Oxford University Hospitals
NHS Foundation Trust

Cover Sheet

Thursday 12 September 2024

Health Oversight and Scrutiny Committee meeting

Title:	**HOSC Epilepsy Paper**

Status:	**For Information**
History:	**Final Version**

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Confidential:	**No**
Key Purpose:	Assurance

Executive Summary

1. The paper summarises the current service provision by OUH for people with epilepsy in Oxfordshire
2. It outlines the pressures on the service and the increasing demand over the last few years
3. It explains the recent legal requirements for prescribing Sodium Valproate to women of child bearing age and the impact that this has had on both patients and staff
4. It highlights the need to comply with these regulations in a safe way and outlines the progress made towards this so far
5. It outlines the requirements regarding the prescription of Topiramate in both primary and secondary care
6. It describes the plans for ongoing improvement of the service and the need for further investment to provide safe and effective epilepsy services across Oxfordshire.

Recommendations

7. This is a briefing paper submitted jointly from OUH and BOB ICB for information and assurance regarding the current and proposed provision of epilepsy services in Oxfordshire with particular reference to the recent changes in regulations for prescription of Sodium Valproate and Topiramate.

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1. Purpose

1.1. This paper provides responses to the questions sent by HOSC on Tuesday 13 August requesting responses for a meeting on Thursday 12 September 2024 to discuss Epilepsy services in Oxfordshire. This meeting was postponed from June 2024.

1.2. The responses have been collated from colleagues at both OUH and the Buckinghamshire, Oxfordshire and Berkshire West (BOB) Integrated Care Board (ICB).

1.3. A short presentation will accompany this paper at the meeting on the 12 September.

2. Background

2.1. Epilepsy is a disorder of the brain characterised by repeated seizures due to uncontrolled bursts of electrical activity. There are many causes of epilepsy including congenital abnormalities, genetic disorders, trauma, tumours, stroke, neurodegenerative diseases, immune and inflammatory disorders, and metabolic disorders. Almost 1% of the population has epilepsy, so it is one of the commonest serious chronic neurological conditions. 30-40% of patients have ongoing seizures despite trying different anti-seizure medications. Patients with seizures and epilepsy often present to the Emergency Department and often require urgent advice and review.

2.2. Epilepsy has a risk of causing severe injury and increases the risk of early death, including a risk of sudden unexpected death in epilepsy (SUDEP). Epilepsy is among the top ten causes of premature death in the UK. It is an important cause of maternal death in pregnancy. Around 50% of epilepsy related mortality is considered preventable. Epilepsy is also associated with an increase in psychological and psychiatric difficulties, and has an impact on driving, education, employment, relationships, pregnancy, and fertility.

3. Oxfordshire OUH catchment, local population. Whether there are any high-risk groups that have been identified.

3.1. The John Radcliffe and Horton Hospitals serve a population of 762,500, so almost 7265 people in the Oxford catchment area have epilepsy. The John Radcliffe Hospital is also a tertiary referral centre for people with complex epilepsy and for people being assessed for epilepsy surgery, so also

receives many additional referrals from outside of Oxford (total catchment area of 2.5 million people).

3.2. Epilepsy particularly affects vulnerable groups including people with learning disability, people with mental health difficulties, children, pregnant women, older people, and people who are homeless or socioeconomically deprived.

4. Oxfordshire Epilepsy Workforce: Adult Oxford Epilepsy Team including full-time equivalent neurologists and specialist (a comment about comparison with other tertiary centres and with similar western European countries would be helpful). What are trends on demands on clinical time and where are these pressures coming from.

4.1. The Adult Oxford Epilepsy Team is a small but very cohesive unit comprising the equivalent of two whole time Consultant Neurologists specialising in Epilepsy, the equivalent of 2.6 whole time Epilepsy Specialist Nurses, one Learning Disability Epilepsy Specialist Nurse (who also has an honorary contract with the Community Learning Disability Service), and one administrative assistant (not currently filled).

4.2. The Team assesses and manages people with suspected first seizures, people with established epilepsy, and people with suspected epilepsy. Oxford is a tertiary Epilepsy centre, so we also manage patients with complex epilepsy from other centres. We are also an Epilepsy Surgery Centre, so fully evaluate patients for epilepsy surgery and vagus nerve stimulation (VNS). We also provide care and advice for inpatients with seizures and epilepsy.

4.3. NICE recommends 9 epilepsy specialist nurses per 500,000 people. Oxford has 3.6 epilepsy specialist nurse for 762,500 people. In comparison, Sheffield is a tertiary epilepsy centre with a similar population catchment area and has the equivalent of 11 epilepsy specialist nurses and at 5 neurologists specialising in epilepsy.

4.4. England has one consultant neurologist per 50,000 people, compared to one neurologist per 25,000 people in France and Germany.

5. Trends of increasing demand

5.1. The increasing clinical demand on this small unit has resulted in significant waiting times to see new and follow-up patients, both for the local population and for tertiary referrals, and a marked increase in workload for the existing staff. As epilepsy treatment becomes more specialised with

new drugs and regulations, primary care physicians are referring increasing numbers of patients into specialist care. For example:

Referrals to the Epilepsy Specialist Nurses have tripled from 104 in 2021 to 323 in 2023, with a 25% increase in patients seen in clinic (1,566 in 2020 to 2,040 in 2023).

Requests for written advice and guidance from General Practitioners requiring response letters from the Epilepsy consultants have increased more than ten-fold from 104 in 2020 to 1,259 in 2023.

The increasing number of patients with vagus nerve stimulators has required the introduction of additional satellite clinics (at the Horton Hospital and in Brackley) to support the expansion in VNS Services.

In Buckinghamshire, there is also the Epilepsy Society Chalfont Centre which provides care to on-site residents who live with epilepsy (https://epilepsysociety.org.uk/what-we-do/our-chalfont-centre). They work in association with UCL in London

6. Are there any community-based based epilepsy services in Oxfordshire? Are there any GPs with a specialist interest in epilepsy across Oxfordshire? the ICB? Is there any training about epilepsy for GPs and community-based professionals? Is there any community-based epilepsy service?

6.1. There are no GPs in Oxfordshire with a special interest in epilepsy known to the team at the John Radcliffe Hospital. There are no GPs within BOB with a specialist interest in epilepsy.

6.2. One community neurology nurse who covers North Oxfordshire supports some patients with epilepsy, but they also support patients with other chronic neurological conditions. Our Lead Learning Disability Epilepsy Specialist Nurse (Lead LD ESN) has an honorary contract with Oxford Health's Learning Disability Service and works closely with the Community Learning Disability Nurses (CLDN's) in Oxfordshire. Part of the Lead LD ESN's role is, in collaboration with Oxford Health, to develop a 'seamless' service for people with a LD and epilepsy – 'A pathway', across both organisations and in doing so, support CLDNs to provide a robust, safe and reliable community-based service for people with a learning disability and epilepsy. Systems and processes take a considerable time to navigate and improve. The Lead LD ESN is also involved in providing epilepsy-related educational updates to CLDN's.

6.3. The Learning Disability Epilepsy Specialist Nurse can visit some patients at home, predominantly patients with Vagal Nerve Stimulation (VNS) devices and arranges 'ad hoc' clinics at the Horton General Hospital.

6.4. Our Epilepsy Specialist Nurses see patients at the monthly VNS satellite clinic in Brackley and can see some patients at the Horton General Hospital.

7. Waiting times: data on waiting times and any trends against recommended NICE good practice including first seizure clinic; follow-up appointments; new tertiary patient; Waiting time for the ketogenic diet for children with severe epilepsy; epilepsy learning disability service.

7.1. We are currently unable to meet some national guidelines. For example:

- Waiting time to be seen in first seizure clinic: 9 months (NICE guidelines: within 2 weeks).
- Waiting time to be seen as a new tertiary patient: almost 12 months (NICE guidelines: within 4 weeks)
- Waiting time to be seen in follow-up: 9-12 months.

7.2. Our current waiting list for ketogenic dietary therapy for children with epilepsy is 3 years. This is significantly higher than other UK centres. The national average is 4-5 months, and highest at other UK centres is 8 months (figures provided by a Ketogenic Dietitians Research Network survey, 2021). As 80% of our patients come off the diet after 2 years, current staffing allows us to take on 17 new patients per year. However, our current referral rate is approximately 36 patients per year, and so the waiting list continues to rise. Nationally, KD referrals are rising annually: 754 patients were following KD in the UK and Ireland in 2017, compared to 101 in 2014; referrals were 45% higher in 2019 compared to 2017 (Whitley et al, 2020). A charity (Daisy Garland) funded a dietetic assistant (DA) post for a fixed period which has now finished.

7.3. There is currently a business case for further Dietitians to provide KD input. The preferred option includes funding for 1.0 WTE dietetic Assistant (band 3), 1 WTE band 7 Dietitian, and 1 WTE band 7 dietitian (temporary 2 year fixed). This is in the process of being finalised and submitted.

7.4. As it will take time for the business case to be approved followed by recruitment and training, year 1 figures reflect only having the DA in post. From year 2, there will be a permanent caseload ability of 80 and an additional 30 people who can start a KD for 2 years. We will therefore have a rolling caseload of 32 patients weaning each year, and the

additional 30 will wean after 2 years. Referrals will continue at 36/year and the waiting list will increase by 4/yr.

Year	Number of Patients on Waiting list	Waiting list duration
1	72	2.3 Yrs
2	24	0.8 Yrs
3	28	0.9Yrs

7.5. This business case will be dependent on additional funding for epilepsy services to provide the increasing number of treatments for an increasing population of people with epilepsy.

8. The new regulation on Valproate and Topiramate. What is the impact on patients of the accelerated Valproate regulation, in particular the OUH Trust response to the statements made in the public petition item on the June HOSC meeting by Dr Judy Shakespeare and Kristi (members of the public who presented at the June HOSC).

8.1. The MHRA has issued new guidance mandating enhanced oversight and review of sodium valproate prescribing for girls and women of childbearing potential, effective January 2024. These are legal requirements as they have been applied to the licence of the medicine. This is because valproate exposure during pregnancy can lead to severe consequences for the unborn child, including physical birth defects (10%) and neurodevelopmental disorders (30-40%). However, valproate is a potent antiseizure medication and the best agent for certain common epilepsy types. Changing valproate to another agent risks loss of seizure control, impacting on quality-of-life and driving, and increasing the risk of injury and mortality.

8.2. All women of childbearing potential already taking valproate must now have a second independent specialist opinion (at least 238 girls and women in Oxfordshire alone who all now require a new patient appointment) to continue valproate. The Oxford Epilepsy Team also manage many patients from Northampton, Kettering, Berkshire, Buckinghamshire, and further afield, so the number of women who will require this second opinion in Oxford will be significantly higher.

8.3. An assessment of the prevalence of Valproate primary care prescriptions was undertaken across BOB: selected data is included in the table below:

	Bucks	Oxon	Berks West	BOB Total

Total number of patients prescribed Valproate	1329	1609	1223	4161
Females under 55	160	238	173	571
Females 55 and over	292	326	214	832
Males	889	1045	835	2769

This table excludes an additional 179 patients who are from non-EMIS practices in BOB for whom we don’t have precise data.

8.4. A second independent specialist opinion is now also required before any patient of reproductive age (males and females) can be newly commenced on valproate.

8.5. The MHRA has some concern that valproate may affect fertility in men, and small animal studies suggest a possible toxic effect on the testes, although the relevance in human is unknown. This must now be discussed with all men already taking valproate, adding to already short clinic consultation times. It is very possible that the MHRA will issue a similar mandate that all males taking valproate (> 1000 boys and men in Oxfordshire alone) will also require a second independent specialist opinion to continue valproate.

8.6. The impact of the MHRA valproate regulations on patients is significant. Women and girls of childbearing potential, regardless of their personal circumstances, are recommended to use a highly effective long-term contraceptive agent to continue or commence on valproate i.e. the implant, Depo injection or the contraceptive coil, from menarche up to the age of 55 years. The risk of poor seizure control in people (particularly children, in whom at least 27% are seizure-free on valproate) is understandably of great concern to patients and their families, who rightly worry about the potential impact on driving and employment, as well as the risk to their lives from uncontrolled seizures.

8.7. People with epilepsy are already experiencing great concerns because of shortages of anti-seizure medications, so access to the right medicine at the right time is even more important. Unlike progressive neurological conditions, lack of access can trigger breakthrough seizures that can be immediately life-threatening. Many women who are understandably concerned that an effective drug may be withdrawn feel that the MHRA regulations do not incorporate sufficient patient involvement with the decision-making regarding valproate or the patient’s right to choice (an opinion tabled at the HOSC meeting on 6th June 2024 by Kristi McDonald).

8.8. The discussions with our patients regarding valproate must therefore be even more comprehensive, sensitive, and collaborative.

9. What is the impact on the workforce in terms of increased workload and in terms of their wellbeing and clinical ethics?

9.1. The impact of the MHRA valproate regulations on staff is significant. The impact of these new requirements on an already overstretched epilepsy team are enormous. Team members are already working many additional hours per week. A second independent specialist opinion for 238 women in Oxford alone is the equivalent of an additional 238 hours of consultant time. This is an underestimate of the number of patients the Oxford team will be seeing because the department also sees people from outside of the BOB ICS. In addition, the more detailed discussions with patients that are now required take a significant amount of additional time in the clinic and required longer and more detailed clinic letters. It is likely that similar requirements will be mandated for male patients, but even if this does not occur imminently, all male patients on valproate now need additional explanation both verbally and in writing, contributing significantly to consultation times.

9.2. The ongoing oversight and audit of the new regulations as well as the mandatory attendance at frequent local and national meetings contribute to the additional workload.

9.3. These requirements cannot be fulfilled or sustained without either additional staffing or cancellation of large numbers of outpatient clinics, for which patients have already waited almost 12 months.

9.4. This additional workload has a significant impact on the morale and work life balance of the epilepsy team.

10. In June the MHRA also announced that the Prevent programme will apply to Topiramate. What data outcomes are required locally for reporting nationally? Is any other data collected locally on outcomes of patients with epilepsy?

10.1. On 21st June 2024, the MHRA announced that the Prevent programme will now also apply to the anti-seizure medication Topiramate, as topiramate has been shown to also be associated with a higher risk of congenital malformations, low birth weight, and intellectual disability. Topiramate is however a very effective anti-seizure medication for certain common epilepsy syndromes.

10.2. Women and girls taking topiramate are now required to use a contraceptive agent, ideally highly effective long-term contraception, from the age of menarche to the age of 55 years. Patients on topiramate now

also require detailed discussion about further detailed discussion about the risks of topiramate to the unborn baby, and the need to use an effective contraceptive agent. The MHRA topiramate risk acknowledgement form now needs to be completed annually. This is a significant amount of additional work. A second independent specialist opinion is not yet required, but it may be in the future. The exact number of women taking topiramate in our catchment area is currently being ascertained.

10.3. An assessment of the prevalence of current topiramate primary care prescriptions was undertaken across BOB: selected data is included in the table below:

EMIS Web practices	Buckinghamshire		Oxfordshire		Berkshire West	
ALL patients (male & female)	610		880		653	
	Number of patients	**% of female pts**	**Number of patients**	**% of female pts**	**Number of patients**	**% of female pts**
Females ≥ 8 to < 56 yrs	295		425		319	
Migraine - coded	216	73%	333	78%	227	71%
Epilepsy - coded	51	17%	65	15%	60	19%
Mental health (unlicensed)	4	1%	7	2%	4	2%
Neuropathic pain (unlicensed)	4	1%	9	2%	4	7%
Other/Unknown Indication	20	7%	11	3%	24	8%

This table excludes an additional 68 female patients (aged 12-54 years) prescribed topiramate between April – June 2024 who are from non-EMIS practices in BOB for whom we don't have precise data.

10.4. Separate MHRA risk awareness forms are provided for epilepsy and migraine indications. Where the patient is on topiramate for epilepsy the discussion and annual review form must be completed between the specialist and patient/carer, for migraine this is under the remit of primary care. No independent second clinical signatures are currently required for the topiramate pregnancy prevention programme forms.

11. **Wantage: OUH has partnered with the Oxfordshire wide system to consider specialist clinics to bring to Wantage Community Hospital. The outcome of co-production and engagement is that epilepsy was included in the long list this year that was shared with the public in July. Please update the Committee on what steps have been taken to progress this proposal?**

11.1. Consultant-led neurology clinics currently run at the JR, the Horton, and are also embedded in psychiatry at the Warneford Hospital. This joint service with psychiatry is unique in England and has been very successful. Our SpRs also rotate to run clinics at Swindon, Northampton, Milton Keynes, Reading and Queen's Square (London). We currently do not have the personnel resources to run additional clinics in Wantage Community Hospital but will continue to review this depending on resources. Work is ongoing to define the services that may be able to operate out of Wantage Community Hospital.

12. **Patient Safety: Who is leading and at what levels of governance locally has consideration and assurance been given of the patient safety of people with epilepsy and their families including the adequacy of resource, funding, workforce and training for the Oxfordshire epilepsy service in the light of population-health needs and the added work and nature of the MHRA regulations on Valproate and Topiramate, and the context of medicines shortages.**

12.1. The system approach has been led by the Quality Team at BOB ICB and has brought together health providers across the ICS including OUH. Following publication of the MHRA alert in November 2023, the BOB ICB patient safety lead established a working group to undertake a gap analysis and develop an improvement plan. This group feeds into the South East regional sodium valproate group who have been escalating the safety and capacity concerns from BOB ICB to the regional system quality group since January 2024.

12.2. In February 2024 the implementation of the MHRA alert was added to the ICB risk register. The risk is: *As a result of the changes to the regulatory requirements of Valproate from MHRA and the resulting national patient safety alert there could be harm to patients and impact on services*. The risk is scored as 20 (25 is the highest a risk can score) and through mitigations the inherent risk scores 15. This risk is highlighted to the South East regional system quality group each month as part of ICB escalations.

12.3. At OUH the Deputy Chief Medical Officer for Patient Safety coordinated a response to the alert with doctors, specialist nurses, pharmacists from

adult and paediatric Neurology departments and the Medicines Safety team. Progress to the alert is regularly reported to the Trust's Medicines Safety Committee, which reports to the Patient Safety and Effectiveness Committee. Updates are also shared through the Trust's Safety, Learning and Improvement Conversation forum.

12.4. There is a separate paper that has been written for HOSC that describes the impact of medicines shortages; we have not experienced any recent supply problems with valproate or topiramate.

12.5. Within the Epilepsy department in OUH, team members (Consultants and Epilepsy Specialist Nurses) regularly attend the meetings of the Medicine Safety Committee and the Task and Finish Group, and the Valproate Regulatory Measures Working Group.

12.6. Professor Sen leads local, national, and international collaborative clinical research projects and is Topic Advisor to the National Institute of Health and Clinical Excellence (NICE) for the Epilepsies. Dr Adcock has led work on National Audits of Seizures.

12.7. At an individual level, every patient seen by the team in clinic has safety advice and SUDEP risk regularly discussed. All women of childbearing potential have regular discussions about contraception and pregnancy and the potential risk to the unborn baby from uncontrolled seizures and anti-seizure medication.

13. The support being provided to tackle SUDEP, suicide and other epilepsy-related premature mortality in Oxfordshire

13.1. We work very closely with our Neuropsychology and Neuropsychiatry colleagues at the John Radcliffe Hospital who help advise and manage psychiatric co-morbidities including depression and feelings of suicidality in our patients with epilepsy, together with the support of our General Practitioners who are at the forefront of managing our patients.

13.2. Professor Sen has worked closely with the patient group SUDEP Action and has published research in the topic of SUDEP, working collaboratively with SUDEP Action.

14. How you plans to continue to develop and to improve epilepsy services moving forward. Is there any planned co-production with the voluntary sector in Oxfordshire and patients with epilepsy and their families?

14.1. A business case has been submitted for approval to appoint at least one additional full-time Consultant Neurologist with an interest in Epilepsy as well as an additional half-time administrative assistant. A permanent long-term appointment is preferred to ensure the sustainable future and safety of epilepsy care in Oxfordshire. Business cases for additional Epilepsy Specialist Nurses will continue to be submitted. An advert for an Epilepsy and Sleep Fellow has also been placed.

14.2. We will ensure that the voluntary sector and patients with epilepsy have a strong voice in developing services across Oxfordshire. The department already has strong links with SUDEP action and actively engages with patients in shaping services.

15. Progress of the implementation of the Valproate requirements so far in adults

15.1. At present, 50 of the first 100 patients have fully completed dual signature MHRA valproate risk acknowledgement forms after valproate MDT meeting discussions for second opinions. We have not cancelled any clinics or any other clinical commitments to implement the MHRA regulations, because we are so concerned about the very long waiting times for patients with epilepsy to be reviewed in clinic and the risk to patient safety if clinics are cancelled. We are therefore conducting the valproate MDT meetings in addition to our usual workload, often after-hours. As many of our patients are very complex, we have chosen to discuss the patients at a multidisciplinary team meeting to ensure maximum safety and governance.

16. Impact on Primary Care and community pharmacy

16.1. Valproate is a 'shared care' medicine for epilepsy, in that it should be initiated in secondary care by the specialist with follow-on prescription and monitoring according to a drug specific Shared Care Protocol (SCP). Prescribing may be continued in primary care following the SCP. Shared care depends on good communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them. The BOB oral valproate medicines SCP specifies the responsibilities of the specialist, primary care prescriber, commissioned GP/sexual health clinic and patient/carer.

16.2. Changes to legislation came into effect in October 2023 requiring dispensers to dispense for all patients (male and female) all licensed valproate containing medicines in the manufacturer's original full pack. The original full pack includes specific warnings and pictograms, including a patient card and the Patient Information Leaflet, and will therefore alert patients on the risks to unborn child. In rare cases, pharmacists can make an exception to the requirement to dispense valproate-containing medicines in the manufacturer's original full pack on an individual patient risk assessment basis.

17. Conclusion

17.1. This is a briefing paper submitted jointly from OUH and BOB ICB for information and assurance regarding the current and proposed provision of epilepsy services in Oxfordshire, with particular reference to the recent changes in legal regulations for the prescription of Sodium Valproate and Topiramate.

17.2. HOSC are asked to accept this paper as assurance of the services provided to people with epilepsy and support an increase in investment into these services in order to improve their delivery and safety to the population served.