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Off Label Medication and Use of Unapproved Drugs

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Review Article

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ABSTRACT

Off-label means the medication is being used in a way not specified in the approved packaging label. Every prescription drug has an approved individual label for that particular disease it's meant for. This label is a written format that helps in providing detailed directions and instructions regarding the approved uses and doses based on clinical studies that the drug manufacturer submits to the FDA before the manufacturing begins. Off-label drug use has been recognised as one of high risk drug prescribing because of lack of necessary information regarding safety of drug and its effectiveness. Even though sometimes Off-label prescribing is good and it's beneficially in treating different disorders, especially when all other approved drug use by particular patient has shown tolerance and there is no other option of treating patient with approved drugs. For this review the data was compiled in a format for better understanding of the off label use of drugs both by physicians and pharmacist. Some of the drugs used for off label purpose includes Minoxidil which is a Vasodilator but is actually also used for hair growth for people suffering from hair loss. Likewise many drugs like Aripipazole, Gabapentin, Amitriptyline, Propranolol, Risperidone, Sildenafil, and Clonidine have off label use which is showcased.

INTRODUCTION

Off-label means the medication is being used in a way not specified in the approved packaging label [1,2]. Every prescription drug has an approved individual label for that particular disease it's meant for. This label is a written format that helps in providing detailed directions and instructions regarding the approved uses and doses based on clinical studies results that the drug manufacturer submits to the FDA [3-8]. Off-label drug use has been recognised as one of high risk drug prescribing because of lack of necessary information regarding safety of drug and its effectiveness [9-14]. Even though sometimes Off-label prescribing is good and it's beneficially in treating different disorders, especially when all other approved drug use by patient has shown tolerance and there is no option of treating patient with approved drugs [12-15]. There is a research that shows that even physician may not be aware of off label drug prescribing practice, this lack of practice results in increased risk of harmful effects and keeps patient at high risk. These problems may increase if the patient is child and it results in active physiological changes in quick manner than in adults (Table 1).

FACTORS AFFECTING OFF LABEL DRUG USE (OLDU)

Some of the consequences that affect the use of Off Label drugs are their approval and the role of FDA and pharmacist in acknowledging community about off label drugs use. OLDU offers elective treatment choices to doctors and patients, and like every single such practice, it includes risks and as well as benefits ^[16-23] (**Table 2**).

Approval

Beneficial uses of medications might be designed for new drug use before the regulatory approval process has been finished ^[24-25]. However the manufacturer of drug may seek FDA approval for a new indication for a current medication by documenting a supplemental New Drug Application. It means a medication could be affirmed for an OLDU ^[26-28]. Also, the drug manufacturer risks in identifying the efficacy of the drug as well as new toxicity while the clinical trials are going, which would be hindered.

Table 1. The above table gives an idea about some of drugs being also used for their off label use along with their label use.

| DRUG | LABELLED USE | OFF LABELED USE |
|-----------------------------|--|---|
| Aripipazole | Anti-psychotic | Dementia, Alzheimer's disease, Anti-depressant, in schizophrenia. |
| Propranolol | High blood pressure, heart disease | Stage fright |
| Topiramate | Antiseizure in combination with phenteramine for weight loss | Bipolar disorder, depression, nerve pain, alcohol dependence, eating disorders |
| Gabapentin | Antiseizure | Nerve pain caused by diabetes, migraines, hot |
| Minoxidil | Arterial vasodilator | To promote hair growth |
| Risperidone | Antipsychotic | Alzheimer disease, dementia, eating disorders, post-traumatic stress disorder. |
| Trazodone | Anti-depressant | Insomnia, anxiety, bipolar disorder. |
| | | |
| Sildenafil | Antihypertensive | To enhance sexual performance in people not diagnosed with erectile dysfunction, to improve sexual function in women taking certain antidepressants |
| Quetiapine | Antipsychotic | Dementia, Alzheimer's disease obsessive compulsive disorder anxiety post-traumatic stress disorder |
| Prazosin | High blood pressure | Post-traumatic stress disorder |
| Amitriptyline | Antidepressant | Fibromyalgia, migraines, eating disorders, pain after shingles infection |
| Atorvastatin Simvastatin | High cholesterol in adults, children with an inherited cholesterol condition | Rheumatoid arthritis, to lower cholesterol in children who lack the inherited condition |
| Clonidine | Anti-hypertensive | Smoking cessation, hot flashes, attention deficit/hyperactivity disorder (ADHD), Tourette's syndrome, and restless legs syndrome, as antidote in organo phosphorus poisoning. |
| Olanzapine | Antipsychotic | As Anti-depressant, in schizophrenia |
| Warfarin | Anti-coagulant | As anti-hypertensive |
| Diclofenac | NSAID | Used along with amitriptyline in chronic pain associated cancer patients |
| Deplcote | Antipsychotic | As an anti-seizure |

Table 2. Risks and benefits of OLDU.

| Risks | Benefits |
|---|--|
| OLDU results in many ADRs than on label use. | Despite the risks, off-label use can afford benefits to patients and physicians to improve therapy. |
| Risks occur in populations where they have not undergone testing. | Some of the off-label uses have come to represent the accepted standard of practice. |
| OLDU can be beneficial and lifesaving for some patients, in most cases, there is little or no scientific evidence to prove the work | OLDU is beneficial, especially when patients have exhausted all other approved options, as may be the case with rare diseases or cancer. |

Moreover, a generic drug manufacturer might not have the financial resources to undertake satisfactory clinical trials [29-31]. In addition, a few medications are getting approval and acceptance for previously off-label uses [32-35]. FDA has prerequisite role in limiting the prescribing of all common available drugs in several ways. First one is to bring changes in drug labelling along with warnings. It can make clear note to physicians that necessary caution is required [36-38].

The FDA may consider undertaking new activities in regulating and managing off-label use, including efficiently collecting post marketing surveillance observations to measure the harmful and beneficial effects of common off-label uses [39-42].

Role of Pharmacist

Harmful effects of medication and drugs can be reduced in the consumers and patients through effective working of pharmacists as well as pharmacovigilance group in the health care system to ensure the safety of medicines [43-46]. Majority of medications and drug use have been banned since 2-5 years in developed countries but are still available for sale in some parts of world. The manufacturing and selling of many drugs used as single dosage as well as dose that are in fixed combinations has been also banned [47-51]. Adverse drug reactions of some off label drugs were still not been reported and they are still sold in market. Here comes the vital role of pharmacist in good label practice, patient guidance, safety and adverse drug issues [52-56]. To make it more effective there is an urgent need of establishing a policy for multidisciplinary approach towards drug safety that can be effectively implemented throughout the entire duration spanning from drug discovery to usage by consumers [57-62].

The major role of the FDA's authority has to limit the promotion of off-label use as well as their expansion in to other alternative outlets like social media, which results in more problems like makes misunderstanding and also misinformation about off-label drug use [63-72]. All these circumstances can be sorted properly by perfect involvement of pharmacists who helps in accurate information and gives valuable counselling services to prescribers as well as patients [73-82]. Pharmacist can full fill the substantial gap of knowledge among patients about the process of drug approval and its risks, benefits [83-88]. It is necessary responsibility of the pharmacist to be aware of the drug indications and whether it is FDA approved for that particular indication [89-91].

CONCLUSION

The fact that off label drug use is most normal in vulnerable populations like paediatric patients, elderly patients and patients with rare diseased conditions like cancer makes it necessary to monitor its use [92-94]. The drugs should be used only under complete supervision of physician or prescriber as well as pharmacist to avoid adverse unwanted effects otherwise it becomes self-medication which is a risky practice [95-97]. Pharmacist who is involved in health care system should be able to educate drug consumers visiting the pharmacy in every aspects like good label practice, patient counselling, providing adequate information regarding ADRs in the form of written slips posters and leaflets, as well as he should assistant pharmacists, pharmacist should refresh and update his

views and knowledge regarding recent advancements and changes in drugs and pharmaceutical sciences [98-100]. Apart from these, regulatory affairs have to take strict actions regarding use of approved and non-approved medications.

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