ETHICS

UNLICENSED AND OFF-LABEL MEDICATION USES IN DERMATOLOGY: A SYSTEMIC REVIEW OF LITERATURES.

Dr.hadi Al-faris [1]

Mubarak Al-kabeer Hospital, Dermatology Department, Kuwait City, Kuwait [1]

Background: It is a common practice for physicians to treat dermatologic conditions with medications that are not indicated for the specific condition being treated. These "off-label" prescriptions are often for medications that have both well accepted therapeutic value in the medical community and proven efficacy on the basis of results of clinical trials.

Objective: The aim of this study is to determine the main risk factors of most unlicensed and off-label medications used in treatment of dermatological diseases worldwide and to make a detailed examination of ethical and legal trends, patterns, preventive methods, possible solutions and recommendations associated with using unlicensed and off-label drugs in dermatology.

Methods: I performed a systemic review of the relevant available studies on unlicensed and off-label medication uses in dermatology worldwide.

Results: I identified 10 epidemiological studies regarding the use of unlicensed drugs and off-label drugs in dermatology worldwide. The selected studies were between year 1998 and 2018.

Conclusion: Off-label medications seem to be commonly prescribed in clinical practice in dermatology and differs between countries, inpatient and outpatient settings and age. However, prescribing off-label medications to patients who expect to receive an effective treatment will likely lead to foreseeable ethical and legal difficulties. Some of the key ethical issues include the impact on patient autonomous decision, informed consent and nature of the relationship between dermatologists and drugs companies . Legally, concerns surrounding the clinical implications, litigation for professional misconduct and FDA policies on off-label uses. A management guideline for off-label drug use is urgently needed.

Keywords: Unlicensed drugs, off-label drugs, dermatology, prescriptions, ethics, legal issues and legislation.