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Review Article

Off-label medications in pediatrics

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ABSTRACT

Usage of off label medications in infants, children and adolescents, is an important public health issue that needs to be addressed. An overwhelming number of drugs are prescribed in every pediatric specialty without proper labeling that is essential to ensure child safety. The problem is larger and more complex in the cases of medications used in neonates, infants and children with chronic and/or rare disease. The article also emphasises that off-label use is often acceptable and is often necessitated because of a lack of gold standard drug trials in this age group.

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1. Introduction

Governmental authorities in each country are supposed to assess the safety, efficacy, and quality of each drug prior to approval for its sale in the market. At the end of this process, pharmaceutical companies are granted market authorization, and the drug gets a license for marketing in the country. The drug also has a label (i.e., drug monograph), specifying the details for the drug use (i.e. target population, dose, indication, specific use).¹ Many of the medications currently used in paediatric age group are lacking documentation regarding the dosage, efficacy and safety as performing clinical trials of new medications in children is always practically difficult due to various reasons. As a result, off label use of drugs has been extensive in paediatric population. It is acceptable to use drugs off label and to publish results related to off-label use, but it is not acceptable to receive remuneration from the sponsor for these uses.

“Off-label” use refers to use of a drug that is not included in the package insert for that drug and not mentioned for

a particular age, route of administration or duration or not mentioned at all in the IAP Drug Formulary (Table 1). Very recent changes in recommendations or guidelines, not followed in practice due to lack of awareness also may amount to ‘off label’ use. However, absence of labeling for specific age group or for a specific disorder does not necessarily mean that the drug’s use is improper for that age or disorder, as it may be due to lack of sufficient evidence.² Guidelines as in IAP Drug Formulary do not regulate the use of drugs. Therapeutic decision-making is guided by the best available evidence and the importance of the benefit for the individual patient.

1.1. Off label use of antibiotics in pediatrics

Antibiotics are the most commonly prescribed drugs in children and off label prescription is very common due to various reasons like prescribing for younger age, prescribing off-label doses, and prescribing at an off-label frequency of drug administration.³ Though few antibiotics have been labelled for the use in paediatric patients, many others such as fluoroquinolones, azithromycin, linezolid, or daptomycin are still being prescribed in an off-label manner.^{4,5} This raises concern in the light of emerging multidrug-resistant

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pathogens.

In NICUs,^{6–9} around 50% of antibiotic use is off label; unlicensed use was 11.6% and 78% of off label use are due to prescriptions outside recommended dose — usually at a higher than recommended dose to ensure efficacy regardless of safety concerns. Other off label use is for off label indications and dosing interval. In the newborn the most common off-label drugs prescribed was ampicillin and gentamicin. The other antibiotics implicated were cefotaxime, vancomycin and amikacin.

In children^{6,10,11} off label antibiotic use ranged from 20-70% in various studies; off label dosing was around 20-25% for ceftriaxone and vancomycin in treatment of LRTI, meningitis and sepsis, 21-24% for off label indication when prescribing cefotaxime and ceftriaxone for surgical prophylaxis and meningitis.⁶ Highest off label use of antibiotics was in children aged less than 2 years^{10,11} and when a child needed in-patient treatment for 6 to 10 days.¹¹ Overuse of IV antibiotics, antibiotics for URTI and misuse of third-generation cephalosporins in management of LRTI in children is rampant even today.¹²

1.2. Off label prescription for asthma and allergy

A large percentage of prescriptions performed for allergy treatment in daily clinical practice are off label. Asthma management guidelines give specific advice on medications and associated doses to be used for children, but make allowances for consultant paediatricians to increase these doses. 35% of prescriptions for allergic disease were considered off-label and majority are frequently in children under the age of 2.¹³ In studies with prospective design, incidence of ADR in off-label drugs ranged from 2 to 39%.¹⁴ Expert Panel Report 3 (EPR-3) endorses LABA in persistent asthma, if not controlled with ICS, but states not to be used <4yr age. GINA alerts that LABA are not approved under the age of 5 and advise the use of anti-leukotrienes (ALT) as an alternative. Off-label use of LABA remains high >30 % under 4's usage for severe asthma not controlled with ICS with or without ALT. Similarly, for treatment of allergic rhinitis, majority of intranasal corticosteroids and some of the anti-histamines lack paediatric approval and this are recognized by the guidelines. These drugs are recommended for children by extrapolation from pharmacological and clinical data in adults. Intranasal Mometasone is approved to use in children above 2 years by US FDA but in Europe it is recommended only after 6 years of age. Intranasal Fluticasone is used in children above 4 years of age but the product leaflet says it is recommended only above 6 years.¹⁵

Worse levels of self-reported asthma control by children and adolescents less than 16 years age when asthma medications were used off label — 6.1% reported more night time, daytime and activity asthma symptoms, and used more short-acting beta2-agonist medication than their

peers.¹⁶

1.3. Off-label prescribing of antiepileptic drugs (AED)

1.3.1. Pharmaco-resistant epilepsy

Off-label prescribing of AEDs is common among patients with pharmaco-resistant epilepsy and is influenced by demographic and disease-related characteristics. In a large Italian cross-sectional study among children with pharmaco-resistant epilepsy, 53 % of children were found to be receiving at least one off-label AED prescription. Among that, clobazam (100 %), lamotrigine (79 %), vigabatrin (55 %), ethosuximide (46 %), and levetiracetam (43 %) were most frequently used off-label, with indication or age being the main causes depending on the specific AED. Higher rates of off-label use were associated with polytherapy regimen, having failed with ≥3 AEDs, generalized epilepsy with structural/metabolic or unknown etiology and increasing seizure frequency.¹⁹

1.3.2. Neonatal seizures

Conventional AEDs have limited efficacy in medically refractory neonatal seizures. Pediatric neurologists recommend treatment of medically refractory neonatal seizures with newer agents, despite a lack of information about their safety or efficacy in this population. 73% of pediatric neurologists recommend treatment of neonatal seizures with one or both of levetiracetam and topiramate. Both are found to be equally effective but adverse events are noted more with topiramate.²⁰

1.4. IVIG for neurological or neuromuscular conditions

IVIG is used as on label and off label (Table 2) in acute disseminated encephalomyelitis (ADEM), adrenoleukodystrophy (ALD), amyotrophic lateral sclerosis (ALS), autism, chronic inflammatory demyelinating polyneuropathy (CIDP), critical illness polyneuropathy, diabetic neuropathy, CNS vasculitis, encephalitis, epilepsy, Guillain-Barré syndrome (GBS), inclusion body myositis, intractable childhood epilepsy, multiple motor neuropathy (MMN), multiple sclerosis, myasthenia gravis (MG) including Lambert-Eaton myasthenic syndrome, opsoclonus-myoclonus, paraproteinemic neuropathy, paediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS), Bickerstaff encephalitis, dermatomyositis (DM), Rasmussen's encephalitis, stiff person syndrome and transverse myelitis.^{21,22}

1.5. Pediatric migraine

Even though migraine significantly impairs quality of life, many children do not receive appropriate treatment as specifically approved drugs are much less in children

Table 1: Reasons for off label use of medications

Off label use	Example
Dose	Low doses of Amoxicilin for respiratory tract infection
Age	Valaciclovir – “safety and effectiveness in children has not been established”
Indication	Azithromycin, used for anti-inflammatory effect in cystic fibrosis
Route	Tobramycin injection used as inhalation in cystic fibrosis

Table 2: Indications of IVIG in neuromuscular disease conditions

First line treatment in	Off label
GBS	Off label
MMN	FDA approved
CIDP	FDA approved
Second line treatment in	Off label
CIDP	Off label
DM	Off label
MG	Off label

Table 3: FDA approved antipsychotic medications and corresponding conditions for youth

Antipsychotic	Age group (years)	Approved conditions
Haloperidol	3+	Psychosis, Tourette syndrome, agitation
Chlorpromazine	6 months-12 years	Severe behavioural problems, schizophrenia, bipolar disorders
Chlorprothixene	6+	Schizophrenia
Perphenazine	12+	Psychosis
Prochlorperazine	2+	Psychosis
Pimozide	12+	Tourette syndrome
Trifluoperazine	6+	Psychosis
Thioridazine	2+ 12+	Severe behavioural problems, psychosis Schizophrenia/ psychosis, depressive disorders
Thiothixine	12+	Psychosis
Paliperidone	12+	Schizophrenia
Asenapine	10+ 6-17	Bipolar disorder Irritability in autism
Aripiprazole	10-17 13-17	Bipolar acute phase Schizophrenia
Olanzapine	13-17	Bipolar acute phase, schizophrenia
Quetiapine	10-17 13-17	Bipolar acute phase Schizophrenia
Risperidone	5-17 10+ 13+	Irritability in autism Bipolar mania Schizophrenia

Table 4: Common paediatric off label applications for approved medical devices¹⁷

Device category	Common labelled indications	Off label applications
Dilatation balloons (angioplasty, valvuloplasty)	Valvar pulmonary stenosis, iliac, femoral, popliteal and renal artery stenosis	Pulmonary artery stenosis, valvar aortic stenosis, coarctation of aorta, pulmonary or systemic vein stenosis
Embolization coils	Arterial and venous embolization	Patent ductus arteriosus occlusion
Stents (biliary, coronary)	Malignant neoplasms of the biliary tree, abrupt/ threatened closure of coronary lumen	Pulmonary artery stenosis, conduit stenosis, coarctation of the aorta, stenting of patent ductus arteriosus, pulmonary or systemic vein stenosis
Cutting balloon	Obstructive lesion of arteriovenous dialysis fistula	Pulmonary artery stenosis and creation of atrial septal defect
Radiofrequency perforation wire	Creation of atrial septal defect	Perforation of atretic pulmonary valve

Table 5: Off-label and on-label use of certain drugs in dermatology¹⁸

Drug	Off label Use Relevant to Dermatology	On label use Relevant to Dermatology
Acyclovir	Laser resurfacing, prophylaxis, Chemical peel, Wire-brush surgery	Herpes genitalis, simplex & zoster prophylaxis Varicella – treatment
Cimetidine	Urticaria, acute in combination with an antihistamine; Warts	
Clindamycin topical	Eczema, infected Folliculitis caused by <i>S. aureus</i> .	Impetigo, localized caused by <i>S. aureus</i> and beta-hemolytic streptococci, including <i>S. pyogenes</i>
Corticosteroids	Pemphigoid Sarcoid, localized cutaneous Vitiligo	Many inflammatory diseases are listed as corticosteroid responsive.
Dapsone	Actinomycotic mycetoma; Cicatricial pemphigoid – desquamative gingival lesions; Dermatitis, subcorneal pustular Granuloma annulare; Lupus erythematosus, systemic – certain skin lesions; Pemphigoid lesions with oral manifestations Polychondritis, relapsing Pyoderma gangrenosum	Leprosy (Hansen’s disease) in combination with other agents Dermatitis herpetiformis
Methotrexate	Dermatomyositis, systemic (polymyositis) Sarcoid Vasculitis	Mycosis fungoides, advanced Numerous cancerous conditions Psoriasis, severe, resistant, recalcitrant, disabling
Isotretinoin	Acne, less severe than nodular Folliculitis Fordyce disease Severe rosacea including nodulocystic rosacea and rosacea refractory to oral antibiotics; Hidradenitis suppurativa; Severe keratinization disorders such as ichthyosis & keratosis follicularis (Darier’s); Pityriasis rubra pilaris	Acne vulgaris – severe recalcitrant nodular

compared to adults. Off-label medications were found to be prescribed 1.5 times more than FDA approved medications for children (60.34% vs 39.65%). NSAIDs like ibuprofen or naproxen are often prescribed but are not approved for migraine. Other off label medications used are calcium channel antagonists like verapamil, antidepressants, anti-seizure medications other than topiramate, beta-blockers other than propranolol, vitamins like vitamin B2, minerals like magnesium, coenzyme Q10, melatonin, cyproheptadine and IV steroids for severe intractable migraine.²³

1.6. Off-label prescription of psychopharmacological drugs in child and adolescent psychiatry

In a cross-sectional study of inpatients and outpatients less than 17 years of age, receiving medical treatment with antidepressants, antipsychotic agents, benzodiazepines, melatonin and/or attention deficit hyperactivity disorder (ADHD) medication (Table 3), 32.3% prescriptions were off-label, and 41.6% received at least 1 off-label prescription; in 72.2% the off-label category was for low age. Off-label rates for various drug classes were as follows: melatonin, 100%; antipsychotic agents, 95.6%; benzodiazepines, 72.5%; antidepressants, 51.1%; and ADHD medication, 2.7%.²⁴

1.7. Off label prescribing in paediatric cardiology

Many barriers exist to conducting paediatric cardiovascular trials, and the majority of therapies used are not evidence based. Studies show that at least 78% of patients receive one or more and 31% get 3 or more off label drugs. The most commonly used cardiovascular medications were furosemide, epinephrine, dopamine, lidocaine and milrinone.²⁵

1.8. Off label use of medical devices in paediatric interventional cardiology

Majority of medical and surgical instruments do not have approval for use in pediatric population; and the challenges of paediatric device development has led to the widespread and necessary practice in pediatric cardiology and cardiac surgery of using devices for “off-label” or “physician directed” applications that are not included in FDA-approved labelling.²⁶ This practice is common and often appropriate, even with the highest-risk (class III) devices (Table 4).

1.9. Off-label medications in paediatric gastroenterology

About one-half of the medications prescribed by a paediatric gastroenterologist are either off-label or unlicensed. It is often because there is no other alternative.

Five most common pediatric gastroenterology diagnosis for which off label medications were prescribed are gastro-oesophageal reflux disease, constipation, and inflammatory bowel disease, triple therapy for helicobacter pylori and malabsorption /nutritional deficiencies. Most commonly used unlicensed medications include cisapride, omeprazole suspension, mercaptopurine liquid and glyceryl-trinitrate ointment whereas commonly used off label medications are domperidone, ranitidine, omeprazole, azathioprine, tacrolimus ointment, metronidazole, mesalazine, polyethylene glycol, paraffin oil and tripotassium dicitratobismuthate.²⁷

1.10. Off-label medications in pediatric rheumatology

Without off-label use of prescription products, the therapeutic options for many rheumatologic conditions are vanishingly few. Among autoimmune rheumatic diseases, systemic sclerosis has the single highest mortality rate but still there is no FDA-approved therapy for systemic sclerosis. Hence off-label use of drugs like cyclophosphamide, mycophenolate mofetil, and methotrexate are routinely used by rheumatologists.²⁸ Infliximab and adalimumab are routinely used to treat uveitis that is idiopathic or secondary to underlying diseases such as juvenile inflammatory arthritis, sarcoidosis, tubulointerstitial nephritis and uveitis syndrome, and Behcet's disease.²⁹ Patients with moderate to severe or refractory juvenile dermatomyositis often benefit from IVIG. Unfortunately, randomized clinical trials testing IVIG in children with juvenile dermatomyositis have not been reported.³⁰ Methotrexate is a first-line agent and the standard of care for a large number of rheumatologic conditions but is only FDA approved for three (rheumatoid arthritis, psoriasis and polyarticular juvenile rheumatoid arthritis).

1.11. Off-label medications in pediatric dermatology

A recent study concluded that it is currently within the standard of care to use off-label prescriptions in treating dermatologic disease.³¹ Table 5 details of off label and on label use of drugs in dermatology.

1.12. Off-label medications in palliative care³²

1.12.1. Anorexia

Anorexia may be helped by prednisolone or dexamethasone. A trial of steroids may be appropriate.

1.12.2. Anxiety

Relief of anxiety can be provided by long-acting benzodiazepines such as diazepam or by continuous infusion of short-acting benzodiazepine like midazolam. Interventions for more acute episodes of anxiety (such as panic attacks) include short-acting benzodiazepines

such as lorazepam given sublingually or midazolam given subcutaneously. Temazepam provides useful night-time sedation in some children.

2. Conclusion

As long as we do not have sufficient pharmacokinetic, pharmacodynamic and pharmacotherapeutic studies of drugs used in pediatric specialities, there is bound to be rampant use of medications off label, especially in neonates and young children. Pediatric drug formularies like IAP Drug Formulary find it a herculean task to detail both evidence based and off label indications for some medications; pediatricians are therefore often left with no option but to be guided by best available data to make an informed clinical decision in a given case.

2.1. Points to remember

1. Off-label medication use is a major concern in paediatric age group.
2. A large number of medicines are used in children by various sub specialties with the reference of data extrapolated from studies in adult population.
3. It is not wrong to use off-label medications but it has to be rationalized and the whole purpose should be to benefit the patient.
4. Therapeutic decision-making should always be guided by the best available evidence.
5. Larger clinical trials in children and establishment of regulatory bodies are need of hour for safe use of these medications in children.

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None.

4. Conflict of Interest

None.

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