

June 2017

Alert No: 29

## Valproate in female patients: HIGH RISK DRUG

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### Background

Valproate is a drug used in the treatment of epilepsy and of bipolar disorder. If taken during pregnancy, valproate can lead to foetal congenital malformations and developmental disorders.

### Incident

A female patient on an ELFT ward was commenced on valproate. Prior to starting the drug, a urine dip pregnancy test had indicated the patient was not pregnant. However, it was later discovered that the pregnancy test result was wrong; the patient was pregnant when valproate was started. When the patient's child was born, it was found to have cardiac abnormalities and facial malformations, likely related to *in utero* valproate exposure.

### Learning points

#### 1) Do NOT routinely prescribe valproate for women of childbearing potential or girls

- Valproate should only be used when alternative treatments are ineffective or not tolerated. If it is considered absolutely necessary to use valproate, prescribers MUST follow the recently updated ELFT ["Protocol for using valproate in women of childbearing potential and girls"](#).

#### 2) Use the available communication materials

- The ELFT protocol requires that the following resources be used when valproate is prescribed or dispensed:
  - [Information booklet for healthcare professionals](#)
  - [Information booklet for patients](#)
  - [Prescriber checklist](#)
  - [Patient consent form](#)
  - [Patient card](#)

#### 3) Pregnancy must be tested for by **blood test** before starting valproate

- Pregnancy tests rely on detection of hCG; which is released after a fertilised egg implants into the uterus.
- Implantation can take up to 12 days to occur following fertilisation; meaning there is a delay between the point of fertilisation and the point at which the pregnancy is detectable by hCG test.
- Additionally, early in pregnancy an hCG blood test is more likely to be accurate than a urine dip test.
- In light of these factors, the ELFT ["Protocol for using valproate in women of childbearing potential and girls"](#) has been updated, and now says that if there is any possibility a patient has recently been sexually active, valproate should not be prescribed until:
  - 14 days have elapsed since the last possible day on which the patient could have had unprotected sex (for example, this could be 14 days from admission or last unescorted leave), AND;
  - A negative hCG serum assay has been obtained after this 14 day period has elapsed.

#### 4) Patients who lack capacity

- The updated ELFT protocol states that, when a patient lacks capacity to consent to treatment:
  - Valproate should only be started on a psychiatric intensive care unit (PICU).
  - Valproate should be stopped before the patient is transferred out of PICU or given leave from the ward.

#### 5) Read the national alerts about valproate

- There has been a national effort to ensure staff and patients are made aware of the risks of valproate in pregnancy. Please ensure you read the following documents:
  - [MHRA Drug Safety Update: Valproate and risk of abnormal pregnancy outcomes](#)
  - [NHSI Patient Safety Alert: Resources to support the safety of girls & women treated with valproate](#)