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Adverse Drug Reactions in Neonates: comparing retrospective spontaneous yellow card reports to prospectively collected reports

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**Introduction:** The UK Medicines and Healthcare products Regulatory Agency (MHRA) encourages the reporting of all adverse drug reactions (ADRs) in children that are ‘serious or result in harm’ (1). The rate of under-reporting of ADRs has been estimated to be approximately 94% and neonatal ADR reports are not influencing the clinical warnings issued by the MHRA (2) (3).

**Aims:** To compare reports of neonatal ADRs actively collected by a researcher from a tertiary neonatal unit to those reported to the UK yellow card system between 2001 and 2010.

**Methods:** An independent researcher collected data on ADRs in a tertiary neonatal care unit by daily ward round attendance, note reviewing and staff questioning. The results collected over four weeks were then compared to the yellow cards submitted to the MHRA between 2001 and 2010 by means of reviewing a recently published paper (3).

**Results:** Between 2001 and 2010 there were ninety seven yellow card reports of neonatal ADRs to the MHRA. Over a four week observational period thirty three neonatal ADR cases were suspected and reported by a researcher. The highest number of yellow card reports were for swine flu vaccinations (eight), whereas the researcher only collected one report relating to a vaccine, with the highest number of reports involving diuretics or antibiotics (six each). The yellow card reports most frequently reported rashes or erythema (twenty one) whereas the researcher most frequently reported electrolyte disturbances (seven), cardiac effects (five) or gastrointestinal effects (five).

**Conclusion:** There are a number of differences between neonatal ADRs reported to the MHRA and those occurring commonly. It is thought the predicted under-reporting of ADRs and lack of knowledge or attention to neonatal ADRs may be contributing to this.

References:

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