Prescribing psychotropic medications in women of childbearing age

by **Dr.Eshe Douglas-Winchester, Dr.Yu Yu Htwe** and **Dr.Oyindamola Ogunwale**

Abstract

Psychotropics can have serious side effects for women of childbearing age.They should be counseled on the risks before being prescribed these medications.

In this clinical audit of 174 women focusing on these five medications (Sodium valproate, Carbamazepine, Lamotrigine, Lithium, Paroxetine), most were not informed about the importance of contraception or the need for annual reviews.

The audit recommends that a risk assessment form be developed and used to ensure that women are adequately informed before and after being prescribed psychotropics. Clinicians should also be trained on how to conduct risk assessments.

Background

Pre-conception advice is particularly important where

- Medication is associated with early teratogenicity.
- Adverse effects associated with the use of anticonvulsant mood stabilisers, such as valproate or carbamazepine, which may have occurred before confirmation of pregnancy.

Aim

To address the following (4) questions by reviewing documents on Rio and EPMA

- Risk of teratogenicity to foetus if they become pregnant.
- Need to consult if they are wishing or planning to become pregnant
- Need for Annual review.
- Need for effective contraception

*Do you use or plan to use any contraception? If not, do you have plans to see a doctor or a contraception clinic?

Methodology

Age
18-51*
(Not included - paediatric population, patients who are pregnant, had a hysterectomy prior to starting medication or breast feeding)

Drugs Included
Valproate, Lithium, Carbamazepine, Lamotrigine, Paroxetine

Data from:
inpatient and outpatient units from EPMA and RIO

Time Period
2022 March 1 - Sep 30

In vast majority **71.73% (137)**, were not informed of **the risk of teratogenicity** regarding the five medications.

only **28.27% (54)** were informed.

71.58 % (136) were not informed about **importance of being on an effective contraception** while using the above-mentioned medications

Only **28.42% (54)** were appropriately advised.

77.66% (146) were not informed about **annual review.**

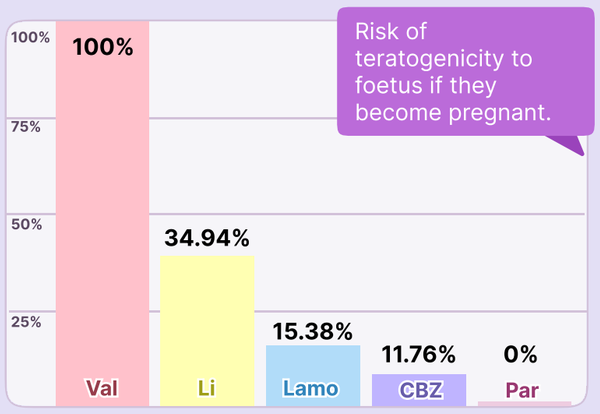
22.34 % (42) were informed.

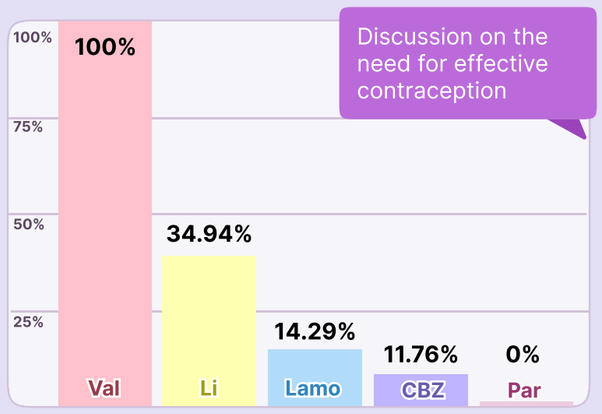
84.90% (163) are not **currently on contraception.**

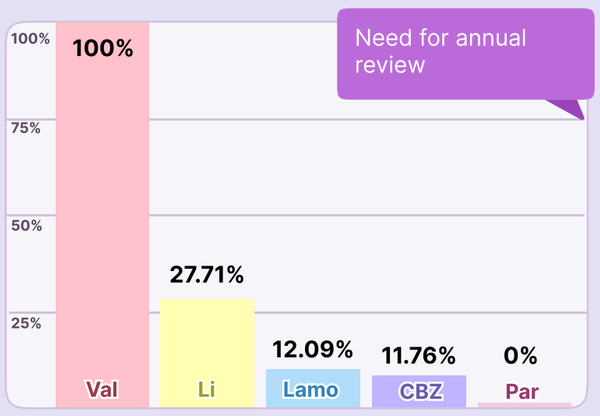
15.10% (29) are on contraception. Yet some of them became pregnant while on medication.

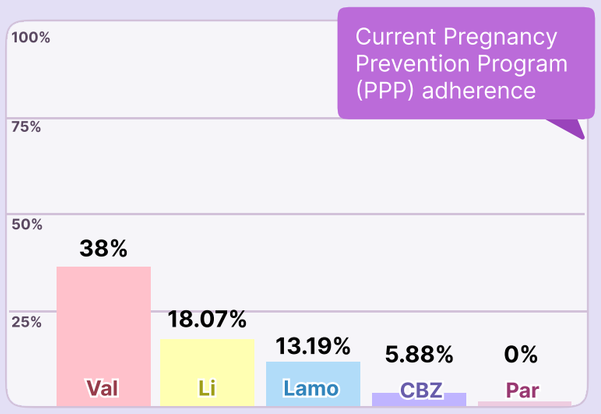
Even though lithium and lamotrigine were most commonly prescribed, **sodium valproate** stood out as the **most compliant** with trust guidelines due to the nationwide implementation of the valproate risk assessment form. In contrast, **paroxetine's inadequate compliance** highlights the need for more attention and better clinical communication practices.

- Valproate **(Val)**
- Lithium **(Li)**
- Lamotrigine **(Lamo)**
- Carbamazipine **(CBZ)**
- Paroxetine **(Par)**





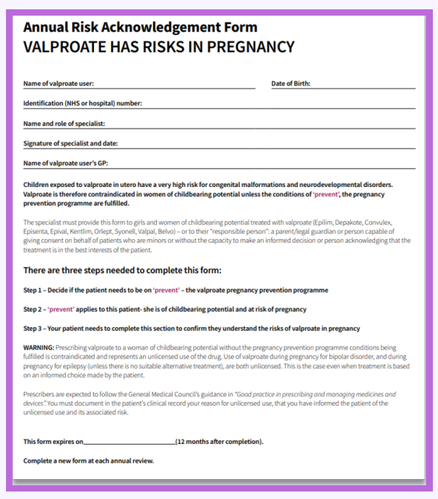




Recommendations

Women of reproductive age taking psychotropics should be informed of teratogenicity risk.

Further assessment and discussions on conception and pregnancy protection should be conducted to allow informed decision-making if pregnancy occurs in the future.



Annual Risk Acknowledgement Form
VALPROATE HAS RISKS IN PREGNANCY

Name of valproate user: **Date of Birth:**

Identification (NHS or hospital) number:

Name and role of specialist:

Signature of specialist and date:

Name of valproate user's GP:

Children exposed to valproate in utero have a very high risk for congenital malformations and neurodevelopmental disorders. Valproate is therefore contraindicated in women of childbearing potential unless the conditions of 'prevent', the pregnancy prevention programme are fulfilled.

The specialist must provide this form to girls and women of childbearing potential treated with valproate (Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Syonell, Valpal, Belvo) – or to their "responsible person": a parent/legal guardian or person capable of giving consent on behalf of patients who are minors or without the capacity to make an informed decision or person acknowledging that the treatment is in the best interests of the patient.

There are three steps needed to complete this form:

Step 1 – Decide if the patient needs to be on 'prevent' – the valproate pregnancy prevention programme

Step 2 – 'prevent' applies to this patient- she is of childbearing potential and at risk of pregnancy

Step 3 – Your patient needs to complete this section to confirm they understand the risks of valproate in pregnancy

WARNING: Prescribing valproate to a woman of childbearing potential without the pregnancy prevention programme conditions being fulfilled is contraindicated and represents an unlicensed use of the drug. Use of valproate during pregnancy for bipolar disorder, and during pregnancy for epilepsy (unless there is no suitable alternative treatment), are both unlicensed. This is the case even when treatment is based on an informed choice made by the patient.

Prescribers are expected to follow the General Medical Council's guidance in *"Good practice in prescribing and managing medicines and devices."* You must document in the patient's clinical record your reason for unlicensed use, that you have informed the patient of the unlicensed use and its associated risk.

This form expires on_____(12 months after completion).

Complete a new form at each annual review.

We want to **implement a similar template** that can be used for discussion by care providers along with a handy fact sheet that will cover the information and questions important to women of childbearing potential.

> "Our end goal is to transform this audit into **a quality improvement project** that ensures standards are maintained and improved outcomes for our service users."

Ref: BMSHFT Clinical guidelines – Prescribing for women of child-bearing potential
Sodium Valproate risk assessment form
BSMHFT Patient information leaflets

NHS
Birmingham and Solihull Mental Health
NHS Foundation Trust