Medication use in early pregnancy- prevalence and appropriateness in a prospective cohort of women

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Introduction

Despite the thalidomide tragedy, medications have been found to be commonly used during pregnancy [1 2 3], with many frequently used medications having inadequate safety data [4].

Aims

This study aimed to determine the extent and nature of medication use in early pregnancy, exploring inappropriate exposures with potential for fetal harm and prescribing for known medical disorders.

Methods

A descriptive study was carried out using the electronic hospital records of women who had a delivery in the Coombe Women and Infants University Hospital, Dublin between 2000 and 2007.

The following were the main outcomes measures:

- prevalence of medication use for any indication
- inappropriate exposures with potential for fetal harm referenced against US FDA safety in pregnancy categories
- appropriateness of prescribing for chronic medical disorders referenced against clinical practice guidelines [5 6 7 8]
- maternal factors associated with medication use

Ascertainment of early pregnancy medication use was by maternal self-report, recorded as part of the booking interview carried out at the end of the first trimester by a midwife. Medications were recorded in the electronic records using both generic and proprietary names. All reported medications were converted to approved non-proprietary names and a medication dictionary was assembled that linked medication names to WHO Anatomic Therapeutic Chemical classification, FDA safety in pregnancy category and OTC status. Binary logistic regression was used to examine maternal factors associated potentially harmful medication use.

Ethical approval was granted by the hospital's Research Ethics Committee.

Results

Category D	Number (%)	Category X	Number (%)
Methadone	496 (0.81)	Oral Contraceptive	1614 (2.64)
Diazepam	188 (0.31)	Emergency Contraceptive	159 (0.26)
Paroxetine	125 (0.20)	Estradiol	80 (0.13)
Prednisolone	123 (0.20)	Flurazepam	26 (0.04)
Quinine	101 (0.16)	Clomifene	22 (0.04)
Valproate	82 (0.13)	Contraceptive Patch	21 (0.03)
Carbamazepine	77 (0.13)	Cannabis	18 (0.03)
Propylthiouracil	52 (0.08)	Cocaine	12 (0.02)
Atenolol	49 (0.08)	Medroxyprogesterone	11 (0.02)
Alprazolam	39 (0.06)	Atorvastatin	10 (0.02)

n=61252

Table 1. Most Common FDA Category D/X Exposures

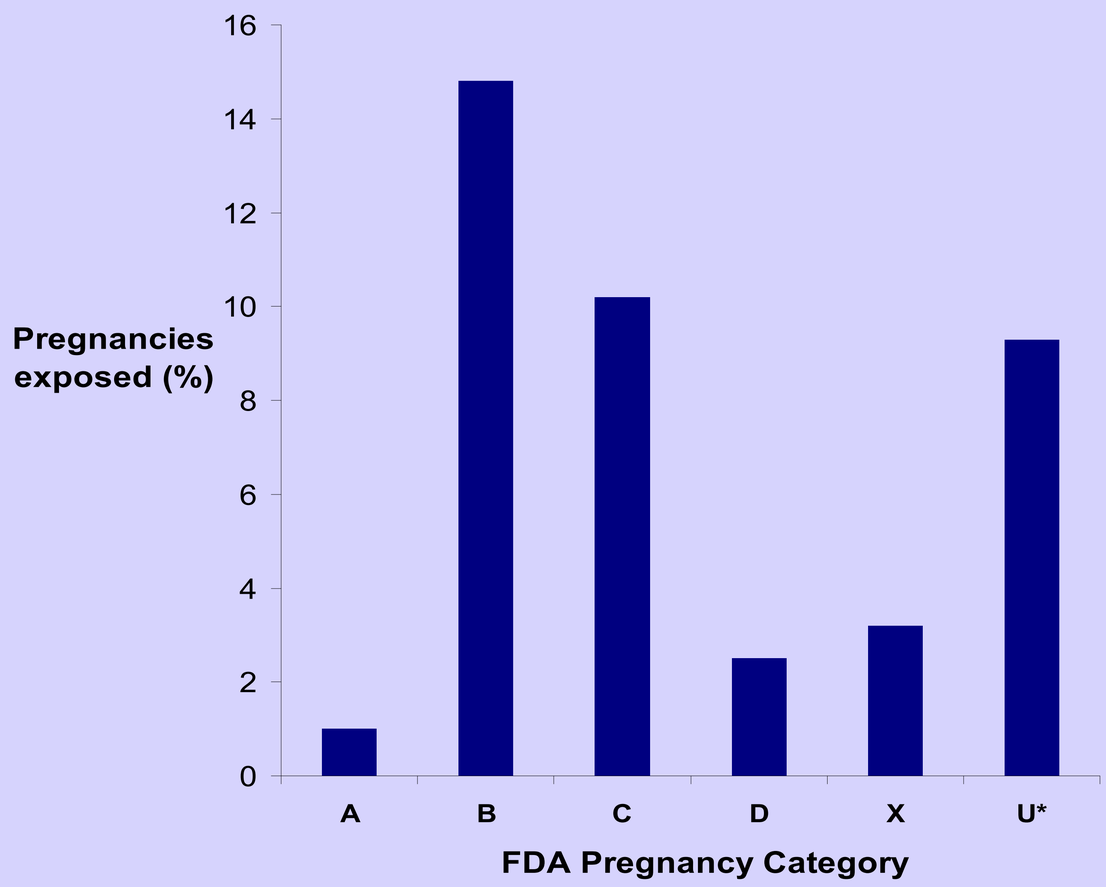
Results

The study included 61252 deliveries with antenatal and delivery suite records.

Prevalence of medication use:

- Any medication excluding folic acid 39.2%
- OTC medications 19.5%
- Illicit drugs or methadone 0.9%
- Herbal medicines/supplements 0.58%

FDA category D and X medications were reported in 2.5% and 3.2% of pregnancies. Excluding oral contraceptives, fertility treatments and progestogens, 2.4% and 0.1% of pregnancies were exposed to FDA category D and X medications. Table 1 and Figure 1 categorise medication use by FDA pregnancy category.



* medications not classified in FDA system. For definition of FDA safety categories, see Reference sheet.

Figure 1. Early Pregnancy Medication Use by FDA Pregnancy Category (excluding folic acid, vitamins and minerals)

Asthma, depression and hypertension were among the most commonly reported chronic medical disorders. Paroxetine was reported by 15.7% of women treated for depression. Atenolol and agents acting on the renin angiotensin system were reported by 20% of women treated for pre-existing hypertension. These medications are highlighted in guidelines as having potential for fetal harm [5 6 7 8].

Factors associated with reporting the use of medications with potential for fetal harm (FDA D/X excl. oral contraceptives, fertility treatments and progestogens) included unplanned pregnancy (odds ratio 1.71, 95% confidence interval 1.54 to 1.90), being unemployed (3.79, 3.23 to 4.45), single (2.36, 2.11 to 2.62), a publicly funded patient (1.56, 1.37 to 1.76) or smoking during pregnancy (3.45, 3.11 to 3.84).

Conclusions

- Four in ten women use medications besides folic acid in early pregnancy, with one in five using an OTC medication
- Women and prescribers need to be aware of the lack of safety data for many medications, and the need for pre-pregnancy planning
- Prescribers should ensure that optimal medications are used when treating women of childbearing potential with chronic medical disorders

References

Reference list and copy of poster attached.