



Off-Label Medications in Pediatrics

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To the Editor: Many medications used in pediatrics lack documentation regarding dosage, efficacy and safety because of the inherent problems of conducting trials in children. As a result, off-label use of drugs in this age group is common.

“Off-label” use refers to use of drugs not included in the package insert; not mentioned for a particular age, route of administration or duration; or not mentioned in the IAP Drug Formulary. Recent updates, not cited in standard textbooks, may also amount to ‘off-label’ use. However absence of labeling for specific age groups or specific disorder does not mean that the drug use is improper, as it may be due to lack of sufficient evidence [1]. A large number of medicines used in children are with reference to data extrapolated from adults.

Antibiotics are often prescribed “off-label” with regard to age, dosing and frequency of administration. Clinical trials that inform neonatal and pediatric antibiotic labeling are scanty. Overall incidence of using unlicensed antibiotics is around 11.4% and off-label prescribing is 46.6% [2]. This raises concern in the light of emerging multidrug-resistant pathogens.

Thirty-five percent of prescriptions for allergic disease were considered off-label; majority in children under 2 [3].

Off-label prescribing of antiepileptic drugs (AEDs) is common in pharmaco-resistant epilepsy. Conventional AEDs have limited efficacy in refractory neonatal seizures, resulting in use of newer agents, despite a lack of information about their safety or efficacy.

Studies show that at least 78% of pediatric cardiac cases receive one or more off label drugs; 31% receiving 3 or more [4].

In pediatric psychiatric patients, 32.3% prescriptions were off-label, 41.6% receiving at least one off-label prescription; most frequent category being low age [5].

Off-label medications are also common in pediatric gastroenterology and pediatric rheumatology.

Rational use of off-label medications may be permitted if it is of benefit to the child. Therapeutic decision-making should always be guided by the best available evidence. Larger clinical trials in children and establishment of regulatory bodies are need of hour for safe use of these medications in children.

Compliance with Ethical Standards

Conflict of Interest None.

References

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