NATIONAL QUALITY BOARD

For meeting on: 05 December 2018

Paper presenter: Dr Aidan Fowler, NHS National Director of Patient Safety

Paper authors: Dr Frances Healey, Deputy Director of Patient Safety (Insight), NHS Improvement
Wayne Robson, Head of Patient Safety (Cross System), NHS Improvement
Dr Matt Forgarty, Deputy Director of Patient Safety (Policy and Strategy), NHS Improvement

Paper for:

Decision	Discussion	Information
X		

UPDATE ON THE NATIONAL PATIENT SAFETY ALERTING COMMITTEE (NaPSAC)

SUMMARY

In a recent year, the Central Alerting System (CAS) issued 121 communications to healthcare providers, originating from seven different alert issuing bodies/teams. As described in the earlier presentation to the NQB from CQC, there is evidence that the safety advice and guidance issued to the NHS by these bodies is not achieving the required impact for the safety of patients. In response to these concerns, the previous Secretary of State for Health and Social Care identified the need to more clearly identify which nationally-issued advice and guidance is safety-critical and mandatory, and this approach was reinforced by the Minster for Health in August 2018. The NHS National Director for Patient Safety was asked to develop a single system for all alert issuing bodies.

The National Patient Safety Alert Committee has been established with Dr Aidan Fowler as chair and Professor Ted Baker as deputy chair, and representation at the highest level from all other alert issuing bodies/teams. It has agreed principles for criteria and thresholds for future National Patient Safety Alerts and for future Alert templates. These principles are currently being developed into shared standards that all alert issuing bodies (including the CMO, DHSC Supply Disruption, the MHRA, NHS Digital, NHSE Operations & EPPR, NHSI Estates & Facilities, NHSI Patient Safety, and PHE) would commit to meeting as accredited issuers of National Patient Safety Alerts. This will underpin CQC inspection of National Patient Safety Alerts.

PURPOSE

The NQB is asked to:

1) **Note** progress on establishing National Patient Safety Alerts; and

2) **Agree** for NaPSAC to be constituted as a sub-committee of the NQB.

ALB involvement in development and sign-off of paper:

NHS England	Care Quality Commission	NHS Improvement	NHS Health Education England
X	X	X	

Public Health England	NICE National Institute for Health and Care Excellence	NHS Digital	Department of Health
X		X	X

UPDATE ON THE NATIONAL PATIENT SAFETY ALERTING COMMITTEE (NaPSAC)

1. ACKNOWLEDGING THE BASE WE HAVE BUILT ON

1.1 MHRA held a UK-wide summit in January 2018 on working in partnership to improve safety messages and alerts; this fundamentally informed NaPSAC's work. The MHRA summit also identified the importance of seperating **safety-critical Alerts requiring organisational action by a set date** from other safety communications. NHS Improvement is leading cross-system work on these via NaPSAC.

1.2 The model for NaPSAC was the NICE Accredited 'kitemark' awarded by their guideline accreditation process, and colleagues from NICE were generous with help and advice.

2. THE COMPLEXITY AND VARIATION OF THE CURRENT ALERT LANDSCAPE

2.1 Please see the PowerPoint presentation.

3. THE ROLE OF NaPSAC

3.1 NaPSAC has responsibility for **safety-critical Alerts requiring organisational action by a set date** as distinct from other safety communications.

3.2 NaPSAC operates by 'credentialing' each alert issuing body/team to issue National Patient Safety Alerts (as the urgency of some patient safety issues makes it impractical for each Alert to be individually authorised).

3.3 See terms of reference in **ANNEX A**, but in brief NaPSAC will:

a) develop common standards and thresholds for National Patient Safety Alerts;

b) develop a single recognisable consistent format for National Patient Safety Alerts to increase provider understanding about which safety-critical and mandatory actions must be implemented;

c) oversee the development of the credentialing criteria for alert-issuing bodies/teams and the assessment and governance processes through which alert issuing bodies/teams will be credentialed; and

d) monitor the National Patient Safety Alerts published by each credentialed alert issuer to ensure that they adhere to the agreed format, standards and thresholds.

3.4 CQC is a core member of NaPSAC, with Professor Ted Baker as deputy chair, as the standards and thresholds agreed by NaPSAC will underpin the CQC inspection of National Patient Safety Alerts and the potential for regulatory response for non-compliance.

3.5 NaPSAC has all types of healthcare providers (e.g. acute trusts, community pharmacies, general practices, mental health services) within its remit, although the targeting of specific individual National Patient Safety Alerts to different sectors will vary, depending on the issue the Alert addresses.

3.6 NaPSAC has invited observers from the devolved nations, as some Alert issuers (e.g. MHRA) have a UK-wide remit, and all current Alert issuers work closely with their counterparts in the devolved nations.

4. PROGRESS TO DATE

4.1 Progress has been facilitated by a strong commitment from all partners, with high level representation at NaPSAC meetings and associated workshops.

4.2 Thresholds, standards and criteria for issuing a National Patient Safety Alert have been agreed in principle and are currently being worked up and tested.

4.3 Engagement with individual alert issuers on clarifying their remit (the scope of their responsibilities for specific aspects of patient safety) is progressing well.

4.4 A workshop has been held to agree key content of future National Patient Safety Alerts, including Behavioural Insights input on designing for impact, and is being taking forward into National Patient Safety Alert template options. The workshop also encompassed links from Alerts through to resources and networks to support implementation when appropriate. Alert issuing bodies/teams have been flexible and collaborative in considering a shift from well-established formats that have been in use for many years.

4.5 Recruitment of Patient and Public Voice to NaPSAC is nearing completion.

4.6 Formal NaPSAC agreement is anticipated at its next meeting (December 17th). The process of evidencing that an alert issuer meets the criteria can then begin. Different alert issuing bodies may progress this at different speeds, but we would hope the first credentialed National Patient Safety Alerts will be issued early in 2019.

5. PROPOSAL TO NQB FOR NaPSAC GOVERNANCE

5.1 Because NaPSAC relies on collaborative agreement form multiple bodies and teams that issue Alerts (including the CMO, DHSC Supply Disruption, the MHRA, NHS Digital, NHSE Operations & EPPR, NHSI Estates and Facilities, NHSI Patient Safety, and PHE) a reporting line to the NQB is proposed, with NaPSAC constituted as a sub-committee of NQB.

NHS Improvement

Paper 2

Update on the National Patient Safety Alerting Committee (NaPSAC)

Dr Aidan Fowler, NHS National Director of Patient Safety

5 December 2018

1. Acknowledgements

Building on the work of:

- MHRA summit for UK partners
- NICE Evidence guideline accreditation

Note governmental support and impetus (past & present SoS)

Note division of responsibilities for cross-system work, and clarification of what had been inconsistent terms:

- **Alerts** for organisational action (NHS Improvement coordinating)
- Other safety **communications** (MHRA coordinating)

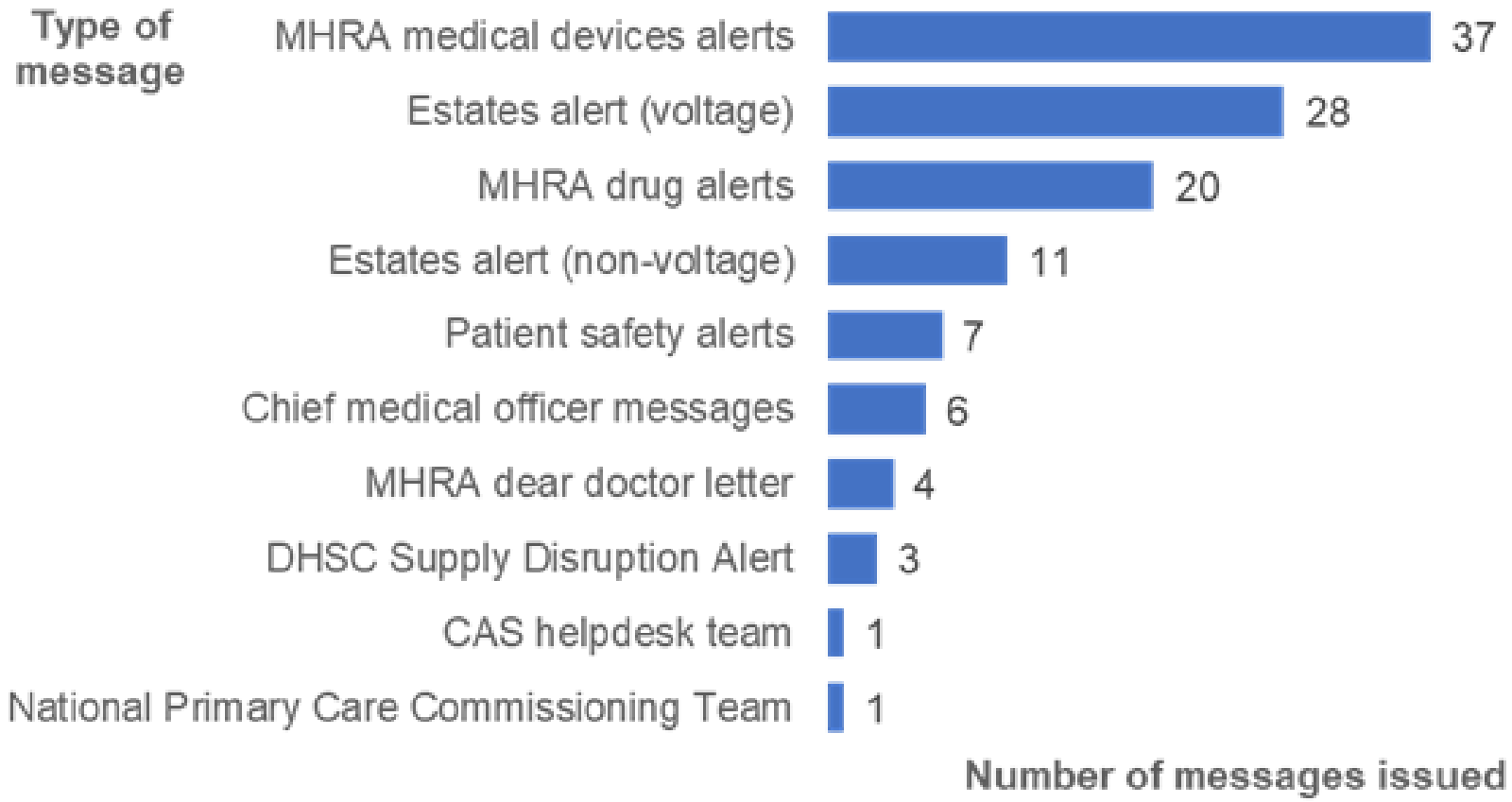
2. The complexity of the alert landscape

MHRA summit for UK partners January 2018

"Many national bodies in England, Scotland, Wales, Northern Ireland, or those with a UK-wide remit, issue communications to the healthcare service asking for action to be taken to protect patient safety. These may be called alerts, bulletins, messages, notices or go by other names, and may be issued via the Central Alerting System or alternative systems, including in the devolved nations.

"Currently some communications issued via CAS ask for action by organisations, and some may be directed at individual professionals to use to change their practice or knowledge."

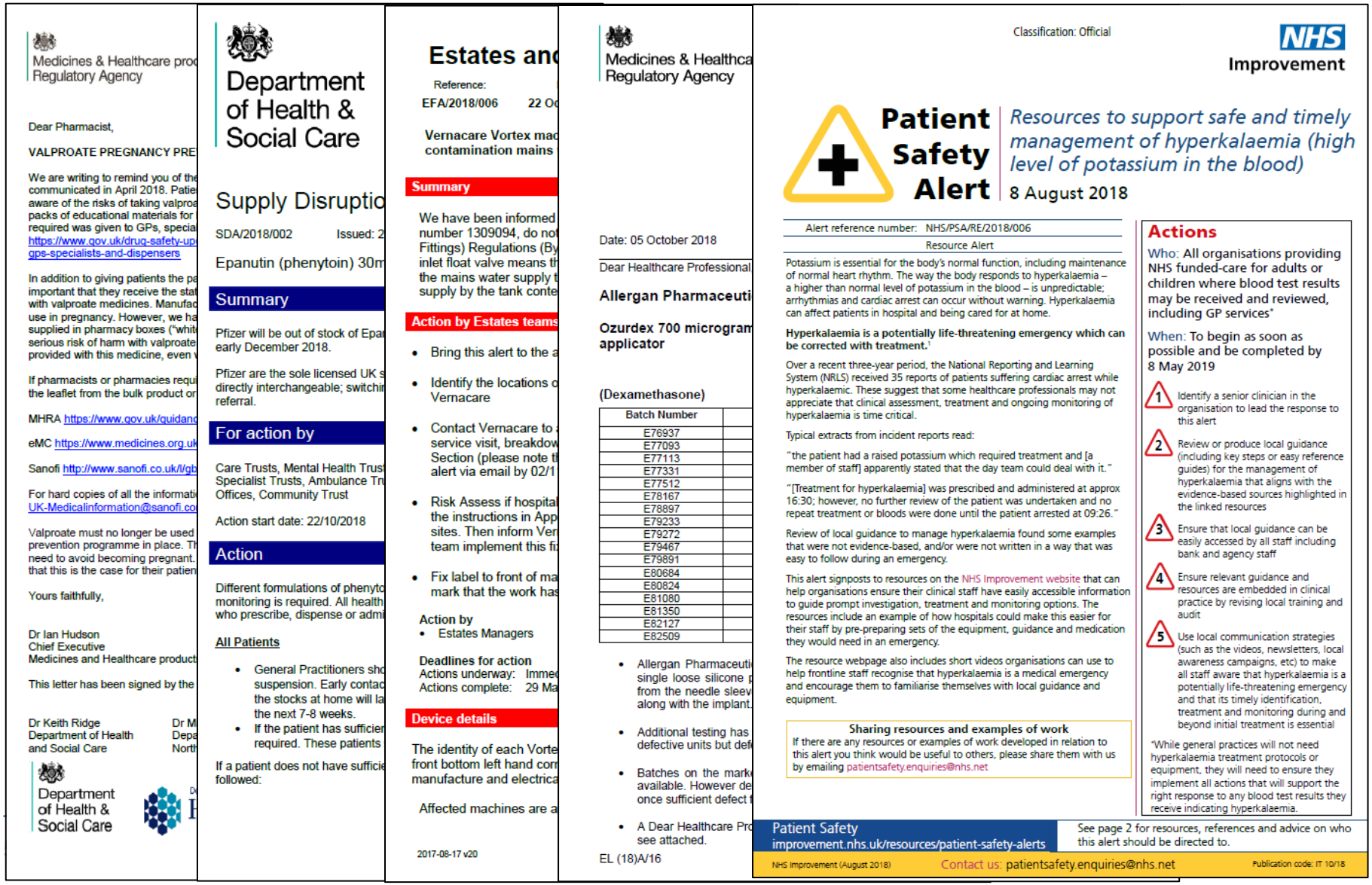
Types/numbers of some safety communications sent via CAS



Number of alerts/notices/messages issued via CAS between 1 November 2017 and 31 October 2018

Many different formats

NHS Improvement



Medicines & Healthcare prod
Regulatory Agency

Dear Pharmacist,

VALPROATE PREGNANCY PRE

We are writing to remind you of the
communicated in April 2018. Patie
aware of the risks of taking valproa
packs of educational materials for
required was given to GPs, specia
https://www.gov.uk/drug-safety-up
gps-specialists-and-dispensers

In addition to giving patients the pa
important that they receive the stat
with valproate medicines. Manufac
use in pregnancy. However, we ha
supplied in pharmacy boxes ("whit
serious risk of harm with valproate
provided with this medicine, even

If pharmacists or pharmacies requ
the leaflet from the bulk product or

MHRA https://www.gov.uk/guidanc

eMC https://www.medicines.org.uk

Sanofi http://www.sanofi.co.uk/l/gb

For hard copies of all the informati
UK-Medicalinformation@sanofi.co

Valproate must no longer be used
prevention programme in place. Th
need to avoid becoming pregnant.
that this is the case for their patien

Yours faithfully,

Dr Ian Hudson
Chief Executive
Medicines and Healthcare product

This letter has been signed by the

Dr Keith Ridge
Department of Health
and Social Care

Dr M
Depa
North

Department
of Health &
Social Care

Department
of Health &
Social Care

Supply Disruptio

SDA/2018/002 Issued: 2

Epanutin (phenytoin) 30m

Summary

Pfizer will be out of stock of Epa
early December 2018.

Pfizer are the sole licensed UK s
directly interchangeable; switchi
referral.

For action by

Care Trusts, Mental Health Trust
Specialist Trusts, Ambulance Tru
Offices, Community Trust

Action start date: 22/10/2018

Action

Different formulations of phenyto
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who prescribe, dispense or admi

All Patients

- General Practitioners sho
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- If the patient has sufficie
required. These patients

If a patient does not have sufficie
followed:

Estates and

Reference:
EFA/2018/006 22 Oc

Vernacare Vortex mac
contamination mains

Summary

We have been informed
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Fittings) Regulations (By
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Action by Estates teams

- Bring this alert to the a
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Vernacare
- Contact Vernacare to
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Section (please note t
alert via email by 02/1
- Risk Assess if hospital
the instructions in App
sites. Then inform Ver
team implement this fi
- Fix label to front of ma
mark that the work has

Action by
- Estates Managers

Deadlines for action
Actions underway: Imme
Actions complete: 29 Ma

Device details

The identity of each Vorte
front bottom left hand cor
manufacture and electrica

Affected machines are a

2017-08-17 v20

Medicines & Healthca
Regulatory Agency

Date: 05 October 2018

Dear Healthcare Professional

Allergan Pharmaceuti

Ozurdex 700 microgram
applicator

(Dexamethasone)

Batch Number	
E76937	
E77093	
E77113	
E77331	
E77512	
E78167	
E78897	
E79233	
E79272	
E79467	
E79891	
E80684	
E80824	
E81080	
E81350	
E82127	
E82509	

- Allergan Pharmaceuti
single loose silicone p
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along with the implant.
- Additional testing has
defective units but def
- Batches on the mark
available. However de
once sufficient defect
- A Dear Healthcare Pro
see attached.

EL (18)A/16

Classification: Official

NHS Improvement

Patient Safety Alert

Resources to support safe and timely management of hyperkalaemia (high level of potassium in the blood)

8 August 2018

Alert reference number: NHS/PSA/RE/2018/006

Resource Alert

Potassium is essential for the body's normal function, including maintenance of normal heart rhythm. The way the body responds to hyperkalaemia – a higher than normal level of potassium in the blood – is unpredictable; arrhythmias and cardiac arrest can occur without warning. Hyperkalaemia can affect patients in hospital and being cared for at home.

Hyperkalaemia is a potentially life-threatening emergency which can be corrected with treatment.[1]

Over a recent three-year period, the National Reporting and Learning System (NRLS) received 35 reports of patients suffering cardiac arrest while hyperkalaemic. These suggest that some healthcare professionals may not appreciate that clinical assessment, treatment and ongoing monitoring of hyperkalaemia is time critical.

Typical extracts from incident reports read:

"the patient had a raised potassium which required treatment and [a member of staff] apparently stated that the day team could deal with it."

"[Treatment for hyperkalaemia] was prescribed and administered at approx 16:30; however, no further review of the patient was undertaken and no repeat treatment or bloods were done until the patient arrested at 09:26."

Review of local guidance to manage hyperkalaemia found some examples that were not evidence-based, and/or were not written in a way that was easy to follow during an emergency.

This alert signposts to resources on the NHS Improvement website that can help organisations ensure their clinical staff have easily accessible information to guide prompt investigation, treatment and monitoring options. The resources include an example of how hospitals could make this easier for their staff by pre-preparing sets of the equipment, guidance and medication they would need in an emergency.

The resource webpage also includes short videos organisations can use to help frontline staff recognise that hyperkalaemia is a medical emergency and encourage them to familiarise themselves with local guidance and equipment.

Sharing resources and examples of work
If there are any resources or examples of work developed in relation to this alert you think would be useful to others, please share them with us by emailing patientsafety.enquiries@nhs.net

Actions

Who: All organisations providing NHS funded-care for adults or children where blood test results may be received and reviewed, including GP services*

When: To begin as soon as possible and be completed by 8 May 2019

1. Identify a senior clinician in the organisation to lead the response to this alert
2. Review or produce local guidance (including key steps or easy reference guides) for the management of hyperkalaemia that aligns with the evidence-based sources highlighted in the linked resources
3. Ensure that local guidance can be easily accessed by all staff including bank and agency staff
4. Ensure relevant guidance and resources are embedded in clinical practice by revising local training and audit
5. Use local communication strategies (such as the videos, newsletters, local awareness campaigns, etc) to make all staff aware that hyperkalaemia is a potentially life-threatening emergency and that its timely identification, treatment and monitoring during and beyond initial treatment is essential

*While general practices will not need hyperkalaemia treatment protocols or equipment, they will need to ensure they implement all actions that will support the right response to any blood test results they receive indicating hyperkalaemia.

Patient Safety
improvement.nhs.uk/resources/patient-safety-alerts

See page 2 for resources, references and advice on who this alert should be directed to.

NHS Improvement

MHRA

Classification: Official

NHS Improvement

Patient Safety Alert

Resources to support the safety of girls and women who are being treated with valproate

6 April 2017

Alert reference number: NHS/PSA/RE/2017/002

Resource Alert

Valproate, also known as valproic acid (brand names include Epilim and Depakote) is an effective medication used to treat epilepsy[1] and bipolar disorder.[2] Although unlicensed for treatment of other conditions in the UK, we are aware of 'off-label' use for migraine or chronic pain.[3]

In girls and women of childbearing potential, valproate should be initiated and supervised by a specialist and **only** when other medications have not been tolerated or have been found to be ineffective.

Unborn babies exposed to valproate during pregnancy are at very high risk (30-40 in every 100)[4,5,6,7] of neurodevelopment disability - such as lower intelligence and autistic spectrum disorders, and also at risk (10 in every 100) of other birth defects.[8] This has been increasingly recognised and reflected in strengthened regulatory guidance issued in 2014.[9] In 2015 the Medicines and Healthcare products Regulatory Agency (MHRA) published the valproate toolkit, providing a set of resources for patients, GPs, pharmacists and specialists.[10] This was added to in February 2016[11] and April 2017 www.gov.uk/governments/publications/toolkit-on-the-risks-of-valproate-medicines-in-female-patients.[12] These resources emphasise the need to avoid the use of valproate in girls and women of childbearing potential; warn women of the very high risks to the unborn child of valproate in pregnancy; and emphasise the need for effective contraception planning and specialist oversight of changes to medication when planning a pregnancy, as abrupt changes to medication can be harmful.

The MHRA resources have had widespread dissemination. This has resulted in a change of clinical practice in some organisations but evidence suggests a further concerted effort is needed to ensure professionals are informing all girls and women of childbearing age. This evidence includes:

- a survey of women in April 2016 that found of those taking valproate (n=624), 20% were not aware of any of the risks of valproate in pregnancy and <20% had received any of the educational materials[13]
- a National Reporting and Learning System (NRLS) search for incidents involving valproate and reported since January 2015 identified 13 reports that indicated valproate had been prescribed, including two that specifically reported no discussion of the risks in pregnancy had occurred. For example: "Patient .... on valproate. No discussion in notes about information or risks given to young female patient taking valproate."

The actions in this alert ask all organisations to undertake systematic identification of girls and women who are taking valproate, and ensure the MHRA resources are used to support them to make informed choices.

Sharing resources and examples of work

If there are any resources or examples of work developed in relation to this alert you think would be useful to others, please share them with us by emailing patientsafety.enquiries@nhs.net

Actions

Who: GP practices, community pharmacies,* acute trusts, mental health and learning disabilities trusts, specialist trusts and all other organisations providing NHS funded-care where valproate is prescribed or dispensed

When: To begin as soon as possible and be completed by 6 October 2017

1. Identify how the resources signposted in this alert can be used to support fully informed decisions on the use of valproate by girls and women of childbearing age.
2. Develop an action plan to ensure all girls and women of or nearing childbearing age taking valproate are systematically identified so that all relevant resources can be used to plan their care.
3. Ensure relevant resources are embedded in clinical practice for current and future patients by revising local training, procedures and protocols.
4. By circulating this Alert or through local alternatives (such as newsletters and local awareness campaigns) ensure staff are aware of the MHRA resources and understand their role in local plans to identify all girls and women of childbearing age taking valproate.

*Community pharmacies should deliver all actions that are within their remit, but systematic identification will typically need to be undertaken by the organisation prescribing valproate.

See page 2 for references, stakeholder engagement and advice on who to direct this alert to.

Medicines & Healthcare products Regulatory Agency

MHRA

Medical Device Alert

MDA/2017/026 Issued: 24 August 2017 at 15:30 Valid until: August 2018

Overhead hoist: Freeway Easy Fit system with a swivelling trolley – risk of fixing pin moving or splaying

Summary

Manufactured by Prism – splayed or misplaced pins may lead to the hoop detaching and dropping the sling.

Action

- Check whether you have a system with a swivelling trolley. See the manufacturer's Field Safety Notice (FSN) on how to do this.
- Inspect these devices to ensure the swivel trolley fixing pin is correctly fitted (see FSN).
- Quarantine any devices with splayed or misplaced pins.
- For all systems with a swivelling trolley, contact the manufacturer to arrange replacement of the fixing pin with a permanent bolt.
- Complete the Field Safety Notice acknowledgement form and return to the manufacturer.

Action by
All those involved in the provision, prescription, use and maintenance of this equipment.

Deadlines for actions
Actions underway: 08 September 2017
Actions complete: 25 September 2017

Department of Health

NHS National Services Scotland

Llywodraeth Cymru Wales Government

Page 1 of 4

Estates and Facilities Alert

Reference:	Issued:	Valid to:
EFA/2017/005	21 November 2017	21 November 2023

Unbranded LED decorative lighting chains, model CL100: risk of electric shock due to inadequate construction – remove from use.

NHS Improvement

Summary

There is a risk of electric shock due to inadequate construction of unbranded LED decorative lighting chains. Implicated units should be immediately removed from use in health and social care premises.

This risk was highlighted via the EU Rapid Reaction System (RAPEX) and Electrical Safety First issued a recall on 4 August 2017. No contact details were available for the manufacturer. This may mean there is no proper legal representative for the products, and the supply chain may be undocumented.

Action

- Bring this notice to the attention of all appropriate managers, staff and users.
- Identify implicated units and remove them from use immediately (to aid identification see model and barcodes in Device details section and images of packaging, lighting chain and controller in the Appendix).
- As a precaution remove any LED light chains from use that look similar to this unit but where the model or barcodes cannot be identified
- Dispose of implicated units in accordance with local guidelines (since the manufacturer cannot be identified)

Action by

- Users, Health & Safety Managers, Estates Officers

Deadlines for action

Actions underway: 28 November 2017
Actions complete: 21 December 2017

Device details

Brand	Unknown
Model	CL100
Bar codes	7 899882 266214 and 6 941985 736055
Manufacture Dates:	Unknown
Distribution Outlets:	Unknown

Distribution

Accommodation Services
Care Home Services

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/005 Issued: 15 February 2018 at 11:30 Valid until: February 2019

Roche Tissue Diagnostics (Ventana Medical Systems) – OptiView DAB IHC Detection Kit, UltraView Universal DAB Detection Kit, OptiView Amplification Kit and Hematoxylin II – Dispenser failure of Hematoxylin II and Horseradish Peroxidase reagents.

Summary

Roche Tissue Diagnostics (Ventana Medical Systems) – Leaking and sticking reagent dispensers may cause weak staining on tissue samples, which may lead to false negatives and misdiagnosis.

Action

- Ensure all relevant members of staff receive the manufacturer's Field Safety Notice, and that they understand the problem and the actions to be taken.
- Affected lots may only be used if same slide controls are used.
- Users who do not use same slide controls should not use affected lots, and are advised to destroy affected kits, and request replacement kits from the manufacturer.
- The use of appropriate same slide controls is highly recommended as it helps ensure the efficacy of all Immunohistochemistry (IHC) assays carried out on every slide on an automated IHC instrument.
- Consider the need to review previous test results obtained using affected lots.
- If any adverse event occurs relating to this issue, please report this to MHRA via Yellow Card or the relevant devolved administrations (Scotland, Wales and Northern Ireland).

Action by

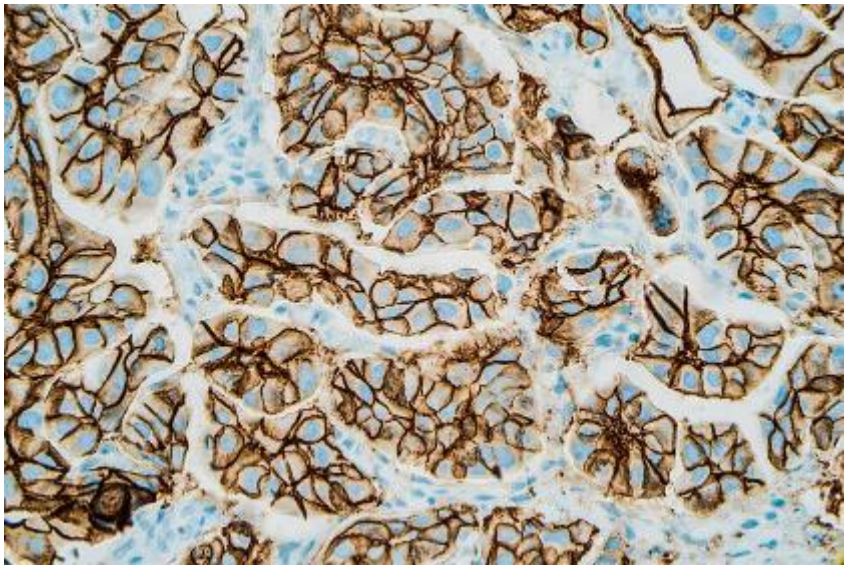
- Directors of pathology
- Laboratory managers
- Lead biomedical scientists (Cytologists / Histologists)
- Purchasing Managers
- Oncologists
- General Surgeons

Deadlines for actions
Actions underway: 01 March 2018
Actions complete: 15 March 2018

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru
Welsh Government



NHS Improvement

Insights from organisational leaders

Prior to the CQC thematic review, workshops/feedback had indicated:

- Providers felt overwhelmed by communications (many local/regional)
- Local systems for dealing with alerts were often based on tradition/custom and practice (sometimes origins decades in past)
- An assumption alerts were intended to warn individuals to try harder not to make mistakes was leading to a *'circulate and sign'* approach, even when coordinated organisational action was needed
- Even when need for action was recognised, delegation to multiple units to act separately, rather than coordinated efforts across an organisation
- Alerts not always on executive/senior/clinical leadership radar

Providers/clinical leaders/executives said they wanted a clear distinction between:

- Safety-critical requirements for coordinated organisational action by a specific date (i.e. **Alerts**)
- Other safety communications

3. NaPSAC operation

See NQB paper and ToR annex:

- Operates by ‘credentialing’ each alert issuing body/team to issue National Patient Safety Alerts
- Agrees and maintains common standards and thresholds
- All alert issuers will use a single recognisable consistent format
- CQC is a core member and process is mindful of regulatory consequences
- Focus inclusive of all types of healthcare providers
- Invited observers from the devolved nations

4. NaPSAC progress

See NQB paper:

- Strong commitment from all partners, with high level representation
- Thresholds, standards and criteria mutually agreed in principle
- Engagement with individual alert issuers on clarifying their remit/scope
- Key content of National Patient Safety Alerts agreed
- Template design for impact underway, including Behavioural Insights
- Recruitment of Patient and Public Voice
- Next NaPSAC meeting timed for 17th December to allow incorporation of additional insights from CQC thematic review before finalising the approach
- Likely that first credentialed National Patient Safety Alerts will be issued in early 2019

5. NaPSAC governance

Because NaPSAC relies on collaborative agreement form multiple bodies and teams that issue Alerts, a reporting line to the NQB is proposed, with NaPSAC constituted as a sub-committee of the NQB.

Paper 2

ANNEX A

Final agreed

Terms of Reference

National Patient Safety Alert Committee (NaPSAC)

Document filename: Terms of reference			
Directorate/ programme	NHS Improvement	**Project**	Creating a credentialing system for Patient Safety Alerts
Lead	Dr Aidan Fowler	**Status**	FINAL
Owner	Dr Frances Healey Dr Matt Fogarty	**Version**	V2.1
Author	Dr Frances Healey Dr Matt Fogarty	**Version issue date**	31/08/2018

Document management

Revision history

Version	Date	Summary of changes
V.1.0	23/03/18	Initial Draft Document for Review (background, proposal and ToR)
V. 2.0	06/08/18	Revised ToR
V. 2.1	31/08/18	Revised ToR after minor comment at 14/08/18 NaPSAC

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title/responsibility	Date	Version
Dr Aidan Fowler	NHS National Director of Patient Safety, NHS Improvement		
Dr Kathy McLean	Executive Medical Director, NHS Improvement		

Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
Mr Aidan Fowler on behalf of all members of NaPSAC		NHS National Director of Patient Safety, NHS Improvement		

Document control

The controlled copy of this document is maintained by NHS Improvement. Any copies of this document held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

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3 Scope of NaPSAC 5

4 Operating NaPSAC Error! Bookmark not defined.

5 Membership of NaPSAC 5

6 Accountability 6

7 Ways of working 7

1 Background

1.1 The core purpose of NaPSAC is to agree, progress and oversee systems which will clearly identify which nationally-issued patient safety advice and guidance is safety-critical.

1.2 This clarity is important for increasing providers' understanding about which safety-critical actions must be implemented by them. It is also an essential precursor to more effective systems through which compliance can be robustly monitored.

1.1 The focus of NaPSAC is on ensuring common standards and thresholds in the processes by which each and every 'authorised' body designates any of their communications as a 'nationally credentialed patient safety alert'. The urgency of many patient safety issues means it would not be realistic for the overarching body to approve the designation of individual Alerts before they are issued.

2 Purpose of NaPSAC

2.1 NaPSAC has been established to design and become the body with responsibility for ensuring the clarity and efficacy of communication that will enable providers to recognise and implement safety-critical actions

2.2 It will operate on a membership and mutual basis to:

2.3 Develop the ways of working by which NaPSAC that 'authorises' National Patient Safety Alert issuing bodies

2.4 Agree and maintain membership of NaPSAC, including membership from all nationally credentialed patient safety alert-issuing bodies, and others as agreed

2.5 Agree its own ways of working

2.6 Agree and maintain the mechanism for designating bodies so they are authorised to issue 'nationally credentialed patient safety alerts' and the associated systems for maintaining and if necessary withdrawing authorisation.

2.7 Agree and maintain the criteria for issuing a 'nationally credentialed patient safety alert' that specifies mandatory safety-critical actions that must be taken by healthcare organisations.

2.8 Agree and maintain the criteria for any sub-types of ‘nationally credentialed patient safety alert’, and ensure these sub-types relate only to logistics of organisational response, rather than suggest ranking of importance (as by definition all are mandatory and safety critical)

2.9 Agree and maintain the title, form and format for ‘nationally credentialed patient safety alerts’

2.10 Agree the route(s) of communication and dissemination of ‘nationally credentialed patient safety alerts’

2.11 Agree the mechanism for self-reporting of compliance with ‘nationally credentialed patient safety alerts’ by organisations

2.12 Agree ‘go live’ date for the ‘nationally credentialed patient safety alert’ system

2.13 Advise on the approach of regulators and other supervisory bodies to regulating compliance with ‘nationally credentialed patient safety alerts’

2.14 Periodically review how these arrangements are operating

3 Scope of NaPSAC

3.1 NaPSAC is focused on communications directed at organisations and requiring specific coordinated organisational action by a specified date to address risks that are life-threatening or involve risk of disability to patients.

3.2 The work of NaPSAC explicitly excludes non-safety critical communications, guidance that does not require action to be completed by a specified date, information directed at individual healthcare staff (i.e. informative ‘safety messages’), or risks to staff or the public.

3.3 NaPSAC would operate in England only, and efforts to align Alerts across the UK would continue to be led by MHRA in the broad sense, and also progressed by specific alert-issuing bodies in England

3.4 NaPSAC will not be responsible for the commissioning or delivery of technical platforms for disseminating ‘nationally credentialed patient safety alerts’ and collecting subsequent responses from providers on action taken, other than as described in 2.10

4 Membership of NaPSAC

4.1 NaPSAC will be chaired by the NHS National Director of Patient Safety (as already decided by Secretary of State).

4.2 The NaPSAC Deputy Chair will be the CQC Chief Inspector of Hospitals (as already decided by Secretary of State).

4.3 NaPSAC membership will include relevant individuals from each of the 'nationally credentialed patient safety alert' issuing bodies. These individuals must be authorised to take decisions on behalf of their body/team in relation to this work. The following bodies/teams are initially represented at NaPSAC on the basis that they either currently directly issue safety messages via CAS or intend to develop the facility to do so:

NHS Improvement's Patient Safety Team
NHS Improvement's Estates and Facilities Team
MHRA Devices
MHRA Drugs
DHSC Supply Disruption
Public Health England
NHS Digital
Office of the Chief Medical Officer
NHS England Primary Care Operations
NHS England Emergency Preparedness & Response

4.4 NaPSAC patient and public representation is initially proposed as two PPV; this would be kept under review

4.5 NaPSAC would also have membership from groups who do not issue Alerts but have a key interest in ensuring the Alerting system is effective. These are currently covered by the membership above, but would be kept under review

4.6 The devolved nations have an interest in the work of NaPSAC in so far as this has implications for the devolved nations. Invitation as observers will be extended to each of the three devolved nations (one observer per nation)

4.7 NaPSAC coordination and secretariat would be provided by the NHS Improvement Patient Safety team (as already decided by the Secretary of State)

5 Accountability

5.1 NaPSAC's route of accountability is to the National Quality Board, subject to confirmation at a future NQB

6 Ways of working

6.1 NaPSAC will determine its own ways of working but these initially include the following:

6.2 To be quorate, NaPSAC must include the Chair or their Deputy and two thirds of members

6.3 NaPSAC will meet quarterly initially, and at intervals it determines appropriate thereafter, with meeting dates agreed at least 2 months in advance

6.4 Papers and items will be circulated 5 working days in advance of meetings. Late papers will not be considered unless otherwise agreed with the Chair.

6.5 Agendas, minutes and papers will be published unless this is not possible without breaching information governance and confidentiality duties.