Observatory
<31\textsuperscript{st} August 2016>
Observatory of recent safe medication practice research, reports, and publications

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- **Riociguat (Adempas)**: not for use in patients with pulmonary hypertension associated with idiopathic interstitial pneumonias

Letters sent to healthcare professionals in July 2016

- **Posaconazole (Noxafil®)**: tablets and oral suspension are not interchangeable

MHRA Recent regulator and statutory body activity


- **Respontin Nebules 250micrograms/1ml & Respontin Nebules 500micrograms/2ml (Ipratropium Bromide) (EL (16)A/10 )**
  - out of specification results for impurities were obtained during routine stability testing. No complaints or adverse reactions relating to this issue have been received by the company to date.

- **Furosemide-Claris 20mg/2ml Injection - AUST R 148003, intended for the Australian market (CLDA (16)A/04)**
  - possible mislabelling of shipping cartons at the manufacturing site, some packs of the above product may have inadvertently been distributed in the UK from Australia

- **Kogenate Bayer Powder and Solvent for Solution for Injection (CLDA (16)A/05)**

- **Helixate NexGen - (CLDA (16)A/06)**
  - Affected batches were manufactured with active ingredient that has either fallen below the potency specification since release to the market or is at risk of falling below specification prior to expiry
Medical Device Alert [https://www.gov.uk/drug-device-alerts](https://www.gov.uk/drug-device-alerts)

• Home use blood glucose monitoring system: TRUEresult and TRUEtrack blood glucose test strips (MDA/2016/014 and MDA/2016/015)
  – risk of false low blood glucose results

• Accu-Chek® Insight insulin pump system manufactured by Roche Diabetes Care with NovoRapid® PumpCart® cartridges (MDA/2016/015)
  – risk of hyperglycaemia
Product Safety Reviews

• The SPS website does continue to have reviews (formerly available with the UKMi website)

Product Safety Assessment

Prednisolone (Pevanti®)
• The Pevanti® range of prednisolone tablets (2.5mg, 5mg, 10mg, 20mg, 25mg), manufactured by Amdipharm Mercury Company Limited

• Dispensing processes/systems (both electronic and paper-based) should be reviewed to minimise the possibility of selecting the wrong prednisolone product.

• Patients should be counselled to ensure that they know the strength of their tablets and how many to take. This will be particularly important for patients familiar with doses made up from multiple 5mg tablets.

• Organisations introducing new strengths of prednisolone will need to raise staff awareness. Consider separating the different strengths by storage on different shelving units within the dispensary or using ‘caution stickers’ to reduce the potential for picking errors.
A systematic review and meta-analysis found that adding a dipeptidyl peptidase-4 (DPP-4) inhibitor (or gliptin) to a sulfonylurea increased the risk of hypoglycaemia by around 50%. The NICE guideline on type 2 diabetes recommends the combination of a sulfonylurea and DPP-4 inhibitor as an option for intensification of treatment in certain circumstances. The guideline recommends that the choice of medicine for managing blood glucose levels should be made following a discussion with the individual person about the benefits and risks of drug treatment, and the options available.
National guidance, publications and resources

- Adverse event and clinical trial data provides growing evidence of adverse drug events associated with all three approved SGLT2 inhibitors.
  http://ismp.org/pressroom/PR20160701.pdf

- Care Quality Commission. Controlled Drugs Patient Safety Newsletter
  http://www.cqc.org.uk/sites/default/files/20160718_controlled_drugs_national_group_patient_safety_newsletter_v1_no2.pdf

- Signal of increased risk of lower extremity amputations observed in trial in high cardiovascular risk patients
  https://www.medicinescomplete.com/mc/bnf/current/PHP34485-canagliflozin.htm

- Vaccinations Update. Meningococcal C (Men C) vaccine is not need at week 12
Is single room hospital accommodation associated with differences in healthcare-associated infection, falls, pressure ulcers or medication errors? A natural experiment with non-equivalent controls
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4904344/

2015 EAHP survey: Managers urged to support systems to reduce medication errors
European Journal of Hospital Pharmacy, Jul 2016, vol./is. 23/4(244), 2047-9956;2047-9964
http://ejhp.bmj.com/content/23/4/244.extract

Exploring behavioural determinants relating to health professional reporting of medication errors: a qualitative study using the Theoretical Domains Framework

Reflections on the current state of infusion therapy
Weinger M.B.,Kline A. Biomedical Instrumentation and Technology, July;August 2016, vol./is. 50/4(253-262)
This months’ papers - overview

Adverse drug events link to severity of the event data needed
Ibinson J.W., Buffington C.W. Anesthesiology, Aug 2016, vol./is. 125/2(431)

Incidence and determinants of medication errors and adverse drug events among hospitalized children in West Ethiopia
Dedefo M.G., Mitike A.H., Angamo M.T. BMC Pediatrics July 2016. 16(81) pp. 1471-2431
http://europepmc.org/articles/PMC4936294;jsessionid=ESPSdMOpO94VbOYFpdyM.1

Examining the July Effect: A National Survey of Academic Leaders in Medicine
Levy K., Voit J., Gupta A., Petrilli C.M., Chopra V. American Journal of Medicine, Jul 2016, vol./is. 129/7(754.e1-754.e5)

Adapting and remodelling the US Institute for safe medication practices’ medication safety self-Assessment tool for hospitals to be used to support national medication safety initiatives in Finland
International Journal of Pharmacy Practice 2016, 24, pp. 262–270
This months’ papers - overview


http://ejhp.bmj.com/content/early/2016/07/26/ejhpharm-2016-000950
Analysis of the medication reconciliation process conducted at hospital admission
Contreras Rey M.B., Prados Y.A., Gomez E.S. Farmacia Hospitalaria, July; August 2016, vol./is. 40/4(246-259)

• Retrospective study
• Conducted in the Pharmacy Department of a 600-bed hospital within a University Specialty Hospital, Spain
• Time frame: 15th January – 14th July 2015 (6 months)

Results

<table>
<thead>
<tr>
<th>Category</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No discrepancies</td>
<td>131</td>
<td>26.5</td>
</tr>
<tr>
<td>Justified discrepancy</td>
<td>51</td>
<td>10.3</td>
</tr>
<tr>
<td>Discrepancy that requires clarification (no justified)</td>
<td>312</td>
<td>63.2</td>
</tr>
<tr>
<td>– Unjustified omission of medication</td>
<td>269</td>
<td>54.5</td>
</tr>
</tbody>
</table>

Severity of errors

<table>
<thead>
<tr>
<th>Category</th>
<th>%</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>2.2</td>
<td>No error, but likely to occur</td>
</tr>
<tr>
<td>B</td>
<td>2.6</td>
<td>Did not reach the patient, thus caused no harm</td>
</tr>
<tr>
<td>C</td>
<td>49.5</td>
<td>If reached the patient, would not be likely to cause harm</td>
</tr>
<tr>
<td>D</td>
<td>19.4</td>
<td>If reached the patient, they would need monitoring/ intervention to prevent harm</td>
</tr>
<tr>
<td>E</td>
<td>6.5</td>
<td>Would cause temporary harm if they had reached the patient</td>
</tr>
</tbody>
</table>
Conclusions
• Medicines reconciliation conducted by pharmacists proved useful
• Were able to identify and prevent medication errors with the potential for clinical consequences for the patient

Limitations
• Presentation of results
• No analysis of the cases where interventions were not accepted as errors
• Restricted of patients included