



RATES AND PATTERN OF OFF-LABEL PRESCRIBING IN A HOSPITAL IN QASSIM REGION, SAUDI ARABIA: A PILOT STUDY

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ABSTRACT

Aim: Off-label prescribing is very common practice worldwide and it may be unavoidable. The aim of the present study was to determine the pattern of off label prescribing in a hospital in Qassim region, Saudi Arabia. **Methods:** This was a cross-sectional pilot study. Hundred prescriptions were collected randomly from 5 different days (20 prescriptions per day) from the pharmacy department of a hospital in Qassim region. Data was analyzed descriptively. **Results:** Fifty percent of prescriptions included an off-label prescribing. However, out of 204 prescribed medications, 65 were off-labeled (31.9 % of the total

number prescribed). The rates of off-label prescribing by gender were 52% among male and 48% among female. By age group; off-label prescribing rate was highest among adolescents (100%), followed by children (68%), adults (56%), infants (40%), young adults and elderly (33% each), and old adults (25%). By prescribed medications; off-label prescribing rate was highest in antibiotics (30 out of 51, 58.8%). By hospital units (i.e. out of 100 prescriptions); off-label prescribing rate was highest among the prescriptions from surgery unit (3 out of 3, 100%), followed by artificial kidney unit (4 out of 5, 80%). By diagnostic category (i.e. out of 100 prescriptions), rate of off-label prescribing was highest among respiratory disorders and infections (24 out of 30, 80%), followed by other infections (6 out of 14, 42%). **Conclusion:** Rate of off-label prescribing in the Hospital is relatively high particularly in antibiotics. Pharmacists in the hospital should educate prescribers about the off-label use trying to reduce rates.

KEYWORDS: Off-label prescribing, prescribing pattern, Saudi Arabia, Pilot study.

INTRODUCTION

The description “off-label prescribing” refers to prescribing a medication for an indication or in a dosage form or for a group of patients that was not approved for by the regulatory authority.^[1,2] Off-label prescribing is very common practice worldwide and it may be unavoidable with a rate reaching 20 percent in western settings.^[2] However, it reaches rates dramatically higher than that among specific patients’ subgroups. It is most common among the groups of patients who are not normally included in clinical trials conducted to evaluate the efficacy and safety of the medications. Those groups included pediatric patients particularly neonates, adolescents, pregnant women and psychiatric patients.^[1,3,4]

The practice of off-label prescribing is challenged by some ethical issues and it may be associated with legal implications.^[2] However, off-label prescribing should not be importantly looked to as a malpractice or linked with illegal behaviors. It is an accepted practice when a suitable treatment option is not existing and represents an extrapolation of an evidence from other groups of patients.^[1,2] Moreover, it may or may not be associated with harms to the patients depending on the justifications considered while prescribing, weighing risk versus benefits to patients and precautions that could be taken. Being not approved for a particular indication or for a certain group of patients does not imply that the drug is rejected by the regulatory authority or it is contra-indicated for that use.^[5] It means simply that indication has not been investigated by clinical trials or not been evaluated sufficiently for the approval by approving board.

Based on the above, there is a need for studying such topic to estimate the magnitude of its practice, determine its pattern, and assess related knowledge and attitudes among prescribers and the associated consequences. To the best of our knowledge there has been no enough literature on off-label prescribing in the Middle East particularly Saudi Arabia. The aim of the present study was to determine the pattern of off label prescribing in a hospital in Qassim region, Saudi Arabia.

METHODS

This was a cross-sectional pilot study conducted in a hospital in Qassim region, Saudi Arabia. Hundred prescriptions were collected randomly from 5 different days (20 prescriptions per day) from the pharmacy department of the hospital. The prescriptions were reviewed by the investigator to check whether prescribing was according to label based on Saudi National Formulary (SNF). Information collected included patient’s gender and age, prescribed drug

category (antibiotics, analgesics, cardiovascular, vitamins and food supplements, corticosteroids and others), hospital unit (emergency room, medical, pediatric, ear nose and throat, surgery, urology, orthopedic, obstetrics and gynecology, artificial kidney unit and dental) and diagnostic category. Body weight is used to check for the appropriateness of dosing and whenever needed (i.e. no information about patient body weight) weight was estimated based on WHO weight for age.^[6] Data was analyzed descriptively.

RESULTS

Table. 1: Rate of off-label prescribing by different medications categories.

Drug category	Number of medications	Off-label rate [n (%)]
Antibiotics	51	30 (59%)
Analgesics	48	4 (8%)
Cardiovascular	11	3 (27%)
Vitamins and food supplements	26	4 (15%)
Corticosteroids	7	2 (29%)
Others	61	22 (36%)
Total	204	65 (32%)

i.e. percentages were out of the total number of medications in the prescribed category.

Table. 2: Rate of off-label prescribing by different hospital units and diagnostic categories (i.e. out of 100 prescriptions).

Unit category	Number of prescriptions	Off-label rate [n (%)]
Hospital Unit		
Emergency room	31	16 (51%)
Medical	14	6 (42%)
Pediatric	13	6 (46%)
Ear nose throat	7	5 (71%)
Surgery	3	3 (100%)
Urology	3	1 (33%)
Orthopedic	6	4 (66%)
Home visit	5	3 (60%)
Artificial kidney unit	5	4 (80%)
Obstetrics and gynecology	9	2 (22%)
Dental	4	0 (0%)
Diagnostic category		
Cardiovascular	10	3 (30%)
Respiratory disorders and infections	30	24 (80%)
Other infections	14	6 (42%)
Others	43	17 (39%)
Unknown	3	0 (0%)
Total	100	50

Out of 100 patients, 52 were male and 48 were female. Infants with the age of <1 year were 10; children aged 1-12 years, 22; adolescents (13-17 years), 2, young adults (18-24 years), 6; adults (25-54 years), 39; old adult (55-64 years), 8; elderly (>65 years), 9. The age was unknown for 4 patients.

A total of 204 medications were prescribed included 51 (25%) antibiotics, 48 (23.5%) analgesics, 26 (12.7%) vitamins and food supplements, 11 (5.4%) cardiovascular, 7 (3.4%) corticosteroids and 61 (29.9%) other medications.

By units (i.e. out of 100 prescriptions); 31 prescriptions were from emergency room; 14, medical unit; 13, pediatric; 9, obstetrics; 7 ear nose and throat; 6, orthopedic; 5, home visit; 5, artificial kidney unit; 4, dental; 3, surgery; and 3, urology and gynecology.

By diagnostic categories (i.e. out of 100 prescriptions); respiratory diseases and infections was the diagnosis written in 30 prescriptions; other infections, 14; cardiovascular diseases, 10; other diagnoses, 43 and unknown diagnosis, 3.

Based on SNF, 50% of prescriptions included an off-label prescribing, 43% labeled and 7% uncategorized due to missing information. However, out of 204 prescribed medications, 65 were off-labeled (31.9 % of the total number prescribed). The rates of off-label prescribing by gender were 52% among male and 48% among female. By age group; off-label prescribing rate was highest among adolescents (100%), followed by children (68%), adults (56%), infants (40%), young adults and elderly (33% each), and old adults (25%).

By prescribed medications (i.e. percentages were out of the total number of medications in the prescribed category, table 1); off-label prescribing rate was highest among antibiotics (30 out of 51, 58.8%), followed by others (22 out of 61, 36%), corticosteroids (2 out of 7, 28.6%), cardiovascular (3 out of 11, 27.3%), vitamins and food supplements (4 out of 26, 15.4%) and analgesics (4 out of 48, 8.3%).

By hospital units (i.e. out of 100 prescriptions, table 2); off-label prescribing rate was highest among the prescriptions from surgery unit (3 out of 3, 100%), followed by artificial kidney unit (4 out of 5, 80%), ear nose and throat (5 out of 7, 71.4%), orthopedic (4 out of 6, 66.7%), home visit (3 out of 5, 60%), emergency room (16 out of 31, 51.6%), pediatrics (6 out of 13, 46%), medical unit (6 out of 14, 42.8%), urology (1 out of 3, 33%) and obstetrics and

gynecology (2 out of 9, 22.2%). No off-label prescribing was found among dental unit prescriptions (4 prescriptions).

By diagnostic category (i.e. out of 100 prescriptions, table 2), rate of off-label prescribing was highest among respiratory disorders and infections (24 out of 30, 80%), followed by other infections (6 out of 14, 42%), other diagnoses (17 out of 43, 39%), cardiovascular (3 out of 10, 30%). No off-label prescribing was found among prescriptions with unknown diagnosis (3 prescriptions).

DISCUSSION

The current pilot study can be considered as a preliminary information about off-label prescribing in Saudi Arabia. However, findings should be interpreted carefully. The rate of 32% off-label prescribing among 204 prescribed medications should be considered as the primary finding. The rates calculated based on the number of prescriptions are overestimation and not represent actual rates because they were calculated according to presence of any off-label prescribed medication in prescriptions. Given that a total of 204 medications were prescribed in 100 prescriptions, the average number of prescribed medications per prescription was 2.4.

The study revealed that the highest rate of off-label prescribing was for antibiotics. This is supported by a study conducted by Jain et al^[4] which showed that off-label prescribing represented 50% of prescription prescribed for neonates in the intensive care unit. Most common off-label medications were anti-infective and antiepileptic. The current study also revealed that the highest rate of off-label prescribing by diagnosis category was for respiratory disorders and infections. Respiratory disorders are common among children^[7,8] and more likely they are antibiotics. However, in a study evaluating the off-label use of parenteral drugs, rate was lowest for antibiotics and maximum for gastrointestinal medications.^[9] A study conducted in Sweden showed that most of the off-label drugs prescribed were for respiratory disorders and infection.^[10]

One of the limitations of the study was that we didn't get an access to the patients' files and the information collected was only based on prescriptions which means information that justify a particular prescribing was limited. Furthermore, some information was missing in the prescriptions. Doctors might have prescribed two prescriptions for one patient and while

we were collecting data randomly we might have taken only one prescription and left the other which might contribute to higher or lower off label use.

CONCLUSION

The Rate of off-label prescribing in the hospital is relatively high particularly in antibiotics. Pharmacists in the hospital should educate prescribers about the off-label use trying to reduce rates.

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