

Cllr J Hanna OBE

Chair, Oxfordshire Health
Overview and Scrutiny
Committee

12 November 2024

Dear NHS England Specialist Commissioning Team,

Epilepsy and the Valproate Policy:

At its public meeting on 12 September 2024, the Oxfordshire Joint Health and Overview Scrutiny Committee (JHOSC) held an item on Epilepsy services. The current state of epilepsy services were discussed, with insights into national and local contexts being provided. Three MHRA national alerts during 2024 around the Pregnancy Prevention Programme with accelerated and new restrictions on anti-seizure medications were also a key aspect of the discussion.

The timeliness of the need for urgent action and consideration of business cases currently under consideration, warrant the Committee sharing some of our draft findings as well as the recommendations that were formally accepted at the Committee on 12 September. The Committee had received written evidence at previous Committees in January that have been shared as attachments to the email containing this letter from:

- SUDEP Action and Epilepsy Action
- Marian Knight, Professor of Professor of Maternal and Child Population Health, Oxford

The Committee wrote to Steve Brine MP, Chair of the Parliamentary Health Scrutiny Committee in January 2024, requesting national scrutiny of the MHRA alert, the proposed timescales for implementation, the lack of a national impact assessment, and the lack of resources to support the new requirements. We received a response that it was included on the list of potential scrutiny items for the Select Committee.

The Committee also liaised with the ICB with a view to an update about the ICB response to the alert and required local action plan and consideration of the suggestion by SUDEP Action and Epilepsy Action that delay is sought to implementation because of the severe pressures in the NHS, and until adequate resources can be made available to local systems. This was based on an understanding confirmed at our meeting on 12 September of the severe likely local impacts that had been brought to the attention of the MHRA, ministers, the NHS, the Patient Safety Commissioner and the Parliamentary Health and Care Select Committee since a surprise MHRA drug safety update in December 2022 <https://assets.publishing.service.gov.uk/media/6399fcf4e90e072aefe10288/Dec-2022-DSU-PDF.pdf> [DSU-PDF.pdf of December 2022](#)

In April, the ICB updated the Committee that a task force comprising consultants, specialist nurses, medicines safety officers, representatives from charities and patients with lived experience had worked on a local impact assessment. In April the committee received:

- The ICB Local impact assessment on the MHRA Pregnancy Prevention Update November 2023 (*This is also attached to the email containing this letter*)

The impact report that was shared with Committee members and the public outlined that there were unavoidable consequences, and current services were ill-equipped to handle the implementation.

Specifically, it was anticipated that approximately 2855 outpatient appointments would be lost due to the new requirements and that “*naturally, this resource impact will result in less patients being prescribed valproate; this impact will be seen in greater mortality, greater morbidity including ED pressure resulting from uncontrolled epilepsy*” and warned that the impact of further expected updates for men and boys would be additional and severe.

The Committee wrote to Victoria Atkins MP, the then Secretary of State for Health (copied to the Chair of the Parliamentary Health Select Committee), to bring the local ICB impact assessment to her attention and to request that until the likely impacts and risks of phase 1 of the policy are assessed and safety addressed, that they allow the local NHS to delay implementation. The Committee received a response from the Department of Health that because of the General Election this would have to be brought to attention after this.

An epilepsy item was added for the June JHOSC agenda and received petitions from the public from Dr Judy Shakespeare and Kristi McDonald (who spoke about the harms that she and other women were experiencing). On the request of Oxford University Hospitals NHS Foundation Trust that they be given the opportunity to liaise with the ICB, the substantive epilepsy item was deferred until 12 September.

Evidence and outcomes of the 12th September JHOSC meeting epilepsy item:

The Committee received written evidence, and it also heard evidence during the epilepsy session on 12th September from:

- Kristi McDonald, expert by lived experience
- Professor Arjune Sen- Consultant Neurologist, OUH.
- Dr Jane Adcock- Consultant Neurologist, OUH.
- Jackie Roberts- Lead Learning Disability Epilepsy Specialist Nurse, OUH.
- Dr Rohini Rattihalli- Consultant Paediatric Medicine, OUH.
- Marcus Neale- Epilepsy Specialist Nurse, OUH.
- Dr Rustam Rea- Consultant, OUH Trust representative.
- Janice Craig- Medicines Optimisation Lead Pharmacist, NICE Medicines and Prescribing Associate, BOB ICB
- Sarah Fishburn, NHSE South East Region.

The Committee found the evidence relating to serious concerns and harms because of local impacts from national policy updates on the Pregnancy Prevention Programme were shared across all NHS stakeholders, and that stakeholders had been escalating these internally for some time. There was strong evidence supporting that the patient safety risks and shortfalls in epilepsy workforce are worsening because of the national Pregnancy Prevention Programme which has accelerated with three updates since 2024 restricting access to anti-seizure medications Valproate (January and September) and Topiramate (June) and patient safety harms across the South-East Region. Shared concerns about

evidence-base, lack of public consultation, lack of a national framework for the protection of children and adults who ought to be offered Valproate and Topiramate and the range of direct and indirect impacts. There was unanimous recognition of the need for urgent action in support of the local epilepsy service. Evidence was received that the epilepsy clinical team were working unsustainable clinical hours so that they avoided worsening of waiting lists for clinics, and their welfare was seriously impacted.

The Committee was shocked by the dire situation and issued the following recommendations to Oxford University Hospitals NHS Foundation Trust and NHS England South-East region on 12 September:

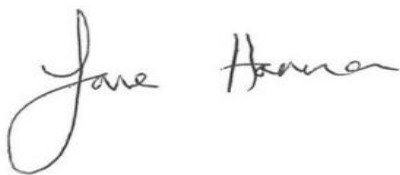
1. For the ICB and Oxford University Hospitals NHSFT to:

- *Give priority to patient safety for people with epilepsy and their families in Oxfordshire, and to the welfare of the Oxfordshire epilepsy team; and to set out how that priority will be addressed through their governance and management at a board level. The governance and management of these priorities should also include co-production with patients with lived experience and their charity representative; and address their concerns regarding tailored and balanced communications and the importance of signposting to existing empowerment tools recommended by MBRRACE (national surveillance on maternal deaths), NHS RightCare, as well as the recommendations from other NHS regions.*
- *To secure further funding and resource for epilepsy services. It is also recommended that managers involved in consideration of the current business case before the Trust take account of the JHOSC findings and the recommendations of the Committee and its full support for the business case as a necessary first step in addressing patient safety and welfare, the sustainability of the Oxfordshire epilepsy service, and wider impacts on public services.*

2. For NHSE South East Region to: Give support to the ICB and Oxford University Hospitals NHS Foundation Trust to help achieve the above prioritisations.

The Committee urges for further funding to be allocated to epilepsy services. In addition, we urge you to escalate to ministers to support the suspension of the MHRA regulatory updates of 2024 pending an independent national review of the UK's Pregnancy Prevention Programme. The Committee has also written to Karin Smyth MP to urge this suspension, as well as to Layla Moran MP (Chair of Parliamentary Health and Care Select Committee) to request national scrutiny of this. The Committee also urges NHSE specialist commissioning to meet with local system partners to enable a solution to the unsafe and unequal provision of funding to the Oxfordshire epilepsy service.

Yours sincerely,



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APPENDICES

Attached by email: Letter SUDEP Action/Epilepsy Action; Letter Marian Knight attached to Local Impact Assessment attached

Considerations of the Committee about:

a) Epilepsy needs and Service.

b) The local impact of MHRA updates 2024 on the Pregnancy Prevention Programme on the epilepsy workforce and patient safety.

A. Considerations of the JHOSC on Epilepsy Needs and Service

On the basis of the written and verbal evidence given to the committee, there was strong evidence supporting:

1. Lack of awareness of epilepsy and stigma. The committee recognised that all people experience abnormal electrical brain discharges and that 1 in 10 people will experience a seizure in their lifetime, but that with someone diagnosed with epilepsy it is a network of electrical discharges. Whilst there are many different epilepsies, 70% of people can be seizure-free if properly diagnosed and treated.
2. Lack of awareness and communication of SUDEP and risks of epilepsy. The Committee's recognition of epilepsy as a treatable `cliff-edge condition` affecting 1 per cent of the population that often presents as an emergency (or sudden fatality for at least 21 people a week ([EB | Epilepsy & Behavior | Prevent 21: SUDEP Summit | ScienceDirect.com by Elsevier](#))). Deaths can result from Sudden Unexpected Death in Epilepsy (SUDEP) or from accident or status or suicide. Children and adults also face absence from school, loss of driving licence, loss of employment and emergencies due to physical and mental health crisis.
3. People with epilepsy and their families can also face injuries, lost school days, loss of driving licence, loss of employment, loss of mental well-being.
4. Clinical and lived experience evidence of stigmatisation still experienced in 2024 at all levels of institutions. The World Health Organisation report [Global, regional, and national burden of disorders affecting the nervous system, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021 - The Lancet Neurology](#) is noted as is the Chief Medical Officer annual report 2001 and 2002 which evidenced this hostile culture contributing to avoidable deaths and harms in epilepsy <https://image.guardian.co.uk/sys-files/Society/documents/2003/07/03/report2002.pdf>
5. The epilepsy service not in a position to take on new national mandatory actions safely. OUH serves a local population of 762,500 (and additional tertiary 2 million catchment) with waiting lists that are not safe for patients. NICE recommends a two-week waiting time for a first seizure, but at OUH this is a 9 month wait (tertiary referral one year). Children with epilepsy not controlled by medication who could benefit from the Ketogenic

diet are waiting 3 years. New referrals to the epilepsy nurse service had tripled and requests from GPs for written guidance and letters had increased ten-fold in 3 years.

6. The adult service only has 2 Full-time equivalent neurologists for this population in contrast with 1 per 12,000 in Western Europe. Whilst NICE recommends 9 epilepsy specialist nurses per 500,000 the Oxford service only has 3.6. The report by Economist impact in 2024 found neurology clinics struggling more than other NHS services with waiting lists raising by 76% between 2021 and 2023 [Neurology crisis costing UK £96bn – Economist report \(epilepsy.org.uk\)](#). The Committee received evidence that there was extremely poor provision for the Oxfordshire epilepsy service compared with other OUH services for similar 'cliff-edge' long-term conditions and that it also fared very badly in comparison with similar services elsewhere like Sheffield. The Committee was concerned to understand why there were these inequalities between different services and between postcodes. It was explained that the present funding of posts was based on national specialist commissioning arrangements, and these were based on historical allocations of NHS posts to individual hospital trusts going back decades.
7. The gap in any primary care service or any specialist primary care clinician across Oxfordshire or the ICB with an interest or role in epilepsy against a backdrop of the cut of epilepsy from the GP Quality Outcomes Framework in 2013. The epilepsy team had worked in co-production with a population in South Oxfordshire to produce an outline plan of how a community-based clinic in South Oxfordshire could benefit patients and staff during 2023 but would need workforce capacity to progress this. Reports reveal a national issue with a gap in risk check, communication and follow up action for the many thousands of adults with epilepsy who present to and are discharged back into the community [NCEPOD - Epilepsy: \(2022\)](#).

B. The local impact of MHRA updates 2024 on workforce capacity and patient safety

Based on the written and verbal evidence given to the committee, there was strong evidence supporting that the patient safety risks and shortfalls in epilepsy workforce are worsening because of the national Pregnancy Prevention Programme which has accelerated with three updates since 2024 restricting access to anti-seizure medications Valproate (January and September) and Topirimate (June). Evidence included:

1. Access to treatment and anti-seizure medications is now extremely challenging. There were shortages of anti-seizure medications with some patients in Oxfordshire having to travel a long distance two weeks before their medicine was due so as not to run out of a source of supply. It was noted that neither Valproate nor Topirimate were in short supply.
2. Valproate taken whilst pregnant is one of medications that carries a high teratogenic potential with a 11% risk of congenital malformations and a 30-40% risk of neurodevelopmental disorders.
3. Valproate also happens to be the most potent medication to treat generalised epilepsies should girls and women have preferences to be safe from SUDEP and other harms and able to lead their best lives [The SANAD study of effectiveness of valproate, lamotrigine, or topiramate for generalised and unclassifiable epilepsy: an unblinded randomised controlled trial - The Lancet; <https://pubmed.ncbi.nlm.nih.gov/31831600/>](#)

4. The ICB local impact assessment report attached found an inequality of access to this medication by girls and women and the MBRRACE report analysing deaths of pregnant mothers and their unborn has found a near doubling of SUDEP against a backdrop of the introduction of the Pregnancy Prevention Programme with women uninformed about the risks of SUDEP (Letter Professor Knight attached). The clinical team alerted the Committee to the harrowing experience of a sister of a sister and a brother both living with epilepsy and the impact of this inequality on the safety and life of the sister <https://www.channel4.com/news/fears-over-dangerous-change-in-prescription-rules-for-epilepsy-drug>. The sister is part of a published thematic examination of the voices of 19 people with epilepsy and their lived experience of the direct damage of avoiding valproate or topiramate, including SUDEP <https://medrxiv.org/cgi/content/short/2024.09.06.24313040v1>

5. The latest UK regulation since 2024 requires two clinical signatures for Valproate and numbers of prescriptions are closely monitored. The programme had been extended to boys and men for the first time in 2024. The Committee heard from the clinical team about International concern, including from the team that generated the data being used that the MHRA Pregnancy Prevention Programme is an outlier using insufficient evidence and lack of balance to rationalise an extreme mandatory policy without a national framework to tailor to include the clinical needs and preferences of the individual.

6. A systematic review in June 2024 of 923 studies was amongst other scientific papers this year which found reassuring evidence that paternal exposure to anti-seizure medication at conception is unlikely to pose any major risk of adverse outcomes for the unborn and there was insufficient evidence for regulatory action <https://jnnp.bmj.com/content/early/2024/08/17/jnnp-2024-334077.abstract>; [Paternal Valproate Treatment and Risk of Childhood Neurodevelopmental Disorders: Precautionary Regulatory Measures Are Insufficiently Substantiated - Garey - 2024 - Birth Defects Research - Wiley Online Library](#).

7. A study in Brain 2024 is noted which found the risk of emergency attendance, hospital admission, injuries, burns and new on-set depression was 1 to 7% higher for patients withdrawn from valproate than in those remaining ON valproate <https://academic.oup.com/brain/article/147/10/3426/7657740>; and a paper in the Journal of Neurology in June 2024 estimated that 21,000–28000 people in the UK will be exposed to the potential hazards of breakthrough seizures. <https://link.springer.com/article/10.1007/s00415-024-12436>

8. Lived experience evidence that the national regulations and patient materials were unbalanced and felt hostile to living patients with a worsening of stigma and discrimination. Kristi McDonald found the national framework and materials were not inclusive of patient preferences and there was no right of appeal. There was no signposting from the NHS or the MHRA to an EpsMon App that had helped her to know her individualised risks and self-advocate. The MHRA national framework and NHS ignored essential information and existing safety empowerment tools valued by patients and recommended by MBRRACE and NHS RightCare [Epilepsy Toolkit](#). She had been involved in a national research meeting where there was discussion about developing a new national App and she did not understand why this was happening. The NHSE said they had met with families across the South-East that had been denied Valproate and had received evidence of patient harms from SUDEP Action.

9. The aggregated regulation and national materials were mandatory without regard for different populations e.g. for children, the LGBTQ community and people with learning disability and epilepsy the MHRA regulations were especially complex. Whilst there was a national framework and materials for protection which extended to hypothetical unborn children, the paediatric team gave evidence there was no national framework for the protection of children or adults living with epilepsy who ought to be offered Valproate or Topiramate to control their seizures and it was unclear who nationally had a responsibility for that.

10. Widespread and shared concerns across the South-East Region about undermining of basic NHS principles of informed consent, shared and balanced decision-making, evidence-based decision-making, transparency specifically in relation to a vulnerable population of patients needing anti-seizure medication for epilepsy or mental health. This included concern about the validity of the second signature in the context of the framework not requiring patient involvement and there being no appeal.

11. The risk to the local NHS identified by the ICB local impact statement severe local impacts on waiting lists, the service and residents was on the divisional risk register and was highlighted regularly at national meetings. The latest surprise update from the MHRA in September 2024 would impact 1045 boys and men in Oxfordshire and this had not yet been factored in to any consideration of what was needed to sustain the service. Nor had the new update on Topiramate.

12. The Committee heard directly from the Oxfordshire epilepsy clinical team who were undertaking excessive working during periods of leave, early mornings and late evenings because of these national demands and the welfare of the team was affected. There were immediate impacts and there was the enduring impact direct and indirect on patient safety and on recruitment and retention.

13. All stakeholders including the region and the ICB were clear that the increase in clinical and administrative workload from the national mandatory requirements had not been funded. The provider Trust representative explained that the impact of the national demands fell purely on the Trust which was affected by cuts year on year and that there was an urgent need for NHS national specialist funding arrangements to tackle the problem and make resource available.

14. There was a widespread impact across management teams in the NHSE and ICB and Trusts of managing the demands of the Pregnancy Prevention Programme. The NHSE manager explained she had been specially seconded and was spending most of her time on it because of the impacts and complexities. The development of strong teamwork across the region and the ICB and stakeholders had been encouraging with development of some local mitigations where these were possible and whole system escalation to the NHS and MHRA.

15. Access to the MHRA was difficult for NHS regions taking many months. When they raised concerns, they were told that although the MHRA was leading the regulatory change, their focus was entirely on the safety of the drug i.e they regulated the medicine not the NHS and any concerns of impacts were for the NHS to resolve. The MHRA view was that there were no deaths associated with the policy. At a recent national meeting the focus was on

reduction of prescribing. There was an absence of any balancing metric including outcomes for patients.

16. Concerns for the welfare of patients, clinicians, bereaved families and their charity representatives including the threat from the Prevent regulatory regime to proposals for piloting a community-based specialist epilepsy clinic in Wantage to support prevention because of lack of capacity.

17. Widespread and shared concerns about the governance processes at the MHRA. The committee heard that the 2024 updates required the most dramatic change in clinical practice for decades and yet updates were usually briefed to stakeholders as a fait accompli. In 2022 there had been no public consultation or consultation with third sector patient and clinical organisations before there was an MHRA drug safety announcement and organisations had complained. There had been three updates in 2024 alone, with the September 2024 update on additional regulations for men and boys a surprise for all stakeholders. The Committee received evidence from one of the epilepsy clinical leads for NICE who compared the robust governance processes required at NICE with the MHRA processes. NICE required a public and transparent evidence-based process from the start which involved third sector patient and clinical stakeholders and public consultation over a prolonged period.

18. The Committee evidence was that third sector epilepsy patient and clinical organisations had raised likely harms from the policy and urged consultation and a rethink since December 2022. It was noted that outcome from engagement had not been included in a statements from ministers to Parliament [Sodium Valproate - Hansard - UK Parliament](#), neither was a plea for a radical rewrite of national materials for clinicians and patients referred to in the statement of engagement with stakeholders in the public impact report <https://www.gov.uk/government/publications/valproate-review-of-safety-data-and-expert-advice-on-management-of-risks>

19. Concerns about accountabilities for deaths and harms under the UK Pregnancy Prevention Programme or the management of harms and support for patients, bereaved families and clinicians. The committee noted evidence from Kristi McDonald that in the MHRA recent private briefing session about the latest update, accountability was explained as ministerial and across the whole health eco-system but that accountability for individualised decisions made under the policy rested with clinicians. The NHSE gave evidence they had written to all professional regulators and had requested clarity on accountability. The GMC had responded that regarding fitness to practice they would take account of exercise of the duty of candour and raising of concerns at an institutional level.