Medicines Safety Matters

A Newsletter from the Derbyshire and Nottinghamshire CCGs Medicines Safety Officers Network. Issue 6 December 2017

Welcome to our regular edition of Medicines Safety Matters; a newsletter produced by your local CCG Medicines Safety Officers .

Our aim is to highlight to you medication incidents that have occurred both locally and nationally, thus promoting and supporting safer practice.

Domperidone Incident

There has been a local medication related incident reported, which involved the prescribing of domperidone for reflux to a patient with existing cardiac conditions and awaiting angioplasty, who subsequently died . Whilst it is currently unclear whether the medication contributed to the patient's death, the prescribing of domperidone was not in line with the guidance issued by the MHRA in 2014[1]. This MHRA alert confirms a small increased risk of serious cardiac side effects particularly in adults over 60 years old, on higher doses of domperidone (>30mg per day) and those taking QT-prolonging medicines or potent CYP3A4 inhibitors at the same time as domperidone. (Potent inhibitors of CYP3A4 include clarithromycin, ketoconazole, itraconazole and many antiretroviral medications[2].) Prescribing of domperidone is now restricted to:

- the relief of nausea and vomiting
- the lowest effective dose, for the shortest possible time (maximum of 10 milligrams three times a day orally in adults). The length of treatment should not usually exceed one week

Domperidone is contra-indicated in patients:

- with conditions where cardiac conduction is, or could be, impaired
- with underlying cardiac diseases such as congestive heart failure
- receiving other medications known to prolong QT interval or potent CYP3A4 inhibitors
- with severe hepatic impairment

References

1. Medicines and Healthcare Products Regulatory Agency. Domperidone: risks of cardiac side effects (May 2014) https://www.gov.uk/drug-safety-update/domperidone-risks-of-cardiac-side-effects (accessed 30.10.2017)
2. Stockley's Drug interactions. www.medicinescomplete.com (accessed 30.10.2017)

Codeine & Tramadol Use in Breastfeeding

A recent Food and Drug Administration (FDA) safety announcement (https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm) has updated its advice around the use of codeine and tramadol in breast feeding mothers due to possible harm to their infants. There is now a strengthened warning to mothers, that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Healthcare professionals are reminded to avoid prescribing these medicines where possible in breastfeeding mothers and to also advise breastfeeding mothers not to purchase over-the-counter medicines containing codeine.

Reminder: taking higher than recommended doses of loperamide (Imodium), including through abuse or misuse of the product, can cause serious heart problems that can lead to death

The MHRA has issued communication on this in September 2017 and has recommended that:

- serious cardiovascular events (such as QT prolongation, torsades de pointes, and cardiac arrest), including fatalities, have been reported in association with large overdoses of loperamide
- healthcare professionals are reminded that if symptoms of overdose occur, naloxone can be given as an antidote
- since the duration of action of loperamide is longer than that of naloxone (1–3 hours), repeated treatment with naloxone might be indicated; patients should be monitored closely for at least 48 hours to detect possible CNS depression
- as for all medicines, patients should be reminded not to take more than the recommended dose on the label
- report all suspected adverse reactions, including those associated with abuse or misuse, to the Yellow Card Scheme

Interplay between OptimiseRx & SystmOne - 'Simple swap' messages: Azithromycin Incident

A near miss prescribing incident involving Azithromycin has occurred locally, which was found to be due to the interplay between OptimiseRx and SystmOne when acting upon 'Simple swap' messages (for most cost-effective option) highlighted by OptimiseRx e.g. Azithromycin capsules to tablets.

This resulted in a patient being prescribed a daily dose of azithromycin 500mg instead of the 250mg three times a week, which is what was originally intended. Upon investigation, the incident was found to be due to the Multilex default dose for Azithromycin tablets being selected by SystmOne when the OptimiseRx 'Simple swap' was actioned.

This system fault was raised as a patient safety issue with both OptimiseRx and TPP (who manage SystmOne). A fix has now been put in place by TPP who did an update on their clinical system to ensure that both doses were displayed at the time of the 'Simple swap' message appearing, which allows the prescriber to either change to the Multilex default dose or keep the dose originally prescribed/intended. However, it is important to note that, if the original dose is selected then the 'issue duration' is still changed to the default, but the original quantity specified remains the same.

Key points

- Take care to check the prescription details carefully whenever a medication switch is made – especially the dose, issue duration and quantity.
- Please report any untoward incidents or issues involving either OptimiseRx or Clinical systems (SystmOne, EMIS) to your local CCG Medicines Management Team.

Screenshot to show how the SystmOne message appears at the point of acting upon an OptimiseRx 'Simple swap' message – using Azithromycin as an example: