

18th December 2023

Dear Georgina and Colleagues,

RE: Patient Safety Alert NatPSA/2023/013/MHRA

The following issues are raised by Epilepsy Action and SUDEP Action in response to the recently released Patient Safety Alert (**NatPSA/2023/013/MHRA**) and the prescribing of sodium valproate.

As two leading charities representing service users, families, and carers, we would like to take this opportunity for you to consider the following risks as a provider of services.

We are aware that 27% of boys and girls are currently prescribed valproate, so the directive will be a significant change in practice for children as well as young adults. This medicine is the most effective for controlling generalised seizures, which the MHRA's public impact assessment recognises.

Context:

We have set out all known risks from the user perspective, these being our members, people with epilepsy, their families, and carers. Whilst this directive is to address newly diagnosed men and boys under 55yrs and all women and girls aged under 55 years, we know phase 2 will go onto address all boys and men under 55yrs on sodium valproate.

a) The directive states that an implementation group be formed which includes patients with experience. Given the timeframe, where is the assurance and scrutiny that 'Informed Consent' and an ability to challenge the decision by the individual is not eroded or dismissed? This is the cornerstone of this change in practice, and one that must be preserved at all costs.

Newly diagnosed patients and patients whose seizures are not controlled will remain at risk for possible serious harm. Whilst there may not be the additional risk of switching from an effective to a less effective medication, informed consent relating to treatment selection will require patient centered communication, specific to that individual.

This is critical for a woman or man who has been effectively controlled on sodium valproate and explicit in their wishes to remain on the drug. Not being able to access a drug which in many cases is the only available option to provide full seizure control, maintain a quality of life (e.g. drive, hold down a job) or prevent SUDEP (MBRRACE 2023 [Reports](#) | [MBRRACE-UK](#) | [NPEU \(ox.ac.uk\)](#)) is unacceptable.

SUDEP is the leading cause of death for people with epilepsy. The [NCEPOD - Epilepsy: \(2022\)](#) report states that people with epilepsy attending ED are a high risk population, with only 13.5% having had SUDEP as a considered risk. This included

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not using existing safety tools recommended by national surveillance bodies (maternal and learning disability deaths and NHS RightCare <https://sudep.org/checklist-resources>; <https://sudep.org/epilepsy-self-monitor>). This is further supported by additional research which indicates that active generalised seizures and nocturnal seizures increase the risk of SUDEP, and that early diagnosis and treatment is vital in prevention.

b) The implementation group must include clinicians and group members who are conversant in epilepsy and the associated implications experienced by people who have tried multiple alternatives.

It is acknowledged that the level of experience in commissioning neurology services and in the delivery of such services is nationally diverse and poorly resourced in many ICB localities. There must be confidence and enough skill to advocate for people who wish to have the 'best life', which means upholding their decision and access to treatments.

c) Given the requirement that all prescriptions must hold two signatories to proceed, and that these be independent and not associates or accountable to the first signature within the workplace, it remains unclear who they will be and what the implications will be to the patient and carer.

It seems that there is little understanding nationally on how to apply this directive, which would indicate that there will be no standard application, with each local area delegated to resolve this at pace. This will test the equity in review and case management. The evidence to date is that access to neurological services for patients is not equal or equitable across the countries and regions.

The available workforce is limited and in places severely under resourced, which has been reported on through many health economies (e.g. Northern Ireland patients waiting 4 years for neurological review).

The number of patients managed in primary care by a GP is unknown, introducing patient pathways which will burden an already stretched secondary care service.

c) As both a provider and commissioner the monitoring and risk management arrangements will be pivotal in providing assurance to patients that the systems and processes are in place to safeguard patient safety; and that the correct treatment plans are in place to ensure that patients are correctly informed, given time to discuss and are part of the structured review process (PPP and annual health check).

There is a danger that off-licence prescribing will become increasingly requested and at the extreme become the norm.

d) The CQC or National Patient Safety team should regulate this directive. They should be defining how this will be reported as a patient safety incident and not the ICB or place. Are we now moving to a 'Never Event' situation and if so, does this fall

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under NHS Resolution should all steps not be implemented? Again, in the first instance patients newly diagnosed will be exempt, as they will not have been prescribed sodium valproate, but existing patients will need to be assessed and become part of this risk management / patient safety process.

e) What are the timescales for implementing the process given the expectation of the MHRA statement:

'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'.

How realistic is this, and how will patients be communicated with to register informed consent or decline? To provide this level of review in primary and secondary care requires a full pathway review, with clear roles and responsibilities. The available resource will impact on delivering these pathways and, significantly, have the largest impact on people most at risk of health inequalities. This risk will be delegated to local areas.

f) Who will be auditing the existing PPP measures and risk assessment compliance? Assurance that the audits are mandatory and will be accountable to the Board of the ICB for monitoring – This needs to be understood to inform our membership.

g) The pathway for the management and monitoring of sodium valproate and pregnancy has been in place for several years, however poor compliance was reported in the Cumberledge Report 2020. This is further supported by research from Epilepsy Action and SUDEP Action which demonstrated that women in a number of cases had not been fully informed of the harms related to ASM's (<https://www.epilepsy.org.uk/involved/campaigns/epilepsy-medications-in-pregnancy-survey-results>).

We have also seen a near 50% increase in SUDEP for women and pregnancy (MBRACCE 2023) including women not informed of SUDEP [Valproate and risk of abnormal pregnancy outcomes: new communication materials - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/news/valproate-and-risk-of-abnormal-pregnancy-outcomes-new-communication-materials).

The pathway for unplanned pregnancy needs to be in place – where is the assurance that this will be managed, and that girls and women will receive the counselling and information they need?

h) As ICBs are developing their digital strategies public trust will be fundamental to this. ICB reporting measures will require review. Currently they only include the digital valproate platform measured outcomes for reduction of valproate prescriptions <https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-and-pregnancy-registry/valproate-use-in-females-aged-0-to-54-in-england-april-2018-to-september-2020> . These need to be supplemented with social value outcomes to

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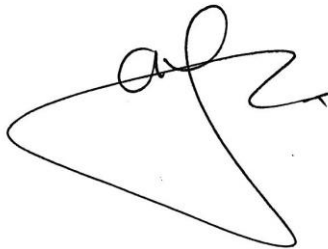
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support ICB programmes tackling health inequalities in children [NHS England » Core20PLUS5 infographic – Children and young people](#) and programmes to make improvements for people with learning disability and autism.

We believe that a national communication to all NHS trust medical directors last week recognises that standards of care are likely to fall because of pressures in the NHS. Given this information and the lack of available resource we do not believe it is possible to implement this directive safely without deferring the deadline of January 31st, 2024. This also will impact on setting realistic timescales to implement not only phase one, but phase 2 of the policy.

Thank you for taking the time to consider our concerns in support of all patients, their carers and family. Should you wish to discuss further please do not hesitate to contact us.

Kind regards,



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