Lothian NHS Board

NHS Lothian Headquarters
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Date 5 November 2026
Your Ref
Our Ref 12023

Enquiries to Richard Mutch
Extension 35687
Direct Line 0131 465 5687
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richard.mutch@nhs.scot

Dear

FREEDOM OF INFORMATION – VALPROATE SAFETY IMPLEMENTATION GROUP

I write in response to your request for information in relation to Valproate Safety Implementation Group.

Question:
1. Do you have a Valproate Safety Implementation Group (VSIG), or an equivalent group responsible for implementing the Alert? If the group has a different title, please state it.

Answer:
Yes, the Valproate Alert Group.

Question:
2. Was the group in place before the Alert was issued, or was it established in response to the Alert? If the latter, please state the date of its first meeting.

Answer:
No, it was established in response to the alert and the first meeting was on the 15th December 2023.

Question:
3. What is the job title of the chair of the VSIG, and which organisation employs them? (I do not require the individual's name.); and which organisations, services and professional groups are represented on the VSIG? If the group has terms of reference, please provide a copy (the names of individual members may be redacted).

Answer:
Chair of Valproate Alert Group:
Lead Pharmacist Controlled Drug Governance and Medicine Safety, employed by NHS Lothian

The following NHS Lothian services and professional groups are represented on the Valproate Alert Group:
- General Practice
- Women and children

- Paediatrics
- Neurology
- Psychiatry
- Medicines Governance
- Pharmacy including hospital pharmacy dispensary managers group
- Community Pharmacy Development Group
- Mental Health
- Sexual Health
- Learning Disabilities

Question:

4. Do you have an action or improvement plan (however titled) in response to the Alert? Please provide a copy of the most recent version held, including any recorded assessment of progress against it.

Answer:

Yes – Improvement Plan January 2025 included

Question:

5. Did you commission or undertake any assessment of the number and needs of patients in your area affected by the new measures (for example, a baseline audit, health needs assessment or equality impact assessment, and how many have intellectual disability and whether these are in care)? If so, please provide a copy of, or link to, the resulting document or documents.

Answer:

Yes – Impact Assessment included

Question:

6. If you hold this information, how many patients in your area were prescribed valproate (a) in the twelve months to 30 November 2023 and (b) in the most recent twelve-month period for which you hold figures, broken down by biological sex? If you hold a figure for how many of these patients were recorded on a learning disability register, please provide it. I recognise that you may hold prescribing data only in aggregated form (for example, as items dispensed rather than patients treated) or without these breakdowns; if so, please provide what you do hold and indicate its source.

Answer:

a) **Dec 2022 to Nov 2023**
   Total: 2634 (897 female, 1737 male)

b) **Aug 2025 to July 2026**
   Total: 2222 (746 female, 1476 male)

The above data has been supplied by our Prescribing Efficiency & Analysis Technical (PEAT) Team and is generated from claims sent in by community pharmacies following confirmed dispensing of the medicine to the patient. There is a lag time of 2-3 months so the most recent period we can report on in August 2025 – July 2026.

We do not hold a learning disability register so unable to provide this data.

Question:

7. Please provide a copy of, or link to, your current local guidance, protocols or shared-care arrangements for the prescribing of valproate that reflect the regulatory measures introduced in January 2024.

Answer:

The following guidelines and protocols included:

- Critical care guideline for the treatment of status epilepticus
- Dispensing Sodium Valproate, Valproic Acid and Valproate Semi-sodium (Valproate) – Standard Operating Procedure

Additional guidance is included on the East Region Formulary and can be accessed using the following links:

- Bipolar disorder
- Genetic generalised epilepsy – adults children
- Dravet syndrome
- Established status epilepticus in hospital on failure of benzodiazepine
- Absence seizures – children
- Focal epilepsy – children

Question:

8. Do you have specific guidance for biologically female patients of childbearing potential who are prescribed valproate and who decline to participate in the Pregnancy Prevention Programme (PPP)? Please provide a copy or link to the guidance.

Answer:

No, we follow the MHRA guidance

Question:

9. Do you have specific guidance for patients with a learning disability (intellectual disability) who are prescribed valproate, including the assessment of their capacity to understand the teratogenic risk of valproate, to participate in the PPP and to complete the Annual Risk Acknowledgement Form (ARAF)? Please provide a copy or link to the guidance.

Answer:
Guidance that is shared with Intellectual Disability Psychiatrists is included.

Question:
10. Do you hold any policy or guidance concerning patients who were previously prescribed valproate and no longer are (for example, on follow-up after discontinuation or switching, or on the identification and support of children exposed to valproate in utero)? If so, please provide a copy or link.

Answer:
No, we follow the MHRA guidance

Question:
11. Do you hold any policy or guidance specific to the prescribing of valproate to biologically male patients, including the requirement for two specialists to approve initiation in new patients under 55 and the MHRA's advice on paternal exposure? If so, please provide a copy or link.

Answer:
No, we follow the MHRA guidance

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/Appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the FOI Reviewer at the email address at the head of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI/Pages/default.aspx

Yours sincerely

ALISON MACDONALD
Executive Director, Nursing
Cc: Chief Executive
Enc.

Improvement Plan Summary Document

For NPSA ALERT (NatPSA/2023/013/MHRA) – VALPROATE 28th Nov 2023

Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients

Explanation of identified safety issue

The MHRA is asking organisations to put a plan in place to implement new regulatory measures for sodium valproate, valproic acid and valproate semisodium (valproate). This follows a comprehensive review of safety data, advice from the Commission on Human Medicines and an expert group, and liaison with clinicians and organisations. Due to the known significant risk of serious harm to a baby after exposure to valproate in pregnancy, these measures aim to ensure valproate is only used if other treatments are ineffective or not tolerated, and that any use of valproate in women of childbearing potential who cannot be treated with other medicines is in accordance with the Pregnancy Prevention Programme (PPP). Given these and other risks of valproate, these measures also aim to reduce initiation of valproate to only in patients for whom no other therapeutic options are suitable.

The regulatory change in **January 2024**, for oral valproate medicines, means that:

A. Valproate must not be started in new patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.

B. At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes

Advise leaders that current safety measures for valproate continue to apply, including the valproate PPP for any girls and women of childbearing potential. See December 2022 Drug Safety Update for further information, including advice for clinicians to consider all other suitable therapeutic options before newly prescribing valproate in patients younger than 55. Advise leaders in general practice and pharmacy that teams should continue to prescribe and dispense valproate but also discuss the current warnings and upcoming measures relating to valproate with their patients and consider together how it affects the patient's individual circumstances. New educational materials should be integrated into local guidance to ensure patients are able to make an informed choice

Group Members (Aug 2024) - redacted

	Chair – Lead Pharmacist CD Governance and Medicine Safety, Professional Secretary – Medicine Safety and Risk Group
	GP prescribing lead – Edinburgh HSCP
	Medicines Utilisation and Review Group (Chair)
	Associate Director of Pharmacy – Specialist Services
	Lead Ph – Medical Paediatrics
	Consultant Obstetrician
	Lead Pharmacist - Neurosciences
	Lead Pharmacists - Neurosciences
	Lead Pharmacist – Community Pharmacy Development
	Lead Pharmacists – Edinburgh HSCP
	Lead Pharmacist – Community Pharmacy Development
	Specialist Doctor Sexual Reproductive Health, Chalmers
	Lead Pharmacist – West Lothian HSCP
	Dispensary Manager – Royal Edinburgh Hospital
	Consultant Paediatric Neurologist
	Lead Pharmacist – East Lothian HSCP
	Medical Consultant – Medicines Governance
	Lead Pharmacist – Medicines Governance
	Lead Pharmacist - Edinburgh HSCP
	Medical Consultant - Neurology
	Associate Specialities – Learning Disabilities
	Associate Medical Director - Psychiatry
	Lead Pharmacist – Midlothian HSCP
	Lead Pharmacist – Royal Edinburgh Hospital

Others
Director of Pharmacy and Medicines

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
NatPSA Action 1						
(a) Designate a new or existing group to co-ordinate the implementation of the new regulatory measures in providers, with oversight from a senior quality group (This group should include (but is not restricted to): a. An appointed chair with delegated responsibility for the actions in this alert	Medicine Safety and Risk Group remit to provide assurance to ADTC on completion of actions from external patient safety alerts. XX, Lead Pharmacist for Controlled Drugs Governance and Medicine Safety, is Professional Secretary for MSRG		**Dec 23**		**XX appointed as Chair of group – has delegated responsibility to ensure that updated guidance is implemented**	**Dec 23**
(b) Representation from clinical leads in all specialities - Medical Directors involved in the prescribing of valproate and clinical leads in **neurology, psychiatry, learning disability and/or autism, contraception and sexual health and general practice, with others included to meet local needs and clinical situations**	Engage with all required clinical areas **Neurology** **Psychiatry** **Learning disability and/or autism** **Women and Children** **Contraception and sexual health** **General practice** **Pain Service** **Primary Care Pharmacy Team** **Hospital Dispensary Teams** **Community Pharmacy Development Team** **East Region Formulary**		31st Jan 24	Contact details for clinical leads	**Clinical Leads - Members of the group** Neurology - **XX** Psychiatry - **XX** Learning disability and/or autism - **XX XX** Women and Children - **Obs - XX** - **Paeds – XX** Contraception and sexual health - **XX & XX**	

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
					General practice - **XX** Pain Service - **XX** Primary Care Pharmacy Team - **HSCP pharmacist leads XX** Hospital Dispensary Teams - **XX** Community Pharmacy Development Team - **XX** East Region Formulary - **XX**	
Other disciplines required to support - Data Analyst to support identification of patient	Review data available to advise Data Analyst of requirements to ensure capture all patients		10th Jan 24	Data Analyst support	Reports available and shared with Group	**5th Jan 24**
Included to meet clinical need						
Prescribing within pain	Liaise with lead for Critical Care theatres and anaesthetics – Michael Gillies to understand use		28th March 24		Contact made to request an update regarding changes for the service Protocol requested to be produced Confirm protocol is in place to support initiation – not required as not initiating treatment	**31st Jan 24** **14th Feb 24**
Prison population	Confirm process regarding patients within prison service		10th Jan 2024		Response from XX, HIS, regarding [Community Pharmacy contractor] risk assessment Shared risk assessment from [Community Pharmacy contractor] shared with the Group	**12th Jan 24**

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
Custody Suites	Confirm local process regarding patients with police custody suites		10th Jan 2024		XX confirmed local processes in place for each HB NHS Lothian currently have Valproate on the stock list for police custody suites and it as agreed that this will remain on the list as not initiated and ensure continuity of care for the patient	**12th Jan 24** **15th Jan 24**
Prisons and Custody Suites	Confirm nursing teams are aware of the updated regulations for valproate and can support patients who may present in custody suites		31st Jan 2024 11th March 24 11th March 24		- Communication regarding alert to Lead Pharmacist – Prisons and Police Custody suites - Confirmation from Prisons received - Confirmation regarding Police Custody Suites - Adopt consistent approach within Prison and Custody suites – XX to confirm – XX confirmed 5/8	**11th Jan 24** **15th Jan 24** **5th Aug 24**
Communication with Hospital Dispensary Teams	Ensure aware of requirements for dispensing valproate medicines and recording where this is not followed		19th March 24		- Comms to Dispensary Managers Group (DMG) regarding Alert - Shared risk assessment approved by REAS where patient is not supplied medicines in original packs with Group - Distributed to all Dispensary Managers for implementation within hospital dispensaries - Confirmation this has been adopted as a single system process within all hospital dispensaries (next DMG meeting 12/3) - Confirmed RIE, ELCH, SJH. REH and WGH Not required - ECC	**15th Dec 23** **9th Jan 24** **22nd Jan 24** **20th May 24**

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
					- Aug 24 – discussion with XX (SJH) further actions required therefore will take back to DMG	
Communication with Community Pharmacy (CP) Teams	Reminder of requirements of the alert and October communication regarding full pack dispensing of valproate		31st Jan 2024		- Alert included in weekly comms to CPs - Reminder sent via weekly comms to CPs 24/06 - Info regarding CP support to remind patients to engage in reviews to be added to newsletter – review SOPs, use all opportunities to discuss when pt presents to collect their medicines (XX & ELF)	**9th Dec 2024** **17th Jan 2024**
(c) A mechanism by which the group can involve and be informed by patients with lived experience	Link with Specialist epilepsy nurses regarding patient lived experience		28th March 24		Link with nurses established but no patient representatives approached yet (Updated from 22nd Jan 2024) Prompt nurses to provide list of patient representatives – List of patients with XX and XX	**29th March 2024**
Understanding patient lived experience	Draft a questionnaire to support discussions with patients with lived experiences. Include questions regarding engagement with annual reviews, reasons for not engaging, not attending, how to improve this part of their care. Are there language or cultural challenges?		28th March 24 20th May 24		Draft questions circulated for comment Plan time for discussions with patients by 25th April 2024 – XX and XX to discuss at next meeting. XX shared details of her experience. XX was able to share some of the experiences from patients with learning difficulties and their families Patient experience responses to be drafted to be able to be shared beyond this group one completed (24/5) awaiting other	**25th April 2024**

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
			20th May 24		Learnings from other HBs – where are the similarities and what have they learnt and plan to do as a result of this insight – 24/06 awaiting information from HIS – XX no further comms from HIS or insights shared by other HBs – FOR ESCALATION – noted within Impact Assessment opportunities	
Understanding patient lived experience	Liaise with representative from Mental Health and Learning and Disabilities for representation from these patient groups* see Action2 (b)		26th Feb 2024		Meeting planned 27th Feb 24 – update at next Valproate meeting	**20/05**
Patient Data						
Prescribing data available regarding patients prescribed valproate – Primary Care reports	Data request - Includes all required medicines - includes male patients - Define new patients - Confirm MCR (Medicine Care and Review) prescribing is captured Regularity of report		28th March 2024		- Confirmed details of medicines required to be included in the reports - Data for numbers of patients received, including male patients - New patients defined as having received medication in last 13 weeks – agreed at meeting on 22nd Jan 2024 - Confirmed MCR information is available, and a new search will be set up - Report will be produced annually to support annual review – agreed at meeting on 22nd Jan 2024 - Report with agreed parameters to be produced – updated	**19th Jan 2024** **22nd Jan 2024**

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
					report received but awaiting most up to date data (lag of 3 months for PRISMs) - Confirm annual process and pt codes/flags required - 2/9 MURG action TBC - 24/06 – Update to reports requested to support Impact Assessment – Analytical Services	**17th July 2024**
Follow governance processes for document and protocol ratification	Submit updated protocols and documents to D&T for ratification Discussed use of national guidelines unless off licence use	**Clinical Directors – all those representing their area of prescribing** **XX (pain service)**			Service specific XX to submit patient pathway/protocol for Pain service to D&T – not required as not initiating (would be off-label and not formulary)	
NatPSA Action 2						
a. Updating all local guidance and protocols relating to prescribing of valproate to reflect the new regulatory position, including definitions of the roles and responsibilities of clinicians and provider organisations, and the recording of compliance with the risk forms	Request for individual clinical areas to submit current documents related to Valproate prescribing and monitoring			Route to circulate information	Comms sent to all teams using Speedread/Memo Information received from clinical areas Information held within MS Teams channel – files added Safety and Educational Resources MS Teams channel – copies of protocols/documents from clinical leads add to folder – Clinical Area documentation	12th Dec 23 22nd Jan 24

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
Update all guidance	Update of East Region Formulary				Submit to Formulary meeting W/C 4th March 24 – update at next meeting Discussion at EJF meeting – not uploaded yet due to lack of agreement regarding language 25/04 – confirmed language used – patients with child bearing potential 24/06 – awaiting proofreading –XX will progress	**25th April 2024** **5th Sept 2024**
Recording of compliance with the risk forms – male and female patients	Request for individual clinical areas to confirm compliance with updated risk forms – newly issued for male and female patients Feedback on using of forms – any comments from those using them	**Clinical Directors – all those representing their area of prescribing**	**28th March 2024**		- XX raised that using new forms and taking time to review protocols based on using these forms	
Update all guidance	Request clinical areas to provide assurance that these documents are updated and there is a process of document control to ensure these remain up to date and reflect current legislation and prescribing	**Clinical Lead for each area to ensure in place** Neurology **XX** Psychiatry **XX** Learning disability and/or autism **XX** Women and Children **XX** **XX** Contraception and sexual health **XX**				

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
Drug and Therapeutic committees to request assurance from clinical services that there is a process to review and update protocols and documents as per MHRA guidance	Communication sent to D&T Chair to highlight expectations of alert		26th Feb 2024		Email sent to D&T Chairs highlighting alert and requesting support to ensure available within clinical areas – 28th March - response received and happy to support to provide assurance	1st March 2024
GP/Consultant referral to specialist contraception's clinic at Chalmers. Details of who to refer is not clear on RefHelp			28th March 2024		Ensure RefHelp 'Who to refer' is updated to include those prescribed valproate - 20/05 awaiting XX sign off 24/06 Confirmed live XX requested strengthening of the message regarding importance of ensuing there is no break in treatment – XX will follow up	25th April 2024
b. Commissioning work if necessary to understand the needs of the affected population, including those people most at risk of health inequalities	Patient lived experience response to include patients from Mental Health and Learning and Disabilities services – As per Action 1 (c) above*				As above - Meeting planned 27th Feb 24 – update at next Valproate meeting Consider support from patient reps. Can family facilitate and support sharing their experience and pt reviews	
Consider impact on patients with respect to health inequalities	Discuss need to complete Impact Assessment of changes		28th March 24 20th May 24		Review if required – advice sought from Equality and HR – this is for the group to decide - will await patient data and review need 24/4 – Agreed to review Impact Assessment requirements and form a group to complete	**10th May 24**

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
					Discussion with XX – Equality, Diversity and Inclusion to support setting up group for completion of IA Invites sent to XX Meeting planned for set up and completion of IA – Wednesday 26th June 2024 Identification of actions and final draft of Impact Assessment outstanding	**17th May 24** **26th June 2024**
c. Reviewing the results of local audit(s) of compliance with the existing PPP measures for girls and women of childbearing potential prescribed valproate	Produce an audit tool to support primary care teams identifying patients prescribed the identified medicines, including those who require PPP and annual review		10th Jan 2024		Audit produced and reviewed by Group – feedback regarding female only audit, include indication and if 2nd specialist sign off	15th Jan 2024
Produce audit template for Primary Care Teams	Review of audit with suggested amendments and guidance documents of the information sources to populate the audits		31st Jan 2024 1st March 2024 28th March 2024		Audit available to HSPC Lead Ph to share with Primary Care Pharmacy teams Guidance notes regarding data collation to be sent to HSCP Lead Ph HSCP Lead Ph to complete data collation – awaiting reports from teams 25/4 - some supplied with data available at present and will receive outstanding when available 20/5 - Some outstanding from WL - received	23rd May 2024

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
Visibility of data held regarding PPP and specialist annual review	Query regarding data sharing and visibility of the required information between primary and secondary care teams	**Secondary care teams**	25th April 24 20th May 24		Query regarding GP systems and visibility of notes discussed with What details to be recorded – standardise across primary and secondary care – template for referral and non-attendance Information to be added to patient notes to be confirmed to ensure consistency in records held – codes to be used to be confirmed How can information regarding non-attending be collated? – is there a read code already available? NOT POSSIBLE – FOR ESCALATION Xx to link with Lead Practice Nurse (XX)* email sent 1/3 – meeting held 3rd April - XX – happy to support comms to nursing teams but also suggested for all prescribers within primary care as pts may be seen by GPs *24/06 New contact – XX Draft comms for GP weekly brief and circulation to nursing teams. Passed onto XX with involvement from XX Comm in GP weekly brief to Include details from updated information from Chalmers and details of process to been followed. Draft article to include involvement from XX Use all opportunities to engage with pts prescribed Valproate	

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
					Primary Care flowchart in development, include actions of not attending/engaging – need for specific read codes to be identified (DB requesting). Also template for referral to be drafted. Secondary Care flowchart? Alert on TRAK XX suggested a letter template be produced should pt not engage TRAK – Significant Information – Yellow Triangle to be used to support information being highlighted at all points of care 24/06 request for clarification of this alerting option – does this fit with NHS Policy, do we need pt consent? XX – asked XX for more details and below was provided, 2/9 XX has escalated to XX for advice *18/07/2024 - Add to process documents - You can add an alert by selecting this category on EPR. A general alert – stating that the patient is on valproate and giving the date the ARAF was signed (for females) and RAF (for males).* *This creates a yellow triangle. These alerts in paediatric services are checked by ED and inpatient services so is a way of communicating that the patient is following the valproate pathway.*	

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
Data sharing across primary and secondary care	Confirm method of communication and if any further considerations, Caldicott authorisation		26th Feb 2024 28th March 2024		Discussion point for meeting agenda. Agreed XX will follow up regarding Caldicott authorisation – query passed onto Caldicott 1/3 – Response confirmed not required	**28th March 2024**
Current compliance with PPP measures for girls and women of childbearing potential prescribed valproate	Confirm current compliance within service of specialist annual review for PPP measures for girls and women of childbearing potential prescribed valproate	**Clinical Director - all those representing their area of prescribing**	26th Feb 2024 – carried forward			
At the next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form. This will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.	Confirm that processes are place to support women of childbearing potential and girls to be reviewed using a revised valproate Risk Acknowledgement Form. This will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.	**Clinical Director - all those representing their area of prescribing**	26th Feb 2024 – carried forward		26/2 **XX** – confirmed the new forms are in use in paeds 9/4 XX - All southeast Scotland ID doctors are aware of and have access to current Valproate forms and are aware that these must be used. Questions surrounding the forms are being directed to me. Will be recording compliance within the department.	

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
d. Commissioning/determining the local pathways of care for women of childbearing potential and girls in relation to the prescribing and review of valproate.	Update on progress within clinical areas having updated their patient pathways	**Clinical Leads - all those representing their area of prescribing**	26th Feb 2024 – carried forward		26/2 **XX** has shared Chalmers draft protocol and is available within Teams files for comment/feedback 9/4 JS – Learning difficulties rep - Each clinician is identifying all patients on Valproate and ensuring they are regularly reviewed, at least annually but usually more often. Neurology and Mental Health - National guidance for specialisms being used	**20th May 24** **20th May 2024**
Information sharing regarding contraception status	Confirmation that there is a process in place that allows contraceptive status to be determined at the annual review for females on contraception, and a system for collecting this information, and there are resources available to support this work	**Clinical Leads - all those representing their area of prescribing**	26th Feb 2024 – carried forward		Primary care work highlights pts eligible for PPP, prescribed contraception and had annual review in L12M (including CHI details) 24/06 XX – Primary Care flowchart in development – to be submitted to GPPC	
Patient access to contraception services	Women and girls of childbearing potential have access to contraception services in a timely manner and relevant data is shared between services	**Clinical Leads - all those representing their area of prescribing**	26th Feb 2024 – carried forward		Discussed when medication initiated and during annual review Support available from specialist services - Chalmers	
e. Planning for and identification of clinical resource to meet the identified needs of the population and implement the new regulatory measures.	Confirmation from secondary care teams of plan to resource the specialist annual review of patients Consider Clinical and administrative resource to support - 24/06 Concern that some patients may not attend Secondary Care for review therefore	**Clinical Directors - all those representing their area of prescribing**	26th Feb 2024 – carried forward		24/06 Primary Care teams complete annual review and refer as required. XX – discussed referral pathway within Mental Health as this includes a process for patients not engaging with reviews	

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
	resource is required within Secondary Care to follow up those not attending				XX to review for neurology and complete risk assessment as required	
Dec 2022 - Following advice from the Commission on Human Medicines (CHM), new safety measures for valproate-containing medicines: CHM recommends that no patients (male or female) under the age of 55 years should be initiated on valproate unless 2 specialists independently consider and document that there is no other effective or tolerated treatment. For patients under 55 years currently receiving valproate, 2 specialists should independently consider and document that there is no other effective or tolerated treatment or the risks do not apply.	Confirmation the CHM recommendations from Dec 2022 are in place	**Clinical Leads - all those representing their area of prescribing**	26th Feb 2024 – carried forward		9/4 XX – confirmed recommendations are in place	
Second specialist involved in Risk Acknowledgement Form	Confirm NHS Lothian process and criteria for second specialist signatory.				Other roles able to support this sign off as second signatory	

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
Annual review – recalling patients	Confirmation that there is a robust process that covers recall of patients for specialist annual review	**Clinical Leads - all those representing their area of prescribing**	26th Feb 2024 – carried forward		9/4 JS – Learning Difficulties – confirmed usual recall of patients but individual clinicians will check this is in place Annual Primary Care review to be established – highlight patients prescribed Valproate, review and refer to secondary care as required, using established routes. Primary care review will include use of letter/text/telephone call to ensure contact is made with the patient. Support may also be sought from Community Pharmacy teams. Pt will be informed why being referred to ensure engage with process. – as per XX comms and flowchart 24/06 See (e) above for action for Neurology	
	Which Group is responsible for collating the information for the annual review? MURG? How often will this be pulled? Aug/Sept and then 6 monthly check of records to ensure patients referred to Secondary care have been seen? For discussion		16th Sept 2024		6 monthly check - Take as AOCB to GPPC (W/C 9th Sept)	
	Aware of workload for recall of patients.					
	Standardisation of the process for recall and escalation to Consultant should patient not attend - Produce flowchart and standard comms (draft letter/email/text) for secondary care teams to use		16th Sept 2024		2/9 XX discussed meeting with XX to establish recall of patients – suggestion 3 appointments planned for patients but currently unclear what actions if non-attendance	

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
	Confirm if scanned copy of risk assessment form will be available to view – will GPs have sight of these? What is the process to notify GPs if pt does not attend? What risk assessment will be completed by Consultants to confirm prescribing within primary care has to continue?					
Recall process	Confirmation that the recall process includes - actions taken when a patient does not engage with the service - a risk assessment is completed in their absence - documented records of the communication and decision making where this situation occurs	**Clinical Leads - all those representing their area of prescribing**	26th Feb 2024 – carried forward		Robust recall process and recording of decisions made regarding patient recall and decision to continue medication if not attending for review XX and XX- ACTION within clinical areas	
NatPSA Action 3						
Based upon the findings of actions 1 and 2, the group should produce an Action and Improvement Plan by the alert deadline that is communicated with all relevant staff to ensure smooth implementation of the new regulatory measures and to allow for continuous	Further meetings of the Working Group to review progress and compliance with regulatory measures **28th March 24 – 3.30-5pm** **25th April 2024 – 3.30-5pm** **20th May 2024 – 9.30-11am** **24th June 2024 10.30-12noon** **5th August 2024 9.30-11am**					

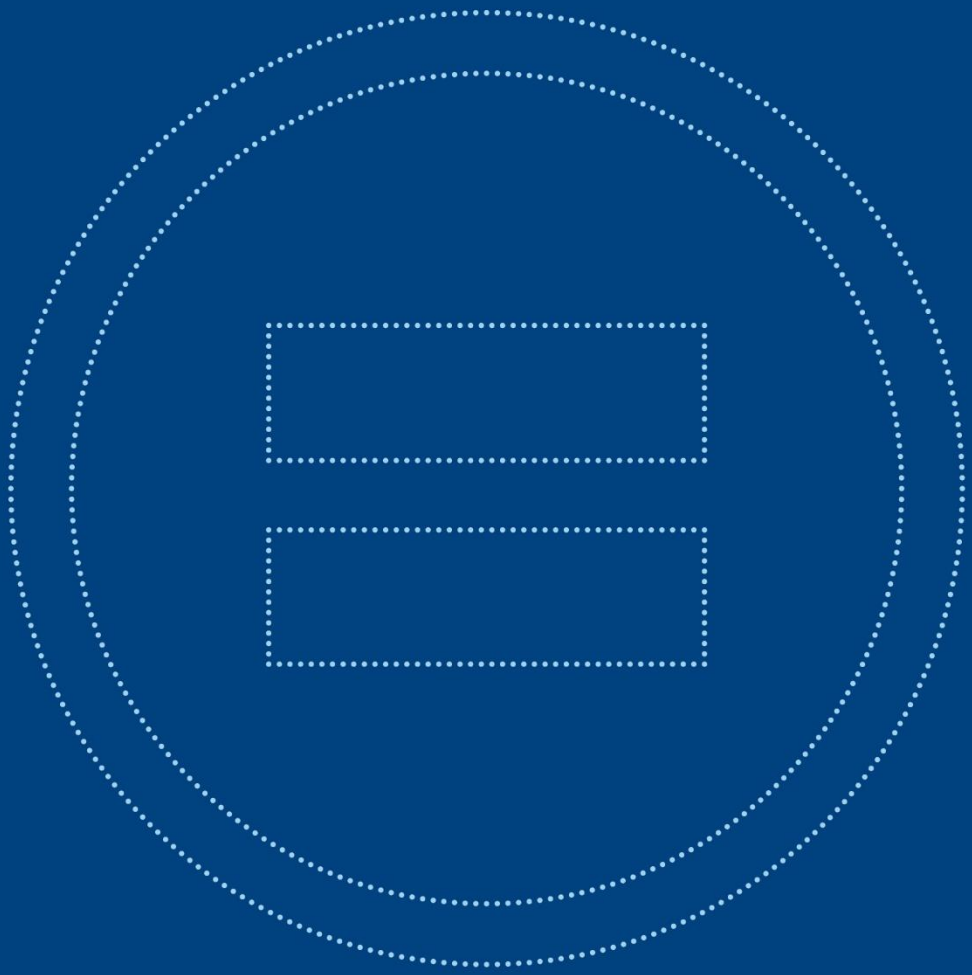
Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
improvement in care of patients who are considering or being prescribed valproate, including ongoing improvement, monitoring and audit.	**2nd September 2024 11-12.30pm** **30th September 2024 11-12.30pm** **28th October 2024 11-12.30pm** **2nd December 2024 11-12.30pm**					
Other queries raised during discussions						
Patients residing in Scotland who have not been diagnosed within Scotland and therefore may not be within the review process (temporary residents, e.g. students)	Query – identified from annual prescribing report and triaged as per other patients				- Discussed with XX (Task and Finish Group) 22nd Jan as an outstanding query - Acknowledged as an ongoing process to support all pts prescribed valproate	
Language used within alert and what will be adopted within EJF	Discussion on 28th March regarding language to be used		**25th April 24** **25th April 24**		- Agreed – childbearing age with a female reproductive system – from EJF discussion - Update at next meeting to confirm EJF agreed language - 'any individual with child bearing potential' Women and girls replaced by females Raised query to XX – National Teratogenic Group (LB) regarding language within Alert, our discussion and highlight to MHRA the need to review description – response from XX acknowledged language and will pass on our comments to Scottish Government	25th April 24 25th April 24

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
Opportunity to learn from this alert to support patients prescribed other teratogenic medicines	Topiramate update announced 20th June 2024					
Is there an opportunity for a National approach to changes like this?					XX – Clinical Fellow for Medicine Safety in role – how can they support these changes? XX - Raised at HIS Valproate Learning event – Feb 2025	
5/8 Acknowledgement that same outstanding actions from June meeting						
Other links	HIS – Community Engagement Team within HIS (support the engagement of people and communities in shaping health and care services) – opportunity to support Valproate patients Other HBs - NHS Fife – XX - NHS Highland – XX - NHS Tayside - TBC - NHS GGC - XX National Valproate Group - XX request to join to support understanding of operational challenges faced by HBs in implementing the alert					

Recommendations Table has been redacted	Actions to Address Recommendation	By Whom	By When	Resource Requirements	Evidence of Completion	Completion Sign-off
Handover once this Group is disbanded	How ensure assurance that processes in place, maintained and reviewed? ADTC – annual prompt for review – MURG/GPPC					

Equality. Fairer Scotland. Children's Rights. Impact Assessment Report

MHRA update to Valproate prescribing



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Description

Guidance pages 4-7

Title of proposed work

Valproate regulatory measures implementation action and improvement plan 2024

Purpose/objective of proposed work

The MHRA has asked organisations to put a plan in place to implement new regulatory measures for valproate following a comprehensive review of safety data, advice from the Commission on Human Medicines and an expert group, and liaison with clinicians and organisations. This is due to the known significant risk of serious harm to a baby after exposure to valproate in pregnancy. Aim is to ensure valproate is only used if other treatments are ineffective or not tolerated. Any use of valproate in women of childbearing potential who cannot be treated with other medicines is in accordance with the Pregnancy Prevention Programme (PPP).

Who will be affected by this proposed work

- People under 55 years old (male or female) who are not currently prescribed valproate
- Women of childbearing potential and girls currently prescribed valproate

Within these groups are:

- People with epilepsy
- People with learning disabilities (epilepsy is more common in people with a learning disability than in the general population and the more severe the learning disability the more likely that the person will also have epilepsy)
- People with bipolar disorder

Report written by:

Lead Pharmacist CD Governance and Medicine Safety

Report authorised by:

Note – only need the job title for person with responsibility for agreeing the final proposal.
Date: Director of Pharmacy and Medicines as Chair of Medicine Safety and Risk Group

PLEASE NOTE

Once your proposal has been agreed and signed off, send the completed Impact Assessment Report to impactassessments@nhslothian.scot.nhs.uk for publication on NHS Lothian website. You can use this email address to feed back on the impact assessment process.

Evidence

Guidance pages 9-15

Evidence used:

Data collection of patients prescribed these medicines

Equality Data – 2011 census

Epilepsy Society

Valproate: review of safety data and expert advice on management of risks (Medicines and Healthcare products Regulatory Agency 2023). This includes evidence from patients and patient charities and other stakeholders.

Summary of evidence findings:

People with learning disabilities

Epilepsy is more common in people with a learning disability than in the general population.

- About 1 in 3 people (32%) who have a mild to moderate learning disability also have epilepsy.
- The more severe the learning disability, the more likely that the person will also have epilepsy.
- Around 1 in 5 people (20%) with epilepsy also have a learning disability.

Treatment of epilepsy usually involves taking anti-seizure medication (ASM) to prevent seizures from happening. Treating people with a learning disability can often be more difficult as their seizures may be more prolonged or frequent. In both cases, this may be due to the underlying cause or brain damage.

Being able to understand their own epilepsy, and how to manage it, is important for everyone taking ASM. Some people with learning disabilities can find it difficult to understand how and why they need to take their ASM. They may need help with understanding this from relatives, carers or the health professionals involved in their care.

People with learning difficulties have a higher risk of sudden death than the general population. This risk increases for those not prescribed Valoprate.

An Inquiry by the Scottish Parliament Health and Sport Committee[1] found that disabled people were a key group affected by health inequalities. They experience health inequalities in two ways, by living in poverty and through discrimination that exists in access to health services. Many disabled people find it difficult to access mainstream transport so often need to rely on more expensive transport, such as taxis, making it difficult and / or more expensive to get to healthcare appointments. Flexible systems such as phone or online appointments are often not available to disabled people either because they are not accessible options for them, or hospitals and surgeries don't use them.

[1] Scottish Parliament (2015) Health and Sport Committee Report on health inequalities

People with learning disabilities face barriers accessing health services, compounded by communication difficulties and a lack of support provided by organisations and wider society. Research by the Scottish Learning Disabilities Observatory (SLDO) found that adults with intellectual disabilities receive poorer health care, despite health care needs being more prevalent.[2] Another piece of SLDO research[3] indicates that adults with learning disabilities are admitted to hospital for preventable conditions more often than the general population and that they often have a longer length of stay than other people.

Women up to age 55

The population aged 16-64 is slightly larger than seen in Scotland, largely due to the working-age population in and around Edinburgh. The proportion of the population over 64 years old is slightly smaller than seen nationally. Around 11 per cent of Lothian's population (just over 100,000 people) live in areas categorised as among the 20 per cent most deprived areas in Scotland. The greatest number of these areas are located within Edinburgh (affecting approximately 62,000 individuals). Proportionately, West Lothian has the highest share of its population (14.3 per cent) living in the most deprived communities.[4]

Evidence in the Women's Health Plan[5] tells us an estimated 1.5 million (1 in ten) women in the UK of reproductive age are affected by endometriosis, and it takes an average of 8.5 years to diagnose. Almost 1 in 10 deaths in women in Scotland each year are caused by ischaemic heart disease. In the most affluent areas of Scotland, women experience 25.1 more years of good health compared to the most deprived areas. It is estimated there are currently 300,000 people in Scotland living with osteoporosis, a condition which is more common in women than men. Women aged under 25 are the group most at risk of being diagnosed with an STI. Death from stroke is more common for women than men. Heart disease is the leading cause of maternal death in the UK. Around 400,000 women in Scotland are of menopausal age. The average age at which a woman will reach menopause is 51. On average, the life expectancy of women with a learning disability is 18 years shorter than for women in the general population. 61 per cent of unpaid carers are women.

[2] Cooper S, Hughes-McCormack L, Greenlaw N et al (2017) Management and prevalence of long-term conditions in primary health care for adults with intellectual disabilities compared with the general population: A population-based cohort study

[3] Dunn K, Hughes-McCormack L and Cooper, S (2017) Hospital admissions for physical health conditions for people with intellectual disabilities: Systematic review

[4] NHS Lothian (2023) Director of Public Health Annual Report

[5] Scottish Government (2021) Women's Health Plan

The most recent Saving Lives, Improving Mothers' Care Core Report[6] found that Black women were 3.7 times, and Asian women were 1.8 times more likely to die than White women. More women from deprived areas are dying and this continues to increase. 1 in 9 women who died had severe and multiple disadvantage.

Trans men

More trans people experience problems with their mental health, including depression and thoughts of suicide and younger trans and non-binary people (age 16-44) are more likely to report a long-term conditions, disability or illness compared to other people the same age. They also have poorer access to health services, including witnessing discriminatory or negative remarks and experiencing inappropriate curiosity. This can lead many trans people to avoid services or treatment.[7]

The NHS Greater Glasgow & Clyde and NHS Lothian LGBT Health Needs Assessment found that non-binary and trans people have very poor health and wellbeing indicators (for example - social health, physical health, mental health). For general mental health, depression and anxiety, LGBT people are at a much higher risk of mental health problems than heterosexual/ cisgender people. This was highest for trans-masculine (75 per cent) and non-binary people (72 per cent). Only 9 per cent of non-binary and 12 per cent of trans masculine people rated their general mental and emotional wellbeing positively. Self-harm and eating disorders were most prevalent among trans masculine and non-binary people. Trans and non-binary people were particularly likely to speak about suicidal thoughts, although these tended to subside after transition. LGBT asylum seekers were most likely to have attempted suicide[8]

There are very few published reports of ovarian cancer in trans men. Trans men may still be at risk because most will have never been pregnant or used the

[6] Knight M, Bunch K, Patel R, Shakespeare J, Kotnis R, Kenyon S, Kurinczuk JJ (Eds.) on behalf of MBRRACE-UK. Saving Lives, Improving Mothers' Care Core Report - Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2018-20. Oxford: National Perinatal Epidemiology Unit, University of Oxford 2022 https://www.npeu.ox.ac.uk/assets/downloads/mbrrace-uk/reports/maternal-report-2022/MBRRACEUK_Maternal_MAIN_Report_2022_v10.pdf

[7] Acting on the evidence: ensuring the NHS meets the needs of trans people | The King's Fund (kingsfund.org.uk)

[8] Leven T (2022) Health needs assessment of lesbian, gay, bisexual, transgender and non-binary people: Full research findings report prepared for NHS Greater Glasgow & Clyde, NHS Lothian and Public Health Scotland

combined oral contraceptive pill, which are known to be protective factors. Good practice guidelines for the assessment and treatment of adults with gender dysphoria recommend that trans men consider a hysterectomy after 4–5 years of testosterone therapy to reduce the risk of endometrial cancer caused by exposure to unopposed oestrogen produced by aromatisation of testosterone. Trans men who have chosen not to undergo GRS are able to conceive.[9]

Supported decision-making

The Scottish Mental Health Law Review[10] recommends people should be supported to exercise their capacity, even in situations of crisis, by reframing the law and the support provided so that interventions in someone's life are based on understanding and focusing on someone's own wishes. The report also recommends wider programmes of action, such as initiatives to reduce the use of coercion and improve the experiences of the people who are subject to it, and to develop a comprehensive system of supported decision-making.

[9] The transgender population: improving awareness for gynaecologists and their role in the provision of care - Price - 2019 - The Obstetrician & Gynaecologist - Wiley Online Library

[10] SMHLR (2022) Final report

Impact on equality & socio-economic disadvantage

Guidance pages 16-22

Disadvantage and discrimination (negative impacts)

Using the evidence you have collected, explain if this decision to pause investment could be discriminatory and/ or put a group of people sharing one of these characteristics at a disadvantage for a reason connected to that characteristic.
Note – for the first two columns answer yes/ no and provide brief explanation.

Relevant group	Will your proposal put people at a disadvantage/ make their lives worse?	Could this be unlawful discrimination? Yes/No	What could be done to reduce/remove this? [mitigating actions]
People in different age groups	Yes – children under age 16 will have to wait longer for diagnosis of autism and this will impact health, education and quality of life.	Direct – no, the reason for the disadvantage is not age. Indirect – no, the P&A decision applies to everyone on the waiting list and does not put one age group at a particular disadvantage compared to others on the waiting list who are not in that age group.	
Disabled people	Yes 1. The majority of children and young people with autism will meet the EA 2010 definition of disability. Receiving an early diagnosis	No. Same reasoning as above.	* Electronic patient letters and patient focus booking systems that allow online booking may

Relevant group	Will your proposal put people at a disadvantage/ make their lives worse?	Could this be unlawful discrimination? Yes/No	What could be done to reduce/remove this? [mitigating actions]
	helps autistic children and young people understand why they are different from others and ensures they have access to the support they need to thrive. They are having to wait longer for diagnosis and getting the support they need, and this has a significant impact on their health, education and quality of life. People who have been diagnosed with autism when children are less likely to die by suicide than people who are diagnosed as adults. 2. Concerns have been raised by families about being contacted by telephone because this isn't always the best form of communication.		reduce disadvantage for some families.
Trans and non-binary people	Potentially yes because longer waits for younger children to receive an early diagnosis has an impact on helping them to fit in, understand themselves and providing support to families to understand and meet their needs.	Direct – no, the reason for disadvantage is not because of gender reassignment. Indirect – no, there is not sufficient evidence that this P&A decision puts trans children with autism are at a particular disadvantage	

Relevant group	Will your proposal put people at a disadvantage/ make their lives worse?	Could this be unlawful discrimination? Yes/No	What could be done to reduce/remove this? [mitigating actions]
		compared to other children with autism on the waiting list.	
People who are pregnant or on maternity leave	No	No	
People from different ethnic backgrounds	Potentially yes. It is not always possible to book an interpreter, and this adds to delays accessing appointments. In community locations interpreters sometimes go to larger sites because can do more appointments.	Direct – no. Indirect – no because there is a limit to what NHS Lothian can do to require interpreters to accept appointments in community locations.	* Work with NHS Lothian ITS to raise awareness of these issues and try to identify a solution. * Identify and implement actions to improve collection of patient ethnicity data.
People with religious or protected beliefs	No	No	No
Men and women [This may include carers, because many are women.]	Yes – there are more boys on the waiting list than girls. They will have to wait longer for diagnosis, and this will impact on health, education and quality of life.	Direct – no, because the reason for disadvantage is not sex.	

Relevant group	Will your proposal put people at a disadvantage/ make their lives worse?	Could this be unlawful discrimination? Yes/No	What could be done to reduce/remove this? [mitigating actions]
	Yes – girls tend not to be diagnosed until older and as a result experience diagnostic overshadowing and masking – which impacts on mental health. Potentially yes. There is evidence that autism may be influenced by genetics as well as, or more than, environmental factors. The earlier a child receives a diagnosis helps their parents to make choices about whether they want to have more children.	Indirect – potentially yes for boys. The PCP applies to everyone on the waiting list but because more boys (2.8%) than girls (0.65%) are diagnosed with autism and the significantly higher number of boys on NHSL waiting list (which is also significantly disproportionate when compared to the local population) it may put boys at a particular disadvantage compared to girls. Whether this can be objectively justified depends on the legitimate aim (need to make financial savings and prioritise urgent clinical need) and if this P&A decision is a proportionate way to achieve the savings. This is a balancing exercise and need to evaluate the	

Relevant group	Will your proposal put people at a disadvantage/ make their lives worse?	Could this be unlawful discrimination? Yes/No	What could be done to reduce/remove this? [mitigating actions]
		discriminatory effect against the reasons for pausing investment. This includes thinking about whether it is appropriate and necessary and if there is no less discriminatory way to achieve financial savings and prioritisation of urgent clinical need.	
People who are heterosexual, lesbian, gay or bisexual	No	No	NA
People who are married or in a civil partnership [only in employment situations]	No	No	NA
Care experienced people	Yes 1. Care experience children experience more barriers accessing health services than the general population and are likely to wait longer to get a referral and potentially more likely to miss appointments during their	No - there is no legal protection from discrimination on basis of care experience.	* Prioritise care experience children and young people on the waiting list as urgent, in the same way as Veterans can be prioritised as urgent.

Relevant group	Will your proposal put people at a disadvantage/ make their lives worse?	Could this be unlawful discrimination? Yes/No	What could be done to reduce/remove this? [mitigating actions]
	patient journey because of changes/ fluctuations in their care. 2. There are examples of children being referred in one area but are moved into care out of area before being assessed and they join the bottom of the new health board's waiting list		* Contact NHS Scotland and Who Cares Scotland to identify a Scotland wide solution when care moves out of area.
People experiencing health inequalities caused by socio-economic disadvantage [This may include people living in difficult circumstances such as people experiencing homelessness, who are in prison or are ex-offenders, people with addictions and people involved with prostitution. Note –	Yes 1. There are more children from the most deprived areas on the waiting list and there is some evidence that children with autism are more likely to be socio-economically. disadvantaged. Children from the most deprived areas experience more barriers accessing health services than children from the least deprived areas and therefore may experience more delays in completing their patient journey. 2. Clinics are being run in local communities because this helps to reduce / remove barriers experienced by people experiencing socio-economic disadvantage. However, there have been times when clinics have to	No - there is no legal protection from discrimination on basis of socio-economic disadvantage.	* Work with community health centres to raise awareness of anticipatory reasonable adjustment duty and how this applies to autism diagnosis clinics. Service (via Head of Equality & Human Rights) to contact National Autism Implementation Team at Queen Margaret University that has dealt with similar issues and may be able to provide advice and support.

Relevant group	Will your proposal put people at a disadvantage/ make their lives worse?	Could this be unlawful discrimination? Yes/No	What could be done to reduce/remove this? [mitigating actions]
travel costs have a particular impact on people experiencing poverty.]	be cancelled with short notice and we are not informed in a timely manner. This can be because the space is being used for something else.		
People experiencing employment inequalities caused by socio-economic disadvantage	No	No - there is no legal protection from discrimination in employment on basis of socio-economic disadvantage.	NA
Carers	No.	No - there is no legal protection from discrimination on basis of caring responsibilities.	

Advancing equality & good relations (positive impact)

Using the evidence you have collected, explain if and how the decision to pause investment could reduce inequalities experienced by groups of people sharing certain characteristics.
Note – answer yes/ no and if yes provide brief reasons.

Relevant group	**Can this help advance equality of opportunity?** [reduce disadvantage, meet different needs, increase participation]	**Can this help foster good relations?** [reduce prejudice & increase tolerance]
People in different age groups	No	No
Disabled people	No	No
Trans and non-binary people	No	No
People who are pregnant or on maternity leave	No	No
People from different ethnic backgrounds	No	No

Relevant group	Can this help advance equality of opportunity? [reduce disadvantage, meet different needs, increase participation]	Can this help foster good relations? [reduce prejudice & increase tolerance]
People with religious or protected beliefs	No	No
Men or women [This may include carers, because many are women]	No	No
People who are heterosexual, lesbian, gay or bisexual	No	No
Care experienced people	No	No
People who experience health inequalities caused by socio-economic disadvantage [This may include people in different or difficult circumstances, such as people experiencing homelessness, who are in prison or ex-offenders, people with addictions and	No	No

Relevant group	Can this help advance equality of opportunity? [reduce disadvantage, meet different needs, increase participation]	Can this help foster good relations? [reduce prejudice & increase tolerance]
people involved with prostitution. Note – travel costs have a particular impact on people experiencing poverty.]		
People who experience employment inequalities caused by socio-economic disadvantage. [This may include people in different or difficult circumstances, such as people experiencing homelessness, who are in prison or ex-offenders, people with addictions, ex-service personnel/veterans and people involved with prostitution. Note – travel costs have a particular impact on people experiencing poverty.]	No	No
Carers	No	No

Impact on UNCRC rights

Guidance pages 23-25

If your proposal does not affect children and young people do not complete this section.

If your proposal affects children and young people up to age 18, use the evidence you have collected to explain how your proposal could impact Children's Rights. Not all UNCRC rights may apply to your proposal. If this is the case, simply say 'Neutral.'

Article 4 UNCRC requires States to take all appropriate legislative, administrative and other measures for the implementation of UNCRC right. For UNCRC rights that involve economic, social and cultural rights – States must take such measures to the maximum extent of their available resources. This is known as the 'progressive realisation of rights,' and reflects "a realistic acceptance that the lack of resources – financial and other resources – can hamper the full implementation of economic, social and cultural rights in some States." (Committee on the Rights of the Child (CRC) general comment No. 5 (2003) on the general measures of implementation of the Convention on the Rights of the Child, para. 8.). However, the degree of flexibility is relative to the resources required to fulfil a particular right e.g. if only a few resources are required to fulfil a given right, the relevance of progressive realisation diminishes.

There are UNCRC obligations that are not subject to resource availability and progressive realisation – in particular the right to for children and young people to enjoy economic, social and cultural rights without discrimination.

There is also an immediate obligation to take deliberate, concrete and targeted measures, making the most efficient use of available resources, to move as expeditiously and effectively as possible towards the full realisation of rights.

In summary, NHS Lothian is obliged to make a best effort, to the maximum of their available resources, to make progress in the realisation of UNCRC economic, social and cultural rights.

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
1 – we must make sure everyone under 18 years old can enjoy all UNCRC rights	Yes	Neutral	No
2 – we must make sure all UNCRC rights apply to every child without discrimination.	Potentially no because the P&A decision may have an impact on children with autism, and within this group there are significantly more boys and care experienced children may be particularly negatively impacted in particular, and may not be able to enjoy their right to good quality health care as other children.	No	Children with autism, and within this group boys and care experienced children.
3 – we must make sure the best interests of the child are a top priority in all decisions and actions that affect the child.	Yes. At the first appointment we ask for information to ensure we use it as part of their patient journey.	No, because we are not progressing this right until the first appointment and children and families are having to wait longer for this. The P&A decision means regression in ensuring top priority is given to best interests of the child.	Children with autism.

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
4 - we must create systems that promote and protect UNCRC rights.	Yes	No. Longer waits for diagnosis means that other support the child and their family needs is not available.	Children with autism, and within care experienced children.
5 – we must respect the rights and responsibilities of parents and carers to provide guidance and direction to their child as they grow up, recognising the child's capacity to make their own choices.	Yes	No, because we are not progressing this right until the first appointment and children and families are having to wait longer for this. The P&A decision means regression.	
6 – we must do everything we can to ensure that children survive and develop to their full potential.	Yes, in relation to recognising the inherent right to life because prioritisation to urgent clinical need.	No. The P&A decision means there is regression in relation to ensuring to the maximum extent possible the survival and development of the child because children are having to wait longer.	Children with autism.
7 – we must respect the right to be registered at birth, to have a name and nationality and as far as possible for children to know and be cared for by their parents.	Neutral	Neutral	Neutral
8 – we must respect and protect children's right to an identity and prevent a child's name, nationality or	Neutral	Neutral	Neutral

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
family relationships from being changed unlawfully.			
9 – we must not separate children from their parents against their will unless it is in their best interests and uphold the right to stay in contact with both parents, unless this could cause them harm.	Neutral	Neutral	Neutral
10 – we must respond quickly and sympathetically if a child or their parents apply to live together in the same country. The right to visit and keep in contact with both parents if they live in different countries.	Neutral	Neutral	Neutral
11 – we must do everything we can to stop children being taken out of their own country illegally by their parents or other relatives, or being prevented from returning home.	Neutral	Neutral	Neutral

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
12 – we must respect the right for children to express their views, feelings and wishes in all matters affecting them, and to have their views considered and taken seriously.	Yes	No, there is regression because we are not progressing this right until the first appointment and children are having to wait longer for this.	Children with autism.
13 – we must make sure every child is free to express their thoughts and opinions and to access all kinds of information, as long as it is within the law.	Yes	No, there is regression because we are not progressing this right until the first appointment and children are having to wait longer for this.	Children with autism.
14 – we must respect children's right to think and believe what they choose and also to practise their religion as long as they are not stopping other people from their rights. We must respect the rights and responsibilities of parents to guide their child as they grow up.	Neutral	Neutral	Neutral
15 – we must respect the right to meet with other children and join groups and organisations as long as this does not stop other people from enjoying their rights.	Yes	No, there is regression because the longer waits will affect children's ability to enjoy this right.	Children with autism.

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
16 – we must respect the right to privacy and protecting the child's private, family and home life, including protecting children from unlawful attacks that harm their reputation.	Neutral	Neutral	Neutral
17 – we must ensure children have access to reliable information from a variety of sources, and help to protect children from materials that could harm them.	Neutral	Neutral	Neutral
18 – we must support parents by creating support services for children and giving parents the help they need to raise their children.	Yes	No, there is regression because the longer waits will affect children's ability to enjoy this right.	Children with autism.
19 – we must do everything we can to protect children from all forms of violence, abuse, neglect and bad treatment by their parents or anyone else who looks after them.	Yes	No, there is regression because the longer waits will affect ability to get support in place to prevent or minimise risk of harm and neglect. There is evidence that disabled children are more at risk of harm and neglect than non-disabled children.	Children with autism.
20 – we must give children who cannot be looked after by their immediate family special protection and assistance,	Neutral	Neutral	Neutral

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
that is continuous and respects their culture, language and religion.			
21 – the process of adoption must be safe, lawful and prioritises children's best interests.	Neutral	Neutral	Neutral
22 – if a child is seeking refuge or has refugee status, we must provide them with appropriate protection and assistance (within our remit/ functions) to help them enjoy UNCRC rights.	Neutral	Neutral	Neutral
23 – we must do all we can to support disabled children and their families to enjoy their right to live a full and decent life with dignity and as far as possible independence and to play an active part in the community.	Yes	No, there is regression because the longer waits will affect children and families' ability to enjoy this right.	Children with autism.
24 – we must provide good quality health care and education on health and well-being so that children can stay healthy.	Yes	No, there is regression because the longer waits will affect children's ability to enjoy this right.	Children with autism

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
25 – we must make sure children who have been placed away from home for the purpose of care or protection (e.g. in hospital) can have a regular review of their treatment, the way they are cared for and their wider circumstances.	Yes	No. There is less opportunity to prioritise care experience children and ensure that they receive the diagnosis and then the care and treatment that will help mee their needs.	Care experienced children with autism.
26 – Governments must provide social security, including financial support and other benefits to families in need of assistance.	Neutral	Neutral	Neutral
27 – we must help families (within our remit, functions) who cannot afford to, to provide their child with a standard of living that is good enough to meet their physical and social needs and support their development.	Neutral	Neutral	Neutral
28 – every child has the right to an education and discipline in schools must respect children's dignity and their rights.	Yes	No, there is regression because the longer waits will affect children ability to enjoy this right.	Children with autism
29 – education must develop every child's personality, talents and abilities to the full and encourage child's respect for human rights, as well as respect for	Yes	No, there is regression because when a child has a diagnosis of autism, this triggers support that allows schools greater understanding of their needs	Children with autism

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
their parents, their own and other cultures and the environment.		and helps to ensure education is be provided at the right time and at the right level.	
30 – we must respect that every child has the right to learn and use their language, customs and religion of their family, whether or not these are shared by the majority of the people in the country where they live.	Neutral	Neutral	Neutral
31 – we must respect the right of every child to relax, play and take part in a wide range of cultural and artistic activities.	Yes	No, there is regression because the longer waits will affect children's ability to enjoy this right.	Children with autism.
32 – we must protect children from economic exploitation and work that is dangerous or might harm their health, development or education.	Neutral	Neutral	Neutral
33 – we must protect children from the illegal use of drugs and from being involved in the production or distribution of drugs.	Neutral	Neutral	Neutral

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
34 – we must protect children from all forms of sexual abuse and exploitation.	Neutral	Neutral	Neutral
35 – we must protect children from being abducted, sold or moved illegally to a different place in or outside their country for the purpose of exploitation.	Neutral	Neutral	Neutral
36 – we must protect children from all other forms of exploitation (e.g. by the media, or for medical research)	Neutral	Neutral	Neutral
37 – we must not torture or cause suffering or other cruel or degrading treatment or punishment. Children should be detained only as a last resort and for the shortest time possible. They must be treated with respect and care and be able to keep in contact with their family.	Neutral	Neutral	Neutral
38 – we must do everything we can to protect and care for children affected by war and armed conflicts.	Neutral	Neutral	Neutral

UNCRC right	Is your work compatible with this right?	Will your work progress this right? [are we taking steps to achieve this right to the maximum of our available resources]	Are any groups of children particularly impacted
39 – we must provide special support to help children who have experienced neglect, abuse, exploitation, torture or who are victims of war to recover their health, dignity, self-respect and social life.	Neutral	Neutral	Neutral
40 – we must treat a child accused or guilty of breaking the law with dignity and respect.	Neutral	Neutral	Neutral
41 – we must comply with national laws and standards that go further than UNCRC rights.	Neutral	Neutral	Neutral
42 – we must actively work to make sure children and adults know about UNCRC.	Yes	No, there is regression because do this from the first appointment. The longer waits will affect children ability to enjoy this right.	Children with autism.

Sharing with decision-makers

Guidance page 26

Explain how you will make sure the results of your impact assessment will be taken into account by decision-makers before a final decision is taken. This should include an explanation about how you will ensure they consider **any mitigating actions you have identified to remove or reduce any disadvantage** and make sure they are implemented.

- The findings of this assessment of the impact of the decision to pause investment in autistic diagnosis clinics on equality and children's rights will be shared with NHS Lothian Financial Improvement Group, including the recommended mitigating actions.

- This information will be used to identify the cumulative impact of the need to make financial savings and clinical prioritisation which will be shared with FIG, CMT and the Board.

- NHS Lothian Acute SMG will consider the recommended mitigating actions and if agreed will direct implementation and monitor their effect.

Monitoring the impact

Guidance page 27

How will you monitor the actual impact of this piece of work on equality, socio-economic disadvantage or children's rights?

What information will you start or continue to collect and report on?	What impact are you measuring
Waiting lists by sex, age, ethnicity, and SIMD every 6 months.	Length of wait for specific groups who we have identified as experiencing disadvantage.

We will approach local third sector organisations who represent children and families with autism to try to identify any more mitigating actions.	Health and social impacts of P&A on specific groups who we have identified as experiencing disadvantage.
Care experience children and young people	If being prioritised as urgent.

Critical care guideline for the treatment of status epilepticus

Status epilepticus (SE) refers to **five or more minutes** of continuous seizure activity or repetitive seizures between which there is incomplete recovery of consciousness[1]. For those patients admitted in SE to Critical Care, it is likely they will be at stage 3 of the management pathway described below.

Evidence suggests that achieving seizure control quickly is a major determinant of good outcome[2]. **The priority in SE management is to achieve rapid termination of seizures, regardless of the agent used.**

Stage 1 – Early SE management 0-15 minutes

Start high-flow 02 via non-rebreather mask. Check glucose.

Administer benzodiazepine if seizure lasts ≥ 5 minutes.

- First choice: lorazepam 4mg iv over 2 minutes.
- OR diazepam * 10mg iv over 2 minutes.

If intravenous access is not available:

- First choice: buccal midazolam 10mg.
- OR rectal diazepam 10mg.

Benzodiazepine dose can be repeated once after 5-10 minutes if first administration does not terminate seizure. Monitor for respiratory depression. Gain iv access.

*Diazepam is rapidly redistributed and may accumulate with repeated dosing.

Continue regular anti-seizure medication (ASM) if prescribed.

Treat underlying cause e.g. hyponatraemia.

Consider iv thiamine if history of alcohol excess or malnutrition.

Stage 2 – Established SE 15-30 minutes

If seizures persist administer loading dose of intravenous ASM. Notify critical care.

Choice of ASM dependent on patient characteristics – there is no evidence of clinical difference in effectiveness or safety between ASMs.

- Levetiracetam 60mg/kg (max dose 4.5g) over 10 minutes.
- Phenytoin 20mg/kg (max dose 2000mg) at max rate 50mg/minute. Use with caution in elderly and patients with cardiac disease (may reduce rate of administration to 25mg/min or lower).
- Sodium valproate 40mg/min (max dose 3000mg over 10 minutes). Caution in pregnancy, acute liver failure or where there are concerns about mitochondrial disease.

Stage 3 – Refractory SE (RSE) 30-60 minutes

Induce general anaesthesia – intubate and ventilate. Continue Stage 2 ASM. Give usual ASMs (if prescribed) alongside emergency treatment.

Start continuous infusion:

- Propofol (≤ 4mg/kg/hr) and/or
- Midazolam loading dose 0.1-0.2 mg/kg iv bolus followed by maintenance iv infusion (0.05-0.5mg/kg/hr). If breakthrough seizures (clinical or electroencephalographical) give further i.v. bolus and increase infusion every 3-4 hr by 0.05-0.1 mg/kg/hr.
- Add second ASM from Stage 2.
- Target MAP > 65mmHg.
- Target Pa02 > 8kPa. Unless clear indication, no need to target low-normal PaC02.

Stage 4 – Super-refractory SE (SRSE) > 24h

Management of SRSE requires complex specialist treatment involving a collaborative approach with neurology and neurophysiology teams. By this stage, seizures are often non-convulsive. Initiate continuous EEG monitoring if not already in place. Agents used for SRSE include (see individual drug sections later in this guideline for doses)

- Phenobarbital
- Lacosamide
- Ketamine
- Thiopentone

Investigations:

- History and examination.
- Bloods:
    - Blood glucose: identify and treat hypoglycaemia
    - FBC, coagulation tests, U&Es, LFTs, calcium, magnesium
    - Daily Propofol-Related Infusion Syndrome (PRIS) bloods are required for patients on high-rate propofol infusions.

  In selected patients:
    - Ammonia
    - Vasculitis screen
- Urine:
    - Toxicology screen (tricyclic antidepressants, amphetamines, cocaine)
    - Pregnancy test
- Imaging: chest radiograph, CT, MRI
- Lumbar puncture. Send CSF for:
    - Culture and sensitivities (include HSV PCR and acid-fast bacilli and TB PCR, VZV PCR and enterovirus PCR if appropriate)
    - Cell count
    - Protein and glucose
    - Autoimmune encephalitis antibody screen
    - Send additional sample for storage
- Patients in Critical Care in SE should have continuous EEG monitoring.

2. Drug Treatment Guidelines:

2.1 Levetiracetam

Intravenous loading dose administration for levetiracetam:

Administer 60mg/kg (max: 4500mg) with 100ml of 0.9% sodium chloride or 5% glucose over 10 minutes. Note: levetiracetam doses are based on the ESETT trial[3] and differ from those in NHS Lothian IV monographs.

Maintenance dose for levetiracetam:

- Levetiracetam: 1000-1500mg IV, oral or NG twice daily. For i.v. administration, dilute the required dose with at least 100ml sodium chloride 0.9% or glucose 5% and administer over 15 minutes.
- Start 10-12 hours after loading dose.
- Aim for reasonable dosing times 12 hours apart.[17]

Known severe renal failure:
Where eGFR is known to be less than 30 mL/min/1.73m^2, then sodium valproate should be used as first choice Stage 2 drug. No dose adjustment is required. Do not delay treatment to wait for blood results. Levetiracetam is an appropriate second-line option. No dose adjustment is required for the loading dose, but the maintenance dose should be reduced, see Table 1.1 below.[17]

Creatinine Clearance	Dose
50-79ml/min	1000mg twice daily
30-49ml/min	750mg twice daily
<30ml/min	500mg twice daily
In CVVHD dialysis: 250mg-750mg twice daily. Likely to be dialysed.[7]	

Table 1.1 Maintenance doses of levetiracetam in renal impairment[7]

Patient already prescribed levetiracetam:
Levetiracetam can be used as the first-choice anticonvulsant drug during Stage 2 at full dose, even if the patient was already prescribed levetiracetam prior to admission. Levetiracetam levels are not available acutely, and supratherapeutic doses of levetiracetam are unlikely to be harmful. If there is concern about administering levetiracetam in this context, sodium valproate or phenytoin can be given instead.[17]

Pregnancy
Levetiracetam is the preferred Stage 2 drug in pregnancy. Avoid sodium valproate where possible, given the risk of teratogenicity.[17]

2.2 Phenytoin

Phenytoin monograph

Loading dose administration for phenytoin:
Administer in 50-250ml of 0.9% sodium chloride (concentration not to exceed 10mg/ml) at a rate not exceeding 50mg/minute through an in-line filter (0.22-0.5 micron). Ensure working cannula in large vein prior to infusion due to risks associated with extravasation (see NHS Lothian IV guide).

Maintenance dose for phenytoin:

- Commenced 6-8 hours after the loading dose.
- If <80kg, 100mg IV three times per day (8 hourly).
- If ≥80kg, 100mg IV four times daily (6 hourly).
- Check phenytoin trough level 24 hours after starting maintenance dose. In general, level is checked daily prior to the first maintenance dose. Aim for level in high therapeutic range and have low threshold for re-loading in patient with falling levels over consecutive days.

Phenytoin dosing in obesity: Obese patients have an increased volume of distribution. The dose for these patients is calculated using an adjusted "dosing weight" (DW) that is equal to the ideal body weight (IBW) plus the product of 1.33 times the excess over IBW. This accounts for the extra volume in distribution in this patient group.[19] In order to calculate the DW you must first determine the patient's IBW.

IBW is calculated as follows:

- IBW females = 45.5kg + (2.3kg per inch over 5 feet)
- IBW males= 50kg + (2.3kg per inch over 5 feet)

DW = IBW + [1.33 x (total body weight – IBW)]

- **Loading dose** = 20mg/kg (using DW). Maximum dose = 2000mg.
- **Maintenance total daily dose** = 4mg/kg total daily dose (using DW). This figure is then given in 4 divided doses.

Interpreting serum concentrations:

- Aim for 15-20mg/litre. In many cases Neurology may recommend aiming for higher levels of 20-25mg/litre. If in doubt, discuss with neurology.
- At target therapeutic concentrations of phenytoin, patients may experience minor central nervous depression and nystagmus, drowsiness or fatigue. Above the quoted therapeutic range (greater than 20 mg/litre), ataxia, slurred speech and incoordination can occur. Seizures and coma can be induced by levels greater than 50 mg/litre.[18]
- Phenytoin levels are now automatically corrected for low albumin when reported on Trak. When interpreting levels always review the "adjusted phenytoin" result. This can also be calculated manually by using the following equation:

$$\text{Corrected level (mg/l)} = \frac{\text{observed phenytoin level (mg/l)}}{(0.9 \times \text{albumin (g/l)} / 40) + 0.1}$$

- Correcting for renal impairment is required in patients with CrCl < 25mls/min as the free fraction of phenytoin increases. Use the following equation and discuss with pharmacy:

$$\text{Corrected level (mg/l)} = \frac{\text{observed phenytoin level (mg/l)}}{(0.01 \times \text{Albumin (g/l)}) + 0.1)}$$

Phenytoin and continuous renal replacement therapy (CRRT):

The literature contains a few case reports which suggest a higher drug clearance during CRRT than expected. This may be related to hypoalbuminaemia and high dialysate flow rates.[22] The unbound fraction of phenytoin has been reported to reach up to 40% in critically ill patients with renal failure leading to substantial drug removal by CRRT.[23]

Top up Phenytoin dose: If the phenytoin level is subtherapeutic and the patient is not well controlled, a top up loading dose should be considered. Top up doses can be calculated using the following equation and Table 1.2 gives approximate increases in phenytoin concentration following doses of 250mg-750mg[19] .

Phenytoin top up dose (mg) = 20 – measured concentration (mg/l) x 0.7 x weight (kg).[18,19]

For example, a top up dose of 500mg administered to a 70kg patient with a serum concentration of 5mg/l should increase the concentration to 15mg/l.

	Concentration increase with top-up dose			
Dose / Weight	50kg	60kg	70kg	80kg
250mg	7 mg/l	6 mg/l	5 mg/l	4.5 mg/l
500mg	14 mg/l	12 mg/l	10 mg/l	9 mg/l
750mg	21 mg/l	18 mg/l	15 mg/l	13.5 mg/l

Table 1.2: Increase in phenytoin concentration with 'top-up' doses. Note: In patients with hypoalbuminaemia, the measured phenytoin concentration must be corrected before using the above table (i.e. use the "adjusted level" on Trak results).

For patients who remain in SE with sub-therapeutic levels, consider a larger "top-up" dose or even reload, following discussion with the critical care consultant.

2.3 Sodium Valproate

Sodium valproate monograph

Loading dose administration for sodium valproate:
Administer 40mg/kg IV (Max: 3000mg) in 50ml of 0.9% sodium chloride or 5% glucose over 10 minutes. Note: sodium valproate doses are based on the ESETT trial[3] and differ from those in NHS Lothian IV monographs.

Where eGFR is known to be less than 30 mL/min/1.73m^2, then sodium valproate should be used as first choice Stage 2 drug, see below. No dose adjustment is required. Do not delay treatment to wait for blood results.

Coadministration of meropenem with valproate renders valproate ineffective. If meropenem must be administered, an alternative ASM must be prescribed.

Maintenance dose for sodium valproate:

- 1000-1200mg IV, oral or NG twice daily. Start at least 6 hours after loading dose.

Ammonia blood concentrations:

- Sodium valproate therapy can cause hyperammonaemia, especially in the early stages of treatment.
- An ammonia concentration should be measured at approximately two days after starting sodium valproate.
- Consider rechecking while on sodium valproate, particularly if the patient's conscious level does not improve despite control of the seizures or if the patient shows signs of encephalopathy.
- Take samples of blood using Lithium Heparin tubes (avoiding any contamination with sweat, and place on ice immediately for transport). Inform the laboratory that the sample is arriving.

Pregnancy and fertility

A 2023 MHRA alert on sodium valproate and it's risks in pregnancy and effects on fertility stated oral sodium valproate must not be started in new patients (male or female) younger than 55 years unless two specialists independently consider and document that there is no other effective or tolerated treatment or that there are compelling reasons that the reproductive risks do not apply.[4] The risk/benefit ratio of using intravenous sodium valproate in RSE favours its use and it remains second choice treatment on Stage 2 of management of RSE. Patients under the age of 55 should be counselled on appropriate contraceptive choices upon recovery.

2.4 Propofol

- Initial bolus 100-200mg IV to induce anaesthesia.
- Maintenance intravenous infusion of up to 4mg/kg/hr.[5]
- Standard concentration - 1gram in 100mls, undiluted.

For patients on prolonged infusions, check serum Creatinine Kinase and triglycerides to exclude Propofol Related Infusion Syndrome (PRIS)

2.5 Midazolam

Midazolam monograph

- Loading dose: 0.1-0.2mg/kg IV bolus.[6]
- Maintenance IV infusion: 0.05-0.5mg/kg/hr. If breakthrough SE occurs, give a further bolus and increase the infusion every 3-4 hours by 0.05-0.1mg/kg/hr.[6]
- Continuous EEG monitoring is essential.
- Consider addition of second anticonvulsant drug from Stage 2.

2.6 Phenobarbital (phenobarbitone)

Phenobarbital monograph

- Loading dose of 10mg/kg IV, up to a maximum of 1000mg.[6]
- Maintenance dose of 120mg IV daily.
- Once the patient is clinically stable and has satisfactory GI absorption, consider changing to 120mg daily orally or via NG tube.

2.7 Ketamine

Ketamine monograph

There is evidence on the use of ketamine as a safer alternative to thiopental, though it is mostly based on isolated case reports. From the information available:

- Loading dose: 3mg/kg IV bolus (using ideal body weight).
- Maintenance IV infusion of 1-5mg/kg/hr.[8,9,10,11,12,13]

There are few published data on the theoretical risk of neurotoxic effects when the drug is used for prolonged periods and its safety in prolonged use is largely untested. It can cause liver impairment at higher doses and LFTs should be checked daily.

2.8 Thiopental sodium (thiopentone)

Thiopental sodium monograph

Intravenous loading dose regime (using ideal body weight):

First Hour	10 mg/kg/hr
Second Hour	7 mg/kg/hr
Third Hour	5 mg/kg/hr

Maintenance intravenous infusion: 4-7mg/kg/hr.[6,15,16,17]
See monograph for further dosing information. Titrate according to EEG. Once EEG is isoelectric, reduce the infusion rate to the lowest dose that will maintain burst suppression. Continue for 24-48 hours to achieve burst suppression.

Serum potassium and thiopental:
Serum potassium concentration may drop during thiopental sodium infusion. However, potassium replacement when infusing thiopental sodium can be dangerous. It can lead to serum potassium rebounding to dangerously high levels on stopping thiopental sodium. **Therefore, it is generally unnecessary to replace potassium unless it falls below 3.0mmol/l, or unless the patient is symptomatic of hypokalaemia, e.g. arrhythmias. On ceasing thiopental sodium infusion, check serum potassium levels every 2 hours for the first 24 hours.**

2.9 Lacosamide

200mg iv loading dose followed by 100mg iv/NG twice daily to commence 12 hours after initial loading dose.
Dose related prolongation of the PR interval has been observed in clinical studies. Use with caution in patients with known cardiac conduction problems or severe cardiac disease (e.g. myocardial infarction, heart failure).[25]

3. Other treatments

- Inhalational anaesthetic agents
- Magnesium infusion
- Hypothermia
- Ketogenic diet
- For auto-immune encephalitis: high dose steroids, immunoglobulin and plasma exchange followed by further immunosuppression with agents such as rituximab or cyclophosphamide. This will be initiated in consultation with neurologist specialist/epileptologists.

4. Burst suppression

"Burst suppression" may be requested by a neurologist. This is where a bedside EEG is used to titrate the drug against suppression of bursts of EEG activity. We use the Nicolet™ Monitor to observe this at the bedside. The drug will usually be thiopental or ketamine.

The evidence for this is not proven and it largely based on expert opinion such as that from Rossetti[21] who says *"In view of present knowledge, an initial course of midazolam anaesthesia targeting EEG burst suppression patterns with an interburst interval of about 10 s for 24 h, followed by progressive tapering over 6–12 h under EEG control, seems to be a reasonable option. Propofol and subsequently barbiturates can be used thereafter"*

In practice, a period of burst suppression followed by lightening of sedation does seem to result in recovery for some patients, perhaps by "resetting" the brain.

What to look for on the Nicolet:
The screen sweep on the Nicolet is about 12 seconds. The target is one burst of activity (of approximately 2 seconds) followed by a flat line on every screen. This would be consistent with an interburst interval of about 10 seconds as suggested above. The aim is to achieve near maximal suppression of brain metabolism short of an isoelectric EEG (flatline) because that could result in overdose and systemic problems.

Fig 1. This is about right. There is one burst per screen.

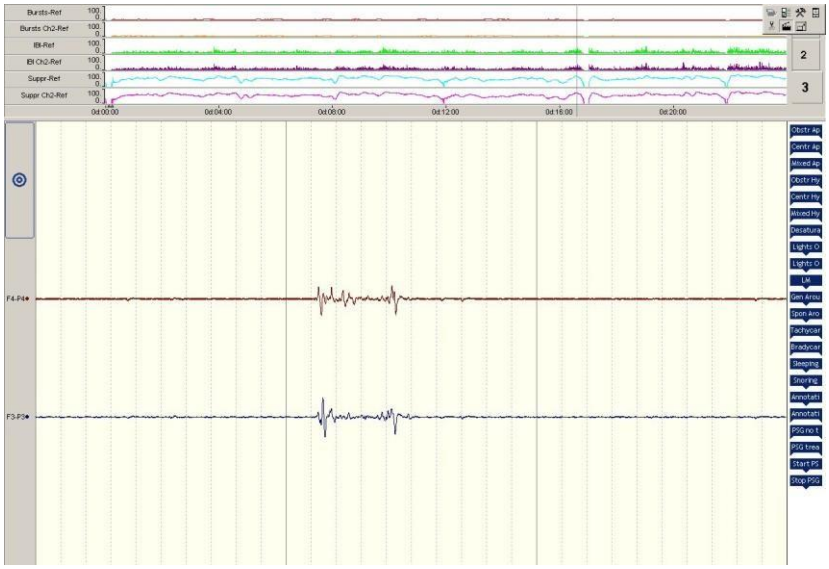


Fig 2.
There is not enough sedation as there are too many bursts per screen. Try an i.v. bolus and possibly increase the rate of infusion.

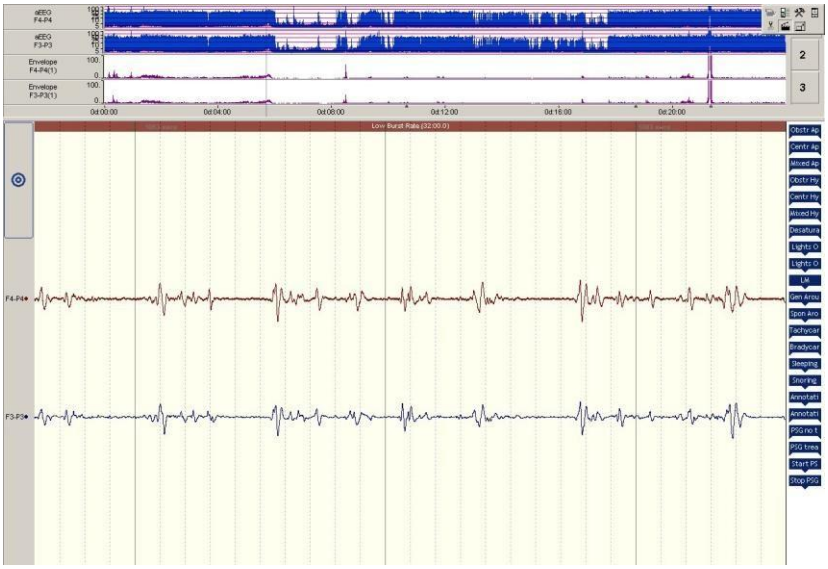


Fig 3.
There is too much sedation. The trace is iso-electric. Turn off the infusion for a while until bursts reappear.

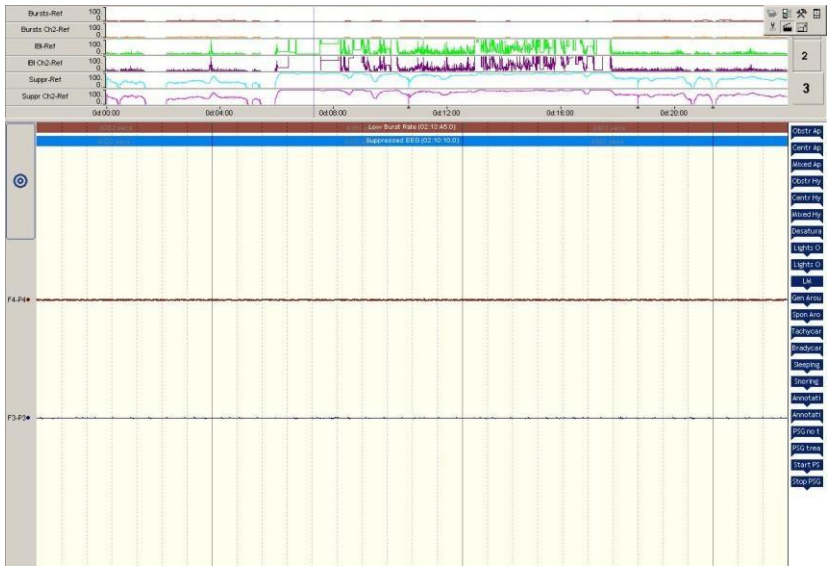
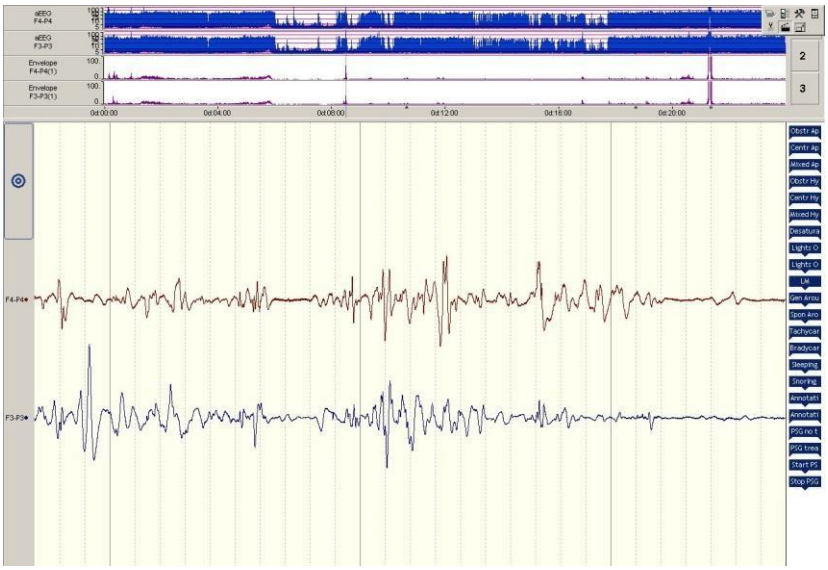


Fig 4 below
This may be fitting.
Needs additional treatment.



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NHS LOTHIAN
PHARMACY AND MEDICINES SERVICE
STANDARD OPERATING PROCEDURE

LOTH DISP 08 - Dispensing Sodium Valproate, Valproic Acid and Valproate Semi-Sodium (Valproate)

Most Recent Changes:

Version:	Date:	Changes Made By:	Details of Change:
1	Sep 24	Redacted	New SOP

Purpose:

The Medicines and Healthcare products Regulatory Agency (MHRA) published a national patient safety alert in November 2023 asking organisations to put a plan in place to implement new regulatory measures for sodium valproate, valproic acid and valproate semisodium (valproate). The regulatory changes were introduced due to the known significant risk of serious harm to a baby after exposure to valproate in pregnancy.

Sodium valproate, valproic acid and valproate semisodium (valproate) should be prescribed and supplied in the original container. There may be occasions whereby the prescriber requests sodium valproate, valproic acid and valproate semisodium (valproate) to be supplied out with the original container for example in compliance aids or short term leave prescriptions. The purpose of this procedure is to ensure all NHS Lothian sites responsible for dispensing sodium valproate, valproic acid and valproate semisodium (valproate) are adhering to regulatory changes.

Scope:

The procedure for dispensing sodium valproate, valproic acid and valproate semisodium (valproate) describes the steps that should be followed by all NHS Lothian dispensing sites when presented with a request for sodium valproate, valproic acid and valproate semisodium (valproate).

NHS LOTHIAN
PHARMACY AND MEDICINES SERVICE
STANDARD OPERATING PROCEDURE

Responsibilities:

It is the responsibility of the prescriber requesting sodium valproate, valproic acid and valproate semisodium (valproate) to complete a risk assessment.

It is the responsibility of the pharmacist professionally checking the request to confirm whether a risk assessment has been completed.

Specific Procedure:

1. Request received into Pharmacy Dispensary for Valproate.
2. Request must be professionally checked by a Pharmacist.
3. Professional check will confirm suitability of supply.

3.1 Original containers confirmed, request passed for processing by dispensary following normal procedure.

3.2 Supply out with original container requested, professional check pharmacist must confirm there is a valid risk assessment (appendix 1) from the prescriber by checking the Valproate folder in the Dispensary, or if working remotely in a clinical area such as a ward, contact the Dispensary staff to confirm if there is a valid Risk Assessment in the Dispensary Valproate folder.

3.2.1 Risk Assessment available and in date (valid for 12 months from date of signature), make a copy and attach copy to the request, return original Risk Assessment back to folder in Dispensary and pass request for processing following normal procedure.

3.2.2 No Risk Assessment available in Dispensary, Pharmacist must contact the prescriber to discuss and request a Risk Assessment.

3.2.3 Once Risk Assessment received, take a copy and attach copy to the request. Original to be placed in Valproate folder in Dispensary. Pass request for processing following normal procedure.

4. At final check/release stage, include a check of the valid Risk Assessment and keep attached to the original request for filing in the Dispensary. Final check following normal procedure.

Forms/Templates to be used:

Appendix 1

Risk Assessment for Exception to Requirement to Dispense Valproate in Original Packs

From 11/10/23 the MHRA provided updated guidance on dispensing valproate only in original packs to ensure all the relevant safety information is available to patients. This applies to both male and female patients. In rare cases, pharmacists can make an exception to the requirement to dispense full packs, on an individual patient basis. In these cases, a risk assessment is needed and must be in place that refers to the need for different packaging. A patient information leaflet must be provided and a valproate pregnancy pictogram sticker applied to the packaging.

Within NHS Lothian Mental Health & Learning Disability Services, all in-patients should be considered for limited supplies on safety grounds and be exempt from original pack dispensing when being considered for pass or self-administration of medicines. Out-patient and discharge prescriptions may be exempt if daily/weekly dispensing or blister packing is required or the patient is at risk of overdose and smaller supplies are required on safety grounds.

Risk Assessment

Patient Name: CHI:

Reason for exception to requirement to dispense in original packs	Please tick
Risk of overdose	
Blister Pack required	
In-patient pass	
In-patient self-administration	

NB: In females of childbearing potential the Pregnancy Prevention Programme must also be in place, including an annual Risk Acknowledgement Form. Please tick box if this applies. ☐

N.B. Form to be reviewed and updated on an Annual basis and uploaded to SciStore electronic patient record.

Prescriber's name (print): Prescriber' signature:

Date: Review date:

Risk assessment for valproate original pack dispensing form v1.0
Author: REAS Clinical Pharmacy

Approved by: REAS Drug and Therapeutic Committee December 2023
Review Date: December 2025

NHS LOTHIAN
PHARMACY AND MEDICINES SERVICE
STANDARD OPERATING PROCEDURE

References:

Medicines and Healthcare Products Regulatory Agency (MHRA) National Patient Safety Alert November 2023 - Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients.

NatPSA-2023-013-MHRA.pdf (publishing.service.gov.uk)

Version History:

Version:	Date:	Changes Made By:	Details of Change:

Title: **Dispensing Sodium Valproate, Valproic Acid and Valproate Semi-Sodium (Valproate)**	
Department: NHSL Pharmacy and Medicines Service	**Version Number: 1**
Issue Date: September 2024	**Review Date: September 2026**
Author: Redacted	**Approved By: Dispensary Managers Group**

NHS Lothian Valproate for ID Psychiatrists

1.No one (male or female) under the age of 55 should be commenced on Valproate unless two specialists independently consider and document that there is no other "effective or tolerated" treatment, or there are compelling reasons why the reproductive risks do not apply.

2.Identify all female patients under the age of 55 on your caseload who are prescribed sodium valproate in any form

3.At their next review MHRA forms must be completed and signed by their responsible clinician, a second opinion, the patient or their representative and their GP. Medicines and Healthcare products Regulatory Agency (filecamp.com)

a. If the patient has a severe learning disability and is well supervised and there is no real chance of pregnancy then this can be considered a permanent absence of risk. It would be good practice still to fill in all the forms and obtain a second opinion on a one-off basis and they still must have a review at least annually.

b. If the patient is at risk of pregnancy a second opinion must be sought and the decision-making process recorded in a clinic letter and the appropriate forms completed and signed. They must be reviewed at least annually. Discussions around teratogenic risk and the importance of consulting a doctor if they are planning a pregnancy or if they have an unplanned pregnancy must be undertaken (see details on forms). These women should be on a form of long term contraception.

4.If patients do not attend appointments an attempt should be made to phone them to discuss this. If this is not successful their GP should be contacted. If all this is unsuccessful a risk assessment should be completed in their absence and the decision-making process and communication thereof should be documented in the patients records.

5.A note of contraceptive use should be documented in each clinic letter. All patients that require contraception should be referred to their GP or sexual health clinic timeously.