SPS Medication Safety Update January 2025

Recent critical patient safety alerts, reports, and publications

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The first stop for professional medicines advice

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Patient Safety Alerts

No new alerts

Alert Update

NHS England » National Patient Safety Alert – Transition to NRFit™ connectors for intrathecal and epidural procedures, and delivery of regional blocks

NHS England's National Patient Safety Team has issued an update on its National Patient Safety Alert around the transition to NRFit™ connectors (NatPSA/2024/002/NHSPS), issued in January 2024.

The update provides guidance on declaring compliance with the alert, and actions to manage patient safety risks where NRFit™ compliant devices are not yet in use for specific procedures.

Recent regulator and statutory body activity

GLP-1 and dual GIP/GLP-1 receptor agonists: potential risk of pulmonary aspiration during general anaesthesia or deep sedation

GLP-1 and dual GIP/GLP-1 receptor agonists are known to cause delayed gastric emptying, which may increase the risk of residual gastric contents despite preoperative fasting.

- Healthcare professionals should be aware of the potential risk of pulmonary aspiration in patients using GLP-1 or dual GIP/GLP-1 receptor agonists who undergo surgery or procedures with general anaesthesia or deep sedation.
- Remind patients to inform their healthcare teams and anaesthetists if they are on GLP-1 or dual GIP/GLP-1 receptor agonists. When used for aesthetic weight loss patients may not readily disclose this information unless directly asked. Be aware that private prescriptions may not always be included in the patient's medical notes or drug history.

Recent regulator and statutory body activity

Class 2 Medicines Recall: Tesco Health Dry Cough Relief 200ml, Asda Strong Dry Tickly Cough 200ml, Almus Dry Cough Relief & Bells Dual Action Dry Cough, EL(25)A/03

Owing to foreign material detected in some bottles of dextromethorphan hydrobromide BP containing products (single customer complaint), manufacturers are recalling several listed batches as a precautionary measure.

Class 4 Medicines Notification: Irbesartan 150 mg and 300 mg film-coated tablets, EL(25)A/02

The listed batches contain an outdated patient information leaflet (PIL; last revised in September 2015), which is missing important updated safety information, as detailed at the bottom of the alert. The latest PIL (updated Aug 2022) is available on the MHRA website.

Class 4 Medicines Notification: Rabeprazole sodium 10mg and 20mg gastro-resistant tablets, EL(25)A/01

Patient Information Leaflet (PIL) in affected specified batches do not contain the most up to date safety information. Healthcare professionals are advised to ensure patients are aware of updated safety information when dispensing affected batch & provide copy of updated PIL.

Class 4 Medicines Notification: Argenx BV, Vyvgart 1000 mg solution for injection, EL (24)A/63

The Patient Information Leaflet in the affected packs of efgartigimod alfa incorrectly contains reference to 2 subcutaneous injection sites (abdomen and thigh) at Step 20. The correct PIL, approved as part of GB marketing authorisation, only contains reference to 1 site (abdomen).

Recent regulator and statutory body activity

TriOn Pharma recalls Vitamin D3 2000iu/ml supplements (Aactive D3) because of excess levels

TriOn Pharma is recalling Aactive D3 Drops and Aactive D3 Solution because they contain higher levels of vitamin D3 than stated on the label. Customers are advised not to take them, and to return them to the store from where they were bought.

MHRA warns against buying weight loss medicines without a prescription

MHRA is reminding the public not to buy weight-loss medicines without a healthcare professional's prescription from beauty salons or via social media due to serious health risks and also highlights that it is against the law to sell medicines in this way.

Pharmacovigilance Risk Assessment Committee (PRAC)

European PRAC initiates review of semaglutide-containing medicines following concerns of an increased risk of non-arteritic anterior ischemic optic neuropathy (NAION)

Two recent observational studies have suggested semaglutide may be associated with increased risk of this eye disorder, which is caused by reduced blood flow to the optic nerve & can lead to loss of vision. The PRAC will review all data & communicate further when appropriate.

Direct HCP communication

Fucithalmic 1% w/w Viscous Eye Drops/ Fusidic acid 1% w/w Viscous Eye Drops - Interim supply of Chinese stock to Mitigate supply disruption

The reworked packs are with Tubes in Chinese language packed in UK registered Outer Carton along with the UK registered PIL in English language

Hydroxocobalamin - Cyanokit® 5 g powder for solution for infusion: – Important information regarding batch 2404 in a product shortage context

The manufacturing of Cyanokit® has been suspended due to an investigation of a deviation related to a risk of microbial contamination. An affected batch is on the UK market and its use presents a minimal but not zero risk of exposure of patients to microorganisms.

SPC changes or Manufacturer RMM

Revised SPC: Micardis (telmisartan) and MicardisPlus (hydrochlorothiazide , telmisartan) Tablets)- all strengths

SPC notes intestinal angioedema has been reported with ARBs. Symptoms include abdominal pain, nausea, vomiting & diarrhoea and resolve after discontinuation. If diagnosed it should be discontinued and monitoring initiated until complete resolution of symptoms

Revised SPC: Opfolda (miglustat) capsules

Paraesthesia has been added as a potential adverse effect of treatment (common).

Revised SPC: Scemblix (asciminib) tablets

Pancytopenia has been added as a potential adverse reaction (uncommon).

Revised SPC: Bupeaze (buprenorphine) transdermal patches - all strengths

Revised SPCs now advises not to use for acute post-operative pain owing to the increased risk of persistent post-operative opioid use and opioid-induced ventilatory impairment.

Revised SPC: VPRIV (velaglucerase alfa) 400 Units powder for solution for infusion

SPC updated to include information on self-administration, which may be considered for patients who have received ≥3 infusions and who tolerated their infusions well. It should be closely monitored by the treating physician & should occur in the presence of a responsible adult.

Revised SPC: Tecentriq (atezolizumab) 1,875 mg solution for injection

SPC updated to add xerosis (severe dry skin; common) and increased blood creatine phosphokinase (uncommon) as adverse drug reactions.

SPC changes or Manufacturer RMM

Revised SPC: Xeljanz (tofacitinib) 5 mg film-coated tablets

SPC now warns ≥1confirmed case of progressive multifocal leukoencephalopathy reported in patients with rheumatoid arthritis on tofacitinib in post marketing setting. It should be considered in differential diagnosis in immunosuppressed with new onset/worsening neuro symptoms.

Revised SPC: Convulex (valproic acid) 300 mg capsules

Revised SPC warns that concomitant treatment with clozapine increases risk of neutropenia and clozapine-induced myocarditis.

Revised SPC: Gazyvaro (obinutuzumab) 1,000 mg concentrate for solution for infusion

Hypogammaglobulinemia has been added as an uncommon adverse effect following recommendation from the European Medicines Agency's Pharmacovigilance committee (PRAC).

Revised SPC: Keytruda (pembrolizumab) 25 mg/mL concentrate for solution for infusion

SPC updated to include information about pericarditis in special warnings and precautions section, and to list pericarditis as a term that represents a group of related events that describe a medical condition, rather than a single event.

Revised SPC: Lumykras (sotorasib) 120 mg film-coated tablets

Section on hepatic impairment added highlighting that compared to subjects with normal liver function, AUCinf was decreased by 25.4% in subjects with moderate impairment & increased by 3.6% in severe impairment, and unbound AUCinf increased by 1.8-fold and 6.3-fold, respectively.

SPC changes or Manufacturer RMM

Revised SPC: Valproate products

Updated SPC includes warning regarding ‘Severe Cutaneous Adverse Reactions’ (SCARs) and angioedema, requiring discontinuation of treatment should they occur. Hyperpigmentation is also added as an adverse effect of unknown frequency.

Revised SPC: Dynastat (parecoxib) 40mg Powder and Solvent for Solution for Injection

SPC updated to note that some NSAIDs and selective COX-2 inhibitors have been associated with an increased risk of generalized bullous fixed drug eruptions (GBFDE).

Revised SPC: Columvi (glofitamab) concentrate for solution for infusion- all strengths

SPC updated with risk management measures, in light of serious cases of immune effector cell-associated neurotoxicity syndrome (ICANS) which could be life-threatening or fatal, that have occurred following treatment with glofitamab.

Revised SPC: Zocor (simvastatin) 10mg film-coated tablets

SPC updated to note that in few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia. Treatment should be discontinued in case of aggravation of symptoms.

Revised SPCs: Regaine (minoxidil) products

SPC updated to note that (reversible) cases of hypertrichosis have been reported in infants following skin contact with minoxidil application sites of patients (caregivers) using topical minoxidil. Contact between children & minoxidil application sites should be avoided.

SPC changes or Manufacturer RMM

Revised SPC: Elvanse Adult (lisdexamfetamine) Hard Capsules- all strengths

Updated to advise that stimulants have been reported to exacerbate Tourette's syndrome (frequency unknown) therefore, clinical evaluation of Tourette's syndrome should precede use of stimulant medications.

Revised SPC: Advagraf (tacrolimus) prolonged release capsules, all strengths

SPCs updated to include data associated with use during pregnancy or lactation from an interim analysis of an ongoing non-interventional post authorization safety study [EUPAS37025].

Revised SPC: Revestive (teduglutide) 5 mg powder and solvent for solution for injection

SPC updated to recommend upper GI endoscopy/other imaging before & during treatment as a precaution, based on results of a rat carcinogenicity study and as development of small intestinal polyps has also been observed several months after the start of treatment in humans.

Revised SPC: Nexplanon 68 mg implant for subdermal use (etonogestrel)

Information in section 4.2 on usage and insertion of the implant immediately post-abortion or immediately post-partum has been updated.

Revised SPC: Multaq (dronaderone) 400mg film-coated tablets

SPC now notes that women of childbearing potential should use effective methods of contraception during treatment with dronedarone and for 7 days after the final dose. Prior to initiating dronedarone, the prescriber should confirm women of childbearing potential are not pregnant.

SPC changes or Manufacturer RMM

Risk Minimisation Materials for Truxima (rituximab)

Materials include a guide for healthcare professionals, which discusses the risk of infections, including progressive multifocal leukoencephalopathy, and how to counsel and monitor patients during therapy. A patient safety information guide is also available.

Risk Minimisation Materials to help reduce the risk associated with using baricitinib Lilly 2 and 4 mg Film-Coated Tablets

A guide for healthcare professionals to assist initial discussion with patients covers pregnancy & breast feeding, infections, changes in lipids, VTE, major adverse CV events, and lymphoma/other malignancies. A Patient Alert Card contains important safety information

Risk Minimisation Materials for Mexiletine hydrochloride hard capsules

Materials include a guide for healthcare professionals on minimising the risks of cardiac arrhythmia and severity of adverse reactions in those with hepatic impairment, and a patient alert card to raise awareness of these risks.

Risk Minimisation Materials for Carvykti 3.2 × 10^6 – 1 × 10^8 cells dispersion for infusion (ciltacabtagene autoleucel)

Materials include important safety and monitoring information for healthcare professionals, a handling guide (to minimise the risk of decrease in cell viability due to inappropriate handling or preparation), and a ‘My CAR-T cell therapy journey guide’ for patients.

Drug shortages and discontinuations

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

Medicine Supply Notification: Hydrocortisone sodium phosphate 100mg/1ml solution for injection ampoules

Hydrocortisone sodium phosphate is in limited supply with stock exhaustion anticipated by late March 2025; anticipated resupply is May 2026. Hydrocortisone sodium succinate 100mg powder for solution for injection/infusion remains available and can support an increase in demand.

Medicine Supply Notification: Xylocaine® (lidocaine) 10mg spray

Xylocaine® (lidocaine) 10mg spray is out of stock until mid-February 2025. Lidocaine 5%/ Phenylephrine 0.5% spray and Lidocaine 50mg/g/Cetrimide 1.5mg/g (Xylonor Gel) remain available and can support an increase in demand. Unlicensed supplies may be sourced, lead times vary.

Medicine Supply Notification: Estradiol (Estradot®) 50micrograms/24 hours, 75micrograms/24 hours, and 100micrograms/24 hours transdermal patches

The 75mcg/24h and 100mcg/24h patches will be out of stock until mid-January 2025, and the 50mcg/24h patches until late February 2025. Alternative brands of estradiol patches (Evorel® and Estraderm MX®) across these strengths are available and can support a full uplift in demand.

Medicine Supply Notification: Isosorbide mononitrate 10mg, 20mg and 40mg tablets (immediate-release)

The 10mg & 20mg tablets are in limited supply until late February 2025, and the 40mg tablets are out of stock until late February 2025. The 30mg tablets remain available but cannot support any additional demand. Modified-release tablets and capsules remain available.

Drug shortages and discontinuations

Medicine Supply Notification: Prednisolone 20mg/100ml rectal solution

Prednisolone 20mg/100ml rectal solution is out of stock until February 2025. Alternative rectal steroids remain available and can support an increased demand.

Medicine Supply Notification: Cefalexin 125mg/5ml and 250mg/5ml oral suspensions, sugar free

These products are out of stock until mid-2025. Cefalexin 125mg/5ml and 250mg/5ml oral suspension (non-sugar free) remain available and can support a full uplift in demand. Two serious shortage protocols permitting supply of a non-sugar free formulation were issued on 10/12/24.

Drug shortages and discontinuations

Medicine supply notification: NovoRapid® (insulin aspart) FlexTouch® 100units/ml solution for injection 3ml pre-filled pens - update

Update to October 2024 notification. NovoRapid (insulin aspart) FlexTouch® 100units/ml solution for injection 3ml pre-filled pens are now out of stock until late February 2025 and will subsequently be discontinued from March 2025.

Medicine Supply Notification: Insulatard® (isophane insulin, human) Penfill® 100units/ml suspension for injection 3ml cartridges

These are being discontinued; stock is anticipated to be exhausted by June 2025. Humulin® I KwikPen® (isophane insulin, human) 100units/ml suspension for injection 3ml pre-filled pens are available and can support a full increase in demand from April 2025.

Medicine Supply Notification: Apomorphine hydrochloride (APO-go® PFS) 50mg/10ml solution for infusion pre-filled syringes

APO-go® (apomorphine hydrochloride) PFS are being discontinued; supplies are anticipated to be exhausted from early April 2025. APO-go® POD (apomorphine hydrochloride hemihydrate) 100mg/20ml solution for infusion cartridges remain available and can support increased demand.

Salazopyrin (sulfasalazine) range discontinued

All Salazopyrin products have been replaced with generic versions. The tablets and gastro-resistant tablets are produced by several manufacturers. An oral suspension and suppository also available. Oral products are not expected to have significantly different release profiles.

Specialist Pharmacy Service

Assessing the clinical impact of lactose in medicines

Web page notes people with lactose intolerance may request lactose-free medicines although the amounts, when present as an excipient, are unlikely to cause symptoms in most. If a lactose free product is required, it provides advice on how to search for appropriate products.

A person-centred approach to polypharmacy and medication review

This updated article, part of a series, outlines how to identify, invite and apply a person-centred framework to support structured medication review.

Resources to support medication review

This updated article, part of a series, discusses resources providing information and guidance that reflects the growing understanding of problematic polypharmacy and overprescribing.

Tools to support medication review

Updated article, part of a series, discusses practical tools that aid medication review by identifying inappropriate medicines, guiding deprescribing, and empowering patients via shared decision making.

Understanding polypharmacy, overprescribing and deprescribing

This updated article, part of a series, explores the causes, consequences and tools to support pharmacy professionals in managing polypharmacy, overprescribing and deprescribing in practice, with links to supporting resources.

Specialist Pharmacy Service

Using dental antibiotic prophylaxis for hydrocephalus shunts

Page discusses considerations for whether the risk of shunt infection from transient bacteraemia during invasive dental procedures warrants non-routine antibiotic prophylaxis.

Shelf lives of aseptically prepared medicines in NRFit syringes

Aseptic units are being asked to provide all intrathecal & epidural injections in NRFit syringes from 31st Jan 2025. There is little published data for aseptically prepared medicines stored in NRFit syringes; extrapolation of stability data from luer lock systems may be required.

Swallowing difficulties- updated SPS pages

Pages relating to use of medicines in swallowing difficulties have been reviewed and updated. Choosing medicines formulations in swallowing difficulties remains a 6-step process and a new page covers this in more detail.

SPS spotlight monthly digest: December 2024

Slides covering activity from across SPS groups (medicines advice, medicines use and safety, quality assurance and medicines procurement) provide updates on existing materials and activities from across SPS, and signpost to upcoming events and activities.

Treating acute hypomagnesaemia in adults

This webpage providing guidance on the safe use of magnesium for acute hypomagnesaemia covers causes, classification, management and choice of oral and IV magnesium replacement, and monitoring.

National guidance, publications and resources

All-Party Parliamentary Group (APPG) on Pharmacy launches inquiry into medicine shortages

The APPG is aiming to develop practical recommendations to address the ongoing challenge of medicines shortages. As part of this, the APPG has issued a call for written evidence from key stakeholders across the healthcare sector, which is open to all those impacted by shortages.

Fluoroquinolones: what do GPs need to know?

Article begins with a case vignette followed by a review of the adverse effects of concern, risk factors, whether topical fluoroquinolones are affected by the MHRA alert, what else a GP should consider, and finishes with how to manage the case in hand. [British Journal of General Practice]

Interim guidance for physician associates working in the medical specialties

Royal College of Physicians publish new interim guidance on the scope, supervision and employment of physician associates (PAs). It sets out 5 key principals, one of which is that PAs cannot prescribe medications regardless of any prior healthcare background while working as a PA. [Royal College of Physicians]

The public health risks of counterfeit pills

Synthetic illicit drugs (e.g. nitazenes) are increasingly packaged in counterfeit pill form, often indistinguishable from authentic pharmaceuticals. This exposes more consumers to unintentional illicit synthetic drug use, necessitating a swift public health response. [The Lancet Public Health]

National guidance, publications and resources

Elective peri-operative management of adults taking glucagon-like peptide-1 receptor agonists (GLP-1)

These drugs are used increasingly in patients receiving peri-operative care and may be associated with risks of peri-operative pulmonary aspiration or euglycaemic ketoacidosis. This consensus statement contains guidance on peri-operative management of adults taking these drugs. [Association of Anaesthetists of Great Britain and Ireland]

Oral methadone and buprenorphine: recommendations

Clinicians should use this guidance, alongside Orange Book, to inform their prescribing of oral methadone & buprenorphine (BPN) as substitute medication to people who are in treatment for opioid dependence. Further guidance on BPN long-acting injections will be published in 2025. [Department of Health and Social Care]

Prevention of Future Death Reports (Regulation 28)

Ava Hodgkinson: Prevention of Future Deaths Report. Delay related death

A delay in issuing of antibiotics occurred due to the community pharmacy not having the specific strength in stock. The patient only received one dose of antibiotics before deteriorating and suffering a cardiac arrest caused by Streptococcus A infection.

Further commentary can be found in the Pharmaceutical Journal.

SPS published in 2022 the article using solid oral dosage form antibiotics in children in response to emergent shortages.

Prevention of Future Death Reports (Regulation 28)

David Joseph Crompton: Prevention of future deaths report. Shortage related death

Coroner's report of death of patient due to patient left without medication (Tegretol) for several days on two occasions. On these occasions the patient was issued with an "IOU" in relation to their Tegretol. After the second occasion the patient suffered epileptic seizures and hypoxic ischaemic encephalopathy and a cervical spine injury as a result of a fall which led to his death.

Joseph Forbes Black: Prevention of future deaths report recommends national action to make naloxone kits more widely available

Although naloxone was not given in this case because the circumstances "did not indicate that the administration of naloxone would be of any use in this instance", the coroner concluded that deaths could be prevented if naloxone kits were more readily available to drug users.

Primary research- Medication Safety

High-risk medication errors: Insight from the UK National Reporting and learning system.

Exploratory Research in Clinical and Social Pharmacy. 17(no pagination), 2025. Article Number: 100531. Date of Publication: 01 Mar 2025.

A retrospective analysis of 1,500 patient safety incidents from the UK's National Reporting and Learning System (NRLS) in 2015 highlighted insulin as the highest-risk medication category, with errors primarily arising from administration, prescribing, and dispensing issues linked to inadequate checks, communication gaps, and staff workloads; findings emphasize the need for enhanced measures, including information technology, to improve medication safety.

Medication reconciliation in the outpatient primary care setting: Barriers and opportunities.

Journal of the American Association of Nurse Practitioners. (no pagination), 2024. Date of Publication: 11 Dec 2024.

The complexity of the healthcare system complicates accurate medication reconciliation, a crucial safety intervention for reducing errors, requiring primary care providers to maintain updated medication lists despite challenges like fragmented providers and incompatible systems.

Use of 400 microg/mL Peripheral Phenylephrine Infusions During Anesthesia: A Safety Initiative.

Hospital Pharmacy. 60(1) (pp 21-26), 2025. Date of Publication: 01 Feb 2025.

A hospital successfully standardized to a 400 microg/mL phenylephrine infusion in operating rooms after a medication error caused iatrogenic hypertension, resulting in improved safety and efficiency with minimal errors and no adverse events.

Primary research- Medication Safety

Detecting clinical medication errors with AI enabled wearable cameras.

NPJ Digital Medicine. 7(1) (no pagination), 2024. Article Number: 287. Date of Publication: 01 Dec 2024.

A wearable camera system utilizing deep learning algorithms was developed to automatically detect potential drug-related errors in real-world operating rooms, achieving 99.6% sensitivity and 98.8% specificity in identifying vial swap errors, demonstrating its potential as a secondary check to prevent medication errors before delivery.

Multiple points of system failure underpin continuous subcutaneous infusion safety incidents in palliative care: A mixed methods analysis.

Palliative Medicine. 39(1):7-21, 2025 Jan.

Around 25% of palliative care incidents reported to the NRLS involved continuous subcutaneous infusions with 72% detailing harms. Recurring contributory factors included discontinuity of care within and between settings, inadequate time, inadequate staffing and unfamiliarity with protocols. The authors conclude that system infrastructure is needed to enable timely supply of medication and equipment, effective coordinated use of continuous subcutaneous infusions, communication and continuity of care.

Effect of integrated medicines management on quality of discharge medication information—a secondary endpoint in a randomized controlled trial

International Journal for Quality in Health Care. 36(4), 2024 Dec 05.

Integrated medicines management (IMM) is a systematic approach to optimise and individualise medication therapy during a hospital stay. A randomised analysis of multimorbid patients demonstrated an improved quality of medication information in discharge summaries.

Primary research- Medication Safety

Spotlight commentary: Changes in pharmacokinetics following significant weight loss.

Br J Clin Pharmacol. 2025 Jan 15.

Commentary suggest that understanding the influence of excess fat, body composition and significant weight changes on pharmacokinetics, and potentially pharmacodynamic parameters can assist in optimizing dosage for this patient population.

Improving medication safety for intensive care patients transitioning to a hospital ward: development of a theory-informed intervention package.

BMC health services research. 24(1) (pp 1476), 2024. Date of Publication: 26 Nov 2024.

A UK theory-informed intervention package was developed to improve medication safety during the transition of ICU patients to hospital wards, addressing barriers and facilitators through qualitative focus groups, with seven core components such as targeted medication reviews and task prioritisation aimed at reducing medication errors and adverse drug events.

Medication errors and mitigation strategies in obstetric anesthesia.

Current Opinion in Anaesthesiology. (no pagination), 2024. Date of Publication: 2024.

Implementation of various types of best practice cost effective mitigation strategies include recommendations to improve drug labelling, optimise storage, determine correct medication prior to administration, use non-Luer epidural and intravenous connection ports, follow patient monitoring guidelines, use smart pumps and protocols for all infusions, disseminate medication safety educational material, and optimise staffing models

Primary research- Medication Safety

Analysis of medication errors in Neonatal Intensive Care: A systematic review.

Medicina Intensiva. 48(11) (pp 654-662), 2024. Date of Publication: 01 Nov 2024.

Medication errors in neonatal intensive care units (NICUs) significantly impact newborn safety, prompting a systematic review of current evidence on health technologies (e.g., smart pumps), cost-effectiveness, nursing practices, and quality improvement models to enhance care quality and safety.

A systematic review and meta-analysis of interventions to delabel low-risk penicillin allergies with consideration for sex and gender

Br J Clin Pharmacol. 2024 Dec 19.

Review (2 RCTs, 26 quasi-experimental studies) found oral challenge similarly effective to skin testing (RR for delabelling 1.04; 95% CI 0.95-1.13). Direct delabelling interventions had a 27% delabelling rate, with nursing staff achieving 29% and allergists/immunologists 6%.