

The risk of a baby being born with a congenital abnormality – the difference between relative and absolute risk

Have you been scared when you have read something that says “Taking drug X to help manage severe pregnancy sickness symptoms increases the risk of your baby having a congenital abnormality by 50%” This is an increase in “relative risk”

What you need to realise is that a 50% relative risk increase in a small absolute risk is still a small “ absolute “risk.

The risk of a baby being born with ANY congenital abnormality is quoted as being around 5% or 50 per 1000 births Some of these abnormalities are minor , for example skin blemishes, abnormalities of fingers and toes etc. Major congenital abnormality rates are quoted as 2-3% or 20 – 30 per 1000 births.

The quoted rates for severe congenital abnormalities are around:-

- Heart problems 6 per 1000
- Limb defects 4 per 1000
- Central Nervous system (CNS) problems 2 per 1000
- Cleft lip & palate 2 per 1000

Let us use these figures to illustrate 1000 women taking Drug X to manage their severe pregnancy symptoms where taking drug X is thought to give a 50% increased risk of having a baby born with cleft lip and palate. The major organ systems of the foetus develop in the first 12 weeks from Last Menstrual Period (LMP) of pregnancy. So it is taking drug X in the first 12 weeks from LMP that could cause foetal abnormalities. Medications taken after 12 weeks cannot usually cause major congenital abnormalities in any major organ system because these are already fully developed.

Among these 1000 women taking drug X compared with 1000 not taking drug X

	Taking Drug X	Not Taking Drug X
Babies born with heart problems	6	6
Limb defects	4	4
CNS Problems	2	2
Cleft Lip & Palate	3	2

So drug X which is thought to cause a 50% increased risk of cleft lip and palate would result in 1 extra baby to be born with a cleft for every 1000 women taking it to control their severe pregnancy sickness symptoms before 12 weeks of pregnancy. If drug X does help to manage their symptoms we might expect to prevent a number of women from having to terminate the pregnancy as well as making the pregnancies of many more manageable.