SPS Medication Safety Update November 2024

Recent critical patient safety alerts, reports, and publications

Jen Smith - Pharmacist

The first stop for professional medicines advice

27/11/24

Patient Safety Alerts

Provisional publication of Never Events report as occurring between April and September 2024

195 events in total. Of the medicines events:

- 7 cases of insulin overdose due to withdrawal from pen (5); wrong syringe (2)
  - Note: PSA in November 2016 re withdrawing insulin from pen devices: https://www.england.nhs.uk/publication/patent-safety-alert-risk-severe-harm-and-death-withdrawing-insulin-pen-devices/
- 6 wrong route meds: oral meds given IV (5); oral given SC (1).
- 1 mis-selection of high-strength midazolam during conscious sedation

Recent regulator and statutory body activity

Class 2 Medicines Recalls

- Labetalol 200mg (Tillomed): recall of one batch due to potential for verapamil tablets to be present in packs of labetalol.

Class 4 Medicines Recalls

- Entyvio (vedolizumab) 108mg: (3 batches) errors in PIL re patient alert card and adverse effects.
- Omeprazole 40mg powder for infusion (Viatris): (2 batches) PIL does not contain the most up-to-date safety information.
- Parasolve (paracetamol) (Kent Pharma UK): caution in use of one batch. Error in PIL: incorrect total daily dose of sodium.
- Zoledronic acid (Ennogen 4mg/5mL concentrate): Patient Reminder Card (PRC) not distributed alongside some batches.

Parliament: Upcoming change in the law: Mental Health Act to be updated. Will affect emergency treatment of mental health crises etc.

Pharmacovigilance Risk Assessment Committee (PRAC)

- Mysimba (naltrexone/bupropion): Strengthening advice about not using with opioids.
  - May not be effective
  - Rare – serotonin syndrome (due to bupropion + other serotonergic meds including some opioids)
- Meeting: 28-31st October:
  - No referral procedures started or concluded.
  - Review of finasteride/dutasteride and suicidal thoughts/behaviours ongoing.
- Next meeting: 25-28th November.

Direct HCP communication

In October 2024, the following letters were sent or provided to relevant healthcare professionals:

Adverse Effects

- Medroxyprogesterone acetate: Risk of meningioma and measures to minimise this risk (also PRAC in September)
- Glatiramer acetate: Anaphylactic reactions may occur months to years after treatment initiation

Supply disruption

- Idacio (adalimumab) 40mg pens and syringes - temporary supply of Swedish/Finnish labelled stock
- PyzchivaTM▼ (ustekinumab) 90 mg pre-filled syringes and PyzchivaTM▼ (ustekinumab) 130 mg concentrate for solution for infusion – interim supply of Nordics Stock
- Fampyra 10mg MR Tablets (fampiridine): Interim Supply of Belgian Stock to Mitigate Supply Disruption

Product Quality

- Infanrix hexa [DTP-polio-HepB-Hib]: Packaging issue potentially impacting the sterility of needle softpacks of 2 batches for Northern Ireland (batch A21CE437A and A21CE376A). (Northern Ireland only)

Find links to these and letters sent in previous months via *Drug Safety Update*.

SPC changes or Manufacturer RMM

New Products

- Thiamine 50mg/mL solution for injection (Galen Limited). New product, licensed for thiamine deficiency when PO treatment is not possible.

Adverse Effects

- Maxtrex tablets: Photosensitivity (uncommon) manifested by exaggerated sunburn reaction in some individuals.
- Lupaxis (tapentadol) MR tablets: all strengths - “special warning” not to use for post-operative pain due to risk of persistent post-operative opioid use. Not on all tapentadol brands.

Risk Minimisation Materials

- Aldurazyme (laronidase): new risk minimisation materials
- Xenpozyme (olipudase alfa): new risk minimisation materials.

Other

- Movicol range: Shelf-life of reconstituted solution reduced from 24 hours to 6 hours.

Drug shortages and discontinuations

Recent medicine shortages and discontinuations are available via: the SPS Medicines Supply Tool (registration required to access)

- Discontinuation of **Etoposide 100mg/5mL and 500mg/25mL soln for infusion vials (Medac)** **27th Dec 2024**
  - Where benzyl alcohol-free preparation is *not* required, alternative supplies are available
  - If benzyl alcohol-free product is required, unlicensed supplies can be sourced but lead times may vary.
- Discontinuation of **Fucidin tablets (sodium fusidate) *and* oral suspension (fusidic acid)** in **Jan 2025.**
  - Switch to alternatives
  - Unlicensed imports will be available.
- Shortage of **Cyanokit (hydroxocobalamin)** 5g vials.
  - Use for cyanide poisoning/smoke inhalation *only*. See ToxBase.
  - Contact Regional Pharmacy Procurement Specialists for mutual aid or consider unlicensed sodium thiosulfate).
  - If alternatives required, consult National Poisons Information Service (0344 892 0111)
- Shortage of **Phenobarbital 15mg tablets (Bristol Laboratories)**
  - Phenobarbital is a “Category 1” anticonvulsant for switching – keep patients on the same brand if possible
  - Other tablet brands are available, or switch to phenobarbital elixir (adults) or liquid (ethanol-free) (children) (see SPS info on phenobarbital liquids and NPPG info)
- This is not a comprehensive list. Only critical safety medication shortages have been highlighted.

Specialist Pharmacy Service

Consultations

- **Safer use of time-critical medicines:** scoping review ahead of creating national programme. **Submit your views/details of improvement work done**.

Pages

- **Supporting safe use of adrenal crisis emergency management kits.** Who, what, and how.
- **Using statins in liver impairment**. Clinical considerations for initiating statins in patients with existing liver problems.

Webinars

- **MSATs – Safe Use of DOACs (webinar):** recording available.
- **Biosimilar and key generic medicines – delivering better value:** 11/12/2024.

National guidance, publications and resources

- **Antimicrobial IV-to-oral switch (paediatrics) – update**. Plain text alternative and additional links added.
- **English surveillance programme for antimicrobial utilisation and resistance (ESPAUR) report**
  - Infections in 2023 surpassed pre-pandemic levels
  - 65% E.coli
  - Widening gap between most and least deprived areas
  - Ethnic differences: white patients more likely to have a bacteraemia at all, but if an Asian patient has a bacteraemia, it's more likely to be a resistant one. Black patients fall in the middle of both.

Prevention of Future Death Reports (Regulation 28)

Procedures and patient safety

Ref: 2024-0476 – Excessive local anaesthetic (ropivacaine) administered during surgery

- Ropivacaine given following verbal order by the anaesthetist
- Order not written down, not checked.
- Drug prepared (incorrectly) by nurse and checked with another nurse but not the anaesthetist.
- This process may be common practice but is prone to error. See: Mackay E, Jennings J, Webber S. Medicines safety in anaesthetic practice. BJA Education. 2019;19(5): 151–157. https://doi.org/10.1016/j.bjae.2019.01.001

Ref: 2024-0633: Potassium infusion – U&Es not done after previous infusion – second infusion given – death due to hyperkalaemia

- SOP on hypokalaemia not followed (daily U&Es not done)
- Potassium given; U&Es not checked after infusion – second infusion given based on old results.
- Same hospital had a patient die due to unrecognised hyponatraemia
- Coroner concerned that junior doctors did not understand the importance of, or follow, Trust procedures for IV fluids/electrolytes.
- See SPS page on Safer Management of Therapeutic Drug Monitoring

Prevention of Future Death Reports (Regulation 28)

Patient-centred care, and when do patient factors change "normal procedure"

Ref: 2024-0635 – Olanzapine depot – post-injection checks not completed & pt died of post-injection syndrome

- Pt had had one depot olanzapine injection before (administered without consent)
- Pt refused to comply with vital signs monitoring
- After administration of the second depot injection, staff were distracted by other events on the ward
- Patient was discovered collapsed in her room; no pulse or shockable rhythm was present.
- Risk of post-injection syndrome (and death?) needs to be made clear to patients
- Not clear whose responsibility post-injection observation was
- Was olanzapine depot appropriate for pt with a history of refusing vital signs checks?

Ref: 2024-0600 – Patient very immobile after surgery – died of DVT/PE after 28 days' heparin course finished

- No guidance regarding what to do about unusual cases – e.g. prolonged immobility, or patients already on anticoagulation
- See SPS Webinar Safe Use of DOACs

Prevention of Future Death Reports (Regulation 28)

Patient or prescriber appreciation of drug toxicity

Ref: 2024-0629: Patient found dead with 4 fentanyl patches applied

- Prescribed only one patch (25 mcg/hr) but had previously disclosed to consultant that he sometimes applied more than one due to pain levels.
- This information **was not communicated to GP**
- Patient's analgesia was not reviewed / no education given re dangers of opioid overdose?

Ref: 2024-0620 – Propranolol toxicity

- Propranolol prescribed for anxiety and depression
- Patient took deliberate overdose
- Under-appreciation (by prescribers) of how toxic beta-blockers can be in overdose?
- **HSSIB report in 2020 stated: It is recommended that the National Institute for Health and Care Excellence reviews and updates guidance on the use of propranolol in the treatment of anxiety and migraine, with particular reference to the toxicity of propranolol in overdose.**

Prevention of Future Death Reports (Regulation 28)

Staff mental health and access to medicines

Ref: 2024-0627 – Vet committed suicide after obtaining drug from his employing organisation

- In this case the vet obtained the drug without verification checks and was allowed to leave the premises with it
- Could equally happen in NHS organisations, especially for staff with ready access to CDs

Ref: 2024-0613 – Theatre assistant obtained sevoflurane – inhaled it at home

- Sevoflurane (unused or partially used) not well monitored – possible for some to be removed

Prevention of Future Death Reports (Regulation 28)

Communication between settings

Ref: 2024-0631: Patient died after CABG – record-keeping and communication

- Different wards/departments used different systems (including some paper) which did not talk to each other.
- Coroner concerned about fragmentation of record-keeping and prescribing systems.

Ref: 2024-0628 – Deaths due to TPN contaminated with *Bacillus cereus*

- TPN provided by NHS establishment under “section 10 exemption” (1 pt) or commercial establishment (2 pts)
- No mandatory reporting of adverse events by Section 10 entities; unclear when Trusts should report (usually to CQC, NHSE)
- Commercial entities are controlled by MHRA and access to wider dissemination of information.
- Risk of a “developing” situation not being disseminated.

Primary research- Medication Safety

Care Settings/Departments

Medication errors and mitigation strategies in obstetric anesthesia (Dec 2024)

- Drug labelling, storage, preparation in advance, non-Luer epidural and IV ports, monitoring guidelines, smart pumps and protocols [Note also September's PSA regarding oxytocin overdose!]

Analysis of medication errors in Neonatal Intensive Care: a systematic review (Nov 2024)

- health technology from smart pumps, cost-effectiveness of medications, the practice of nursing professionals on the medication administration process and quality improvement models
- Also see NPPG info on peripheral inotropes and standardised infusion concentrations

Safety of inpatient care in surgical settings: cohort study and editorial. (Nov 2024)

- ADRs identified in >1/3 patients admitted to hospital for surgery.
- Rate hasn't improved much over the decades.
- Editorial makes the point that reasons are multi-factorial, but the patient/family are an under-used resource in patient safety.

Primary research- Medication Safety

Drug Classes

Body surface area in obesity: clinical challenges and call for improvements (Nov 2024)

- Equations may be inaccurate (e.g. DuBois may overestimate by up to 15%) – this is more than the 10% often-recommended maximum “rounding error”) for chemo.

Mitigating and preventing perioperative opioid-related harm (Dec 2024)

- Review: discusses strategies to prevent harm, plus policy and guidelines.

Primary research- Medication Safety

Drug-Specific

Apixaban trough concentrations in atrial fibrillation patients with reduced renal function (Nov 2024)

- Patients with moderate renal dysfunction had higher apixaban levels.
- Authors suggested dose reduction or monitoring levels.

Determination of the optimal obesity-adjusted dosing weight for enoxaparin (Nov 2024)

- Actual bodyweight is the worst. Adjusted Body Weight (lean or ideal BW + 40% of excess) most likely to result in anti-Xa levels within range.

American consensus guideline and good practice points on using continuous glucose monitoring (CGM) systems in hospital. (Oct 2024)

- Increased interest in using CGM in hospitals.
- Insight and opinions from laboratory medicine, endocrinology, nursing.
- See also *Drug Safety Update* on insulin pumps and CGM – guidance on reporting incidents (Oct 2024)

Primary research- Medication Safety

Other

Collaboration to remove barriers to pump integration with the electronic health record (Nov/Dec 2024)

- Task force, end users surveyed, solutions implemented, use of smart pump programming increased.

NIHR: What drives unprofessional behaviour in healthcare? (Nov 2024)

- Unprofessional behaviour by healthcare staff adversely affects patient safety
- Multifactorial; often driven by poor workplace culture/experience.
- Human Factors/Systems approach to patient safety