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

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Recent regulator and statutory body activity
Proton pump inhibitors: very low risk of subacute cutaneous lupus erythematosus

Proton pump inhibitors (PPIs) are associated with very infrequent cases of subacute cutaneous lupus erythematosus (SCLE), a non-scarring dermatosis that can develop in sun-exposed areas.

If a patient treated with a PPI develops lesions—especially in sun-exposed areas of the skin—and it is accompanied by arthralgia:

- advise against exposing the skin to sunlight
- consider SCLE as a possible diagnosis
- consider stopping the PPI unless it is imperative for a serious acid-related condition; a patient who develops SCLE with a particular PPI may be at risk of the same reaction with another PPI
- symptoms usually resolve on PPI withdrawal; consider topical or systemic steroids for treatment of SCLE only if there are no signs of remission after a few weeks or months
- report any suspected side effect with PPIs, or to any medicine, on a Yellow Card

UKMI comment: Practical implications to support safe prescribing may include identifying, reviewing and managing patients on PPIs who have reported SCLE with arthralgia.
Drug Recall: Lacri-Lube Eye Ointment - small black particles on or around the nozzle of the tube

- (Allergan Limited) Small number of complaints have been received about small black particles found on or around the nozzle of the tube (EL (15)A/08).

- Class 2 medicines recall: batches of Lacri-lube 5g and 3.5g are being recalled

Lacri-Lube Eye Ointment

• The black particles originate from the inside of the cap and are formed when the cap is over tightened on the nozzle during manufacture of the tube. The particles may be introduced into the product at point of administration and may, therefore, get into the eye.

• This issue is likely to result in a shortage of the product on the UK market. Unaffected stock is expected to be available by late November 2015 but it is unlikely that supply will return to normal until Q1 2016.

UKMI comment: Practical implications may include steps to manage the likely shortage of the product on the UK market up to Q1 2016. These may include temporary inclusion of alternatives on primary and secondary care formularies.
Pseudoephedrine and ephedrine: update on managing risk of misuse in the UK

- Pseudoephedrine and ephedrine are medicines used as nasal decongestants, which are available from pharmacies. Between 2007 and 2008, the MHRA introduced restrictions on their use because of concern that medicines containing these active substances could be used in the illicit manufacture of the class A controlled drug methylamphetamine.

- Implementation of measures to regulate sales, and the additional voluntary actions overseen by the pharmacy profession, has made an important contribution to managing the risk of misuse of pseudoephedrine and ephedrine in the UK.

*UKMI comment: pharmacists, particularly community pharmacists should remain vigilant and informed of the risk of misuse associated with these drugs.*
The Yellow Card smartphone app was launched in July

- It allows direct reporting to the Yellow Card Scheme
- Free to use for everyone on iOS and Android
- Users see an immediate response that shows Yellow Card has been accepted
- Submit updates to Yellow Cards already submitted
- View previous Yellow Cards submitted through the app
- Create a ‘watch list’ of medications to receive official news and alerts
Yellow Card smartphone app update

- At end of August 2015, the app had been downloaded 723 times on Apple devices and 314 times on Android.
- Resulting in 27 suspected ADR reports being submitted which have contributed to MHRA signal detection activities.
- Positive feedback has been received for the app’s suspected ADR overviews and its news items for relevant products of interest.
- The MHRA are closely following the number of suspected ADRs received via the app and the safety issues identified from these reports.
- They are also looking at the most common medicines that are being followed by app users via their watch lists to improve understanding of what news and information is of most interest to users.
Contact MHRA with your views and suggestions

For any feedback on the app, either about how it works now or features you would like to be added in future, please email: web-radr@mhra.gsi.gov.uk

UKMI comment: download the app and start building your watch list of medicines you frequently prescribe, medicines used in an area in which you specialise, or those that you or a family member are taking.
Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC has started a safety review: EMA/593548/2015

Review of nasal and mouth sprays containing fusafungine

- The European Medicines Agency (EMA) has started a review of nasal and mouth sprays containing the antibiotic fusafungine, used to treat infections of the upper airways such as sinusitis and tonsillitis.

- The EMA will now review the available data on the benefits and risks of medicines containing fusafungine, and issue an opinion on the marketing authorisations of these medicines across the EU.

- The review is due to complete in December 2015, while the review is ongoing and pending further communication, patients should speak to their doctor or pharmacist if they have any questions or concerns.

*UKMI comment: this product is not available in the UK. The most common European trade name is Locabiotal.*
None identified this month, previous memos available via:

This months’ papers


- FDA announces plans to improve heparin safety. Drug Topics 2015 159(8) [https://www.questia.com/library/p62489/drug-topics/.../vol-159-no-8-august]

This months’ papers


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The impact of electronic prescribing systems on the incidence of prescribing errors within in-patients settings: A systematic review

IJPP 2015;23:26-27

• Aimed to review and evaluate the effects of e-prescribing systems on the incidence of prescribing errors in hospital patients

• Error analysis indicated that the use of e-prescribing systems introduced different types of prescribing error

• e-prescribing systems are effective tools in reducing the incidence of prescribing errors in hospitalised patients but future research requires more rigorous design and standardised definitions of prescribing error.
The impact of electronic prescribing systems on the incidence of prescribing errors within in-patients settings: A systematic review

- A recent systematic review revealed the following:
  - Median error rates 7% with medication orders; 52 errors per 100 admissions and 24 errors per 1,000 patient days
  - Errors not resulting in harm still led to additional work and/or increased cost of patient care
The impact of electronic prescribing systems on the incidence of prescribing errors within in-patients settings: A systematic review

- In this review, 39 studies met inclusion criteria
- 85% conducted at a single hospital site
- Study design varied, but 54% were prospective
- 59% adults, 31% paediatrics, 10% both
- 85% of studies demonstrated a significant reduction in prescribing errors associated with e-prescribing but...15% showed an increase or no effect
Improving transitions of care for patients on warfarin: the safe transitions anticoagulation report

Journal of Hospital Medicine 2015;10:615–618

• Adverse drug events are common during the transition from hospital to primary care. Anticoagulants are among the medication classes for which the incidence is highest

• This study aimed to develop a concise report to improve the timeliness of INR testing and quality of warfarin management following discharge from hospital

• The Safe Transitions Anticoagulation Report (STAR) was developed, containing essential information on anticoagulation
Improving transitions of care for patients on warfarin: the safe transitions anticoagulation report

- A retrospective administrative database review was conducted of 505 patients in the pre-intervention period and 292 patients in the intervention period who were discharged on warfarin.

- There was no change in the frequency of obtaining an INR value within 10 days of discharge (41.4% vs. 47.6%, p = 0.09), and no increase in attaining a therapeutic INR level within 10 days of discharge (17.0% vs. 21.2%, p = 0.14). Clinicians reported that the STAR improved “workflow and efficiency” (58%) and “patient safety” (77%), and led to an altered warfarin dose for 34% of survey respondents.
Improving transitions of care for patients on warfarin: the safe transitions anticoagulation report

• This study found that a concise anticoagulation report embedded in the discharge summary was perceived by primary care physicians as improving patient safety, but had no impact on clinical outcomes

• This suggests that this electronic medical record tool would need to be a component of a broader multifaceted intervention to be effective.
Thank you

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