‘Observatory’: a knowledge update

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Recent regulator and statutory body activity from:
New guidance on reporting suspected ADRs in children

• The MHRA has announced new simplified guidance for healthcare professionals reporting suspected adverse drug reactions (ADRs) in children to its Yellow Card Scheme.

• It was considered that reporting all suspected ADRs in children was impractical for busy healthcare professionals and potentially acted as a barrier to reporting.

• The new guidance is simpler and aligned with the reporting guidelines for adults. All suspected ADRs that are serious, medically significant or result in harm should be reported, and all those that are associated with newer drugs and vaccines identified by the black triangle symbol ▼.
MHRA News

Dexamethasone injection reformulation

• From October 2014 the Organon brand of dexamethasone 4 mg/ml injection (Organon Laboratories Limited) will be replaced with a new formulation called Dexamethasone 3.8 mg/ml solution for injection (Aspen Pharma Trading Limited). As a result, the storage conditions, presentation, and packaging will change.

Advice for healthcare professionals:

• Take the new concentration of dexamethasone (3.8 mg/ml) into account when diluting the product for use (see dosing card on MHRA website)
• Store the reformulated product in a refrigerator at 2 to 8°C
• Use up your stocks of the old formulation before using the new formulation.
• Consult the new summary of product characteristics, technical information leaflet, and dosing card for further information

Note that two other brands of lower strength are also on the UK market. UKMi have produced a Product Safety Assessment discussing the issues involved. Available at www.ukmi.nhs.uk
EMA Press Release

*Strengthened restrictions on valproate prescribing*

- The Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA has recommended strengthening the restrictions on the use of valproate medicines due to an increased risk of birth defects and developmental problems in children exposed to valproate in the womb.

- It is being recommended that valproate medicines should not be used to treat epilepsy and bipolar disorder in girls, women who can become pregnant or pregnant women unless other treatments are ineffective or not tolerated.
Never Events Policy Framework Review consultation online

• Its purpose is to make it clearer as to what needs to be done, and by whom, to prevent never events. Part of the review will also consider financial penalties for never events.

• The review is focusing on five key issues: the purpose, definition, list of, management, and application of learning from never events.

• Some medication Never Events have been changed.
Remove:

- Overdose of midazolam during conscious sedation
- Opioid overdose of an opioid/opiate-naïve patient
- Wrong gas administered
- Failure to monitor and respond to oxygen saturation

Merged:

- Wrong route chemo
- Wrong route oral/enteral treatment
- Intravenous admin of epidural medication

All merged to become: **Wrong route medication**
Literature round-up

• Overestimation of glomerular filtration rate among critically ill adults with hospital-acquired oligoanuric acute kidney injury

• Minimization of administration route errors with subcutaneous rituximab

• The effectiveness of a 'Do Not Use' list and perceptions of healthcare professionals on error-prone abbreviations

• Worksheets with embedded checklists support IV chemotherapy safer practice

• The prevention of contrast-induced nephropathy (narrative review)
Literature round-up

• **Prescribing quality in older Veterans: a multifocal approach**  
  MA Steinman, Y Miao, WJ Boscardin, KDR Komaiko, JB Schwartz  
  (published early online 8 Jul 2014)

• **Interventions to reduce medication errors in pediatric intensive care**  
  E Manias, S Kinney, N Cranswick, et al  

• **A real-time assessment of factors influencing medication events**  
  AW Dollarhide, T Rutledge, MB Weinger, et al  
  Journal for Healthcare Quality Sep-Oct 2014;36(5):5-12

• **Impact of medication reconciliation and review on clinical outcomes**  
  EC Lehnbom, MJ Stewart, E Manias, JI Westbrook  
Impact of Medication Reconciliation and Review on Clinical Outcomes

- Australian systematic review to examine the evidence regarding the effectiveness of medication reconciliation and review and to improve clinical outcomes in hospitals, the community, and aged care facilities.

- Medication reconciliation identified unintentional medication discrepancies in 3.4% to 98.2% of patients. There is limited evidence of the potential of these discrepancies to cause harm.

- Medication reviews identified medication-related problems or possible adverse drug reactions in 17.2% to 94.0% of patients.

- The evidence demonstrates that medication reconciliation has the potential to identify many medication discrepancies and reduce potential harm, but the impact on clinical outcomes is less clear. Similarly, medication review can detect medication-related problems, but evidence of clinical impact is scant.

- Overall, there is limited evidence that medication reconciliation, as currently performed, significantly improve clinical outcomes, such as reductions in hospital readmissions.

Thank you for listening

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