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ADVERSE EVENTS ASSOCIATED WITH LABELED AND OFF-LABELED USE OF MEDICATIONS IN CHILDREN

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Backgrounds and aims: The lack of specific drugs and labeling recommendations for the paediatric population is a long-standing problem and predisposes children to adverse effects. The study aimed to determine: the incidence, pattern, seriousness and predictors of adverse effects associated with labeled and off-labeled use of medication in children.

Methods: A prospective and intensive surveillance was conducted over nine months. Adverse event to labeled and unlicensed or off-label use of medications was detected and assessed for their incidence, seriousness and predictors of adverse events. Seriousness was asessed by using E2A guidelines of ICH-GCP.

Results: A total of 1504 medications administered to the 388 enrolled patients. Of these, 232 (16%) medications were off-labeled use. Of the 82 adverse drug reactions (ADRs) reported from 58 patients, 53 (64.6%) and 29 (35.4%) were associated with labeled and off-labeled use of medications respectively. Incidence of ADR was found to be high with off-labeled use of medications (11.9% vs 4.2%). Antibacterials [27 (33%)] was the most commonly involved drug class. Skin and appendages [32 (31%)] was found to be the most commonly affected organ system. Thirty three (40.2%) ADRs were serious in nature. Patients aged 11-15 years [OR: 3.42 (0.67-17.3); $p< 0.16$), and administration of≥4 medications [OR: 1.17 (0.52-2.5); ($p< 0.69$) were the predictors of ADRs in children.

Conclusions: Incidence of adverse events was high for off-labeled use of medication. Patients aged 11- 15 years and receiving ≥4 medications were the predictors of ADRs in children.