National Medication Safety Network

Observatory
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National Medication Safety Network
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Observatory of recent safe medication practice research, reports, and publications

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Recent regulator and statutory body activity

NHS England

MHRA Regulating Medicines and Medical Devices

European Medicines Agency Science Medicines Health

FDA U.S. Food and Drug Administration

UKMi UK Medicines Information
Medicines: company-led recalls

April 2015

• Clexane 40mg (enoxoparin sodium) - Sanofi
  – Batch 4LL66 distributed from 12 January 2015
  – Recall due to a small number of breakages of syringe barrels reported in France
Drug Safety Update

Dimethyl fumarate (Tecfidera)

March 2015

• Fatal PML in an MS patient with severe, prolonged lymphopenia
• Check full blood counts before prescribing
• Monitor patients - check FBC including lymphocytes every 6-12 months or more frequently if clinically indicated
• Monitor patients with lymphopenia closely for signs of PML
• Stop treatment immediately and investigate if PML suspected
• Report adverse drug reactions on a Yellow Card
Medical safety alert
Epilim/sodium valproate GR tablets

March 2015

• Smell associated with some batches is said to be result of foil packaging

• No impact on quality or efficacy of tablets and therefore patients should continue to take medication

• Batches are not being recalled

• Batches packed in foil sourced from an alternative supplier expected by end April 2015 and distribution of impacted batches will cease at this time
New restrictions on use of hydroxyzine

March 2015

- Previously known risk of QT interval prolongation and torsades de pointes have lead to new dosing recommendations and warnings
  - Contraindicated in:
    - Acquired or congenital QT prolongation
    - Known risk factor for QT prolongation – CVD, electrolyte imbalance, family history of sudden cardiac death, significant bradycardia or concomitant use of drugs known to prolong QT interval and/or induce torsades de pointes
  - Use lowest possible dose for shortest possible time
    - Children – Max dose depends on weight
    - Adults – Max total dose 100mg/day
    - Elderly – Use not recommended but if they do max 50mg/day
  - Product information to be updated
Preventing medication errors in the EU

April 2015

• EMA on behalf of EU regulatory network has released two draft good practice documents that aim to improve reporting, evaluation and prevention of medication errors by regulatory authorities and the pharmaceutical industry in the EU.

• One guide focuses on prevention of medication errors and the other on how suspected adverse reactions caused by medication error are recorded, coded, reported and assessed

• Also released as an addendum to this good practice guidance is document on the risk of medication errors linked to new high-strength insulin

• Stakeholders to send comments to EMA by 14th June 2015
Pharmacovigilance Risk Assessment Committee (PRAC) recommendations

April 2015

• Recommendation for updating advice on use of high-dose ibuprofen
  – Review confirms small increase in risk of cardiovascular problems in patients taking high dose ibuprofen (≥2400mg per day)
  – No increase in cardiovascular risk with ibuprofen doses up to 1200mg per day
  – PRAC recommend updating advice in product information for ibuprofen
Pharmacovigilance Risk Assessment Committee (PRAC) recommendations

April 2015

• Further measures to minimise the known risk of osteonecrosis of the jaw associated with zoledronic acid and denosumab.
  – Product information to be updated.
  – A patient reminder card to be introduced to include the following:
    • The benefit of treatment of osteoporosis.
    • The risk of osteonecrosis of the jaw.
    • The need to highlight dental problems with doctors/nurses before starting treatment.
    • The need to ensure good dental hygiene.
    • The need to inform dentist of therapy with zoledronic acid or denosumab and to contact the doctor and dentist if problems occur.

• Measures to be considered for other IV bisphosphonates in upcoming reviews.
FDA warns of serious slowing of the heart rate when amiodarone is used with sofosbuvir (Sovaldi/Harvoni) in combination with another direct acting antiviral drug

- Patients can develop serious and life-threatening symptomatic bradycardia
- Advised changes to product information
- If combination unavoidable patient should be heart monitored for 48 hours as inpatient followed by daily monitoring of heart rate for at least first 2 weeks of treatment
NICE Quality Standard QS85
Managing medicines in care homes
March 2015

• Covers the prescribing, handling and administering of medicines for all people living in care homes, and the provision of care or services relating to medicines to those people

• This includes:
  – Health or social care service providers sending a discharge summary, including details of the person’s current medicines, with a person who transfers to or from a care home
  – Prescribers who are responsible for people who live in care homes providing comprehensive instructions for using and monitoring all newly prescribed medicines.
  – A multidisciplinary team undertaking medication reviews for people who live in care homes

• Also with provision to support those who wish to self-administer medicines
NICE Guidance [TA335]

Rivaroxaban for preventing adverse outcomes after acute management of acute coronary syndrome

March 2015

• NICE recommends that rivaroxaban can be used in combination with aspirin plus clopidogrel, or aspirin alone, for preventing atherothrombotic events in people who have had an acute coronary syndrome with elevated biomarkers.

• Before starting treatment, there must be an assessment of a person’s bleeding risk as rivaroxaban is associated with a higher risk of causing bleeding than clopidogrel in combination with aspirin or aspirin alone.

• Careful consideration should also be given to whether treatment is continued beyond 12 months, as there is limited experience of treatment with rivaroxaban up to 24 months.
This month’s papers


- A study of Foundation Year doctors’ prescribing in patients with kidney disease at a UK renal unit: a comparison with other prescribers regarding the frequency and type of errors. European Journal of Hospital Pharmacy 2015;doi: 10.1136/ejhpharm-2014-000620 http://ejhp.bmj.com/content/early/2015/03/31/ejhpharm-2014-000620


- Safe drug prescribing and medication for children through a web-based medicine database. International Journal of Clinical Pharmacy, February 2015, vol./is. 37/1(264), 2210-7703
This month’s papers


• Common contra-indications and interactions of drugs in orthopaedic practice. Bone and Joint Journal, April 2015, vol./is. 97B/4(434-441), 2049-4394;2049-4408

• Appropriate use of medicines: Interest of a collaboration between poison control center and regional pharmacovigilance center. Fundamental and Clinical Pharmacology, April 2015, vol./is. 29/(59), 0767-3981


MSO Web Event 29th April 2015
Patterns in spontaneous adverse event reporting among branded and generic antiepileptic drugs

- [Clinical Pharmacology and Therapeutics May 2015;97(5):508-517](#)
- Used US FDA Adverse Event Reporting System to look at 5 antiepileptic drugs
- Looked at temporal trends in AE reporting before and after generic introduction and surveyed quality of information
- Manually reviewed narratives from 2500 AE reports
Patterns in spontaneous adverse event reporting among branded and generic antiepileptic drugs

• Results:
  – Generics account for >90% of dispensed anti-epileptic drugs dispensed
  – Suspect product type (brand or generic) could not be identified in 84% of reports
  – Generic products (16%) were more identified than brand name products (<1%)

• Results suggest pharmacovigilance stakeholders should act to promote more detailed reporting practices
• Implications for reporting to our own Yellow Card Scheme
Preventing iatrogenic overdose: a review of in-emergency department opioid-related adverse drug events and medication errors.

- Retrospective study conducted in 2 urban emergency departments
- Potential iatrogenic opioid overdoses were identified from medical records when naloxone was administered
- Cases involving medication errors resulting in harm were reviewed for patient, provider or system based factors which may have contributed to the event
Preventing iatrogenic overdose

• Results:
  – 73 patients with opioid related AE that required naloxone
  – 43 had medication errors which resulted in harm
  – Factors that contributed to events included
    • Chronic health problems that could predispose individual to event
    • Failure to adjust opioid dosing in elderly or for hepatic or renal impairment
    • Multiple doses or routes of administration
    • Co-administration of opioids with other sedating drugs
    • System based problems with patient handovers and pharmacy oversight
  • Worryingly none of errors identified through hospitals voluntary reporting system
  • Authors developed list of strategies to reduce medication errors and harm