What's New in the Patient Safety World

March 2013

Sedative/Hypnotics and Falls

We've tried for years, with varying degrees of success, to get physicians to use sedative/hypnotic drugs less frequently in hospitalized patients. We've long recommended that routine "prn" orders for such not be included on standard order sets (see our August 2009 What's New in the Patient Safety World column "Bold Experiment: Hospitals Saying No to Sleep Meds"). ISMP has echoed that approach (see our March 23, 2010 Patient Safety Tip of the Week "ISMP Guidelines for Standard Order Sets"). In our May 2012 What's New in the Patient Safety World column "Safety of Hypnotic Drugs" we discussed many of the safety issues related to sedative/hypnotic drugs. They frequently are contributing factors to patient falls, delirium, and opioid-related respiratory depression. Sometimes we'll see withdrawal syndromes in patients who have been receiving such drugs chronically. They may also play a role in predisposing some patients to aspiration. And they are a frequent contributor to events occurring in patients with sleep apnea. They appear on Beers' List or other lists of drugs potentially contraindicated in the elderly. In 2 columns (May 2012 "Safety of Hypnotic Drugs" and November 2012 "More on Safety of Sleep Meds") we we also discussed the possible link between such drugs and mortality. In the latter column we also noted a study linking hypnotic use with hip fractures in nursing home patients (Berry 2012). This study found that nursing home residents taking the newer non-benzodiazepine hypnotics were 70% more likely to suffer hip fractures.

Of the sedative/hypnotic agents, zolpidem is the most widely prescribed in the US. Now a new study shows that **zolpidem is associated with over a 4-fold increased risk of falls in inpatients** (Kolla 2013). They looked at fall rates in a large database of inpatients and were able to compare patients who received zolpidem with those in whom zolpidem had been prescribed but not administered and those in whom it had not been prescribed. They found that zolpidem use had an odds ratio of 4.37 for being associated with falls in inpatients, a finding that held up strongly even after adjustment for a whole host of other clinical and demographic variables. The number needed to harm (NNH) was calculated to be 55 and the risk appeared to be beyond that attributable to other medications.

Also in January 2013 zolpidem was the subject of an FDA drug safety communication (FDA 2013). That communication recommended lower doses of certain drugs containing zolpidem because of the potential increased risk of next-morning impairment for activities requiring mental alertness, such as driving. Though women may be more at risk than men the FDA recommended lower doses in both women and men. They

recommended the dose of zolpidem be lowered from 10 mg to 5 mg for immediate release products (Ambien, Edluar, and Zolpimist) and from 12.5 mg to 6.25 mg for extended-release products (Ambien-CR). Note that there was no dose change recommendation for Intermezzo, the lower dose zolpidem approved in November 2011 for middle-of-the-night awakenings. The label for that drug already included a recommended lower dose for women. That safety communication includes both the safety data leading to the new recommendations plus multiple practical recommendations for both patients and healthcare providers regarding use of zolpidem products.

Prescribing sleep meds, whether for inpatients or outpatients, is often done without much thought. All too often they are thought of as being relatively harmless. Knowing the downside is an important first step. But putting in place various system fixes (eg. removing them from standardized order sets, using clinical decision support tools, etc.) may play a more important role.

References:

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Home

Tip of the Week Archive

What's New in the Patient Safety World Archive