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Adverse Drug Reactions and Off-label and Unlicensed Medicines in Children: A Prospective Cohort Study of Unplanned Admissions to a Paediatric Hospital

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Aims

We examined the impact of off-label and unlicensed (OLUL) prescribing on adverse drug reactions (ADRs) causing unplanned admissions to a paediatric hospital. We hypothesised that off-label and unlicensed prescribing may be a risk factor for ADRs.

Methods

Prescription data from a twelve month prospective cohort study of ADRs detected in children admitted to a paediatric hospital were scrutinised. Clear definitions of off-label and unlicensed medicine use were established, allowing medicines to be classified systematically. The relative risk for OLUL medicines being implicated in an ADR was calculated. Logistic regression analysis was carried out with exposure to OLUL medicines included as one of the predictor variables.

Results

Off-label or unlicensed medicines were more likely to be implicated with an ADR than an approved medication (relative risk 1.67; 95% CI 1.38, 2.02). Logistic regression analysis indicated that there was a trend towards an increased ADR risk with exposure to an off-label or unlicensed medicine (odds ratio 1.414; 95%CI 0.926, 2.158).

Conclusion

In a heterogeneous population of children admitted to hospital, off-label and unlicensed medicines are more likely to be implicated in an ADR than approved medicines. Further work is needed to explore why off-label and unlicensed medicines may be more likely to be implicated in an ADR. It will be important to consider the ‘types’ of off-label and unlicensed medicine used and the characteristics of both the medicines implicated and the patients affected by ADRs.