



# Australian Pregnancy Register of Antiepileptic Drugs for Women in Pregnancy with Epilepsy and Allied Conditions

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## What is the Australian Pregnancy Register?

From previous research it is known that women with epilepsy who are taking antiepileptic medication have a slightly higher incidence than the general population of having babies with birth defects, 2-3% for the general population versus 4-6% for women with epilepsy on medication. Information from pregnancy registries is a valuable resource for the study of comparative risks and benefits of anti-epileptic drugs in pregnancy.

The Australian Pregnancy Register (APR) is an independent research project, supported by the Epilepsy Society of Australia, Epilepsy Australia, Epilepsy Action, Sanofi–Aventis, Janssen-Cilag, Novartis, Pfizer and UCB Pharma. The APR is affiliated with a similar project of EURAP (International Registry of Antiepileptic Drugs and Pregnancy). The research has been approved by the ethics committees of major hospitals.

The APR collects information about pregnant women with epilepsy, treated and untreated, to determine which antiepileptic medications are safest for the baby while protecting the mother from seizures. The APR collects information before and after the delivery on the mother's medical and family history, social and educational background, past pregnancies, and details about her epilepsy and its treatment. The APR also enrolls pregnant women who are taking antiepileptic medications for conditions other than epilepsy, such as for control of pain and treatment of mood disorders. Participation by pregnant women with epilepsy is voluntary.

Information is gathered from telephone interviews by trained nurses. Four interviews are conducted altogether: on enrolment, at seven months gestation, at one month post delivery, and at one year following delivery. During the interviews, women have the opportunity to ask any question relevant to the pregnancy and birth, their epilepsy and their antiepileptic medication.

The APR has information on over 1100 pregnancies. Results are published regularly. From the APR we now know that:

- over 95 per cent of pregnant women with epilepsy deliver a healthy baby, even under medical treatment
- if a woman is seizure-free for at least 12 months prior to pregnancy, her chance of remaining seizure-free during the pregnancy and delivery is significantly reduced
- sodium valproate in doses above 1100mg per day is associated with a greater risk of foetal abnormality than other antiepileptic drugs, however, sodium valproate in lower doses is a more effective in preventing seizures, especially in primary generalised epilepsy

Women should be treated with the best drug which controls their epilepsy, before and during pregnancy. Changing medications after conception runs considerable risk of breakthrough seizures, with its own risks to the mother and baby. Folic acid supplementation is advisable for all pregnant women, but it is not certain whether there is additional benefit in women with epilepsy. Pre-pregnancy counselling in women with epilepsy is strongly recommended.

## Journal articles published by the APR

Vajda, F.J., O'Brien, T., Hitchcock, A., Graham, J., Lander, C. & Eadie, M. (2007). [The Australian antiepileptic drug in pregnancy register: Aspects of data collection and analysis](#). *Journal of Clinical Neuroscience*, 14(10), 936-942.

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Vajda, F.J.E., Hitchcock, A., Graham, J., O'Brien, T., Lander, C., & Eadie, M. (2007). [The Australian Register of Antiepileptic Drugs in Pregnancy: The first 1002 pregnancies](#). *The Australian & New Zealand Journal of Obstetrics & Gynaecology*, 47(6), 468-474.

Vajda, F.J.E., O'Brien, T., Graham, J., Hitchcock, A., Lander, C., & Eadie, M. (2006) Pregnancies in women with epilepsy. *Journal of the Royal College of Physicians of Edinburgh*, 36, 201-207.

Vajda, F.J.E., Hitchcock, A., Graham, J., Solinas, C., O'Brien, T.J., Lander, C.M., & Eadie, M.J. (2006). [Foetal malformations and seizure control: 52 months data of the Australian Pregnancy Registry](#). *European Journal of Neurology*, 13(6), 645-654

Vajda, F.J., O'Brien, T.J., Hitchcock, A., Graham, J., Cook, M., Lander, C. & Eadie, M.J. (2004). [Critical relationship between sodium valproate dose and human teratogenicity: results of the Australian register of anti-epileptic drugs in pregnancy](#). *Journal of Clinical Neuroscience*, 11(8), 854-858.

Vajda, F.J., O'Brien, T.J., Hitchcock, A., Graham, J. & Lander, C. (2003). [The Australian registry of anti-epileptic drugs in pregnancy: experience after 30 months](#). *Journal of Clinical Neuroscience*, 10(5), 543-549.

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