

INTRODUCTION

- Sodium valproate is a widely used mood stabiliser with a strong evidence base in bipolar affective disorder and other psychiatric conditions¹.
- It carries significant reproductive safety risks requiring clear communication with both men and women.
- In women, exposure during pregnancy is associated with a high risk of congenital malformations and developmental disorders^{2, 3}.
- In men, it has been linked to potential fertility effects and increased risk of neurodevelopmental disorders in children of fathers treated with valproate three months prior to conception⁴⁻⁶.
- Recent Medicines and Healthcare products Regulatory Agency (MHRA) guidance has introduced additional measures addressing reproductive risks in male patients.

AIM

- To evaluate compliance with the MHRA safety requirements for sodium valproate prescribing within the Waltham Forest Community Learning Disability Team.

METHOD

- All patients prescribed sodium valproate for psychiatric indications were assessed against criteria based on MHRA guidance, with a target standard of 100%:

 - Completion of the Risk Acknowledgement Form (RAF) in female patients
 - Documentation of risk discussions in male patients using the RAF as a structured tool
 - Provision of the MHRA Sodium Valproate Patient Guide to all patients

- Patients without RAFs were contacted for discussion of risks and benefits and completion of forms.
- A re-audit was conducted following intervention using the same methodology to assess improvement against the 100% audit standard.

RESULTS

Patient characteristics:

	Male <i>n</i>	Female <i>n</i>	Total <i>n</i>
Number of patients	14	5	19
Age			
<55 years	12	5	17
55-60 years	2	0	2
Diagnosis			
Bipolar disorder	8	3	11
Schizoaffective disorder	1	1	2
Other psychiatric indications	5	1	6
Daily dose of sodium valproate			
≤1000 mg/day	4	2	6
1000-2000 mg/day	10	3	13
>2000 mg/day	0	0	0

Compliance with audit criteria:

Criterion	Baseline	Post-Intervention	Standard
Female RAF completion	50%	100%	100%
Male risk discussion (RAF used)	14%	43%	100%
Provision of MHRA Sodium Valproate Patient Guide	21%	42%	100%

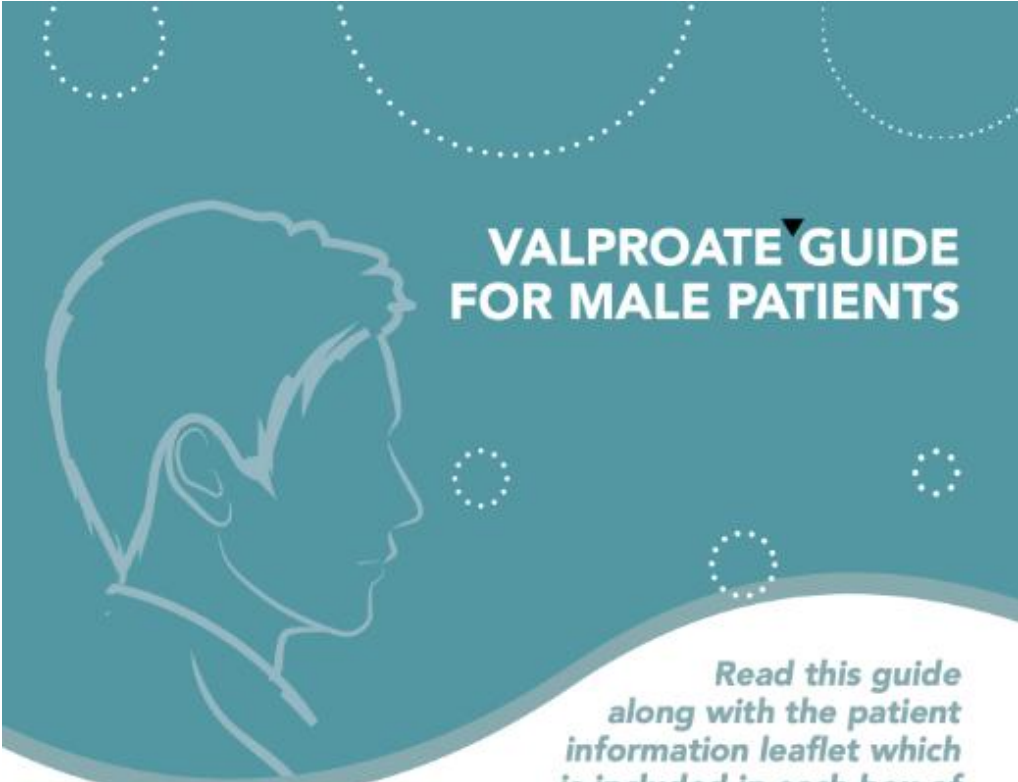
DISCUSSION

- A total of 19 patients were identified as taking sodium valproate for psychiatric indications, which represented 12.3% of the total psychiatry caseload (154 patients).
- Intervention resulted in improvement across all criteria, with full compliance achieved for RAFs in females. The higher rate of completion may reflect greater clinician familiarity with established guidance for females.
- Compliance in documentation of risk discussions in male patients and provision of patient information remained below the expected standard.
- The audit highlighted gaps in compliance with MHRA requirements for the prescribing of sodium valproate in our service.
- We identified a need for more accessible patient information of the valproate guide – no resources available.
- Pharmacy liaison to support in achieving MHRA target of 100% for RAF completion.
- Ongoing re-audit is required to ensure sustained improvement.

CO-DESIGN OF EASY READ PATIENT GUIDE FOR MALE PATIENTS

- A key focus of this project was to ensure all patients prescribed sodium valproate were provided with the Sodium Valproate Patient Guide as recommended by MHRA.
- Compliance in this area remained suboptimal which may reflect practical barriers, including limited availability of hard copies, lack of translated versions, and absence of easy read formats.
- The lack of an easy read version of the patient information guide is particularly relevant within a community learning disability service, where accessible materials are essential to support understanding.
- An outcome of the audit was to develop an easy read sodium valproate guide for males given the more recent MHRA guidance and results showing lack of risk discussions in male patients.

Process:



Valproate Guide for Male Patients



Read this guide along with the patient information leaflet which is included in each box of your medicine

WHAT YOU SHOULD KNOW

This guide contains key information about the risks of valproate. Ask your doctor, nurse or pharmacist if you have any questions.

KEEP THIS GUIDE. YOU MAY NEED TO READ IT AGAIN.

Scan for audio!



Has anyone told you about the risks of Sodium Valproate? *



☐ Yes ☐ No ☐ Not sure

Patient/Carer feedback:

- 71% of respondents said they would like an easy read patient guide
- ‘All important information is there’*
- ‘Everything is in the guide’*
- ‘I can’t read & I have Dyslexia so I don’t want a written guide, but a simple audio guide would be good.’*
- ‘A simple video with easy facts, pros and cons... not long, no jargon. So, there’s a task or a simple audio that is short and clear. Thank you for asking.’*
- ‘X & I think a short video &/or audio would be good for those unable to read & for blind/partially sighted people & others who prefer audio.’*

Future Directions:

- We have incorporated patient responses into the guide, including adding an audio option. We plan to send to forums outside the service to obtain further feedback.
- Approach MHRA with the aim to formally publish our easy read sodium valproate guide for male patients.
- Develop further accessible information to support patients in decision-making, including an easy read RAF.

References:

1. Mari J, Dieckmann LHJ, Prates-Baldez D, Haddad M, Rodrigues da Silva N, Kapczynski F. The efficacy of valproate in acute mania, bipolar depression and maintenance therapy for bipolar disorder: an overview of systematic reviews with meta-analyses. *BMJ Open*. 2024;14(11):e087999. doi:10.1136/bmjopen-2024-087999

2. Meador KJ, Baker GA, Browning N, Cohen MJ, Bromley RL, Clayton-Smith J, et al. Fetal antiepileptic drug exposure and cognitive outcomes at age 6 years (NEAD study): a prospective observational study. *Lancet Neurol*. 2013;12(3):244–52. doi:10.1016/S1474-4422(12)70323-X

3. Tomson T, Battino D, Bonizzoni E, Craig J, Lindhout D, Perucca E. Comparative risk of major congenital malformations with eight different antiepileptic drugs: a prospective cohort study of the EURAP registry. *Lancet Neurol*. 2018;17(6):530–8. doi:10.1016/S1474-4422(18)30107-8

4. Christensen J, Trabjerg BB, Dreier JW. Valproate use during spermatogenesis and risk to offspring. *JAMA Netw Open*. 2024;7(6):e2414709. doi:10.1001/jamanetworkopen.2024.14709

5. European Medicines Agency. Potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines: PRAC recommends precautionary measures [Internet]. Amsterdam: European Medicines Agency; 2024 Jan 12 [cited 2026 Sep 17]. Available from: <https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-8-11-january-2024>

6. Medicines and Healthcare products Regulatory Agency. Valproate use in men: as a precaution, men and their partners should use effective contraception [Internet]. London: MHRA; 2024 Sep [cited 2026 Sep 17]. Available from: <https://www.gov.uk/drug-safety-update/valproate-use-in-men-as-a-precaution-men-and-their-partners-should-use-effective-contraception>

7. electronic Medicines Compendium. Valproate: additional risk minimisation material [Internet]. Leatherhead: Datapharm [cited 2026 Sep 17]. Available from: <https://www.medicines.org.uk/emc/rmm/104334/Document>

8. Photosymbols [Internet]. [cited 2026 Sep 17]. Available from: <https://www.photosymbols.com/>