

RGH Pharmacy E-Bulletin

Volume 44 (4): October 31, 2011

A joint initiative of the Patient Services Section and the Drug and Therapeutics Information Service of the Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia. The RGH Pharmacy E-Bulletin is distributed in electronic format on a weekly basis, and aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications.

Editor: Assoc. Prof. Chris Alderman, University of South Australia – Director of Pharmacy, RGH

© Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia 5041

Medication safety in pregnancy

In pregnancy, the use of medications (both prescription & over-the-counter) is often managed with great caution. The issue can be compounded by an increased need for medications, as pregnant women can be affected by ailments such as constipation, haemorrhoids, nausea, nasal congestion, heartburn, hypertension, oedema, and an amplification in general aches and pains. An increased risk of birth defects or miscarriage caused by drugs is a common concern for both parents-to-be and practitioners involved in their care. As such, information surrounding safety of drugs is paramount in minimising potential drug-induced harm to a pregnancy. The Australian Drug Evaluation Committee (ADEC) categorises drugs based on their safety in pregnancy. These categories serve as a good guideline, but sometimes conflict with statements in product information or other reliable sources. In Australia the background birth defect rate is approximately 3-5%. Medications are thought to account for less than 1% of all birth defects. Two simple principles to consider when deciding if a drug is safe to be used during pregnancy are the timing and size of a dose reaching the embryo or fetus.

Timing

The main consideration here is the number of weeks of gestation. The first two weeks post fertilisation, prior to organogenesis (i.e. 4 weeks gestation) is a vulnerable time for the developing embryo. At this time, the effects of maternal drug use can be considered to have an 'all or nothing' effect. If the drug is damaging, a miscarriage is possible, if not, the fetus is likely to develop as normal. It is important to consider the three trimesters, the organs and systems that are developing at various stages and the potential effects of drugs on these developments. The critical period for development of various organs is 2-8 weeks post-conception, but this may vary – for example doxycycline can be safely used in the first 18 weeks of gestation, before the teeth have begun to mineralise, but after this can cause discolouration of the teeth.

Dose

The most important dose to consider in pregnancy is the dose which reaches the fetus. Considering the route of administration and nature of the medication is important when predicting how much drug the fetus will be exposed to. A good example is Sofradex® ear drops (dexamethasone, framycetin & gramicidin), which when administered at appropriate and effective doses, does not reach high enough systemic concentrations to have any impact in pregnancy. This product is considered very safe for pregnant women, but still is ADEC category D suggesting potential for harm. In addition, drugs with a large molecular weight or which are highly protein bound in the mother's circulation are less likely to cross the placenta and enter the foetal circulation, and thus the potential for harm with drugs of this nature is also low.

Most medications which are teratogenic in humans are recognised and well understood. They produce predictable patterns of teratogenesis and wherever possible are avoided in pregnancy. However, maternal health is also an important consideration, and sometime the use of a known teratogen is considered to be unavoidable to sustain maternal health (e.g. in epilepsy). Quality use of medicines becomes especially important in pregnancy as a definitive indication is required to warrant the use of pharmacotherapy, especially if there is any risk (however small) to the developing fetus. The Organization of Teratology Information Specialists (OTIS) is a North American-based organisation with a website that provides useful fact sheets and information for the general public and health care professionals with regards to safety of medications, vaccines, herbal products and other common and environmental exposures in pregnancy. (<http://www.otispregnancy.org/>) In Adelaide, South Australia, the Women's and Children's Hospital pharmacy department run a medicines and drug information service for health care professionals and the general public to answer enquiries about the safety of medication in pregnancy, breastfeeding and paediatrics. They can be contacted on 08 81617222 during business hours.

Acknowledgment – This E-Bulletin is based on work by Nerida Grosser, Pharmacy Intern, RGH.

FOR FURTHER INFORMATION – CONTACT THE PHARMACY DEPARTMENT ON 82751763 or email: chris.alderman@rgh.sa.gov.au
Information in this E-Bulletin is derived from critical analysis of available evidence – individual clinical circumstances should be considered when making treatment decisions. You are welcome to forward this E-bulletin by email to others you might feel would be interested, or to print the E-Bulletin for wider distribution. Reproduction of this material is permissible for purposes of individual study or research.