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

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Recent regulator and statutory body activity

MHRA

- Licensing of biological products: biosimilars, ATMPs and PMFs in a no deal scenario This guidance sets out the procedures that the MHRA will introduce to regulate Biological medicines in the event of no deal. (Published 18 March 2019)

- enFlow® IV fluid and blood warmer – risk of unsafe levels of aluminium leaching from the device – updated safety advice from manufacturer (MDA/2019/016) Advice is to use an alternative fluid warming device

- WHO alert on Falsified Iclusig (ponatinib) – no suggestion that these counterfeits are in circulation in the UK. If in doubt contact the UK license holder. WHO alert has full photographs of packaging.
Company-led drug alert - Ozurdex implant recall (MDR 95-08/18)

Allergan Pharmaceuticals Ireland is further recalling batches due to the possibility that a single loose silicone particle of approximately 300 microns in diameter may become detached.

Medical Device Alerts

- All T34 ambulatory syringe pumps need a sponge pad fitted to the battery compartment to prevent battery connection issues (MDA/2019/013) - instructions provided to reduce the risk of delay to therapy and loss of infusion if the battery loses connection. The ‘Battery Fitting and removal’ section of manual has been updated to provide further clarifications on new foam pad and specific instructions regarding insertion and removal of the battery into the pump.
Pharmacovigilance Risk Assessment Committee (PRAC) and other EMA


- EMA now operating from Amsterdam 11/03/2019
Direct HCP communication

**OZURDEX® 700 micrograms intravitreal implant (dexamethasone):** Update on silicone particle issue: Supply of new (defect-free) stock and recall of remaining stock in the market.

https://assets.publishing.service.gov.uk/media/5c8f77bcd915d07b20fa1e6/UK_Final_Ozurdex-DHPC.pdf

**Belatacept (Nujolix)**
Update on the temporary restriction in supply (initiated in March 2017) (letter sent directly to HCP, not online yet)
Drug shortages and discontinuations

- **Shortage of tetracosactide 1mg depot injections**
  Manufacturers have indicated it will be unavailable until mid-2019. Specialist importers have confirmed unlicensed products have been sourced.

- **Shortage of Dimercaprol 50mg/ml injection**

- **Shortages of flupentixol injections**
  Various flupentixol strengths will be unavailable until April 2019. Some strengths will be unavailable so manipulation of available products may be required.

- **Shortage of metoprolol 50mg and 100mg tablets (update)**
  Memo advises on use of alternative beta blockers. https://www.sps.nhs.uk/articles/shortage-of-metoprolol-50mg-and-100mg-tablets/
Drug shortages and discontinuations

- **Shortage of bumetanide 5mg tablets**
  - Mylan, sole supplier not able to provide date for when product will be made available. Supplies of 1mg tablets and 1mg/5ml liquid remain available.

- **Shortage of Sandimmun (ciclosporin)**
  - Sandimmun 50mg and 100mg are out of stock till early May 2019. Limited supplies of the 25mg likely to be depleted mid-late March 2019.

- **Shortages of sevelamer carbonate 800mg tablets**
  - Supplies currently limited. Further deliveries from Sanofi (Renvela brand) and Creo (generic) are expected w/c 4th and 11th March 2019. Sevelamer Hydrochloride 800mg tablets (Renagel brand) remain available but insufficient stock to cover uplift in demand.
Drug shortages and discontinuations

- **Shortage of metopirone 250mg capsules**
  - Expected to be out of stock until July 2019. Advice is for patients to be referred to their specialist to advise on alternatives.

- **Shortage of Rabies vaccine (Rabipur)**
  - Limited supply are currently available and likely to continue through first half of 2019. Sanofi Pasteur are able to support the full market with their unlicensed Rabies vaccine (Verorab). NATHNAC have issued further information: https://travelhealthpro.org.uk/news/389/rabies-vaccine-availability

- **Shortages of Gastrografin**
  - Deliveries until July are expected to be limited and intermittent. Stock levels should begin to normalize from beginning of Q3 2019. Unlicensed specials importers have been able to source products.
Specialist Pharmacy Service


- **Can a local authority delegate authorisation of PGDs to a CCG using a Section 75 partnership agreement?** [https://www.sps.nhs.uk/articles/can-a-local-authority-delegate-authorisation-of-pgds-to-a-ccg-using-a-section-75-partnership-agreement/](https://www.sps.nhs.uk/articles/can-a-local-authority-delegate-authorisation-of-pgds-to-a-ccg-using-a-section-75-partnership-agreement/)

- **Influenza post exposure prophylaxis and treatment: PHE PGD templates to support the supply of oseltamivir and zanamivir** [https://www.sps.nhs.uk/articles/public-health-england-phe-national-templates-for-antivirals/](https://www.sps.nhs.uk/articles/public-health-england-phe-national-templates-for-antivirals/)

- **MI Databank Adverse Drug Reaction Reporting ADR feedback** [https://www.sps.nhs.uk/articles/midatabank-adverse-drug-reaction-adr-reporting-feedback/](https://www.sps.nhs.uk/articles/midatabank-adverse-drug-reaction-adr-reporting-feedback/)
• **MUSN Monthly Webinar – Safety of Injectable Medicines** (Recording is available at the following link: https://www.sps.nhs.uk/meetings/musn-monthly-webinar-safety-of-injectable-medicines/)

• **Regional Medicines Optimisation Committee Newsletter**

• **Safety in Lactation: Drugs used in nausea and vertigo**
  https://www.sps.nhs.uk/articles/midatabank-adverse-drug-reaction-adr-reporting-feedback/

• **Medicines Q&A What is the sodium content of medicines?**

• **When Patient Group Directions (PGDs) are not required.** Guidance on when PGDs should not be used and advice on alternative mechanisms for supply and administration of medicines https://www.sps.nhs.uk/articles/when-patient-group-directions-pgds-are-not-required-guidance-on-when-pgds-should-not-be-used-and-advice-on-alternative-mechanisms-for-supply-and-administration-of-medicines/
Rapid over infusion of Parenteral Nutrition in babies
In September 2017, the national patient safety team at NHS Improvement issued a Patient Safety Alert NHS/PSA/W/2017/005. Lessons learnt: remove old bag before hanging new bag; all fluids must have giving set attached to pump before attaching to patient; consider use and number of octopus extensions in use and potential for error.

NHS Long Term plan to reduce toll of ‘hidden killer’ sepsis
Hospital staff must alert doctors if patients with suspected sepsis do not respond to treatment within an hour. The guidance drawn up with the Royal College of Physicians, The Royal College of GPs, NICE and the UK Sepsis Trust, states that staff should look for sepsis at an early stage in patients coming to A&Es and those who are already on wards.

Updated guidance on the safe and secure handling of medicines
Guidance covers administration of medicines in general and can be applied to any healthcare setting where medicines are administered. Consider reviewing your local policy.
National guidance, publications and resources

Labelling error with phenobarbital 30mg/1ml and 200mg/1ml ampoules
In Martindale’s phenobarbital 30mg/1ml and 200mg/1ml ampoules have the same EAN type barcode. Martindale are aware of issue and investigating problem. Issue may arise when scanning barcode into robot – will assume all stock is same strength.

Ophthalmic Safety Alert- Do not use apraclonidine (lopidine) in infants below 6 months of age
Apraclonidine 1% and 0.5% should not be used in the diagnosis of paediatric Horner syndrome. This is due to reports of severe adverse effects.

MHRA guidance and publications on a possible no deal scenario
Information about the regulation of medicines and medical devices if the UK leaves the EU with no deal. (Being regularly updated – updates are at the bottom of the page.)
1. A new approach of assessing patient safety aspects in routine practice using the example of "doctors handwritten prescriptions"


4. Targeting the Fear of Safety Reporting on a Unit Level

5. Liquid Drug Dosage Measurement Errors with Different Dosing Devices

6. Clinicians' perceptions of opioid error-contributing factors in inpatient palliative care services: A qualitative study
https://journals.sagepub.com/doi/10.1177/0269216319832799

7. Medications and patient safety in the trauma setting: a systematic review
8. Examining medication safety incidents in in-patient mental health settings: A 7-year analysis of incidents reported to the National Reporting and Learning System

9. The Prevalence and Nature of Medication Errors and Adverse Events Related to Preadmission Medications When Patients Are Admitted to an Orthopedic Inpatient Unit: An Observational Study
https://journals.sagepub.com/doi/10.1177/1060028018802472

10. Comparison of Medication History Accuracy Between Nurses and Pharmacy Personnel
https://journals.sagepub.com/doi/10.1177/0897190017739982

11. Medication errors associated with customized gentamicin dosing

12. Patient safety: Determine high risk factor of medication discrepancies to target patient reconciled in geriatric pathway

13. Quality improvement priorities for safer out-of-hours palliative care: Lessons from a mixed-methods analysis of a national incident-reporting database

15. It is time to define antimicrobial never events
https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/it-is-time-to-define-antimicrobial-never-events/CA198D720E26E6CDE112A8258FCFBFF2

16. Pharmaceutical interventions to improve safety of chemotherapy-treated cancer patients: A cross-sectional study
https://journals.sagepub.com/doi/10.1177/1078155219826344

17. Medication Histories in Critically Ill Patients Completed by Pharmacy Personnel
https://journals.sagepub.com/doi/10.1177/1060028018825483

18. Robotic dispensing improves patient safety, inventory management, and staff satisfaction in an outpatient hospital pharmacy

19. Effects of chemotherapy prescription clinical decision-support systems on the chemotherapy process: A systematic review

20. Introducing New Implementation of Bar Code System
21. The expanding saga of hydrochlorothiazide and skin cancer
https://www.jaad.org/article/S0190-9622(18)32997-9/fulltext

22. Incorporating medication administration safety in undergraduate nursing education: A literature review

23. Targeting the Fear of Safety Reporting on a Unit Level

https://link.springer.com/article/10.1007%2Fs11095-019-2577-8
Examining medication safety incidents in in-patient mental health settings: A 7-year analysis of incidents reported to the National Reporting and Learning System
Alshehri G.H.; Keers R.N.; Ashcroft D.M et al
Pharmacoepidemiology and Drug Safety; Feb 2019;28:5-6

• Systematic review of 20 studies
• Frequency of medication errors and adverse drug events ranged from 10.6 to 17.5 and 10.0 to 42.0 per 1000 patient-days, respectively.

Medication incidents reviewed over a 7-year period to 2017 using a retrospective review was carried out of all medication safety incidents submitted from in-patient mental health units to the NRLS.

Descriptive analysis undertaken to determine the number of medication incidents over time, and then to characterise the incidents according to their nature, location, severity and type of medication class involved.
This month’s papers - details

- 94,159 medication incident reports were included, the majority of which were due to medication errors (99.5%).

- 90% in-patient mental health services.

- Medication incidents occurred most frequently in the administration stage 53.4% then prescribing 16.5% the dispensing 11.5% stages.

- Most frequently reported were omitted medicine 18.2%, wrong frequency 12.6% and wrong/unclear dose 10.8%.

- Medicines from central nervous system were commonly reported

- The clinical outcome analysis of the medication incidents demonstrated that most incidents resulted in no harm, whereas the remaining incidents resulted in low harm (9.3%), moderate harm (1.1%), severe harm (0.04%), or death (0.004%).

- So a tenth of medication incidents reported in mental health hospitals resulted in harm to patients. Fifty percent of incidents occurred in the medication administration stage, with medication omission and antipsychotics being frequently implicated.