CLINICAL ALERT

Quality and Safety

17 May 2013 **No: 15**

Prescribing sodium valproate to women of childbearing age

Sodium valproate is now well established as having teratogenic properties. Babies exposed to sodium valproate in utero have a 1.5% risk of neural tube defect compared with 0.08% in the general population. In addition, sodium valproate is associated with an increased risk of skeletal defects, hypospadias and heart defects. The reported rate for all malformations including neural tube defects is 5.7% compared with 1.5% for the general population. Furthermore, a relationship between sodium valproate exposure in utero and learning disability has been demonstrated. Lastly, moderate to severe facial dysmorphias are reported in 44% of babies exposed in utero and more recent evidence points to an increased risk of autism in exposed children.

Trust Audit findings of April 2013

Trust-wide audit of female in-patients of child bearing age prescribed sodium valproate:

- 13 % of female in-patients of child bearing age prescribed sodium valproate.
- 57% did not have a documented pregnancy test.
- 86% did not have a documented discussion regarding the teratogenicity and other effects on the developing foetus of sodium valproate exposure.
- 86% had not been provided contraception.
- 86% were not prescribed folic acid.

Good practice requires the following when sodium valproate is considered as a treatment for women of childbearing age:

Sodium valproate should not be used as first line treatment in women of child-bearing age.

If sodium valproate is prescribed then clinicians MUST:

- Have documented discussions with the patient about the risks to the developing foetus if taken while pregnant.
- Have documented discussions relating to using reliable contraception e.g. implant etc., even if the woman states she is not currently in a sexual relationship with a man.
- An assessment of capacity must be undertaken and documented with regard to consenting to taking sodium valproate and its inherent risks.
- The dose of sodium valproate should be limited to 1g/day, administered in divided doses and in slow release form only, with 5mg/day of folic acid. However, if this dose is ineffective then consideration has to be given to it being used at all as the risks to the developing foetus appear to be dose dependent.
- Women should be supported by clinical staff to access appropriate contraceptive advice e.g. attending GP, Family Planning and Sexual Health clinics.