

# THE OTHER HALF OF THE RISK: INCLUDING MEN IN VALPROATE SAFETY PRACTICE

## A Two-Cycle Audit of Compliance with MHRA Guidelines in a Community Mental Health Team



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### Introduction

Recent findings have shown that the considerable reproductive and developmental risks linked to sodium valproate are not limited to women of childbearing potential, but also affect men, a demographic previously not recognised as being at risk.

In response, the MHRA issued updated prescribing and monitoring guidance in 2024, mandating enhanced scrutiny over treatment initiation, ongoing monitoring, and risk communication.

Recognising an ethical duty to ensure transparency and patient autonomy, the East Bromley Intensive Case Management in Psychosis (ICMP) team undertook this audit to assess compliance with national standards and address the emerging ethical implications of valproate use across genders.

### Aims

- Establish a registry of all patients on valproate.
- Assess baseline compliance with national standards.
- Evaluate clinical documentation regarding:
  - clinical rationale for treatment
  - risk discussion
  - contraception advice
  - informed consent and completion of Annual Risk Acknowledgement Forms (ARAF)
  - provision of updated MHRA materials
- Identify areas for improvement.
- Implement targeted interventions to strengthen compliance and support shared decision-making.

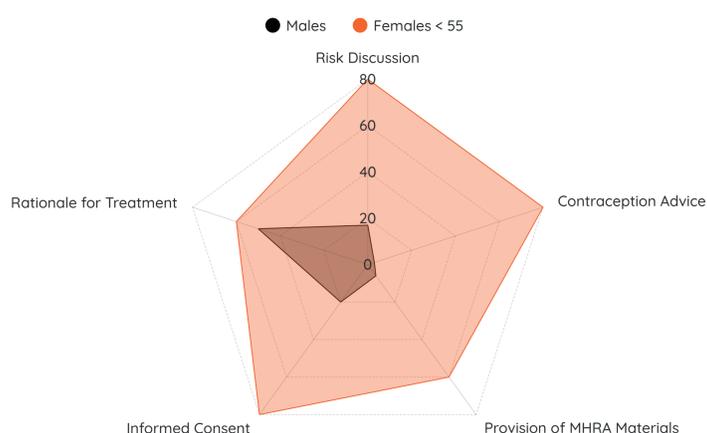
### Methods

- **Cycle 1:** A retrospective review of all 330 ICMP patients (via RiO and the London Care Record) was conducted to create a registry of all patients prescribed valproate. Baseline data captured adherence to updated guidance, including documentation of risk discussions, contraception advice, informed consent, ARAF completion, and provision of MHRA materials.
- **Interventions:** Targeted interventions were then implemented, including clinician education, structured outpatient reviews (26 conducted), distribution of MHRA materials, and the creation of a live ARAF tracking system.
- **Cycle 2:** A focused re-audit in July 2025 evaluated the impact of these interventions.

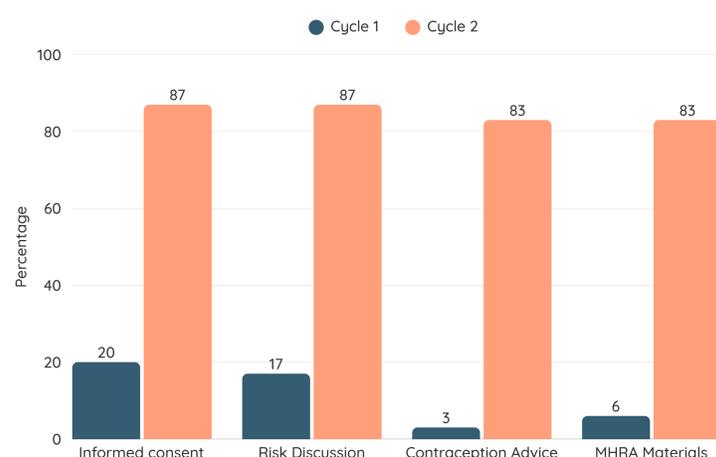
### Results

- A registry of 46 patients was created (30 males, 5 females <55 & 11 females >55).
- Baseline compliance was low across all measures, particularly among men.
- None of the eligible females had a dual-signed Annual Risk Acknowledgement Form (ARAF).
- The pathway for obtaining second consultant sign-off was clarified, and all eligible females were reviewed and referred accordingly.
- 26 structured reviews resulted in 13% switching to alternative treatment and 9% still deliberating their decision, strongly reflecting improved shared decision-making.

Cycle 1 - Baseline Compliance  
Disparity Across Genders



Improvement in Risk Communication and Documentation in  
Male Patients After Targeted Interventions



### Conclusion

This project not only improved measurable compliance but also reaffirmed the ethical duty of clinicians to revisit long-standing treatment decisions in light of new evidence. The findings emphasise that patient safety and informed consent are not static achievements but ongoing responsibilities. By taking active steps to review emerging guidance and re-engage long-term patients in shared decision-making, services can uphold both regulatory standards and the moral integrity at the core of psychiatric practice.