Epsom and St Helier University Hospitals NHS Trust

First do no harm

A Quality Improvement project supporting the safe prescribing and dispensing of Sodium Valproate in women of childbearing age

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AIM

To highlight the role Community Pharmacy teams play in ensuring the safe dispensing and prescribing of valproate in women of child bearing age in South West London.

BACKGROUND

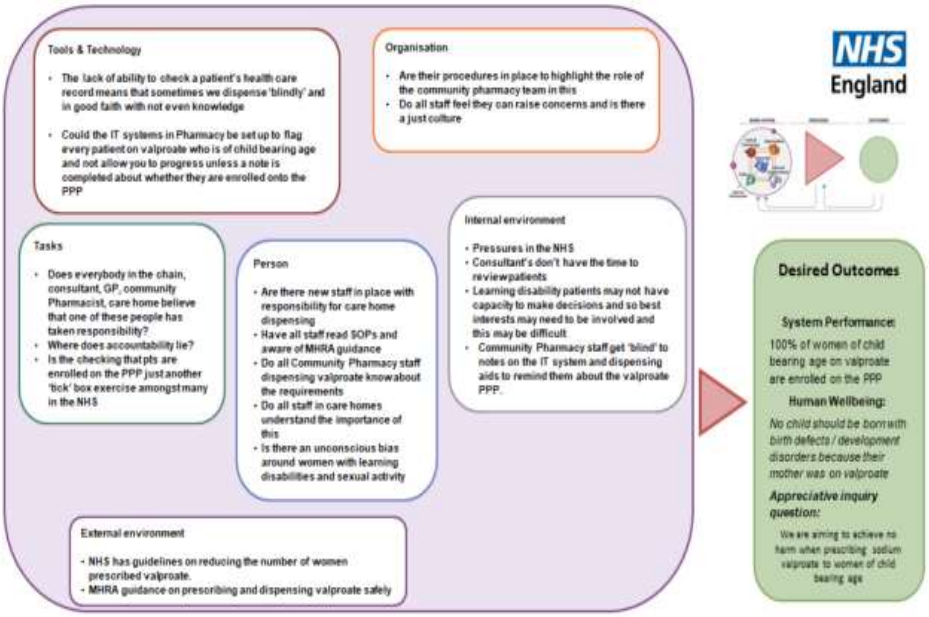
Valproate is a treatment for epilepsy and bipolar disorder. Children born to women who take valproate during pregnancy are at significant risk of birth defects and persistent developmental disorders. Therefore, MHRA set guidance in 2018 that valproate medicines must **not** be used in women or girls of childbearing potential **unless** a Pregnancy Prevention Programme (PPP) is in place[1].

Despite awareness of this issue, according to a safety report issued in 2020, three babies per month are still being born after exposure to valproate [2].

The devastating issue of sodium valproate has been described by Henrietta Hughes, the patient safety commissioner, as "**a far bigger scandal than thalidomide**"[3].

METHODS

- Produced a stakeholder map
- Carry out a PDSA cycle:
  - PLAN - To carry out an audit of all of the prescriptions dispensed for valproate for women of child bearing age in our Pharmacy. The following standards were set for the audit:
  - 100% of patients are provided with a Patient Card & Guide by the pharmacy every time valproate is dispensed
  - 100% of patients who are not on highly effective contraception in line with the pregnancy prevention programme are referred/signposted to their GP practice or specialist, where appropriate.
  - DO - Carry out this audit over 4 weeks in January 2023
  - Evaluate 'work as done' vs 'work as imagined' and the 'efficiency/thoroughness' trade off
- Used SEIPS to help break down the complex elements involved in the safe prescribing of valproate to women of child bearing age with learning disabilities



South West London Integrated Care System

RESULTS

- PDSA: STUDY
  We identified 25% of our patients on valproate were NOT enrolled on the pregnancy prevention programme
  These patients were ones that were in our Learning Disability care homes
- Stakeholder conversations:
  - Care home staff said 'these women can't/won't get pregnant' so it doesn't matter
  - Care home Pharmacist and the SWL Mental Health team were concerned
  - Community Pharmacy teams recognised their role in this to raise awareness every time

CONCLUSIONS

In South West London (SWL), there are still women of child bearing age who are being prescribed valproate without the appropriate safeguards in place.

This audit and themes from a literature search were that there are specific issues, in particular, with supporting the safe prescribing of valproate in women of childbearing age with learning disabilities which include[4]:

- specific issues gaining consent from people with and without capacity
- that the regulations lack suitable adjustments for specific ID-related factors like learning disabilities[5]
- ethical concerns relating to patient choice and carer's conceptions[6].

RECOMMENDATIONS

Whilst this project only identified a small number of patients, even **one woman** of childbearing age on valproate without appropriate contraception is **too many**. The recommendations are:

1. To raise this further within the SWL Valproate safety group to work out next steps to reduce this.
2. To liaise with senior clinicians involved in the prescribing of valproate in learning disability care homes to highlight the need to ensure safe prescribing.

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