



Pattern of Use Unlicensed Medication in Adult and Pediatric: A Retrospective Study at Major Tertiary Care Hospital in Saudi Arabia

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INTRODUCTION

Unlicensed medication use or Off-label medications use is known as the use of approved medication by Food and Drug administration (FDA) with the un-authorized used or absence of information for their indication, dose, route, frequency, or duration in treatment of specific condition.

These Off-label drugs use is associated with low-quality evidence and prescribed without standard algorithm or guideline or sequence, which may predispose patients to medication errors.

OBJECTIVES

Our aim is assessing scope of practice of using unlicensed medication among different specialties.

- Evaluating the rate of off-label drugs usage
- Determining most common reasons of off-label medication use among different specialties
- Identify most common specialties that use off label medication
- Evaluate level of evidence of reference that have been requested

METHODS

A retrospective chart review from September till December 2021 of prescriptions prescribed as off-label medication use by collecting all off label use forms known as form B was approved by the P&T committee at Prince Sultan Military Medical City (PSMMC). The study was approved by ethical committee in PSMMC, IRB Approval number (1423). The data collected from October 2021 to January 2022.

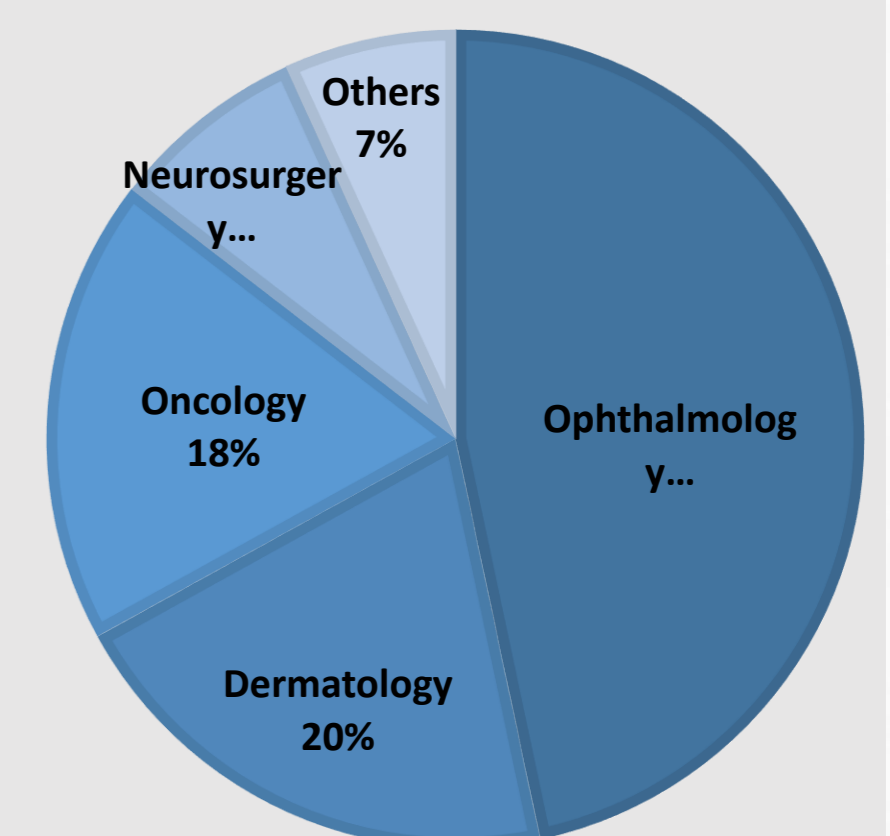
Study included patients of all ages receiving at least one off-label medication. Demographic data and prescriptions collected will be described using descriptive statistics (frequencies and percentages for categorical variables, means and standard deviations for continuous variables whenever applicable). Analyses is performed using the SPSS version 26 statistical software .A p -value < 0 .05 is considered as statistically significant.

RESULTS

- **Total** off-label prescriptions (in/out-patients) was **145**.
- The **average age is 43**, with an SD of 18.3.
- The prescriptions for females constituted (31.7%), while for males was (68.3%).

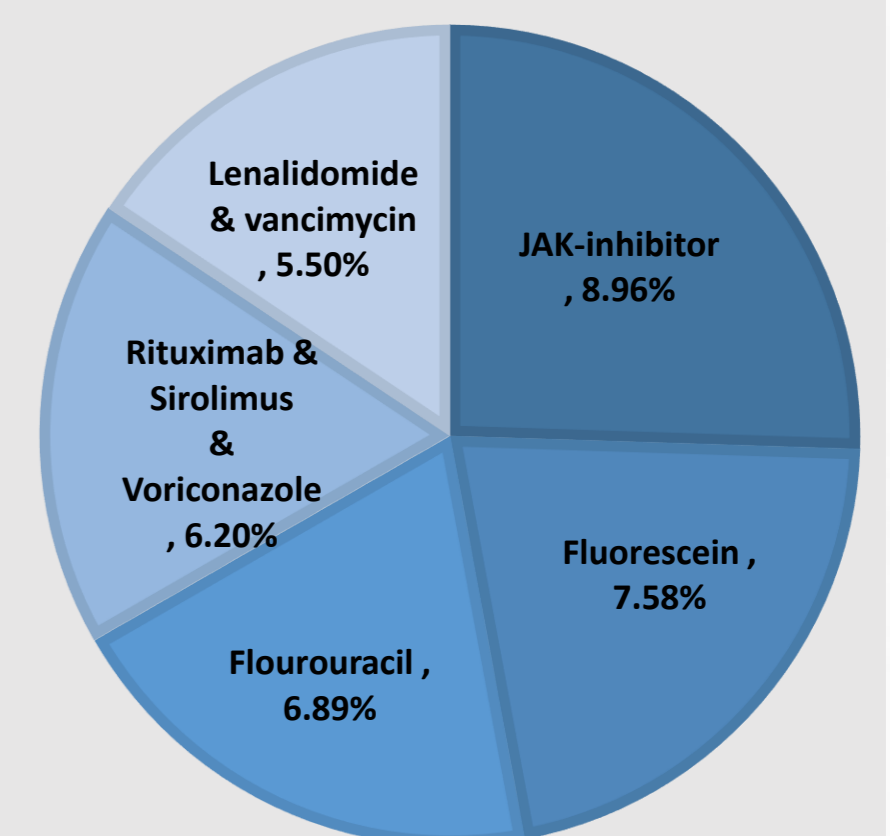
- Unlicensed drugs prescribed as per specialty were:

(33.1%) in Ophthalmology, (14.4%) in dermatology, (13.1%) in oncology Department, (5.5%) in Neurosurgery, (4.82%) shared by (Nephrology, Infectious and obstetrics & gynecology.



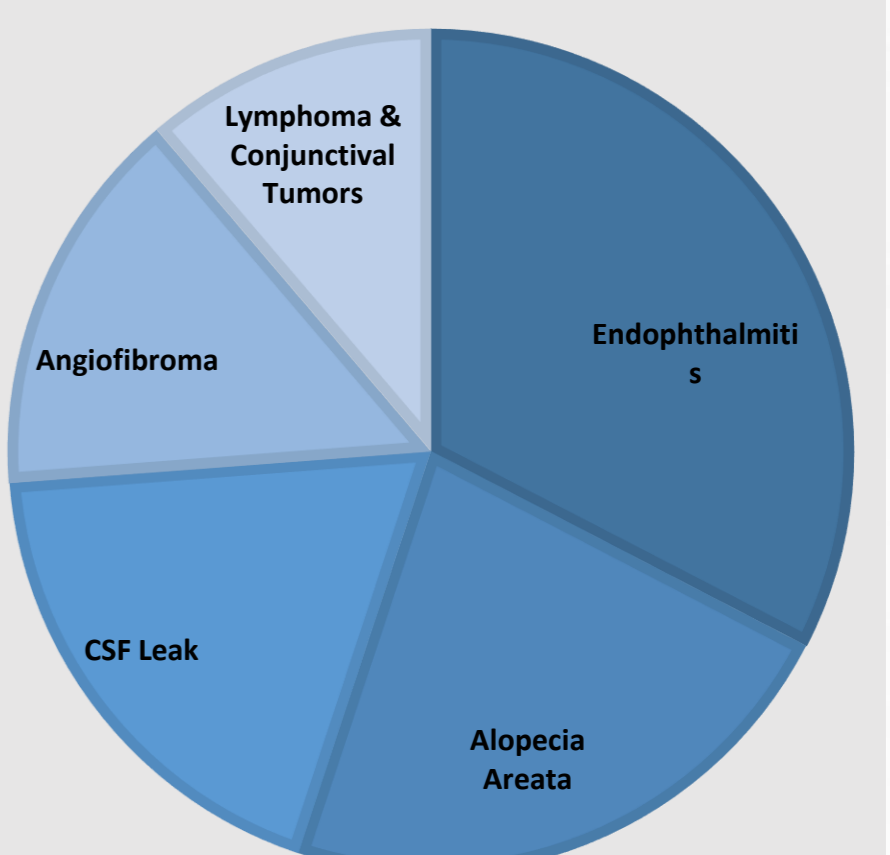
- As per medication type:

JAK-inhibitor had the most considerable unlicensed drug usage (8.96%) followed by Fluorescein (7.58%), Flourouracil have (6.89%), Rituximab & Sirolimus & Voriconazole take forth place by(6.20%) and Lenalidomide & vancomycin taking fifth place by (5.5%).



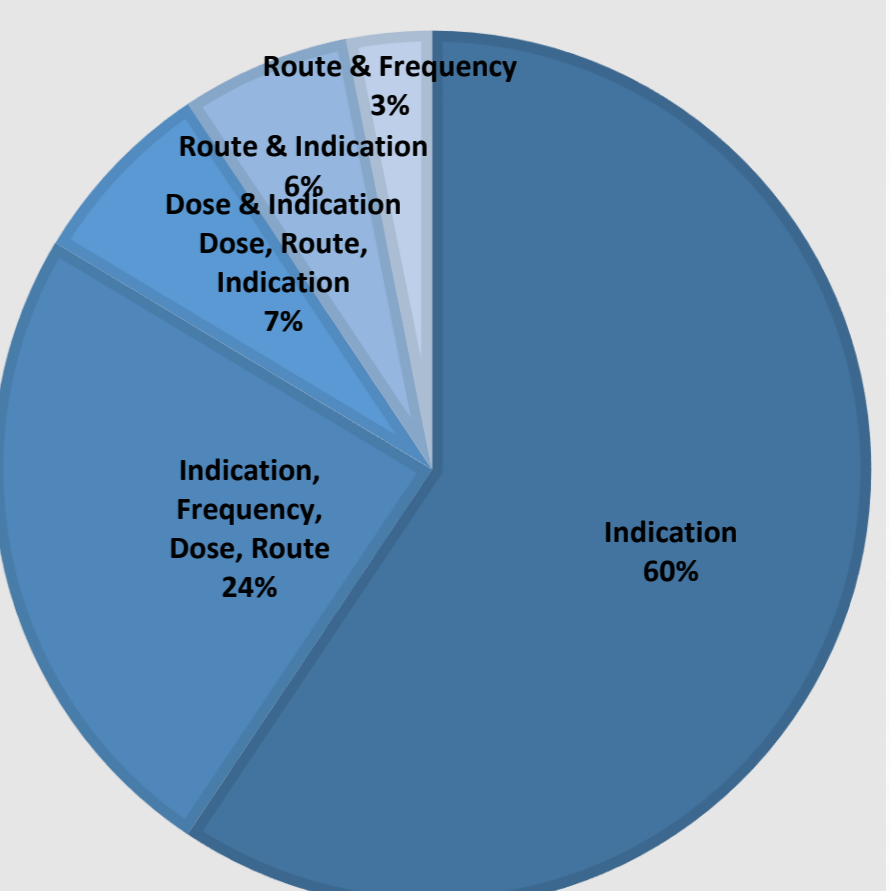
- As per indication:

Endophthalmitis (12%) followed by Alopecia areata (8.27%), CSF leak (6.89%), Angiofibroma (5.51%), Lymphoma & conjunctival tumors shared by (4.13%).



- As per error:

Indication (52.4%) followed by error in (indication, frequency, dose, and route) 21.37%, error in (dose & indication) and (Dose , route , indication) shared by 6.2%, error in (route & indication) take 5.51% from errors and fifth one is error in (route & frequency) which take 2.75%.



CUNCLOSION

Off-label use raise concerns regarding patient safety. This study's unlicensed medication class variability attempted to confirm that physicians employed this treatment option ethically but inefficiently. Prescribers of unlicensed medications need to be adequately supported by current and new evidence. Further research is required throughout the kingdom to begin the off-label legislative procedure under SFDA jurisdiction.

REFERENCES

