Reducing Inequalities for Women of Childbearing Potential with Mental illness taking Valproate

Teratogenic effect of Valproate → 20,000 affected costing NHS £181 billion → Lack of systems to safeguard women and the unborn child → Redesigned Clinical pathway with a core digital solution to improve patient safety and address inequalities

NHS Surrey and Borders Partnership NHS Foundation Trust

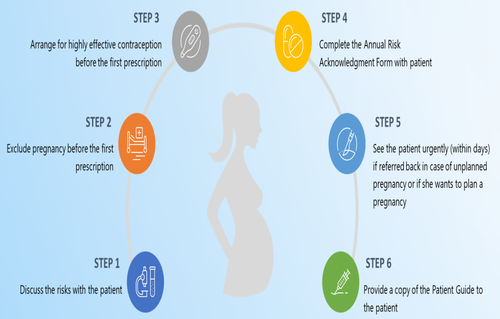
Background

- Valproate is commonly prescribed for Epilepsy and Bipolar disorder worldwide [1]
- Teratogenicity of valproate in animals was first reported in the 1970s [2]
- If valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and 1 in 10 are at risk of birth defects [3]
- Since April 2018, a total of 247 women have taken valproate during pregnancy, with 46 pregnancy exposures between October 2020-September 2021[4]
- UK has a higher rate of valproate prescribing than many other countries in Europe. This suggests that the number of female patients prescribed valproate in the UK (for any indication) could be further reduced. [4]
- Since 1973, 20,000 people are known to have been affected by valproate, and it is estimated this has cost £181 billion to NHS [4]
- Medicines and Healthcare Products Regulatory Agency (MHRA) endorsed a regulation in March 2018 that valproate must no longer be used in any woman or girl able to have children unless she has a Pregnancy Prevention Programme (PPP) with evidence of Annual risk acknowledgment form (ARAF) in place.
- A nationwide POMH 2018 audit found risk acknowledgement form did not exist for more than 50% across 55 Mental Health Trusts.
- According to the Equality Act of 2010 Section 129, the protected characteristics of age, disability, pregnancy and sex has been compromised in this aspect, leading to unsafe prescribing for women of child-bearing age with mental illness/epilepsy.

Aim

- To Identify all women in primary and secondary care within Surrey taking Valproate for mental illness and implement pregnancy prevention programme for them
- To design and build a clinical pathway using a digital solution at its core to support clinicians to implement PPP

Pregnancy Prevention Programme (PPP) Steps



TRUST AUDIT FINDINGS

Parameter	2018	2019	2020
Number of patients	26	17	16
Has the risk been discussed with the patient?	50%	53%	75%
Has pregnancy been excluded	42%	18%	Not audited
Has an arrangement for a highly effective contraception been made	35%	35%	Not audited
Evidence of an annual risk acknowledgement form (ARAF)	**46%**	**47%**	**81%**

SABP data showed that the pregnancy prevention programme (PPP) was complete in only 46% and 47% of women taking valproate in 2018 and 2019 respectively. By 2020 though, this figure had risen to 81%.

Several issues were identified including:

- Lack of awareness of the responsibilities of all involved in the prescribing, dispensing and monitoring of patients on valproate
- Issues with referral and recall of patients requiring the PPP
- Patients with no PPP in place and at risk of pregnancy without the necessary review

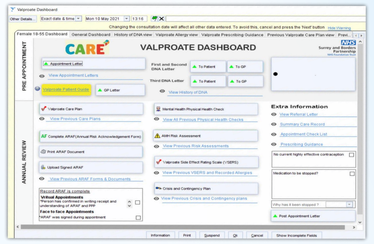
SABP and Surrey Heartlands Medicines Safety spearheaded a multi-disciplinary solution to ensure safer valproate prescribing in mental health through a clinical and digital redesign.

Objective of the Valproate service redesign

- To create a registry of women of child-bearing potential who are prescribed valproate by building a virtual based caseload
- To create a bespoke, end-to-end, holistic digital solution directly into our primary clinical system (SystmOne)
- To create a digital system that supports the capture, monitoring and process facilitation of the valproate best practice pathway
- To create a digitalised GP referral form

CUMBERLEGE REVIEW RELEASED IN JUL 2020

Pathway Redesign for Improvement of Sodium valproate Medication prescribing



Issues with identifying women of childbearing potential on valproate in primary and secondary care	• Digital registry of all women of childbearing potential on valproate to ease identification by creating a virtual caseload
Lack of communication across primary & secondary care	• Customised digital GP referral form for ARAF reviews • Annual reviews can be completed fully based on the information shared • Improved relationship between Primary Care and Secondary Care
Lack of support for healthcare professionals to ease the process of PPP	• A one-stop "valproate dashboard" containing all steps involved for a specialist to complete the PPP • Clear Standard Operating Procedures detailing the processes
Lack of overview for regular compliance check	• Live digital visualisation feature that will aid all users to check for compliance in real-time • Comprehensive training for all teams using the systems
Uncertainty about the responsibilities of stakeholders creating unnecessary steps in the process for both patient and staff	• Collaborative approach and co-production with stakeholders to redesign digital and clinical pathway • Patients kept within the specialist system on a virtual caseload and automatically recalled • Patients will be seen when needed rather than waiting for a GP referral which allows for better planning of clinics

- A valproate working group was set up which consisted of specialist mental health professionals, specialist pharmacists, digital teams, and primary care clinicians.
- Consultative measures were taken to co-design & co-produce with end-users and patients.
- A valproate champion was assigned to support end users with the valproate process after completion of the redesign
- Awareness around valproate and the project was raised through communication newsletters and presentations at various events
- Support from the learning adoption team has provided training for teams to ease the use of the new process

- Learning disabilities team involved to design easy read written materials for women with learning disabilities
- Collaborated with National Valproate Patient Safety Officer in implementing SNOMED codes to simplify exchange of clinical information easier between systems
- Conducted Knowledge exchange events to share learnings for wider impact

Redesigned Clinical Pathway

The GP will make a once-only referral using a referral form linked to Primary Care prescribing systems which ensures all necessary information is available at specialist review

Following the appointment process, the woman will either remain on the active caseload or be put on the new "virtual" caseload if she is stable and an annual review is all that is required.

Teams will be able to review their virtual caseload, through a specifically designed dashboard. It will also be used to identify women who are approaching the time of their annual review to invite them into clinic without the need for GP referral

Non-engagement with the annual review will be highlighted and the GP informed.

Clear information will be given to the GP and the woman taking valproate on the risks of continuing treatment without the pregnancy prevention programme in place.

Advice from the MHRA on the management of non face-to-face appointments to complete the annual review has also been encompassed within the pathway. This process will document confirmation of completion of the ARAF form and receipt of the patient education materials

Conclusions/Next steps

- The new valproate pathway aims to ensure prescribers of valproate adhere to the MHRA regulations to reduce human suffering and cost
- Women will only be treated with valproate in a way that safeguards the health of unborn children
- Valproate related risk forms in other languages and easy read format are pursued through MHRA to leave no woman behind because of language barriers
- Co-production in the design of the pathway ensured that the solution was not only clinician-driven, but patient focussed
- The digital design of this project is being shared with Acute Trusts across Surrey to ensure no pregnancy is exposed to valproate
- Digital design of this project was a finalist in the HSJ patient Safety Award 2021
- Our vision is to create a patient-centric App that can function outside any EPR system to communicate and collect valproate specific information reducing inequalities that arise due to multiple EPR systems within the NHS.

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