

The Pattern of Off-label and Unlicensed Drug Use in Adult and Pediatric Patients in the Kingdom of Saudi Arabia: Multicenter Retrospective Study

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ABSTRACT

Background: Screening approved medications to identify therapeutics for drug repurposing is an effective tactic, and a deep research into off label drug use (OLDU) is required. Unfortunately, OLDU has not been extensively studied in Middle East. Our study aimed to evaluate the extent of OLDU in Saudi Arabia.

Methods: Retrospective study carried out for 12 months period at six tertiary hospitals in Saudi Arabia. Each prescription was evaluated as unlicensed or OLDU based on the product information or based on Food and Drug Administration (FDA) approval.

Results: A total of 288 prescriptions were analyzed, where the reasons for off-label prescribing were OLDU by indication (94.42%), OLDU by different age group (2.09%), and other reasons represented (3.48%). Adults/geriatrics (≥ 18 years) received (89.05%) of the orders, and children (1-11 years) received (7.78%) of the orders. Both adolescents (12-18 years) and neonates (1-29 days) received (1.42%) of the orders per each category, while infants (1 month-1 year) received (0.36%) of the orders. The therapeutic classes most often prescribed were antidepressants (21.88%), antidiabetics (17.71%), and atypical antipsychotics (10.06%).

Conclusions: Off-label prescribing was found in most adults/geriatrics suffering from depression, and diabetes mellitus. The most common reason for off-label prescription was off-label by indication. The results call for the need to conduct more studies with larger sample size, do more investigations on the OLDU in the whole kingdom, and develop policy for OLDU across hospitals.

Keywords: Off-label medication, Guidelines, Prescriptions

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