UKMi Observatory
Wednesday 29th November
Observatory of recent safe medication practice research, reports, and publications

Presented by
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Patient Safety Alert (Directive): Confirming removal or flushing of lines and cannulae after procedures.
Recent regulator and statutory body activity

MHRA

Class 4 Drug Alert: higher levels of histamine in some batches of Gentamicin Sulphate injection. A recall is not appropriate at this stage. Monitor closely for ADR: anaphylactoid or hypotensive reactions and increased heart rate.

Class 4 Drug Alert: glass particles detected in batch of Bleo-Kyowa. Inspect reconstituted product under bright light and use a standard 5-micron filter needle to withdraw from vial.

Gadolinium contrast agents (used for MRI enhancement): MHRA awaits final decision from EC

Monthly Falsified Medicines Directive monthly newsletter
The newsletter is available by email request only to FMD.safetyfeatures@mhra.gov.uk
Drug Safety Update
https://www.gov.uk/drug-safety-update

Methylprednisolone injectable medicine containing lactose: do not use in patients with cows’ milk allergy. Solu-Medrone 40 mg may contain trace amounts of milk proteins.

Gabapentin (Neurontin): rare risk of severe respiratory depression even without concomitant opioid medicines.

Isotretinoin (Roaccutane): rare reports of erectile dysfunction and decreased libido reported.

Clozapine: reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus. Vital that constipation is recognised and actively treated.
HPV vaccines: Available evidence does not support it is linked two specific syndromes, complex regional pain syndrome (CRPS) and postural orthostatic tachycardia syndrome (POTS) in young women and girls.

Decision from the European Ombudsman concludes ‘no maladministration by the Agency in the handling of its safety review of HPV vaccines’.


EMA concludes review and recommends further restrictions for multiple sclerosis medicine Zinbryta due to risk of serious liver damage:

Zinbryta only for patients who have tried at least two other disease modifying treatments and cannot be treated with other treatments.

An acknowledgment form to be used to confirm risks and that patients understand the importance of monitoring and checking for signs of liver damage.

Pharmacovigilance Risk Assessment Committee (PRAC)

**Hydroxyethyl-starch containing medicines:** PRAC starts a new review as studies show low adherence to 2013 restrictions aimed at reducing risks of kidney injury and death.

Jazz Pharmaceuticals: Small amounts of particulate matter (PM) have been observed from Erwinase® batch 184g. Use a standard 5-micron filter needle to withdraw reconstituted product from vial.
https://assets.publishing.service.gov.uk/media/59f081f4e5274a18bc07411c/ERWINASE_19_Sept.pdf

All recombinant human erythropoietins: Risk of severe cutaneous adverse reactions with darbepoetin alfa, epoetin alfa, epoetin beta, epoetin zeta and methoxy polyethylene glycol-epoetin beta
https://assets.publishing.service.gov.uk/media/59f0822740f0b61abba11387/Epoetins_30_Sept.pdf
• Training poster for the administration of **paracetamol 10mg/ml infusion (Actavis)** which includes weight-based dosing. 

• **Jylamovo (methotrexate) 2mg/ml oral solution** guide to mitigate the risk of medication error and what to do in the event of a medication error. 
  http://www.medicines.org.uk/emc/medicine/34271
Drug shortages and discontinuations

Shortage of Diazemuls (diazepam 5mg/ml emulsion for injection): SPS memo provides advice on alternative options
https://www.sps.nhs.uk/articles/shortage-of-diazemuls-diazepam-5mgml-emulsion-for-injection/

Shortage of tranexamic acid tablets 500mg (all brands): SPS memo provides advice on alternative options
https://www.sps.nhs.uk/articles/shortage-of-tranexamic-acid-tablets-500mg-all-brands/
UKMi Product Safety Assessment report: Truxima® and Rixathon® (rituximab biosimilars).


Drugs and Therapeutics Bulletin: An update on the bleeding risks associated with DOACs.

http://dtb.bmj.com/content/55/11/129

New EudraVigilance system is live
Better safety monitoring for patients across Europe


Pregabalin and gabapentin: proposal to schedule under the Misuse of Drugs Regulations 2001

- Consultation 13 Nov 17 – 22 Jan 18
- Seeks opinions as Class C drugs under the Misuse of Drugs Act 1971 and placed in Schedule 3 to the Misuse of Drugs Regulations 2001.


This month’s papers - overview


- Systematic review of randomised trials in which healthcare professionals provided community-based medical services that aimed to reduce medication errors leading to hospital admissions, emergency department visits, or mortality.
- Included 30 studies: 26 studies as organisational and 4 as professional actions.
- Most of the studies took place in the UK and the USA
- Based on moderate- and low-certainty evidence, interventions in primary care for reducing preventable medication errors probably make little or no difference to the number of people admitted to hospital or the number of hospitalisations, emergency department visits, or mortality.
- More work needs to be done in improving the quality of the studies regarding selection of participants and adequate blinding of participants and study assessors. Participants dropping out of the studies was another concern in the certainty of evidence. Funding of the included studies came from various sources and it is difficult to decide whether the funding affected the results of the studies.

Electronic systems


https://link.springer.com/journal/40264/40/10

- Conference abstract presented at the Pharmacovigilance in the 21st Century conference- Liverpool UK 15-18 October, 2017:


- Aim: To examine ADR reporting trends post legislation changes including the impact of joint initiatives with NHS Improvement to increase reporting of medication errors.

- Results: No. of ADR reports arising from medication errors increased by 95% since 2012.

- Drug safety signals: Poor medication storage of an anticoagulant leading to increased lack of efficacy; cases of overdose arising from lack of visibility of transdermal opioid patches.

- Conclusion: Reporting of medication errors has nearly doubled in the past 5 years. Collaboration of patient safety organisation and increased communication with Medication Safety Officers is an important factor behind this increase.

- EU pharmacovigilance legislation focuses on medication errors and increased error reporting to EudraVigilance

- This study aims to characterise spontaneously reported cases of medication errors in EudraVigilance over the period 2002–2015

- A total of 147,824 case reports were retrieved, approximately 60% of these case reports were retrieved with the narrow Standardised MedDRA Query (SMQ).

- Case reports of medication errors in EudraVigilance steadily increased between 2005 and 2015

- A new Standardised MedDRA Query for medication errors facilitates data retrieval and analysis