

Med. Pharm. J. Original article

# Pharmacists' and Parents' Awareness and Attitudes Toward Off-Label Drug Prescribing in Pediatrics, Zawia (Libya)

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DOI: [10.55940/medphar2025116](https://doi.org/10.55940/medphar2025116)

Submitted: 12-May-2024

Accepted: 30-Mar-2025

Published: 02-Apr-2025

## ABSTRACT

**Background:** Off-label medicine prescriptions—where medications are used in a manner not specified in the official labeling—are commonly practiced across the globe, particularly in pediatric care. However, many of these prescriptions are made without adequate clinical evidence to support their safety and efficacy in children.

**Objective:** This study aimed to assess and compare the knowledge, awareness, and perspectives of both pharmacists and parents regarding the off-label use of medications in pediatric patients.

**Methods:** A descriptive cross-sectional survey was conducted over a three-month period, from January to March 2023, targeting pharmacists and parents residing in Al Zawia city. Data collection was carried out through a structured questionnaire, which was divided into two main sections: one for pharmacists and one for parents. The instrument was carefully designed based on prior validated studies and was translated into Arabic to facilitate comprehension and encourage prompt responses. The questionnaire collected both demographic information and opinions related to off-label drug use in children. A total of 150 participants were enrolled, including 100 parents and 50 pharmacists. The surveys were self-administered, with each taking approximately five minutes to complete. Participants were randomly selected to ensure a representative sample.

**Results:** Analysis of the collected data revealed a relatively high level of awareness and understanding among both pharmacists and parents regarding the concept and implications of off-label drug use in pediatric populations. Pharmacists demonstrated a more in-depth knowledge, likely due to their professional background, while parents showed a basic yet important awareness of the subject. Most respondents expressed concerns about the lack of proper guidelines and scientific validation for such prescriptions.

**Conclusion:** The findings suggest that there is a commendable level of knowledge and awareness among both pharmacists and parents concerning off-label prescribing for children. This highlights the importance of ongoing education, clear regulatory policies, and open communication between healthcare professionals and caregivers to ensure safe and effective pediatric pharmacotherapy.

**KEYWORDS:** Awareness and Attitudes, Cross-Sectional Studies, Off-Label Drugs, Pharmacists, and Parents.

## INTRODUCTION

It's common to characterize the off-label use of medications in pediatrics—that is, the prescription of drugs that are not approved for a certain age or form of application—as an ethical dilemma [1–3]. According to empirical research, using medications in children off-label dramatically raises the likelihood of an adverse drug reaction. Since there are significant differences between adults and children, as well as between children of different ages, regarding pharmacodynamics and pharmacokinetic responses to medications, the validity of this approach is called into doubt [4,5]. According to some research, off-label drug use is linked to adverse drug reactions, endangering the patient's safety. Most doctors view off-label medication as appropriate, think the advantages outweigh the dangers, and even seem to have little comprehension of the potential outcomes, with little concern about the possibility of adverse effects, untested efficacy, and problems involving informed consent [6,7]. For instance, children with chronic renal insufficiency frequently experience arterial hypertension. They require long-term antihypertensive therapy with medications, although they have not yet been licensed for use in children [7,8]. Angiotensin-converting enzyme inhibitors, such as captopril, enalapril, and Ramipril, are the first-choice medications. Given the lack of pediatric clinical trials, the dosage used is based on adult experience. According to empirical research, using medications in children off-label dramatically raises the likelihood of an adverse drug reaction [9,10].

The US Food and Drug Administration (FDA) has only allowed a drug to be marketed for the list of "on-label" indications for which it has been approved since 1962. However, doctors are free to recommend any drug that has been approved for any use. "Off-label" use is typical and possibly beneficial in the pharmaceutical industry, which generated \$321.3 billion in sales in the US in 2010, accounting for 2.2% of US GDP [11,12]. Utilizing a medication off-label may be necessary to provide the best care for a patient's unique indication. Additionally, because FDA-approved medications have previously passed safety standards in clinical studies, repurposing them for new purposes could be an especially cost-effective form of innovation. However, unsuccessful off-label use is wasteful from a social perspective. Off-label use has occasionally also resulted in patients suffering physical injury [13–15]. According to research, 74% of pediatricians said they knew little about this procedure. Compared to their primary care counterparts, specialists were more familiar with the term "off-label prescribing" [16–18]. Antibiotics, for example, can save the lives of children and pregnant women when used outside the prescribed dosage. Many diseases lack approved treatments, in part due to the difficulty of conducting clinical trials or the rarity of the conditions or because it may not be profitable to market a treatment for them. Off-label use is generally accepted as legal unless it violates moral principles or other safety laws. Off-label drug use is ethical and acceptable as long as reliable

data and evidence support it. Many prescription and over-the-counter medications are used quite successfully off-label [19]. Furthermore, careless drug usage can lead to resource waste, increased resistance to infections, serious health hazards, chronic pain, a rise in adverse drug reactions and interactions, and delays in receiving the appropriate treatment after mistakes have been made [20]. The sale of antibiotics without a prescription increases the likelihood that people won't take them as prescribed and promotes poor medication choices. Many local pharmacies dispense antibiotics without a prescription, which is against strict regulatory requirements [21,22]. Clinical pharmacists are aware of the common underlying mechanisms, but in recent years, there has been an increase in interest in how pharmacogenetics contributes to the clinical significance of interactions [23]. Several international studies have confirmed the crucial role that chemists play in implementing and providing pharmacogenomic services, including promoting the use of PGx in healthcare settings, establishing, selecting, recommending, and ordering PGx tests, performing PGx sampling and testing, recommending pharmacotherapy based on PGx results, optimizing medications, therapeutic drug monitoring, and adjusting dosage based on PGx results, educating other medical professionals about PGx. [24,25]. Therefore, the dispensing chemist plays a crucial and often overlooked role in evaluating a prescription drug objectively while keeping the patient's best interests in mind [26,27]. A chemist can assess a prescription drug's suitability from several perspectives, including safety, efficacy, legal framework, and ethical

considerations. Physicians and chemists must collaborate effectively to produce outcomes that safeguard patients. The pharmacist is responsible for administering medication, the doctor for prescribing, and the pharmacist serves as the final barrier between the patient and therapy [28,29].

**Objective of study** to evaluate the knowledge and views of pharmacists and parents regarding the off-label use of drugs in pediatric patients.

### **MATERIALS AND METHODS**

A cross-sectional study based on a questionnaire was conducted from January to March 2023. The questionnaire consisted of two parts, addressing the awareness and attitudes of pharmacists and parents toward off-label drug prescribing in pediatrics. The survey participants were randomly selected from parents and pharmacists in Al Zawia city. The self-administered questionnaire was adapted from previous studies, and we employed simple statistical analyses.

The questionnaire for the first part, tailored to pharmacists, included demographic data and questions specific to their expertise. The second section focused on parents' demographic data, as well as their knowledge and views regarding the off-label use of medications in children.

In this study, 150 samples were collected from 100 parents and 50 pharmacists. The questionnaire forms were created in Arabic for all participants (parents and pharmacists) to ensure quicker responses. Each survey took approximately 5 minutes for participants to complete.

### **RESULTS**

Fifty of participants were pharmacists who completed the questionnaire and were included in the final analysis. The

participant characteristics of the pharmacists included 68% female and 32% male, with a mean age of 30-60 years and 1-5 years of experience (Table 1).

**Table 1: Demographic data of pharmacists**

Variables	Number (%)
Female	34 (68%)
Male	16 (32%)
Mean age 30-60 years	50 (100%)
Years of experience 1-5 years	50 (100%)

Regarding knowledge of off-label drugs, 88% of pharmacists possessed knowledge, while 12% lacked it. For the meaning of off-label drug dose, age, and uses, 88% responded affirmatively, and 12% responded negatively. For the first time, you knew the meaning of an off-

label drug: 42% during the study and 58% during work. For having enough knowledge about off-label drugs for children, 44% said yes, 20% no, and 36% not sure. Through your experience, what did you notice? Forty-four percent of the children were treated safely, 48% experienced side effects, and 8% had treatment failure. For those worried about prescription off-label drugs for children, 84% said yes and 16% said no see Table 2.

For parents, there were 61% females and 39% males, with a mean age between 30 and 60 years old. The educational level of most participants was a diploma, higher diploma, or bachelor's degree Table 3.

**Table 2: Knowledge of pharmacists about off label**

Variable	Response	Number (%)
Awareness/Knowledge of Off-Label Drugs	Awareness or Knowledge	44 (88%)
	Lack of Awareness or Knowledge	6 (12%)
Do you know the meaning of off-label drug dose, age, and uses?	Yes	44 (88%)
	No	6 (12%)
When was the first time you knew the meaning of an off-label drug?	While studying	21 (42%)
	During work	29 (58%)
Do you have enough knowledge about off-label drugs for children?	Yes	22 (44%)
	No	10 (20%)
	Not sure	18 (36%)
Through your experience, what did you notice?	The child was treated safely	22 (44%)
	Side effects	24 (48%)
	Treatment failure	4 (8%)
Are you worried about prescription off-label drugs for children?	Yes	42 (84%)
	No	8 (16%)

**Table 3: Demographic Data of Parents**

Variable	Response	Number (%)
Gender	Female	61
	Male	39
Mean age	30-60	100
Educational level	House wife	4
	Secondary school	4
	Diploma	16

	Higher diploma	18
	Bachelors	40
	Master	10
	PhD	8

For parents to be aware of off-label use, all participants understand that there is a difference between medicines for children and adults. For reading the instruction leaflet before you give your child a prescribed drug, 73% always, 16% sometimes, and 11% never. For knowing there are off-label drugs or unlicensed doses, age, and uses, 60% said yes and 40% said no. For concern about the safety and efficacy of the drug, 54% said yes,

29% said no, and 17% said sometimes. For worrying about the danger of drugs to the child, 64% said yes, 25% said no, and 11% said sometimes. When asked if they would ask the doctor or pharmacist about the seriousness of this drug, 60% said yes, 23% said no, and 17% said sometimes (Table 4).

**Table 4: Knowledge of Parents About Off-Label Drug Use**

Variable	Response	Number (%)
Did you know that there is a difference between medicines for children and adults?	Yes	100
	No	0
Do you read the instruction leaflet before you give your child a prescribed drug?	Always	73
	Sometimes	16
	Never	11
Did you know there are off-label drugs or unlicensed doses, age, and uses?	Yes	60
	No	40
Are you concerned about the safety and efficacy of the drug?	Yes	54
	No	29
	Sometimes	17
Do you worry about the danger of drugs to the child?	Yes	64
	No	25
	Sometimes	11
Do you ask the doctor or pharmacist about the seriousness of this drug?	Yes	60
	No	23
	Sometimes	17

**DISCUSSION**

This study examined pharmacists' knowledge of off-label use. We found that there were more female pharmacists than male, as in Zawia, more females studied in the pharmacy faculty. Additionally, according to another study, the majority of students in the pharmacy

faculty in Zawia were female [27,30]. Most of the pharmacists had good knowledge about off-label use; during work, they knew the child was treated safely and worried about prescription off-label drugs for children because they knew the side effects of drug use. Community chemists need to



comprehend the problems associated with off-label drug usage to ensure public health and safe medication use [31,32]. According to a study conducted in Italy, pediatricians were well aware of the detrimental effects of off-label drug use [33]. In contrast to other healthcare professionals, community chemists do not acquire as much expertise during their undergraduate studies or through their experience [34]. Most respondents acknowledged that they had learned about off-label prescribing through their experience dispensing rather than through formal undergraduate or graduate education, which is comparable to what general practitioners have described [35]. Most of the participants' parents were female, and most had a high level of education. There were 100 participants in total. All the participants know there is a difference between medicines for children and adults; most read the instruction leaflet before giving their child a prescribed drug, there are off-label drugs or unlicensed doses, age, and uses, and they are concerned about the safety and efficacy of the drug and ask the doctor or pharmacist about the seriousness of this drug because most of them had a good educational level and knowledge about off-label [36]. The majority of parents believed that doctors should inform them about off-label medications, but there should be uniformity in the information provided by different medical professionals regarding the use of off-label medications, without creating ambiguity or confusion, to prevent adverse effects [37].

Their high level of confidence in their medical profession may be the reason for this finding. These findings underscore the importance of improving

communication between parents and medical staff, particularly those with higher-level titles, when off-label prescriptions are being prescribed. Various informed consent procedures have been proposed in Australia based on varying degrees of evidence about off-label medication [38–44].

Eighty percent of the parents who responded to the study emphasized that physicians should first weigh the risks of off-label medications. Every patient is different when using medications off-label, and the risk-benefit analysis should be based on high-quality research [45,46]. The prescriber can critically evaluate therapeutic studies to determine the "strength of evidence" and assess whether the research findings apply to the specific circumstances of each patient. Many studies have linked off-label medications to an increased risk of adverse drug reactions, raising concerns about their safety [11,45–50].

## **CONCLUSION**

The pharmacists and parents demonstrated a good understanding of the dispensing of off-label medicines to children. Awareness regarding off-label prescribing in children remained high among most study participants.

## **Recommendation**

There are advantages and disadvantages to using off-label medications. Data on safety, efficacy, and manufacturing procedures must be thoroughly reviewed before drugs and the FDA can approve therapies. Although it can be expensive and time-consuming, this procedure ensures that patients receive drugs that are as safe and effective as possible. Off-label pharmaceutical use has hazards but can be beneficial for your care in some

circumstances. The off-label drug may exacerbate pre-existing medical issues or interfere with other prescriptions you use. Finally, before considering taking an off-label medicine, it's wise to critically assess online claims and review all the advantages and disadvantages with your healthcare team.

## ACKNOWLEDGMENT

None

## Funding

None.

## Author contribution

A.F.S. contributed to data collection, analysis, and manuscript drafting as part of her academic research; S.A. and E.A.B. were responsible for the study design, supervision, and critical revision of the manuscript; E.A.B. contributed to data interpretation and manuscript review.

## Ethical approval

The University of Zawia's College of Pharmacy Ethics Committee granted ethical approval for this study under approval number 2023-024 in accordance with the Helsinki Declaration.

## Conflict of interest

None

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## How to cite this article:

**Amir S, Beshna EA, Sulayman AF.** Pharmacists' and Parents' Awareness and Attitudes Toward Off-Label Drug Prescribing in Pediatrics, Zawia (Libya). *Med Pharm J*. 2025; 4(1): 1-9.

DOI: [10.55940/medphar2025116](https://doi.org/10.55940/medphar2025116)

Available from: <http://pharmacoj.com/ojs/index.php/Medph/article/view/116>