National Patient Safety Alert

British Orthopaedic Association | The Association of Coloproctology of Great Britain and Ireland | Royal College of Podiatry | NHS

Elimination of bottles of liquefied phenol 80%

Date of issue:	25 August 2021	Reference no:	NatPSA/2021/008/NHSPS

This alert is for action by: All acute trusts, trusts providing community services, and organisations providing podiatry services, including where these are provided by general practices.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards). In acute trusts, the executive lead should be supported by clinical leads in pharmacy, podiatry and surgery.

Explanation of identified safety issue:

Phenol, a caustic compound used for its antimicrobial, anaesthetic, and antipruritic properties, is highly toxic and corrosive. It can cause burns, severe tissue injury and is rapidly and well absorbed causing systemic toxicity.[1]

'High strength' phenol is available in different preparations:

- Bottles of liquefied phenol 80% (typically 7mL or larger): these can be ordered via pharmacy departments as an unlicensed pharmacy Specials product[2] or by clinical teams directly from wholesalers.
- Phenol swab packs: these contain an ampoule of phenol 89% with a cotton bud applicator attached (licensed as a medical device).

Current prescribing and supply data shows that the main use of 'high strength' liquefied phenol is in podiatry and orthopaedic foot surgery for destroying the nail matrix. This data also suggests some limited use in other clinical areas where it is no longer recommended.

Review of incidents identified a report where liquefied phenol 80% was administered to a child instead of the prescribed paraldehyde rectal enema,[A] used to treat status epilepticus. The patient required emergency admission to hospital and intensive treatment to minimise the corrosive effects of phenol on their intestinal tissue.

Subsequent review of reported incidents over a 5-year period identified 30 further incidents including:

- Harm from use: eg referral of a child to a specialised burns unit for treatment of burns to the lower leg sustained when liquefied phenol 80% spilled from a bottle during treatment for toenail avulsion.
- Mis-selection: eg administration of unlicensed liquefied phenol 80% instead of licensed oily phenol 5% injection during a procedure to remove a rectal polyp.

Oily phenol 5% injection, an analgesic sclerosing agent[3], is licensed for the treatment of haemorrhoids; it does not need to be eliminated as part of this Alert.

Actions required

Actions to be completed as soon as possible and no later than 25 Feb 2022

1. Identify where liquefied phenol 80% is used and update procedures/guidelines to substitute use for a safer, suitable alternative.
2. Ensure clinical areas have stock of agreed safer alternatives and then remove bottles of liquefied phenol 80% from clinical areas, and update stock lists.
3. Amend electronic prescribing systems to ensure liquefied phenol 80% cannot be prescribed.
4. Amend current purchasing systems, and introduce ongoing controls on purchasing, to ensure liquefied phenol 80% cannot be purchased inadvertently via the pharmacy department or any alternative purchasing route.

Professional guidance includes:

Chemical ablation of nail matrix: The Royal College of Podiatry[4], British Orthopaedic Association and British Society for Children's Orthopaedic Surgery do not support use of bottles of liquefied phenol 80% and advise use of licensed phenol impregnated swabs.

Pilonidal sinus: The Association of Coloproctology Great Britain & Ireland do not support the use of bottles of liquefied phenol 80% and advise use of safer, suitable alternatives.

Anaesthesia of tympanic membrane: British Society of Otology do not support the use of bottles of liquefied phenol 80% and advise use of safer, suitable alternatives.

Genital molluscum infection: British Association for Sexual Health and HIV does not support the use of phenol.[5]

For further detail see: https://www.england.nhs.uk/2021/08/elimination-of-bottles-of-liquefied-phenol-80

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Notes

A: The packaging and labelling of Specials containers for liquefied phenol 80% and paraldehyde rectal solution were very similar. In response to previously reported incidents[4] involving confusion between other products produced as pharmacy Specials, a short-life working group has been established to produce NHS guidance on best practice, specifically for the labelling and packaging of Specials, whether made by NHS or non-NHS manufacturers, to support a 'purchasing for safety' agenda.

Patient safety incident data

The National Reporting & Learning System (NRLS) was searched for incidents reported to have occurred on or after 13 May 2016 and uploaded to the NRLS by 21 April 2021 containing reference to 'phenol' or any synonyms. All incidents were reviewed, and 31 relevant incidents were identified (including the trigger incident): nine, reported as no harm, related to mis-selection of bottles of liquefied phenol and 22 described actual harm to patients or staff from use of this product (reference PSI441). These included four reports describing significant harm from using bottles of liquefied phenol 80%: damage to the rectal area of two patients, burns to both arms of a member of staff and burns to the leg of a child. NRLS is only designed to capture patient safety incidents, so incidents involving staff would not routinely be captured by the NRLS.

Identified concerns included:

- burns to patients and staff because of spillage or splashes when using bottles of liquefied phenol 80% for ablation of the toenail matrix, including delays in healing requiring vascular review.
- confusion between bottles of unlicensed pharmacy Specials of liquefied phenol 80% and other products in similar packaging.
- confusion between bottles of unlicensed pharmacy Specials of liquefied phenol 80% and ampoules of licensed 5% oily phenol.

References

1. Phenol monograph. Toxbase: https://www.toxbase.org/
2. Association of Pharmaceutical Specials Manufacturers: https://apsm-uk.com/
3. Electronic Medicines Compendium. Datapharm: Oily Phenol Injection 5% w/v: https://www.medicines.org.uk/emc/product/3608/smpc#gref
4. Royal College of Podiatry: https://cop.org.uk/news/national-patient-safety-alert-phenol-august-2021
5. British Association for Sexual Health and HIV. UK national guideline for the management of genital molluscum in adults. July 2014 (under review) https://www.bashh.org/documents/Molluscum%20contagiosum%202014%20final.pdf
6. NHS England and NHS Improvement. National Patient Safety Alert: Risk of death from unintended administration of sodium nitrite. 06 August 2020 https://www.england.nhs.uk/publication/national-patient-safety-alert-risk-of-death-from-unintended-administration-of-sodium-nitrite/

Stakeholder engagement

- Royal College of Podiatry
- British Orthopaedic Association
- British Society for Children's Orthopaedic Surgery
- The Association of Coloproctology Great Britain & Ireland
- British Society of Otology
- British Association for Sexual Health and HIV
- NHS Pharmacy Production Committee
- National Patient Safety Response Advisory Panel (for a list of members and organisations represented on the panel, see https://www.england.nhs.uk/patient-safety/patient-safety-alerts/

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.