Observatory
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Observatory of recent safe medication practice research, reports, and publications

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Resources to support the safety of girls and women who are being treated with valproate 6 April 2017.


A resource alert has been issued jointly by NHS Improvement and the Medicines and Healthcare products Regulatory Agency (MHRA) to support the safety of girls and women of childbearing potential being treated with valproate.
**Launch of pilot reporting scheme for harms associated with illicit drugs, particularly new psychoactive substances**

MHRA has launched a pilot scheme for healthcare professionals in the UK to report suspected adverse reactions to illicit drugs, particularly new psychoactive substances.

A pilot reporting website, the Report Illicit Drug Reaction form, will be available for 1 year for healthcare professionals across the UK who come into contact with patients experiencing harm associated with use of illicit drugs, particularly new psychoactive substances. The pilot aims to better collect data on harms from illicit drug use, to support provision of clinical guidance to professionals.

**SGLT2 inhibitors: updated advice on increased risk of lower-limb amputation (mainly toes)**

An update on the risk of lower-limb amputation (mostly affecting the toes) with sodium-glucose co-transporter 2 (SGLT2) inhibitors following the completion of a European review. Although there is no evidence confirming the increased risk seen with canagliflozin with other SGLT2 inhibitors (dapagliflozin and empagliflozin), data available are limited and the risk may also apply to these medicines. Healthcare professionals are reminded that preventive foot care is important for all patients with diabetes, including those receiving SGLT2 inhibitors. For canagliflozin, patients who have risk factors for amputation should be carefully monitored; consider stopping canagliflozin treatment if patients develop foot complications.
Recent regulator and statutory body activity

Class 2 Medicines Recall: Diclo-SR 75 Tablets (Diclofenac Sodium)
Strides Pharma UK Ltd, trading as Co-pharma, is recalling specific batches of Diclo-SR 75 Tablets as a precautionary measure
Drug alert General practice Issued: 29 March 2017

All Alaris™ GS, GH, CC, TIVA, PK, Enteral Syringe Pumps, and, Asena™ GS, GH, CC, TIVA, PK, Syringe Pumps – risk of uncontrolled bolus of medicine
Manufactured by CareFusion/BD Medical – identify and replace broken backplate spring in the plunger assembly and note updated preventative maintenance schedule for these pumps
Medical device alert Anaesthetics and 4 others Issued: 12 April 2017
Recent regulator and statutory body activity

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 20-23 March 2017 (click here for details)

6 medicines were recommended for approval –
- Dinutuximab beta Apeiron (dinutuximab beta)
- Refixia (nonacog beta pegol)
- Elmiron (pentosan plyphsulfate sodium)
- Trumemba (a meningococcal group B vaccine, recombinant, adsorbed)
- Axumin (fluciclovine (18F))
- Ivabradine Accord (avabradine)

Optimising safety information for medicines in Europe throughout product lifecycle (click here for details)

The EMA has issued new guidance and process improvement for periodic safety update information (PSURs). The process for reviewing PSURs has been streamlined and now ensure that all PSURs for the same active substance are reviewed at the same time by one authority resulting in consistent safety information.
Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Risk Assessment Committee (PRAC): 3-6 April 2017
PRAC concludes review of safety signal for Uptravi

At its April meeting, the Pharmacovigilance Risk Assessment Committee (PRAC) completed the safety review of Uptravi (selexipag), which is used to treat pulmonary arterial hypertension, a life-threatening condition involving abnormally high blood pressure in the arteries of the lungs. The review was initiated following the deaths of five patients in France. The PRAC concluded that the data examined do not suggest an increase in mortality with Uptravi and the medicine can continue to be used by both new and existing patients according to the current prescribing information. More information is available here.
Recalls, market withdrawals and safety alerts
The FDA has posted information from Mylan about the voluntary recall of selected lots of EpiPen and EpiPen jnr manufactured by Meridian Technologies (click here for information)

Initially recall was just US but 31/3/17 the voluntary recall was extended to cover additional markets in Europe, Asia, North and South America.

The issue? Failure to activate or increased force needed to activate the device. Incidence of the defect is extremely rare

No drug alerts seen in last 12 months in UK but be aware e.g. when working with non-UK based users of services.
Drug shortages and discontinuations

No new medicines shortages reported in Shortages, Discontinuations and Patent Expiries section of SPS website (click here)
**Product Safety reviews**

**Products In-Use Intrathecally version 2**
The table is a compilation of products in-use intrathecally within the NHS. This was originally compiled in December 2014 and has been updated to include information regarding whether the drugs listed have a CMU Contract line for intrathecal administration. NHS PASG do not endorse this list as being suitable for Intrathecal administration but provide additional information in this document that should be considered when preparing intrathecal preparations.

**New product evaluations – a resource for medicines management (March 2017)**
A reminder that the latest version of this resource is now available, all new/updated information is highlighted in red.
National guidance, publications and resources

Faculty of Sexual and Reproductive Health (click here)

These updated emergency contraception guidelines (March 2017) new guidelines highlight that women should be informed that it is possible that higher weight or BMI could reduce the effectiveness of oral emergency contraception, particularly levonorgestrel.

WHO launches global effort to halve medication-related errors in 5 years

The Global Patient Safety Challenge on Medication Safety aims to address the weaknesses in health systems that lead to medication errors and the severe harm that results. It lays out ways to improve the way medicines are prescribed, distributed and consumed, and increase awareness among patients about the risks associated with the improper use of medication.


http://www.who.int/patientsafety/medication-safety/en/
National guidance, publications and resources

Electronic Medicines compendium (www.medicines.org.uk)


   The prescription guide aims to ensure correct prescribing of ActiqR to minimise risk of misuse/pharmacodependence, abuse, medication errors, drug diversion, accidental exposure, overdose, off-label use, respiratory depression and dental decay in patients on opioids.

2. Educational Risk Minimisation Materials for Xeljanz (tofacitinib) are available here. The Prescriber Brochure provides advice for HCPs on how they can minimise important risks Associated with tofacitinib. The initiation and maintenance checklists remind HCPs of these risks, and recommended tests before and during tofacitinib administration.
This month’s papers - overview

The risk associated with injectable drug preparation errors observed in pharmacy aseptic units (conference abstract)
Almatroudi A et al  International Journal of Pharmacy Practice; Apr 2017; vol. 25 ; p. 40

Medication Reconciliation Failures in Children and Young Adults with Chronic Disease during Intensive and Intermediate Care
Decourcey D.D. et al  Pediatric Critical Care Medicine; Apr 2017; vol. 18 (no. 4); p. 370-377

Automated detection of look-alike/sound-alike medication errors
Rash-Foanio C. et al  American Journal of Health-System Pharmacy; Apr 2017; vol. 74 (no. 7); p. 521-527

Standardizing concentrations of adult drug infusions in Indiana
Todd A et al  American Journal of Health-System Pharmacy April 2017, 74 (7) 491-497

Automated identification of antibiotic overdoses and adverse drug events via analysis of prescribing alerts and medication administration records
Kirkendall E.S. et al  Journal of the American Medical Informatics Association; Mar 2017; vol. 24 (no. 2); p. 295-302
This month’s papers - overview

'Smart' intravenous pumps: How smart are they?
Franklin B.D.  BMJ Quality and Safety; Feb 2017; vol. 26 (no. 2); p. 93-94

The impact of electronic prescriptions on medication safety in Finnish community pharmacies: A survey of pharmacists
Kauppinen H et al  Int J Med Inform. 2017 Apr;100:56-62

The impact of an integrated electronic medication prescribing and dispensing system on prescribing and dispensing errors: a before and after study
Hodgkinson M R et al.  Journal Of Pharmacy Practice And Research April 2017; vol 47 (2); 110-120

*Transfer of care - a randomised control trial investigating the effect of sending the details of patients' discharge medication to their community pharmacist on discharge from hospital
Hockly M et al  The International Journal Of Pharmacy Practice 27th March 2017 (early view)

Medication Reconciliation During Hospitalization and in Hospital-Home Interface: An Observational Retrospective Study
This month’s papers - details

*Transfer of care - a randomised control trial investigating the effect of sending the details of patients' discharge medication to their community pharmacist on discharge from hospital*

Hockly M et al

The International Journal Of Pharmacy Practice 27th March 2017 (early view)

**Methods**

In a randomised, controlled trial, 33 participants in two groups, control and intervention, had their discharge letter sent to either their GP only or their GP and nominated community pharmacy after hospital discharge. At least 3 weeks after hospital discharge, the participant's current GP's medication record and their self-described medication regime was obtained. Discrepancies between their GP medication record and their discharge letter and between the participant's self-described medication regime and their discharge letter were counted. The number of discrepancies (relative to the number of drugs prescribed) in the intervention group was compared with the control group for each of the above two categories, using the chi-squared test to determine the statistical significance of any differences between the two groups.
Results
The intervention group had statistically fewer discrepancies than the control group for both data sets: GP records compared with the discharge letters ($P < 0.0005$); participants' self-described medication regimes compared with the discharge letters ($P < 0.00005$).

Conclusions
Sending a copy of patients' discharge letters to their community pharmacists could be beneficial in reducing post-discharge prescribing discrepancies and improving patient understanding of the changes made to their medicines.