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Awareness and Experience of Using Off-label Drugs by Doctors and Pharmacists in Libya

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ABSTRACT

Background: The off-label use refers to the administration of an authorized medicinal product in a manner not specified in its official labeling. This practice raises significant legal, ethical, and safety concerns, particularly given its widespread prevalence. However, many healthcare professionals have limited awareness of the definition, scope, and clinical implications of off-label drug use. This study aimed to assess the knowledge and perceptions of pharmacists and physicians regarding off-label drug use in Libya. Methods: A prospective, questionnaire-based cross-sectional study was conducted among doctors and pharmacists in Libya. A total of 374 licensed Libyan healthcare professionals were targeted between September 2024 and March 2025. Results: 160 participants were included in the final analysis. Most respondents were female (n=106, 66%), with pharmacists and clinical pharmacists constituting the majority (37% and 23%, respectively). Additionally, 131 participants (82%) were affiliated with tertiary care settings, and most had 1-4 years of work experience (n=110, 69%). Only 69 respondents (44%) were aware of the correct definition of off-label drugs, particularly pharmacists and clinical pharmacists (p=0.02 and p=0.002, respectively). Off-label prescriptions were reported by 63 respondents (43%), with a higher prevalence among males (p=0.002). A significant proportion of participants were unaware of any institutional or national policies regarding off-label prescribing (64% and 72%, respectively). Concerns about the efficacy and safety of off-label prescribing were prevalent (61% and 68%, respectively). Notably, 62% of respondents reported encountering adverse drug reactions related to off-label prescriptions. Furthermore, 131 participants (82%) emphasized the importance of pharmacist involvement in off-label drug use decisions. Conclusion:

These findings underscore the need for targeted educational interventions and formal regulatory guidelines to promote safer prescribing practices and improve patient outcomes, particularly among physicians engaged in off-label drug use.

Keywords: Off-label Prescribing, OLDU, Off-label promotion, Patient Safety.

INTRODUCTION

The term Off-label drug use (OLDU) is widely referenced across medical literature, continuing medical education programs, and various media outlets. Yet, we propose that many health care professionals have an under appreciation of its definition, prevalence, and implications. (OLDU is defined as "drugs prescribed and used outside their licensed indications with respect to dosage, age, indication, or route" In other words, the off-label use refers to the use of an authorized medicinal product in an unauthorized manner. This raises many legal, ethical and safety issues, especially when taking into account the prevalence of this practice. Data from the literature show that in Europe 13–69% of medicines are used off label, especially in some medical fields such as pediatrics, oncology, neurology, orphan diseases, cardiology and ophthalmology [1], [2],[3]. Prescribing medications is acknowledged as a complex endeavor that requires continuous oversight and improvement. Furthermore, it relies on an understanding of clinical pharmacology principles, pharmacological expertise, and specifically the experience of the prescribing physician. Nonetheless, off-label prescribing poses issues, particularly in specific populations such as pediatric, pregnant, and elderly patients, due to the absence of randomized controlled trials in these demographics and the variability in medication metabolism. Use of off label or unlicensed drug to treat relatively is widespread[4], [5]. Off-label use of medication could represents a problem of safety for the patient and a legal risk for the prescribing physician if patients have an unwanted or bad outcome from treatment. There exists a deficiency in the harmonization of evidence, the information accessible to physicians, and its use in clinical practice, which contributes to the prevalence of off-label medicines. Efforts have been undertaken to enhance understanding of pediatric treatments; however, additional targeted interventions are required, particularly in light of the existing lack of harmonization[6],[7]. While off-label medicine use is justifiable, it can lead to various complications. Initially, off-label prescribing may compromise patient safety in specific therapeutic situations where a favorable benefit-risk ratio is not thoroughly validated. This mostly results from the absence of comprehensive evaluation of off-label drug use by regulators, guideline developers, or healthcare policymakers. Secondly, off-label usage presents liability concerns regarding adverse occurrences, rendering clinicians susceptible to possible legal repercussions[2].

The standards governing off-label drug usage have not been standardized globally. In certain industrialized nations, including the United States, France, and Britain, national laws, rules, or guidelines regarding off-label drug use have been instituted, permitting sensible off-label drug utilization in these countries[8],[9],[10]. Under US Food and Drug Authority (FDA) regulations, physicians are permitted to prescribe medications for off-label purposes; however, drug manufacturers are prohibited from promoting these usage [11]. A recent court ruling and state and federal legislation in USA have undermined regulations against the advertising of drugs for non–FDA approved reasons ("off-label promotion"), resulting in potential patient damage by allowing manufacturers to promote the use of insufficiently tested medications[12], some

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argue that professionals should be able to prescribe off-label appropriately without experiencing stigma or professional disapproval related to their practice [13].

According to European Union (EU) pharmaceutical legislation, it is prohibited to place on the market a medicinal product without a marketing authorization. As an exception, an unauthorized medicinal product can be used in order to meet the individual need of a particular patient or group of patients, but there is an explicit condition that the medicinal product is in the authorization procedure or at least in the clinical trial phase[14].The absence of regulations for off-label use has prompted certain EU nations to elucidate, regulate, and oversee this activity via guidelines or legislative amendments (e.g., the United Kingdom, Italy, France, Spain).The most studied pattern of prescribing is in the psychiatric and pediatric specialties[3]. While FDA publications do not enumerate off-label uses, several medication compendia encompass both labeled and off-label applications. According to the Social Security Act, "medically accepted indication" for Medicare coverage refers to uses that, in addition to those sanctioned by the FDA, have been assessed and endorsed in various compendia, or for which there exists "supportive clinical evidence in peer-reviewed medical literature[15].

In 2023, the FDA issued a draft guidance offering advice to corporations regarding provider-directed communication for off-label drug utilization. The agency recognized the utility of off-label applications of licensed medications for conditions lacking sanctioned treatments. Nevertheless, the regulator emphasized the necessity of preserving the accuracy of information regarding such applications, depending on comprehensive study data that delivers clinically pertinent insights[16]. The criteria for appropriate off-label drug prescription are most clearly described in German pharmaceutical law. According to the Declaration on Good Off-Label Use 6 Practice (GOLUP Declaration) developed by the expert group of the European Medicines Agency in 2016, the off label drug administration is considered reasonable subject to specific criteria[17] (Figure 1).

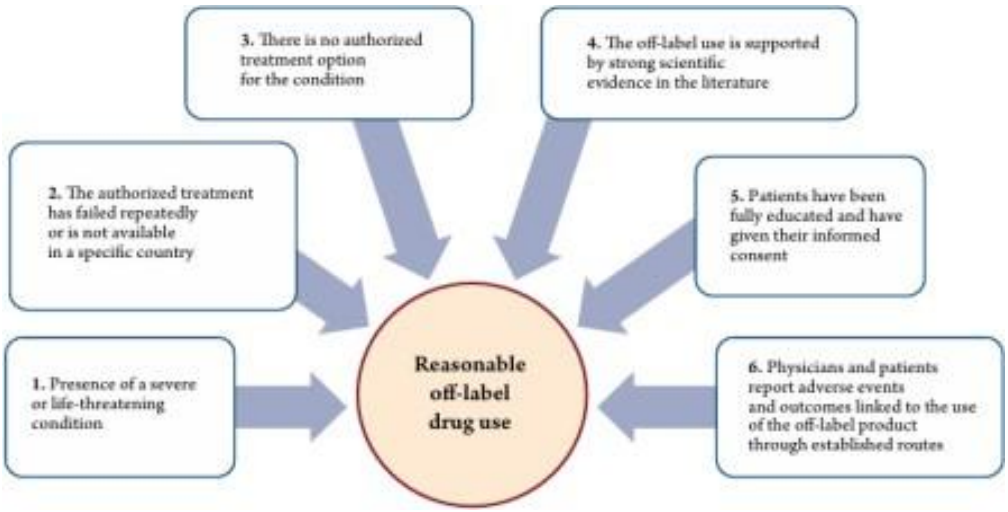

Figure 1: Criteria of reasonable off-label drug administration according to the Declaration on Good Off-Label Use Practices (GOLUP)

Examples of commonly utilized OLDUs exist in every medical discipline. Table 1 shows examples of common off-label uses of selected drugs according to Drug Facts and Comparisons

and published literature. The Libyan law lacks a specific delineation of off label prescribing. [18],[19],[20],[21],[22]. There is limited information available on the awareness and perspectives of physicians and pharmacists regarding off-label prescribing in Libya. To address this gap, our study aimed to evaluate the knowledge and attitudes of these healthcare professionals toward off-label drug use within the country. The results of this research are expected to contribute to the existing literature and support the development of targeted awareness and educational initiatives, ultimately enhancing off-label prescribing practices and promoting the safety of the pediatric population.

Table 1: Examples of Common Off-label Uses of Drugs

Category and drug	Off-label use(s)
Diphenhydramine	Chemotherapy-related emesis, insomnia
Propofol	Intracranial hypertension
GLP 1RA	Obesity
Dexamethasone, propofol	Postoperative nausea
Meperidine	Postanesthetic shivering
Amiodarone	Supraventricular tachycardia
Aspirin	Antithrombosis in atrial fibrillation, Kawaskai disease
Atorvastatin, simvastatin	Extended-interval dosing for hyperlipidemia
Indomethacin	Pharmacologic closure of patent ductus arteriosus
Azathioprine	Atopic dermatitis, pemphigus; psoriasis
Erythromycin	Gastroparesis
Omeprazole	Reflux-related laryngitis
Alendronate	Hypercalcemia of malignancy
Magnesium sulfate	Premature labor
β-Blockers	Social phobia, public speaking
Citalopram	Alcoholism, irritable bowel syndrome, obsessive-compulsive disorder
Fluoxetine	Diabetic neuropathy, fibromyalgia, hot flashes, premature ejaculation
Trazodone	Insomnia in elderly patients
Sildenafil	Sexual dysfunction symptoms in women

A study has revealed that 50% of the psychiatrists frequently (very often or often) prescribe second-generation antipsychotics (SGAs) for off-label indications. Considering the very restricted array of approved treatments for Bipolar Disorder (BD), the off-label utilization of certain SGAs may be deemed suitable for individuals whose BD is refractory to drugs with established indications for the condition. Recent findings indicated that psychiatrists possessed awareness, although they exhibited varied views towards the prescription of off-label medications. Pharmacists' perceived responsibility and beliefs regarding off-label prescribing are insightful that can be utilized for improving patient care. In India, off-label prescribing is prohibited under the Amendments to the Indian Medical Council Act 2 2 [11], [23], [24],[25]. To mitigate liability, clinicians ought to prescribe drugs just for indications they deem to be in the patient's best interest. Moreover, healthcare providers must to familiarize themselves with OLDU to evaluate the associated risks and advantages, hence delivering optimal care to their patients. In 2019, Mei M. and his team revealed that although Pediatric off-label drug use is widespread in Shanghai, China, enhanced education and training on off-label drug utilization should be administered to certain healthcare providers[1], [2].

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Researchers from Russia, performed a survey in 2021 targeting physicians in clinical specialties, identifying their need for information regarding the hazards associated with the off-label use of medications in clinical practice. In 2022, Saudi investigators Alyami, D. and colleagues determined that off-label drug use among pediatric patients is prevalent in the Kingdom of Saudi Arabia, and healthcare personnel treating children are cognizant of the notion of off-label pharmaceuticals[4], [17].

Off-label prescriptions are challenging to monitor, as prescribers typically annotate "off- label" only in rare instances. Globally, many examples of off-label prescribing are available in the real-world practice. Off-label use of Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) like Semaglutide, Liraglutide, Dulaglutide and Tirzepatide for non-diabetic weight loss (which regulators have linked to social media promotion) created worldwide supply shortages. Although the FDA has approved three GLP-1 RAs for weight reduction, many of them are still used off-label by healthcare practitioners. Metformin's off-label uses encompass the management of gestational diabetes, the mitigation of weight gain associated with antipsychotic medications, the prevention of type 2 diabetes, and the treatment and prevention of polycystic ovarian syndrome (PCOS) [26],[27], [28].

OLDU is prevalent. In 2006, Radley and colleagues revealed that 21% of prescriptions within a cohort of frequently utilized drugs were for off-label purposes. The off-label utilization of antidepressants, anticonvulsants, and antipsychotics is significant and more common among older patients. β-adrenergic antagonists are frequently given for off-label indications, with specialists more often recommending off-label β-blocker usage than primary care providers. Tricyclic antidepressants lack FDA approval for neuropathic pain treatment; yet, this drug class is regarded as a first-line pharmacological management option for neuropathic pain [29], [30], [31],[32].

Aspirin serves as an intriguing illustration of OLDU. Aspirin is presently licensed by the FDA for administration to patients experiencing pain, fever, rheumatic disorders, and cardiovascular conditions, including acute myocardial infarction, prior myocardial infarction, angina pectoris, and past cerebrovascular disease. Aspirin lacks an indication for cardiovascular disease prophylaxis in diabetic individuals, however recommendations advocate for its usage in this population. Aspirin prophylaxis for coronary disease in high-risk patients constitutes an off-label application [33]. In Libya, only one study, published in March 2025, has examined the awareness and attitudes of pharmacists and parents toward off-label drug prescribing in pediatric care. The findings indicate a noteworthy level of knowledge and awareness among both groups regarding the use of off-label medications in children. The aim of the study is to Awareness and Experience of using off-label Drugs by Doctors and Pharmacists in Libya.

METHODOLOGY

Study Design and Setting

A prospective questionnaire based cross-sectional study was conducted among physicians and pharmacists in Libya. Licensed Libyan physicians and pharmacist were included in the duration between September 2024 and March 2025.

Inclusion and Exclusion Criteria

Only licensed physicians and pharmacists were included in the study**.**

Sample Size Determination

A minimum sample size of 374 was calculated with the Raosoft® (© 2004 by Raosoft, Inc.) online calculator using the following parameters: 5% margin of error, 95% confidence interval for a target population of 2.2 million (According to World Health Organization (WHO), Libya – Health Indicators in 2024, No of Libyan physicians = 11163 and Pharmacists= 2232), and an estimated response distribution of 50% (35).

Data Collection Instrument

A validated modified self-questionnaire from a previous studies was used[2],[4],[17]. The questionnaire encompassed items related to demographic information, including years of professional experience, gender, medical specialty, and hospital level. Also, the questionnaire involved questions asking about awareness and experience with off-label drugs. An electronic Google Forms survey was used and distributed on different social media platforms such as WhatsApp, Facebook and Telegram. Features of Google Forms, such as "required to proceed" to ensure the study criteria would be fulfilled, were employed. The following question was provided at the beginning of the questionnaire: "Are you licensed doctor or pharmacist?" If the answer were "yes," the participant would continue to go through questions in the questionnaire; however, if the answer were "no," the questionnaire form would be submitted directly. All information will be kept private and used for scientific research. Informed consent were provided to all participants before filling out the questionnaire.

Data Analysis

The obtained data was statistically processed using the IBM SPSS Statistics 25.0 (USA) and Microsoft Office Excel software suites. The parameters was compared using the chi- square test. The differences were considered significant at $p < 0.05$. Adjustment for specific covariates was calculated by ANOVA, p-value ≤ 0.05 was considered significant.

Ethical Considerations

Study was presented for ethical approval by the Institutional Review Board. Approval was attained with the certificate Reference N0: MCP-2024-00271. The investigators have assert that all procedures contributing to this study comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975 and its later amendments. All information kept private and used for scientific research.

RESULTS

Table 1: Sociodemographic characteristics of study populations (n=160)

Variable	Frequency (%)
Gender	
Female	106 (66)
Male	54 (34)
Specialty	
Clinical Pharmacist	37 (23)
Dermatologist	1(1)
General Practitioner	5 (3)
Internist	4 (3)
Nephrologist	1(1)

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Obs&gnaecologist	1(1)
Pediatrician	4 (3)
Pharmacist	59 (37)
Surgeon	2 (1)
Others	46 (27)
Level of Hospital	
Primary	24 (15)
Secondary	5 (3)
Tertiary	131 (82)
Years of Experience	
≥15 years	9 (6)
10-14 Years	16 (10)
5-9 Years	22 (14)
1-4 Years	110 (69)

Sociodemographic Characteristics

A total of 160 participants submitted questionnaires through the Google form website. Most of the respondents were females (n=106, 66%, p-value= 0.001) (Table 2). Likewise, the majority of the respondents were pharmacists and clinical pharmacists (37%, 23% respectively, p-value= 0.05). However, 131 (82%, p-value= 0.00) of the participants affiliated with a tertiary care setting. The majority of participants were early-career healthcare professionals with 1-4 years of experience (n=110, 69%, p-value= 0.000).

Table 3: Awareness of physicians and pharmacists regarding off-label prescribing (n=160)

Variable	**Frequency (%)**
Off-label drug is defined as:	
Drugs prescribed and used outside their licensed indications with respect to dosage, age, indication or route	76 (48)
Drugs that are not approved for any indication by the Libyan Food and Drug Administration.	12 (8)
All of the above	69 (44)
Have you ever prescribed off-label drugs	
NO	97 (57)
Yes	63(43)
Are you familiar with the definition of off-label drug use	
No	64(40)
Yes	96(60)
How often do you prescribe drugs off-label?	
Frequently	19 (11)
Never	69 (43)
Occasionally	22 (14)
Rare	44 (28)
Very frequently	6 (4)
Do you consider your knowledge is adequate about the use of off-label drugs?	
No	20 (12)
Not sure	108 (68)

Yes	32 (20)
Would you like to get more information about the risks and benefits of off-label administration of drugs in clinical practice?	
No	14(9%)
Yes	146 (91%)
Is there any guideline or policy of off label use in your hospital?	
I Don't know	102 (64%)
No	33 (21%)
Yes	25 (15)
What is the process of off-label drug use in your hospital?	
Applying with relative information and evidence	36 (22)
Being approved by the ethics committee	39 (24)
Being approved by the pharmacy and therapeutic committee	19 (12)
I Don't know	52(33)
Monitoring the adverse reaction	9 (6)
Obtaining informed consent	5 (3)
Is there any law or regulation regarding off-label drugs in Libya?	
I don't know	115(72)
No	21(13)
Yes	24(15)

Table 3 illustrates the level of awareness among physicians and pharmacists concerning off-label prescribing. 69 of the participants (44%) correctly identified the definition of off-label drugs. The majority of the pharmacists and clinical pharmacists (98%) aware exactly what off-label prescribing is (p-value= 0.02, 0.002) respectively. There was no significant association between years of experience and awareness of the definition of off-label prescribing in the total sample (p-value =0.1). 63 (43%) of the respondents prescribed off label medication, however, males have prescribed off label more than female (p = 0.002). No significance in the association between prescribing off label medications and specialty (p= 0.66). 96 participants (60%) were familiar with the definition of off-label drug use. One third of the participants (52, 33%) don't know the process of off-label drug use in their hospital. The respondents stated that they don't know if there was a policy of off label prescribing in their hospitals or in Libya were (64%, 72%) respectively.

Table 4: Experiences of physicians and pharmacists regarding off-label medicines (n=160)

Variable	**Frequency (%)**
Are there any concerns about the efficacy of off-label prescribing?	
No, no concerns at all	15 (9)
Yes, major concerns	98 (61)
Yes, minor concerns	47 (29)
Are there any concerns about the safety of off-label prescribing to children?	
No, no concerns at all	14 (8)
Yes, major concerns	107 (68)
Yes, minor concerns	39 (24)
What are the risks associated with the use of off-label drugs?	
Adverse reactions	99 (62)

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Improper formulations	9 (6)
Increase of therapeutic errors	33 (21)
Inefficiency	15 (9)
No risk	4 (2)
What is/are the parameter(s) of the drug use that was/ were off-label (please select one or more)?	
Route of administration	4 (2)
Contraindications	30 (19)
Contraindications, Others	6 (4)
Dosage frequency	4 (2)
Indications	15 (9)
Indications, Contraindications	10 (6)
Others	12 (8)
Special population (pregnant women, elderly, etc.)	17 (11)
Special population (pregnant women, elderly, etc.), Contraindications	12 (8)
Special population (pregnant women, elderly, etc.), Indications, Contraindications	12(8)
Is it necessary for pharmacists to intervene when off-label drug use happen?	
No, it intervenes the normal routine	29 (18)
Yes	131(82)

Table 4 presents the experiences of physicians and pharmacists with off-label medications. Around two-thirds of the healthcare professionals (98, 61%) expressed significant concerns about the efficacy of off-label prescribing. Likewise, 107 respondents (68%) reported major concerns regarding its safety. 99 respondents (62%) encountered adverse medication reactions resulting from off-label medicine prescriptions. Notably, 131 (82%) of the participants claimed that pharmacist intervention is essential when off-label drug use is required

Table 5: Medications most commonly used in off-label prescribing (n=160)

Variable	**Frequency (%)**
Which drugs did you prescribe off-label?	
Valacyclovir	13(8)
Meropenem	6 (4)
Linezolid	6 (4)
Aspirin	8 (5)
Atenolol	2 (1)
Amitriptyline	5 (3)
Nortriptyline	6 (4)
Gabapentin, Topiramate	7 (4)
Lamotrigine	3 (2)
Carbamazepine	4 (3)
Sodium valproate	1 (1)
Acetylcysteine	16 (10)
Sildenafil	5 (3)
Propranolol	16 (10)
Antipsychotics e.g., risperidone	7 (4)
Olanzapine, quetiapine	2 (1)

The detailed analysis of the use of specific off- label drugs showed that they were used in 37 % of the cases to treat psychiatric and neurologic disorders. Other pharmaceutical drugs most frequently used off- label were Acetylcysteine (16 %), Propranolol (16 %), Val acyclovir (13 %), Aspirin (8 %), and Risperidone (7 %) (Table 5)

DISCUSSION

Healthcare professionals in Libya and around the world are increasingly confronted with ethical and professional obligations to promote and maintain safe medication practices. Therefore, it is essential to address the challenges associated with off-label prescribing. To the best of our knowledge, only one study has investigated the awareness and attitudes of pharmacists and parents toward off-label drug prescribing in pediatric care. In contrast, the present study explores the perspectives of healthcare professionals across various disciplines in Libya regarding medications off-label prescribing. We contemporaneously explored a range of healthcare providers in the Libya in terms of their views pertinent to the prescribing of off-label drugs. Our findings were consistent with earlier research conducted in other countries, indicating a prevalence of off-label drug usage and a significant familiarity among healthcare providers with the concept of off-label drug application[2],(36).

The findings indicate a high level of awareness among pharmacists and clinical pharmacists, with 98% accurately identifying the definition of off-label prescribing. This suggests that the concept of off-label drug use is well understood within this professional group. Additionally, the majority of participants expressed the belief that pharmacist intervention is essential when off-label drug use is required. This highlights a strong professional consensus on the critical role pharmacists play in ensuring the safe and effective use of off-label medications. This also reflects a strong level of trust in pharmacists as key guardians of medication safety and efficacy. This indicates that the healthcare professionals perceives pharmacists not only as dispensers of drugs, but also is essential healthcare professionals responsible for ensuring that medications are used appropriately, particularly in complex or non-standard situations. A significant proportion of the survey participants acknowledged substantial safety concerns associated with off-label medication, consistent with prior findings [2]. Off- label medications have risks, however they also offer numerous advantages, particularly when patients have exhausted all other approved treatment options(37). In numerous other nations, the practice of dispensing off-label medications is legal[2],(38),(39). Nonetheless, Libya lacks a formal rule or regulation governing the prescription of off- label pharmaceuticals, which may lead to intricate ethical and legal dilemmas, particularly concerning medical culpability. Remarkably, 15% of the healthcare experts surveyed indicated the existence of a law pertaining to this matter in Libya. In this study, the reported frequency of off-label pharmaceutical drug prescribing was comparable (43%) to previously documented findings in the literature. In a similar study by Francesca S. and colleagues, carried out in a comparable sample size, 40 % of participants prescribed drugs off-label. However, Maria D. et.al. Reported very low frequency of off-label prescribing pattern among healthcare practitioners (19%) [3]. Although 80% of the experts reported insufficient knowledge regarding off-label drug prescribing, 43% still engaged in such practices. This discrepancy highlights a concerning gap between clinical decision-making and evidence-based knowledge. The clinical implication of this finding is significant: prescribing medications without a thorough understanding of their off-label use may increase the risk of adverse drug reactions, ineffective treatment, and potential legal or ethical issues. It underscores the urgent need for targeted education and training programs to ensure that healthcare. Professionals are

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equipped with the necessary knowledge to make informed and safe prescribing decisions, ultimately improving patient care and minimizing risk. It is of concern that 9 % of participants prescribing drugs off-label are confident that there are no risks involved efficacy, while 8 % of respondents believe that the off-label drug administration does not involve a safety concerns. Although there was no statistically significant association between the prescribing of off- label medications and medical specialty, a notable proportion of these prescriptions were concentrated in the psychiatric and neurologic fields. This trend may be attributed to the widespread use of antipsychotic medications, which are commonly employed across a variety of conditions beyond their primary indications, including neuropathic pain and other neurological symptoms(40). The primary strength of this study was the diversity of healthcare experts who participated in the questionnaire from various locations of Libya. Nonetheless, there are specific constraints as well. The inadequate response to this questionnaire may impede the representation of all Libyan healthcare professionals. A further restriction pertains to the self-reported questionnaire, as outcomes may be significantly affected by the subjective aspects of healthcare practitioners. Finally, about two thirds of the respondents are female pharmacists or clinical pharmacists with early career (1-4 years) of experience. This finding may potentially affecting the study's outcomes and restricting the applicability to more seasoned practitioners or male participants. Possible impact on the awareness and perception is that early-career practitioners may possess limited practical exposure to off-label drug utilization and may depend more on formal education than clinical practice. Also, the dominance of female pharmacists among this sample may represent the existing labor distribution in Libya's pharmaceutical sector. Moreover, although the respondents stated they are aware of off-label prescribing, the findings may underscore the necessity for focused educational or policy measures regarding off-label drug usage, especially for less experienced pharmacists and other healthcare practitioners who may face such scenarios in practice.

CONCLUSION

Despite the relatively rare occurrence of off-label drug administration as shown by the study and available publications, the present survey showed significant demand for medical information on the prevalence of off-label prescribing as part of clinical practice. This issue became particularly relevant in the recent years when pharmaceutical drugs were widely prescribed off label to treat many ailments. The use of a drug, whether off or on label, should be based on sound scientific evidence, expert medical judgment, or published literature whenever possible. As a foundational study conducted in Libya, our findings offer valuable insights for all stakeholders involved in off-label drug use—particularly physicians. The results underscore the need for the development of customized training programs aimed at bridging knowledge gaps and guiding responsible prescribing practices. Furthermore, the study highlights an urgent call for official regulatory bodies to establish clear guidelines and policies governing off-label prescribing. Such measures would not only standardize practice but also enhance medication safety and ultimately contribute to better patient outcomes across the healthcare system. This study's nature necessitated a cursory examination of the research topic, indicating that more comprehensive investigations might be beneficial in the future, particularly on national off-label practices and efforts to address obstacles.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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