

→ Introduction



Sodium valproate is widely used for bipolar disorder and other psychiatric conditions but carries significant teratogenic and reproductive risks.



In November 2023, the MHRA issued a National Patient Safety Alert requiring enhanced prescribing safeguards, including a second consultant sign-off for new valproate initiations in **patients under 55**.

Ensuring adherence to these safeguards is essential to reduce preventable harm.



AIM: To assess compliance with MHRA valproate prescribing mandates and evaluate improvement following dissemination of audit findings.

→ Methods



Methods Overview

Retrospective audit using electronic clinical records (SystemOne / eCare).



Inclusion Criteria

- Patients <55 years
- Prescribed valproate for mental health indications



Outcome Measures

Primary outcome:

- Second consultant sign-off compliance

Secondary outcome:

- Blood monitoring compliance (Cycle 1 only)



Audit Timeline

CYCLE 1 (Baseline)

Dec 2023 – Jun 2024
• 52 patients included



CYCLE 2 (Follow-up)

Jun 2024 – Apr 2025
• 9 patients included

→ Results

CYCLE 1 (Baseline)

0%
COMPLIANT

0 of 6 eligible patients



Absolute improvement:
+50 percentage points

CYCLE 2 (Follow-up)

50%
COMPLIANT

2 of 4 eligible patients



Secondary Outcome (Cycle 1)

Blood Monitoring Compliance:

77%

77% (40 of 52 patients)



Cycle 2 Details

Total Patients Analysed: 9

50%

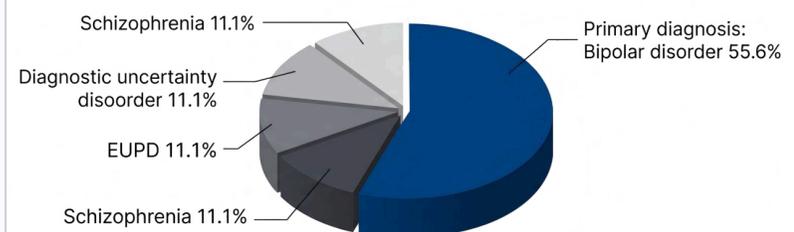
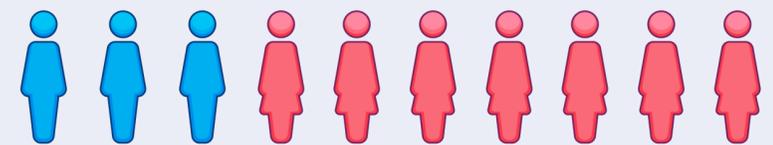
- 50% (2) Compliance
- 50% (2) Incomplete

→ Demographics

Demographics (Cycle 2)

Male: 33.3%

Female: 66.7%



→ Discussion



- Dissemination of audit findings to clinical teams resulted in a substantial improvement in compliance with the second consultant sign-off requirement.
- However, compliance remains incomplete, with ongoing gaps identified particularly among eligible female patients.
- These findings highlight the need for system-level interventions and clearer accountability in prescribing processes.

→ Conclusion



- This two-cycle audit demonstrates that audit-driven clinical engagement can improve adherence to regulatory safety requirements.
- Further interventions are required to achieve consistent compliance with MHRA valproate prescribing safeguards.

Recommendations

- Pharmacy alerts for prescriptions lacking second sign-off
- Clear consultant responsibility for arranging documentation

- Local monitoring of compliance
- Re-audit within 6–12 months