been in patients with renal insufficiency who did not have the dose reduced to 75 mg twice daily^{1,2}.

REFERENCES

1. Pradaxa Prescribing Information 2012
2. <http://www.ismp.org/quarterwatch/pdfs/2011Q4.pdf>

Rivaroxaban (Xarelto®)

Rivaroxaban is an oral Anti-Xa inhibitor anticoagulant approved for the prevention of thromboembolic event following hip and knee surgery, prevention of stroke in patients with atrial fibrillation, and treatment of DVT/PE. The ISMP identified 356 adverse events associated with rivaroxaban during the first quarter of 2012. **The most common event was a serious thromboembolic event (44% of all events), including pulmonary embolism.** The finding was unusual because the primary event was not hemorrhage (as with other anticoagulants warfarin, Pradaxa®, Lovenox®), but thrombosis. Bleeding was next most common with 34% (158) of the events.

The ISMP also stated that during the FDA review of rivaroxaban, the reviewers questioned the convenient once-a-day dosing schedule. Significant peaks and troughs from blood level studies were to be eliminated by twice a day dosing but surprisingly, the drug received approval as once a day medication.

The ISMP concluded in the quarter report that the predominance of reports for thromboembolic events, not seen with other anticoagulants, constitute a signal of possible sub-therapeutic doses or some other form of unexpected lack of efficacy for rivaroxaban and that this finding should be investigated further¹.

Janssen Pharmaceuticals, the manufacturer of rivaroxaban, attributes the large number of adverse reports to the drug's large market share (22.5%) due to a successful launch of the drug.

REFERENCES

1. <http://www.ismp.org/quarterwatch/pdfs/2012Q1.pdf>

Sodium citrate 4% Locking solution (catheter anticoagulation) for Dialysis Patients with Heparin Induced Thrombocytopenia (HIT)

Heparin is the primary catheter-locking agent for patients with haemodialysis catheters. This can be a problem if a patient has a history of or is suspected of HIT. Sodium citrate has been used as an anticoagulant in laboratory and dialysis settings.

A recent 12 month retrospective study of 286 patients on haemodialysis, comparing the efficacy of heparin with sodium citrate in maintaining catheter patency, found there was no significant difference between the groups except the lower cost of sodium citrate¹.

At PTMC, sodium citrate is available from the pharmacy to be used as a locking solution for dialysis patients who are suspected of, or who have a history of HIT.

REFERENCES

1. Sodium citrate 4% Locking solution for central venous dialysis catheters. Grudzinski et al. Nephrol Dial Transplant 2007 (22);471-476

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