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ASSESSMENT OF OVER-THE-COUNTER UTILIZATION OF TOPICAL CORTICOSTEROIDS IN ADDIS ABABA

BY

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ASSESSMENT OF OVER-THE-COUNTER UTILIZATION OF TOPICAL CORTICOSTEROIDS IN ADDIS ABABA

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This is to certify that the thesis prepared by Netsanet Bantayehu, entitled: Assessment of over-the-counter utilization of topical corticosteroids in Addis Ababa and submitted in partial fulfillment of the requirements for the Degree of Master of Science in Pharmacoepidemiology and Social Pharmacy complies with the regulations of the university and meets the accepted standards with respect to originality and quality.

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Abstract

Assessment of over-the-counter utilization of topical corticosteroids in Addis Ababa, Ethiopia

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Addis Ababa University, 2015

Topical corticosteroids (TC) are generally safe when used rationally which otherwise may cause significant morbidity among people. Over-the-counter (OTC) use of TC is prevalent worldwide and is found to cause undesirable adverse effects. Particularly its use for cosmetic purpose is a very common practice in Africa including in Ethiopia. The purpose of this study was to assess the extent of OTC use of TC, identify factors contributed for the same, the most common types of facial dermatoses noted among the dermatology outpatient department attendees of the selected health facilities, and also to assess the extent of availability of TC in selected cosmetics shops of Addis Ababa. A cross sectional study was carried out in the dermatology OPD attendees of Alert Hospital and Rank clinic, and also in selected cosmetics shops of Addis Ababa from February 10 to March 10, 2015. Data was collected by using screening question format, pretested questionnaires, observation check list and key informant interview. A total of 927 patients with facial dermatoses were screened; of those 200 (21.6%) reported to have used TC on their face. The age of the patients ranged from 18 to 65 years with mean age of 29.96 years (SD=8.56 years). Of the 200 patients who had used TC on their face, 158 (79.0%) obtained the drug as OTC. More females reported OTC use of TC as compared to males (p = 0.049). The types of facial dermatoses noted in majority 46 (29.1%) of the patients was found to be Acne, followed by Melasma in 32 (20.3%) and Rosacea in 23 (14.6%). Community pharmacies for 78 (49.4%) of the patients and cosmetics shops for 50 (31.6%) were the commonest drug sources. Out of the total 9 cosmetics shops surveyed; TC containing preparations were available in 7 cosmetics shops. The easy access as OTC, the unregulated sales and use of TC for cosmetics purpose are the contributing factors identified for misuse of these groups of drugs. Public education, proper regulation of sales practice of TC and the introduction of a continuing medical education programme or training for health professionals are critical to reduce irrational use of TC.

Keywords: Topical corticosteroids, OTC, drug retail outlets, facial dermatoses

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List of abbreviations

CSA	Central Statistical Agency of Ethiopia
FMHACA	Food, Medicine and Health Care Administration and Control Authority
FDA	Food and Drug Administration
HPA	Hypothalamic–Pituitary–Adrenal axis
OPD	Out Patient Department
OTC	Over-the-counter
SPSS	Statistical Package for the Social Sciences Program
TC	Topical Corticosteroids

1. Introduction

1.1. Background

Since their introduction in early 1950's, topical corticosteroids (TC) have become the cornerstone of treatment mainly for non-infective dermatologic disorders associated with inflammation (Saravanakumar *et al*., 2012; Rathi *et al*., 2012; Ference *et al*., 2009).

TC are generally safe when used rationally which otherwise may cause significant morbidity among people. According to World Health Organization (WHO) estimation, more than half of all pharmaceutical products are inappropriately prescribed, distributed, and sold and more than half of all patients use medicines incorrectly (Yousefi *et al*., 2012). Likewise, apart from the well-known indications it has become increasingly apparent that TC are being misused by prescribers and patients in different areas of the world (Askari *et al*., 2013). Face is the commonest site of such misuse, especially over-the-counter (OTC) use of TC over the face as a skin lightening agent is a very common practice in Africa (Ly, *et al*. 2007; De Souza, 2008).

Inappropriate use of TC may produce local adverse effects or systemic adverse effects. Adverse effects mainly depends on the potency of the corticosteroid and the vehicle, the condition of the skin on which the drug is applied such as thickness of the stratum corneum, humidity and density of hair follicles, and patient related factors which include occlusion of the area, as well as frequency and method of application (Karthikeyan *et al*., 2012; Horn *et al*., 2010). Thus appropriate use of TC needs to consider different factors such as: the type and strength of TC, the patient's history of onset, course and duration of the disease along with age, sex, socio economic status and special physiological conditions (Chabassol and Green 2012; Rathi *et al*., 2006).

Previous studies indicated significantly increased proportion of dermatological visits related to a number of local and systemic adverse effects from misuse of TC over the face, ranging from dermatitis and skin rashes to the development of diabetes mellitus, hypertension and renal problems (Bhat *et al*., 2011; Nnoruka and Okoye, 2006). The quick amelioration of signs and symptoms of many facial dermatoses, the easy access of TC by the people and their use as a cosmetics agent are the most important reasons for irrational use of these groups of drugs (Rathi *et al*., 2012; Narwane *et al*., 2011).

Easy access to TC without medical prescription from drug retail outlets as well as from informal sectors such as cosmetics shops and open markets encourage the practice of OTC use and expose the community to the ill consequences for their unwarranted use. To design interventions in the area, determining the magnitude of the problem and identifying sources of TC are important. Such information is lacking in Ethiopia.

1.2. Statement of the problem

Inappropriate use of TC was found to cause different dermatological complications. Despite its complex adverse effects, misuse of TC over the face for cosmetics or skin lightening purpose has been a common practice throughout the world (Bhat *et al*., 2011; Rathi *et al*., 2012). In particular, the use of TC as a cosmetic bleaching agent is a very common practice among females in Africa, Middle East, Asia, Caribbean and Latin America. This is perhaps having fair skin is associated with beauty and sign of higher social status (Rathi *et al*., 2012; Sarasawat *et al*., 2011).

The case further worsens in developing countries, resulting in additional unplanned cost in terms of scarce resources. In most African countries, this is intensified by the easy access as OTC at affordable prices from informal markets, unregulated sale, inappropriate prescription by some health professionals and poor dispensing practice by pharmacy professionals (Malangu *et al*., 2006; Narwane *et al*., 2011; Nnoruka and Okoye, 2006). Studies indicated the significantly high proportions of dermatological visits in Sub-Saharan Africa were related to local and systemic complications from misuse of TC (Ly *et al*., 2007).

Different studies revealed that, one of the major reasons for using TC on OTC basis is for cosmetics purpose (Rathi, 2006; Nnoruka *et al*., 2006). In a study conducted at 12 dermatology centers in India showed that, from a total of 2926 patients with facial dermatoses, 433 (14.8%) were using TC, of which 126 (29%) used as a fairness/general purpose cream (Sarasawat *et al*., 2011). Twenty three percent of the patients in another study from India also used TC for cosmetics purpose (Ambica *et al*., 2014). In a study conducted in Lahore, Pakistan, in 200 patients using TC; the main reasons were found to be, for management of acne and to improve dark complexion (Chohan *et al*., 2014). A study conducted to show the consequences of depigmenting agents in Nigeria, has also revealed that from patients attending a dermatology clinic, TC were used for cosmetic purposes as depigmenting agents by 313 (57.2%) patients (Nnoruka and Okoye, 2006).

In most cases females and youngsters living in urban or sub urban areas are more prone to inappropriate use of TC. In Sub-Saharan Africa, its use is particularly common among women with reported prevalence rates of use between 26-67% (Dadizie and Petit, 2009; Ly, 2007). Majority of the patients 36% in a study from India were youngsters in the age group of 20-30

and were from rural/suburban areas (Sarasawat *et al*., 2011). Another study showed that majority 152 (76%) of TC users were found to be females (Chohan *et al*., 2014). Similarly a study done in India documented that, 71% of the patients were also females (Ambica *et al*., 2014).

A number of different complications are associated with misuse of TC depending on the type of product and extent of use (Rathi *et al*., 2012). According to the study that have involved more than 21 different steroids and their combinations, class I TC (the strongest or super potent), contributed for 89.6% of dermatological complications such as steroid-induced acne in 45.3%, mycoses in 40.4%, and macular hyperpigmentation of face in 37.2% of the patients (Nnoruka and Okoye, 2006). Another study conducted to study the adverse effects of topical steroid abuse in India, revealed that from 200 patients with a history of topical steroid use on face, majority of patients were using potent (class II) topical steroids, and the common adverse effects reported were erythema, telangiectasia and xerosis (Bhat *et al*., 2007). The commonest type of facial dermatoses noted in Indian study was found to be Acne (Sarasawat *et al*., 2011)

Despite its complex adverse effects, use of TC without a medical prescription (OTC) appears to be very wide spread in the world. And different sources of drugs for OTC use have been reported from different countries. The study from India reported that 59.3% of TC users obtained the drug on OTC basis without a medical prescription (Sarasawat *et al*., 2011). It was also 64% in another study conducted in India (Ambica *et al*., 2014). A study from China also indicated 72.1% of TC users obtained the drug on OTC basis (Lu H *et al*, 2009). Local pharmacies, beauticians and friends were identified as the source of TC for OTC use (Lu H *et al*, 2009; Ambica *et al*., 2014).

In 2012, Food, Medicine and Health Care Administration and Control Authority (FMHACA) released updated OTC medicines list for Ethiopia and, TC are not allowed to be accessed without prescription (FMHACA, 2012). However, misuse of TC is widespread in Ethiopia. In recent years haphazard use of TC on OTC basis has been noticed among the general population and has become the sources of concern for most health professionals including dermatologists (Nigussie and Gedif, 2014). The extent and reason for OTC use of TC, the unregulated sale, the easy access in informal sectors like cosmetics shops and the adverse effect caused to these groups of drugs goes unnoticed and yet not documented in our country.

This study was carried out to assess the extent of OTC use of TC, identify factors contributed for the same, the most common types of facial dermatoses noted in the dermatology outpatient department attendees of the selected health facilities, and also to assess the extent of availability of TC in selected cosmetics shops of Addis Ababa, Ethiopia. So this information will shade light on the extent of the problem and raise awareness among regulatory authorities for taking appropriate actions.

1.3. Literature review

1.3.1. The role of TC

Topical corticosteroids have a long history of effectiveness in a wide spectrum of dermatological conditions especially those characterized by hyper proliferation, inflammation and immunological involvement. Topical corticosteroids act by binding to a specific receptor in the cellular cytoplasm and modulating the transcription of multiple genes that leads to the suppression of the production of inflammatory substances such as prostaglandins and leukotrienes, and also inhibits the recruitment of inflammatory cells into the skin. Based on the United States of America (USA) drug classification system, they are classified in to seven by their ability to constrict capillaries; class I is the strongest or super potent and class VII is the weakest and mildest, whereas the United Kingdom (UK) classification has four different categories (Carlos *et al*., 2013; Horn *et al*., 2010).

Topical corticosteroids are classified by their strength but the relative strength of TC are dependent on: concentration, the presence of absorption-enhancing ingredients (e.g. urea, salicylic acid, propylene glycol), the intrinsic activity of the compound (for instance, betamethasone valerate is not as potent as betamethasone dipropionate) and the ability to penetrate the barrier of the epidermis, as determined by the vehicle in which it is applied (ointments are more potent than creams, e.g. betamethasone dipropionate 0.05% is found in a number of categories). By changing its vehicle from a cream to an ointment its potency increases from moderate Class III to Class II potent and even it becomes more potent to be catagorized under class I, when it is delivered in an optimized vehicle (Divyashanthi and Manivannan, 2014; Rathi *et al*., 2012).

In practical application, selection of the vehicle depends on the type of lesions and the anatomical region; ointments are used to treat dry, scaly and hyper keratinized lesions because ointments generally improve the drug's penetration as they occlude the skin and enhance hydration and absorption of their occlusive nature. On the other hand creams are used specifically to treat lesions of intertriginous areas and are cosmetically acceptable. Generally creams are less potent than ointment of the same medicine (Padma et al., 2013).

In persuing TC based treatment; An appropriate TC has to be selected according to the affected area, patient's age and clinical presentation. As an example, higher potency TC are used in diseases such as psoriasis, lichen planus hypertrophicus, lichen simplex chronicus and lichen amyloidosus where the skin is thickened and penetrability is decreased. Moderately potent TC are used for various dermatoses such as atopic dermatitis and allergic contact dermatitis as well as in other disorders such as vitiligo, polymorphous light eruptions and discoid lupus erythematosus (DLE), Topical corticosteroids which are categorized as weaker or low potent are preferred for treating large surface areas, for longer term application and for older people who have increased skin fragility, in such cases the type of treatment should also be capable to reduce inflammation for the initial treatment of face, flexures, groin and under the breasts or armpits. The use of more potent corticosteroids should be reserved for unresponsive cases to be used under close supervision (Brazzini *et al*.,2002; Rathi *et al*., 2012).

1.3.2. Irrational use of TC

Most commonly used drugs in dermatology includes antifungals, antivirals, antibiotics, antiseptics, anti parasitic, antihistamines, local anaesthetics, keratolytics, emollients, minerals, vitamins and TC. Topical corticosteroids are among the most commonly groups of drugs used in dermatology for the management of several dermatoses (Kumar *et al*., 2011).

A study conducted to assess the *utilization pattern of Topical Steroids in ALERT Hospital* reported that, topical steroids and its combinations 315(28.4%) were the most commonly prescribed classes of drugs followed by anti-fungals 245(22.1%) of the total (Nigussie and Gedif, 2014). Another study conducted in an Indian Tertiary Care Teaching Hospital shows that anti-fungals (23.15%) were the most commonly prescribed classes of drugs followed by TC (19.61%) and antibiotics (16.72%), and the major combination preparations prescribed were steroids in combination with antibiotics, anti-fungals and keratolytics (Bijoy *et al*., 2012).

According to WHO's 2001 definition, rational drug use means that patients receive medications appropriate to their clinical needs, in doses that meet their own requirements, for an adequate period of time and at the lowest cost to them and their community. TC should be used rationally as far as practically possible in order to avoid adverse drug effects. Inappropriate use of TC can alter the normal presentation of superficial bacterial and fungal infections. Also, chronic topical corticosteroid application may lead to skin atrophy and other systemic complications (Rathi and Kumrah, 2011).

The appropriate treatment using TC depends on considering the patient's history of onset, course and duration of the disease along with age, sex, socio economic status and special physiological conditions like pregnancy, lactation. In this regard attention should be paid in course of treatment in more vulnerable groups. It is known that children are among the more vulnerable to adverse effects of TC due to their difficulty in metabolising potent TC and their larger skin surface area:body weight ratio increases percutaneous absorption in case of children (Rathi *et al*., 2012). The elderly are also more susceptible to adverse effects due to skin fragility. Female patients are also more prone to TC adverse effects due to their tendency

to use TC indiscriminately. Caution is also needed to use TC during pregnancy and lactation. TC are classified under pregnancy category C by the US Food and Drug Administration (FDA), Studies in animals have shown that TC are systemically absorbed and may cause fetal abnormalities but there are no well-controlled studies of the teratogenic potential of most of the TC in pregnancy, and thus recommended to be used only if the potential benefit justifies the potential risk to the fetus. Although there are no reported adverse effects during lactation TC should not be applied directly to the nipples before breastfeeding (Rathi *et al*., 2012; Sarasawat *et al*., 2011).

For the rational and responsible use of TC, patients should be given advice about skin care. This includes the use of soap-free cleansers and moisturizer which will affect the skin's overall integrity and improve the clinical outcome (Kumar *et al*., 2011). Patients should also be given advice and counseling during TC use which plays an important role to a better clinical outcome. This includes explanation about: the amount of drug, duration of application and avoidance of factors which may aggravate the disease or cause side-effects of the drug, the amount of TC to be applied and the use, the side effects of TC so that they may be on the lookout for early signs of these groups of drugs, application method because over-application may lead to disastrous consequences and hence strict compliance and the dangers of repeating prescriptions and sharing of medicines among friends and relatives has to be addressed, and recently it is also recommended to use honey skin creams in order to heal and prevent the hidden dangers of steroid creams like eczema, psoriasis and rosacea following prolonged use of steroids (Divyashanthi and Manivannan, 2014).

The available range of formulations and potency of TC gives flexibility to treat all groups of patients, different phases of disease, and different anatomic sites. When used appropriately and not under occlusion, TC are generally safe which otherwise were the cause of significant morbidity among people. TC produces more frequently local adverse effects and less frequently systemic adverse effects (Kumar *et al*., 2011).

1.3.3. Adverse effects of TC

Adverse effects associated with TC use depend mainly on the potency of the corticosteroid and the vehicle, the condition of the skin on which the drug is applied such as thickness of the stratum corneum, humidity and density of hair follicles, and patient related factors which include occlusion of the area, as well as frequency and method of application, too frequent or

faulty methods of application increase the chances of adverse effects (Bhat *et al*., 2011; Rathi *et al*., 2012).

Acute effects to TC use may result in burning sensation, itching, irritation, dryness, or redness at the site of application, and the most common local adverse effect to these groups of drugs is atrophy of the skin. An increase in skin transparency and brightness, telangiectasia, striae, purpura,and easy bruising scars and ulceration may also appear due to dermal atrophy as a result of the direct antiproliferative effects of TC. The use of TC on the face can induce eruptions such as steroidal rosacea, acne and perioral dermatitis. Other local adverse effects include: disease recurrence due to a rebound effect when treatment is stopped, tachyphylaxis or loss of clinical improvement after a period of use and masking or stimulation of some cutaneous infections like tinea incognito. And to a lesser extent local adverse effects include hypopigmentation, delayed wound healing and glaucoma when these drugs are applied around the eye (Hengge *et al*., 2006).

Studies indicated significantly increased proportion of dermatological visits related to a number of local and systemic adverse effects from misuse of TC over the face, ranging from dermatitis and skin rashes to the development of diabetes mellitus, hypertension and renal problems (Bhat *et al*., 2011; Nnoruka and Okoye, 2006). The quick amelioration of signs and symptoms of many facial dermatoses, the easy access of TC by the people and their use as a cosmetics agent are the most important reasons for irrational use of these groups of drugs (Rathi *et al*., 2012; Narwane *et al*., 2011).

Topically applied high and ultra high potency TC can be absorbed well enough to cause systemic adverse effect and produce systemic symptoms, such as headache, indigestion, increased appetite, restlessness, and increased risk of infection. Systemic reactions such as hyperglycemia, glaucoma, and adrenal insufficiency have also been reported to follow topical application. Endocrine disturbance as a result of reversible suppression of the hypothalamic–pituitary–adrenal axis (HPA) increased risk of systemic side effects in children and infants. This is because of the increased absorption and the metabolism of the absorbed glucocorticoids is also less rapid in children and infants. The combination of excess absorption and less metabolism causes suppression of endogenous cortisol production. Under these circumstances, Addisonian crisis may occur if the drug is suddenly stopped after prolonged therapy. Prolonged suppression of cortisol production may also cause growth retardation (Carlos *et al*., 2013).

1.3.4. Factors contributing for misuse of TC

According WHO estimation, more than half of all pharmaceutical products are inappropriately prescribed, distributed, and sold and more than half of all patients use the medicines prescribed for them incorrectly (Yousefi *et al*., 2012). In recent years it has become increasingly apparent that TC are being misused by prescribers, dispensers and patients. Apart from the well-known indications, they are being used for undiagnosed skin rash by health professionals, self treatment and for cosmetics purpose by patients. This is because of the quick amelioration of signs and symptoms of many skin disorders by the application of TC in short period of time (Narwane *et al*., 2011; Askari et al., 2013).

Factors which contributed for misuse of TC includes: the easy access as OTC by the people, the unregulated sale, inappropriate administration and poor dispensing practice by the pharmacy professionals and nonmedical advisers like friends or relatives, telling them to use it as fairness or cosmetic creams, anti-acne, anti-fungal therapy and even for any type of skin eruptions (Sweileh, 2006; Narwane *et al*., 2011).

Several studies have reported on misuse of TC and on factors contributing to it. A study conducted in India, showed that from 200 patients with facial dermatoses who used topical steroids over face, most of patients were between age group of 15 to 30 (55%). Females (71%) outnumbered males (29%). The most common reason for misuse was found to be the management of acne in 61% followed by use as a fairness cream in 23% (Saraswat *et al*., 2011).

Another study undertaken in Dakar, Senegal, showed that, from 368 adult women presenting at a dermatological centre, 194 (52.7%) were using of bleaching products at the time of the investigation. Of the products used TC (glucocorticoids) was responsible for the majority (70%) of the observed complications (Ly *et al*. 2007).

A study conducted to examine the misuse of topical steroid products for skin lightening among patrons of pharmacies in Pretoria found that, eighty three percent of the 225 participants were females and 50.7% were in 20-40 years of age. Of the total participants,

majority (75.1%) were also black Africans, and the study reported that the prevalence of topical steroid misuse for skin lightening purpose to be 35.5% (Malangu *et al*., 2006).

2. Objective

2.1. General objective

- To assess the OTC utilization pattern of TC in the selected health facilities, and to assess the extent of availability of TC in selected cosmetics shops of Addis Ababa, Ethiopia.

2.2. Specific objectives

- To determine the extent of OTC use of TC
- To describe the most common types of facial dermatoses noted
- To identify the sources of TC for OTC use
- To identify factors associated with OTC use of TC
- To determine the extent of availability of TC in selected cosmetics shops

3. Methods

3.1. Description of the study area and settings

This study was carried out in selected dermatology specialized health facilities and cosmetics shops of Addis Ababa, Ethiopia. Addis Ababa is the capital city of Ethiopia with a total population of 3,384,569 as reported on the 2007 census conducted by the central statistical agency of Ethiopia with annual growth rate of 3.8% (CSA, 2007). Its area is estimated to be 540 Km^2 with altitudes ranging from 2200 to 3000m above sea level, average temperature of 22.8°C and average rainfall of 1,180.4 mm (AACA IB, 2013).

The city is divided into ten sub-cities which are the second administrative units next to city administration. The sub-cities are also divided into woredas, there are 116 woredas in the City Administration. At the time of this study, the number of woredas varies among sub-cities based on their size (AACA IB, 2013). The number of drug retail outlets was 747 and there were 603 public and private health facilities (28 hospitals, 26 health centers, 507 clinics and 42 health posts) in Addis Ababa city administration.

3.2. Study design

A cross sectional study design using qualitative and quantitative data collection methods were conducted in selected dermatology specialized health facilities and cosmetics shops in Addis Ababa, Ethiopia. Data was collected from February 10, 2015 to March 10, 2015.

3.3. Source and study population

The source population of the study was all cosmetics shops in Addis Ababa and all patients who attended OPD of the dermatology health facilities in Addis Ababa. All patients with facial dermatosis who attended the OPD of ALERT Hospital and Rank clinic during the study period were the study population. And selected cosmetics shops in Woreda 10 under Arada sub-city of Addis Ababa were used as the study population. The study also included key informants from FMHACA and cosmetics shops and dermatologists working in OPD of the selected health facilities.

3.4. Sampling procedure and sample size determination

The study facilities were selected using purposive sampling technique. During the study period, there were seven private and one public dermatology specialized health facilities in Addis Ababa, out of which two dermatology health facilities (ALERT hospital and Rank clinic) were selected for the study. ALERT hospital was selected purposively due to the fact that it is the only specialized public dermatology hospital, and Rank clinic was selected because it is one of the private dermatology specialized public health facilities with higher patient load.

All patients of any age and sex with facial dermatosis who attended the OPD of dermatology health facilities during the study period were taken consecutively for the study. Cosmetics shops in Kebele 10 of Woreda 10 under Arada sub-city of Addis Ababa were also selected by purposive sampling techniques, because it is the area where many cosmetics shops are found and most people are assumed to visit. The selection of key informants was based on purposive sampling to address different issues related to TC. A total of 16 key informants, one from FMHACA, nine from cosmetics shops and 6 dermatologists from the selected health facilities were included.

3.5. Data collection methods and instruments

Both quantitative and qualitative data collection methods were employed. All relevant and necessary information for the study was collected from the screening question, from the verbal interview and by using a check list. A screening question format and a structured questionnaire was used to assess the extent of OTC utilization of TC and the most common facial dermatoses noted on the face of attendees in the selected dermatology specialized health facilities.

To screen out those who used TC containing preparation, patients were asked about their current use of any topical formulations including cream, ointment, and lotion on their face. The formulation in question were checked weather it contained a corticosteroid or not, by asking the patient or by seeing the prescription/used tube or by showing samples of popularly used preparations and then a structured questionnaire eliciting patient related parameters such

as age, sex, average house hold income, educational status and drug related data such as description of the drug, prescription sources and reason for use were obtained after confirming the formulation used to contain a corticosteroid (Annex II). Others data about the sex, age and type of facial dermatoses screened by dermatologists however were recorded in the screening question format (Annex I).

The questionnaire was designed in such a way that all the relevant variables were included so as to meet their respective objectives. It was prepared in English and translated into Amharic, and then to English to maintain consistency. For the key informant interviews, a semi-structured questioner for interview was used in order to investigate core ideas related to irrational use of TC and the reasons behind such misuse. The extent of availability, the sources and sales practices of TC in cosmetics shops were assessed through an observation check list and an interview by asking or by using popularly used brand preparations (Annex III).

Observation for availability of any TC containing preparation in the selected cosmetics shops were done by the principal investigator using an observation checklist. Key informant interviews with the dermatologists, an expert from FMHACA and cosmetics shop sales managers were conducted by the principal investigator.

3.6. Study variables

- **Dependent variable:**
  - ✓ Extent of OTC use
- **Independent variables:**
  - ✓ Sex
  - ✓ Age
  - ✓ Economic status
  - ✓ Educational status
  - ✓ Occupational status
  - ✓ Marital status
  - ✓ Reason for use

3.7. Data quality assurance

After completing the data collection instruments, 8 nurses working in the study facilities were recruited for the data collection and they were trained on the aim of the study, data collection tools and procedures. Before the actual survey was conducted, pretesting of the questionnaire was done on 10 patients in ALERT hospital and modifications were done accordingly. Regular cross checking, inspection and scrutinizing of information on the research instruments was done to ensure the quality of the data. During the data collection process, supervision was made by the principal investigator and corrective measures were taken immediately for the identified problems.

3.8. Data entry and analysis

Descriptive statistics was used to determine frequencies and percentages. Quantitative data was checked and then entered using EPI-INFO version 3.3.2 statistical packages and the data was exported to SPSS version 16 for data analysis. The relationship between dependent and independent variables was also examined using logistic regression. A p-value of < 0.05 was taken as significant with 95% confidence interval.

Qualitative data obtained from the key informant interviews was grouped based on similarities and differences of perspectives between different respondents and analysis was conducted thematically.

3.9.Ethical consideration

Approval and permission of the research was obtained from Addis Ababa University, School of Pharmacy Research and Ethics Review Board. An official letter of cooperation was written from the School of Pharmacy, Addis Ababa University to Alert Hospital and Rank clinic and the study was conducted after securing permission from the selected health facilities.

Moreover, informed consent was sought from every participant after explaining about the nature of the study, objective, and expected duration of the interview. Every participant was informed that participation in the study was fully voluntary. To assure anonymity, the name

and address of the study participants were not recorded on the questionnaires and all the information gathered was treated as confidential.

3.10. Operational definitions

Topical corticosteroids: Any preparation in the form of cream, ointment or lotion to be applied in the skin which contains one or combinations of TC.

Community Pharmacies: drug retail out lets which could be a pharmacy, drug shop, or rural drug vendor

OTC use: use of TC without appropriate prescription paper

Facial dermatoses noted: As reported by dermatologists who diagnosed the patient

4. Results

4.1. Survey findings from selected dermatology specialized health facilities

Socio-demographic characteristics of TC user patients

During the study period, a total of 927 patients (176 males, 751 female) with facial dermatoses were screened at the OPD of dermatology health facilities, out of which 200 (21.6%) had used TC on their face (Annex VI). The age of the screened group ranged from 1 to 88 years with mean age of 28.9 years (SD=10.7 years).

Out of the 200 patients who had used TC on their face, 158 (79.0%) obtained the drug without a medical prescription on OTC basis. The socio-demographic characteristics of patients who had used TC are summarized in Table 1. Of those who used TC on their face, females accounted the majority 186 (93.0%), and the age of the patients ranged from 18 to 65 years with mean age of 29.9 years (SD=8.56 years). Nearly half 91 (45.5%) of them were married. Majority of the patients 79 (39.5%) had higher (college or university) education and nearly equal proportions 78 (39.0%) had attended their secondary education. Three fourth 150 (75.0%) of the patients were from Addis Ababa.

Table 1: Socio-demographic characteristics of patients who used topical corticosteroids, in selected dermatology health facilities of Addis Ababa, February 2015 (n=200).

Characteristics	**Categories**	**Frequency n (%)**
Sex	Female	186 (93.0)
	Male	14 (7.0)
Age group (Years)	18 - 24	58 (29.0)
	25 - 31	66 (33.0)
	32 - 38	49 (24.5)
	38^{+}	27 (13.5)
Place of Residence	Addis Ababa	150 (75.0)
	Out of Addis Ababa	50 (25.0)
Marital status	Single	109 (54.5)
	Married	91 (45.5)
Occupational status	Government employee	39 (19.5)
	Nongovernmental employee	12 (6.0)
	Private business	62 (31.0)
	Unemployed*	87(43.5)

Educational status	Illiterate	18 (9%)
	Primary (1-8)	25 (12.5)
	Secondary (9-12)	78 (39.0)
	College/University	79 (39.5)
Average monthly family income	No income	63 (31.5)
	Below 1000 ETB	38 (19.0)
	1000-2500 ETB	46 (23.0)
	Above 2500 ETB	53 (26.5)
	Total	**200 (100.0)**

**Students, Housewives, Pensioners*

The types of facial dermatoses noted

Different types of facial dermatoses were noted among patients who used TC on OTC basis (Table 2). The most common types of facial dermatoses noted were found to be Acne in 46 (29.1%) of the patients, followed by Melasma in 32 (20.3%) and Rosacea in 23 (14.6%).

Table 2: Types of facial dermatoses noted among patients using topical corticosteroids on OTC basis, in selected dermatology health facilities of Addis Ababa, February 2015 (n=158).

	Frequency
Type of facial dermatoses noted	**N (%)**
Acne	46 (29.1)
Melasma	32 (20.3)

Rosacea	23 (14.6)
Steroid Dependent Face (SDF)	8 (5.1)
Perioral Dermatitis (PD)	7 (4.4)
Photocontact Dermatitis	7 (4.4)
Acne and Melasma	7 (4.4)
Seborrheic Dermatitis (SD)	6 (3.8)
Others*	22 (13.9)
Total	**158 (100.0)**

**Telangiectasia, Ochronosis, Discoid Lupus Erythromatus (DLE), Tinea Incognito (TI), Tinea Faciei (TF), Atopic Dermatitis (AD), Actinic Lichen Palinus (ALP), Irritant Contact Dermatitis (ICD), Vitiligo and Xerosis.*

Extent of OTC use of TC

Out of the 200 patients who had used TC on their face, 158 (79.0%) obtained without a medical prescription on OTC basis. Of these, 98 (62.0%) used it for cosmetics purpose, and the remaining 60 (38.0%) applied for treatment purpose.

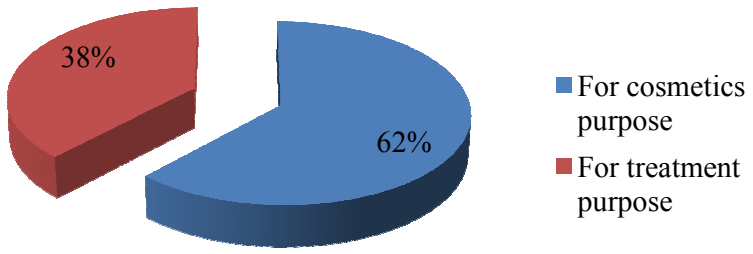

Figure 1. Patients' reasons for OTC use of TC, in selected dermatology specialized health facilities of Addis Ababa, February 2015 (n=158).

Length of use, frequency of use and area of application of TC by the patients who reported to use TC on their face by the sources of prescription are depicted in Table 3. Majority of the patients 138 (69.0%) had reported that they applied TC all over the face; while the remaining patients 62 (31.0%) claimed to have applied it only over part of the face. The length of TC use found to vary from less than one month to more than six months, and majority of the patients 84 (42.0%) had reported that they were using the drugs for more than 6 months. Regarding the daily frequency of applications, majority of the patients 171 (85.5%) was applying the TC once per day.

Table 3: Length of use, frequency of use and area of application of topical corticosteroids, in selected dermatology specialized health facilities of Addis Ababa, February 2015 (n=200).

	Sources of Prescription

Variables	Categories	OTC n (%)	Prescribed n (%)	Total n (%)
Length of use	For more than 6 months	73 (36.5)	11 (5.5)	84 (42.0)
	Between 1 and 6 months	55 (27.5)	19 (9.5)	74 (37.0)
	Less than 1 month	30 (15.0)	12 (6.0)	42 (21.0)
Area of application	All over the face	120 (60.0)	18 (9.0)	138 (69.0)
	Only over the affected area	38 (19.0)	24 (12.0)	62 (31.0)
Daily frequency of use	Three times or more	4 (2.0)	0 (0)	4 (2.0)
	Twice	14 (7.0)	11 (5.5)	25 (12.5)
	Once	140 (70.0)	31 (15.5)	171 (85.5)
	Total	**158 (79.0)**	**42 (21.0)**	**200 (100.0)**

Types of TC used as OTC

Different types and potencies of TC containing preparations were used as OTC by patients (Table 4). Bethametasone Valerate 0.1% cream and Clobetasone propanoate 0.05% cream were found to be the most commonly drugs used by majority of the patients, which were in 40 (25.3%) and 33 (20.9%) of the patients respectively.

Table 4: Types of TC applied among patients using topical corticosteroids on OTC basis in selected dermatology health facilities of Addis Ababa, February 2015 (n=158).

Descriptions of TC	**Frequency n (%)**
Betamethasone valerate 0.1% cream	40 (25.3)
Clobetasol propionate 0.05% cream	33 (20.9)
Betamethasone dipropionate 0.064% cream	19 (12.0)
Fluocinolone acetonide 0.025%	17 (10.8)
Mometasone furoate 0.1% cream	12 (7.6)
Clobetasol propionate 0.05% ointment	10 (6.3)
Betamethasone valerate 0.1% ointment	7 (4.4)
Betamethasone dipropionate 0.064% ointment	5 (3.2)
Hydrocortisone acetate 1% cream	5 (3.2)
Others*	10 (6.3)
	158 (100.0)

**Bethametasone dipropanoate 0.05% ointment, Hydrocortisone Acetate 1% ointment, Bethametasone valerate 0.05% ointment, Bethametasone dipropanoate 0.05% cream, and combination of Fluocinolone acetonide 0.025% and Bethametasone valerate 0.05% cream.*

Sources of TC for OTC use

The sources of drugs (TC) for OTC user patients are shown in Figure 2. Nearly half 78 (49.4%) of the patients identified community pharmacies as their source of TC followed by cosmetic shops which accounts for 50 (31.6 %).

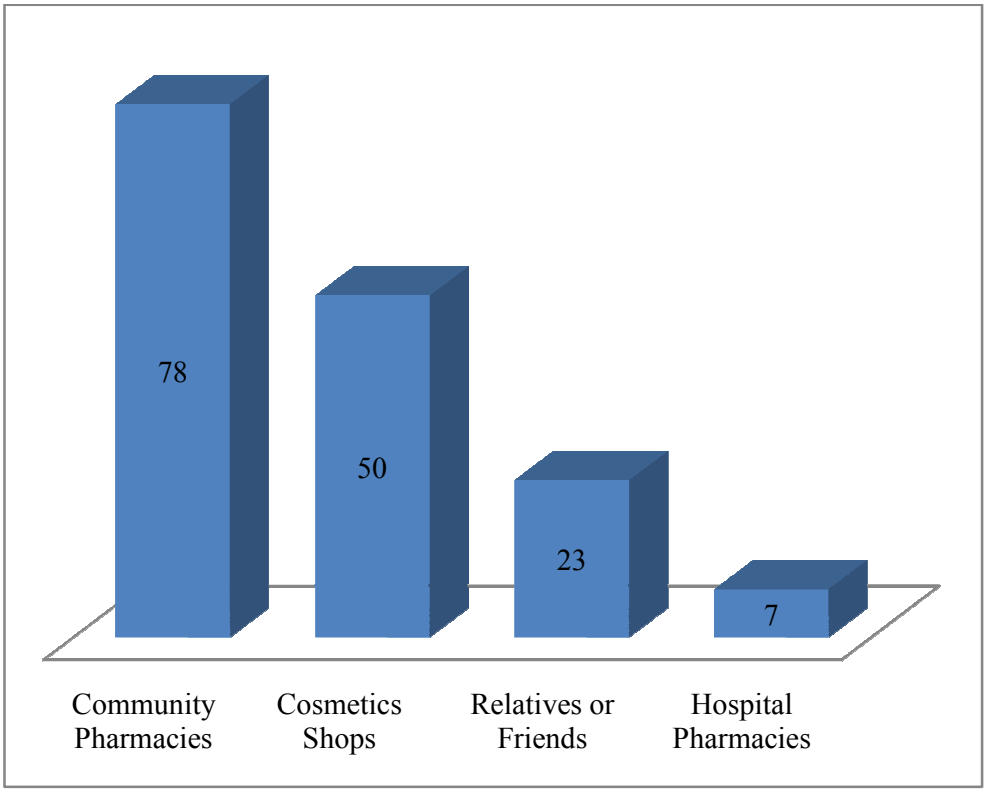

Figure 2. The sources of TC for OTC users, in selected dermatology specialized health facilities of Addis Ababa, February 2015 (n=158).

Factors associated with OTC use of TC

Multinomial logistic regression analysis was used to determine association between patients' socio-demographic variables and the source of prescription. Accordingly a statistically significant association was detected between sex of the patients with OTC use, so that more females reported OTC use of TC as compared to males (p = 0.049, AOR = 20.41; 95% CI [10.10-500.00]). A significant association (p=0.003) was also detected between educational status and OTC use (AOR = 0.005; 95% CI [0.000-0.170] However, no significant associations were detected between patients' age, marital status, level of income and occupational status with OTC use (Table 5).

Table 5: Association between patients' socio-demographic variables with OTC use in selected health facilities of Addis Ababa, February 2015.

Variables		OTC Use		Crude OR (95% CI)	Adjusted OR (95% CI)
		Yes n (%)	No n (%)		
Sex	Female	150 (75.0)	36 (18.0)	3.13 (1.02-9.62)	20.41 (10.10-500.00)*
	Male	8 (4.0)	6 (3.0)	1	1
Age group (Years)	18 - 24	44 (22.0)	14 (7.0)	1.10 (0.385-3.143)	0.536 (0.048-6.016)
	25 - 31	53 (26.5)	13 (6.5)	1.427 (0.498-4.09)	1.801 (0.237-13.67)
	32 - 38	41 (20.5)	8 (4.0)	1.794 (0.570-5.646)	10.51 (0.952-116.08)
	38^{+}	20 (10.0)	7 (3.5)	1	1
Marital status	Single	90 (45.0)	19 (9.5)	1.602 (0.808-3.176)	1.708 (0.685-4.263)
	Married	68 (34.0)	23 (11.5)	1	1
Occupational status	Government employee	30 (15.0)	9 (4.5)	1.061 (0.435-2.588)	0.225 (0.022-2.314)
	Nongovernmental employee	9 (4.5)	3 (1.5)	0.955 (0.236-3.855)	0.107 (0.005-2.215)
	Private business	53 (26.5)	9 (4.5)	1.874 (0.793-4.430)	0.351 (0.037-3.322)

	Unemployed	66 (33.0)	21 (10.5)	1	1
Educational status	Illiterate	10 (5.0)	8 (4.0)	0.181 (0.058-0.568)	0.005 (0.000-0.170)*
	Primary (1-8)	15 (7.5)	10 (5.0)	0.217 (0.077-0.615)	0.156 (0.019-1.257)
	Secondary (9-12)	64 (32.0)	14 (7.0)	0.663 (0.275-1.597)	0.347 (0.073-1.648)
	College/University	69 (34.5)	10 (5.0)	1	1
Average monthly family income	No income	48 (24.0)	15 (7.5)	0.487 (0.182-1.303)	1.242 (0.071-21.698)
	Below 1000 ETB	27 (13.5)	11 (5.5)	0.374 (0.182-1.303)	1.242 (0.071-21.698)
	1000-2500 ETB	37 (18.5)	9 (4.5)	0.626 (0.213-1.839)	0.846 (0.133-5.403)
	Above 2500 ETB	46 (23.0)	7 (3.5)	1	1

* *P*-value < 0.05

4.2. Availability of TC in selected cosmetics shops

Of the total 9 cosmetics shops surveyed, at least one TC containing preparation was available in 7 cosmetics shops. Different types and brands of TC were obtained and are summarized in Table 6. The drug available in most 5 cosmetics shops was found to be Betnovate cream (Betamethasone valerate 0.1%).

Table 6: Descriptions and brand names of TC available for sale in the selected cosmetics shops in Addis Ababa, February 2015 (n=7).

	Extent of availability	
Descriptions of the TC	**Frequency**	**Percent**
Betnovate cream (Betamethasone valerate 0.1%)	5	71.4
Dermovate cream (Clobetasol propionate 0.05%)	2	28.5
Dermovate ointment (Clobetasol propionate 0.05%)	2	28.6
Betacet-N cream (Betamethasone dipropionate 0.012% and Neomycin 0.5%)	4	57.1
Dermalar cream (Fluocinolone acetonide 0.025%)	2	28.6

4.3. Qualitative data findings

Key informant interview and observation at cosmetics shops

A sales manager of each cosmetic shop was interviewed. The age of the informants ranged from 29 years to 45 years. The majority 5 (55.6%) were males. The experience in selling cosmetics ranged from 1 to 15 years and majority of the respondents 8 (88.9%) had an experience of more than 4 years. As many 7 (77.8%) of the respondents had attended higher (college or university) education while the remaining 2 (22.2%) had completed secondary education (grade 12).

According to the key informants, the sources of TC are; informal importers (local name Merkato), hostesses, import from Dubai and pharmacies.

All sales managers reported that, there is no restriction and supervision from any institute about the products they sale. However, it was observed that majority of the cosmetics shops had shelved TC containing preparations separately from other cosmetics.

Key informant interviews with dermatologists

The key informant interviews using a semi-structured questioner were held with a total of six dermatologists, from which 4 were males and the rest were females. The age of the informants ranged from 33 to 52 years.

The aim of the interview was to investigate core ideas related to irrational use of TC and factors behind for such misuse in Ethiopia. All the dermatologists described that, although the magnitude of irrational use of TC has shown great increment time to time, it has got little attention by the community and also by the regulatory bodies; They also mentioned that, the number of patients who visited the OPDs of dermatology health facilities following irrational use of TC particularly on OTC basis over the face has increased. Majority of the informants explained that, use of TC without a medical prescription is more prevalent among the urban community than the rural, by females, in the age group of 20 years to 30 years and by those with high income. These groups of drugs are mainly misused as a fairness cream for cosmetics purpose.

The key informants described that, Acne, Rosacea, Hyper/Hypohydrosis, Photocontact Dermatitis, Melasma, Steroid Dependent Face and Telangiectasia were the most common adverse effects seen from inappropriate use of TC by majority of their patients. Regarding the factor for misuse of TC in our country, all the key informants believed that, the easy access by the public as OTC from drug retail outlets as well as cosmetics shops, the unregulated sales, use for cosmetics purpose and lack of awareness by the community are the factors contributed for irrational use of these groups of drugs. One of the key informants explained that,

"Apart from OTC dispensing practice of TC by pharmacy professionals, misuse of these groups of drugs is quite common from inappropriate prescription of potent TC by some health professionals even for undiagnosed skin rash …It is better to restrict TC use only based on prescription of dermatologists or by those health professionals who took special training on dermatology practice."

The key informant dermatologists lastly recommended public education through special media programmes, proper regulation of sales practice of TC in drug retail outlets, cosmetics shops as well as open markets and the introduction of a continuing medical education programme or training for health professionals are critical to reduce irrational use of TC.

Key informant from Addis Ababa FMHACA

The interview was held with health professionals and institutions regulatory and inspection case team focal person from Addis Ababa City Administration FMHACA, According to this key informant, inappropriate utilization of drugs without a medical prescription in recent years is becoming a common problem among the community in Ethiopia, including Addis Ababa which could result in wastage of resources, increases resistance of pathogens, and generally entails serious health hazards such as adverse drug reaction & prolonged suffering.

The commonest groups of drugs used as OTC described by the key informant includes Antibiotics, Analgesics, Hormonal drugs and skin bleaching products such as TC. Concerning the regulation of the sources of drugs, the key informant stated that,

"Drug retail outlets and informal sectors like open shops are the sources for most OTC use….. Though it is a common practice to inspect drug retail outlets annually, OTC dispensing practice was not given attention. However, we didn't yet inspect informal sectors or shops for availability of drugs."

5. Discussion

This study was conducted with the intention of determining the extent of OTC use of TC, identify factors contributed for the same, the most common types of facial dermatoses noted among the dermatology outpatient department attendees of the selected health facilities, and also to assess the extent of availability of TC in selected cosmetics shops of Addis Ababa, Ethiopia. This study revealed that, from the total of 927 patients with facial dermatoses screened, 200 (21.6%) had used TC on their face, which is comparable with a study done in India 14.8% (Sarasawat *et al*., 2011). This indicated that a large number of patients with facial dermatoses who visited the dermatology OPD were following TC use, while the one from Iraq were 7.9% (Al-Dhalimi *et al*., 2006).

In the current study, more females 186 (93.0%) were found to use TC than males, this finding is in agreement with the studies done in India 71% (Ambica *et al*., 2014), 76 % in Pakistan (Chohan., 2014) and 67.8% in Iraq (Al-Dhalimi *et al*., 2006). Most of the patients 66 (33.0%) in this study were in the 25–31 years age group, which is comparable with a study in India 36% were in the age group of 20-30 were in India (Sarasawat *et al*., 2011). However, majority 50% of TC users were in the age group of 10-19 years in Iraq (Al-Dhalimi *et al*., 2006), this difference could also be attributed to the data of this study which was limited to facial use whereas the study in Iraq was TC use anywhere in the body.

Misuse of TC over the face, especially on OTC basis is a common problem in dermatology practice worldwide and is often associated with different dermatological complications. The commonest types of facial dermatoses noted in majority of OTC user patients in this study was Acne in 46 (29.1%) also similarly reported, in 45.3% of the patients from a study in Nigeria (Nnoruka and Okoye, 2006), in 57.5% of the patients in India (Sarasawat *et al*., 2011), in 36.4% of the patients in Iraq (Al-Dhalimi *et al*., 2006), and 52% in another study in India (Ambica *et al*., 2014) while in the study from Pakistan the common type of facial dermatoses in 51.8% of the patients was facial erythema (Chohan *et al*., 2014).

A number of studies have been reported from different countries where use of TC on OTC basis without a medical prescription appears to be very wide spread. This study also indicated that, from those 200 patients who had used TC on their face, 158 (79.0%) obtained without a medical prescription on OTC basis. Similarly a study conducted in India reported that 59.3% of TC users obtained the drug on OTC basis without a medical prescription (Sarasawat *et al*., 2011). It was also 64% in another study conducted in India (Ambica *et al*., 2014).

With regard to the reasons for use, the current study showed that TC was used as OTC for cosmetics purpose in 98 (62.0%) of the patients. This is also in agreement with other studies done in different countries, it was 29% in India (Sarasawat *et al*., 2011), 65.7% in Iraq (Al-Dhalimi *et al*., 2006), 57.2% in Nigeria (Nnoruka and Okoye, 2006) and 23% in another study in India (Ambica *et al*., 2014).

This study also found that, different types and potencies of TC in different dosage forms as a cream or ointment were identified to be used by patients as OTC; The TC used by majority of the patients were classed as potent or super potent and the drug commonly used by majority of the patients in 40 (25.3%) were Betamethaone Valerate followed by Clobetasol propionate 0.05% cream in 33 (20.9%) of the patients. This indicated that the use of TC particularly the potent or super potent ones as cosmetic bleaching agent is a very common practice among the patients, and it was also reported in studies done in many countries (Sarasawat *et al*., 2011; Nnoruka et *al*., 2006; Lu *et al.*, 2009; Al-Dhalimi *et al*., 2006; Chohan *et al*., 2014). The drug commonly used by majority of the patients was also similar which is Betamethaone Valerate, 76% in pakistan (Chohan *et al*., 2014), 58.9% in India (Sarasawat *et al*., 2011), 37% and 42.1% in Iraq (Al-Dhalimi *et al*., 2006), But differs from the finding in China where Clobetasol propionate 0.025% cream was used by majority 17.3% of the patients (Lu *et al.*, 2009).

The findings of this study indicated that, community pharmacies in majority 78 (49.4%) of the patients and cosmetics shops in 50 (31.6%) were the commonest drug sources. This shows that, a weak drug sales regulation and poor dispensing practice by the pharmacy professionals could be attributed to the easy accessibility of these groups of drugs as OTC. Similarly, local pharmacies, friends and relatives were also identified as the source of TC for OTC use by different studies (Ambica *et al*., 2014; Sarasawat *et al*., 2011; Lu *et al.*, 2009).

The current study indicated that, a significant association between sex and with OTC use. Multinomial logistic regression analysis detected a statistically significant (p=0.049) association between sex of the patients with OTC use (AOR = 20.41; 95% CI [10.10-500.00]), that identified females as the fundamental element in OTC use of TC. In this and most other studies females are more prone to use TC. This could be because; the use of TC for cosmetics purpose is associated with beauty, and females are more concerned to look beauty than their counter parts.

A significant association (p=0.003) was also detected between educational status and OTC use (AOR = 0.005; 95% CI [0.000-0.170], however, no significant associations were detected between patients' age, marital status, level of income and occupational status, indicating that TC are widely used on OTC basis for different purposes by dermatology OPD attendees regardless of age, level of income or marital status.

This study also covered the extent of availability of TC at cosmetics shops, and out of the total 9 cosmetics shops surveyed; TC containing preparations were available in 7 cosmetics shops. Different types and brands of TC were available in the cosmetics shops. It was also noted from the quantitative survey that dermatology health facilities finding, the sources of TC in 50 (31.6%) of OTC user patients was from cosmetics shops.

This study also incorporated the ideas of key informants related to irrational use of TC and factors behind such misuse, and accordingly, misuse of TC by the community particularly among females and the youngsters in our country is a common problem and the factors contributing for irrational use of these groups of drugs are the easy access by the public as OTC in drug retail outlets as well as cosmetics shops, weak regulation of sales, use for cosmetics purpose and lack of awareness by the community.

Although this result clearly showed that use of TC on OTC basis without a medical prescription is common among OPD attendees in the selected dermatology health facilities of Addis Ababa, the dermatological diagnoses on the face were based mainly on clinical grounds noted by the dermatologists and not confirmed by further investigation. Future research should investigate the prevalence and type of local and systemic complications following TC misuse in different areas of our country. Furthermore, for detailed association appropriate examination of the side effects of these groups of drugs need to be conducted in every dermatology health facilities.

6. Strengths and limitations of the study

Strengths

- ✓ The study objective addresses an important and new issue as use of TC on OTC basis could be considered as one of the public health problems in a country where there is weak drug sales regulation and lack of wide controlled medical education.
- ✓ The study employed a prospective study design by using mixed method approaches
- ✓ The study covered cosmetics shops
- ✓ The study incorporated the ideas of key informants

Limitations

- ✓ As this was an OPD-based study and, therefore, it may or may not accurately reflect the community data
- ✓ The use of a purposive sampling method to select the health facilities as well as cosmetics shops

7. Conclusion

The results of this study revealed that, irrational use of topical corticosteroids over the face, especially on OTC basis is responsible for a significant proportion of visits to dermatology health facilities. Unwarranted OTC use of TC without a medical prescription is quite common especially among female patients. The study showed that, 158 (79.0%) of the 200 patients who had used TC on their face obtained the drug without a medical prescription as OTC. The types of facial dermatoses noted in majority 29.1% of the patients was found to be Acne, followed by Melasma in 20.3% and Rosacea in 14.6%.

The easy access of TC in community pharmacies, hospital pharmacies as well as cosmetics shops by the patients contributed for misuse of these groups of drugs as OTC. Moreover, the study determined the extent of availability of TC in cosmetics shops, out of the total 9 cosmetics shops surveyed; TC containing preparations were available in 7 cosmetics shops

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8. Recommendations

Based on the study findings, the following recommendations are forwarded,

For FMHACA,

- The sales and marketing of prescription only drugs like TC must be controlled, which could be done by imposing fines and penalties on the marketers of these groups of drugs.

For FMoH, Ethiopian Dermatology and Venereology Society and AACAHB,

- Health education to the general public about the dangers of using prescription only drugs including TC as OTC through media. Health education programmes should target females by using leaflets, television and radio.
- Sensitizing primary health care providers and other health professionals regarding the adverse effects of TC misuse on the face and enable them to recommend suitable and safe alternatives.

For health facilities, dermatologists and other healthcare professionals,

- Training programs should be organized to promote awareness of other healthcare professionals who prescribe and dispense the drugs.
- Avoiding irrational prescription and OTC dispensing practice of TC pharmacy professionals

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Annexes

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DEPARTMENT OF PHARMACEUTICS AND SOCIAL PHARMACY,

SCHOOL OF PHARMACY

I. <u>Screening question format</u>

Name of the dermatological center…… identification number……

Interviewer name……Qualification……..Signature…….

Ser. No.	Date	Sex	Age (yr.)	Type of facial dermatoses noted	Current use of any topical formulation cream/ointment/lotion to the face Yes or No	The formulation in question contained a corticosteroid Yes or No

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II. A structured questioner for patient interview in selected dermatological health facilities

Questioner ID /...../...../...../

The aim of this study is to assess the associated factors, the most common types of facial dermatoses noted, and the extent of OTC utilization of TC on the face in the dermatology OPD attendees of the selected health facilities, and also to ascertain the extent of availability in selected cosmetics shops of Addis Ababa, Ethiopia. Your participation is encouraged as your feedback is vital for the successful completion of the study.

You are kindly requested to be honest in answering all question's as it will be solely used for research purpose. The interview will take around 20-25 minutes of your time and your responses will be confidential, anonymous and data will be analyzed in aggregates. If you have any questions, please contact the principal investigator Netsanet Bantayehu with a mobile phone number of +251 911 976 449 or e-mail: netsanetba@yahoo.com.

Questioner Information

This questioner will be conducted for patients with facial dermatoses who have a positive answer for TC use in the screening question.

Name of the dermatological center…… identification number……

Date of the interview /……/date /……/month /……./year

Start time /……/hour /……/minute

End time /……/hour /……/minute

Interviewer name……Qualification……..Signature…….

No.	Question Descriptions	Answer Code
Part I. Patient Information		
1.	Gender	1. Male 2. Female
2.	Age (in years)	
3.	Marital status	1. Single 2. Married 3. Divorced/Separated 4. Widowed
4.	Place of residence/address	1. Addis Ababa 2. Out of Addis Ababa

5.	Occupational status	1. Student 2. Government employee 3. Non-governmental organization employee 4. Private business 5. Unemployed 5. Other----------
6.	Household average monthly income	1. No income 2. Less than 450 ETB 3. Between 450 and 1000 ETB 4. Between 1000 and 1500 ETB 5. Between 1500 and 2000 ETB 6. Between 2500 and 3000 ETB 7. Between 3000 and 3500 ETB 8. Between 3500 and 4000 ETB 9. More than 3500 ETB 10. I don't know
7.	Educational background	1. Cannot read or write 2. Read but cannot write 3. Read and write only 4. Primary education first cycle (1-4) 5. Primary education second cycle (5-8) 6. Secondary education first cycle (9-10) 7. Secondary education second cycle (11-12) 8. College, University or higher
8.	The type of facial dermatoses noted (Check from the patient card)	----------

Part II. Drug (TC) use related questions		
9.	Where do you get the preparation you applied?	1. Community pharmacies 2. Hospital pharmacies 3. Cosmetics shops 4. Relatives and friends 5. I didn't remember 6. If other, specify_____
10.	What was source of the prescription?	1. Prescribed 2. OTC
11.	Brand name and composition of TC containing product used on the face (Name, strength & dosage form and brand name)	
12.	To which part of your face did you apply the preparation?	1. All over the face 2. Only over the affected area
13.	For what purpose did you apply the preparation?	1. For cosmetics purpose 2. For treatment purpose 3. If other, specify_____
14.	For how long did you apply the preparation?	1. For more than 6 months 2. Between 1 and 6 months 3. Less than 1 month
15.	How frequently did you apply the preparation?	1. Continuously 2. Intermittently
16.	How many times did you apply per day?	1. Three times or more 2. Twice

		3. Once

THANK YOU FOR YOUR RESPONSE

አዲስ አበባ ዩኒቨርሲቲ

ድህረ-ምረቃ ትምህርት ቤት፣

ፋርማሲዩቲክስና ሶሻል ፋርማሲ ትምህርት ክፍል፣

ፋርማሲ ትምህርት ቤት

<u>በተመረጡ የቆዳ ህክምና ማዕከላት ለሚታከሙ ህመምን የተዘጋጀ መጠይቅ</u>

የመጠይቁ መለያ /...../...../...../

የዚህ ጥናት አላማ በአዲስ አበባ ያለዉን የቶፒካል ኮርቲኮስቴሮይድስ ያለ ታኪም ማዘዣ አጠቃቀም እና እነዚህን መድሀኒቶች ያለ ሃኪም ትዕዛዝ በተጠቀሙ ታካሚዎች ላይ የሚያደርሰዉን ጉዳት ለመፈተሽ ነዉ፡፡ ከዚህም በተጨማሪም በተመረጡ የኮስሞቲክስ መደብሮች መገኘት አለመገኘታቸዉን ይዳስሳል፡፡ ጥናቱ አግባብነት ላለዉ የቶፒካል ኮርቲኮስቴሮይድስ አጠቃቀም አስተዋጽኦ ያደርጋል፡፡ ይሄም ለማሕበረሰቡ ግንዛቤ ለመፍጠር እና ለተቆጣጣሪ አካላት አስፈላጊዉን የማስተካከያ እርምጃ ለመዉሰድ ይረዳል፡፡

በዚህ ቃለ-መጠይቅ ዉስጥ እንዲሳተፉ የተጠየቁት ጥናቱ ለቆዳ በሽታዎች ስለሚታዘዙት ቶፒካል ኮርቲኮስቴሮይድስ ስለሆነና እርስዎ ደግሞ ለዚህ ጥናት ከተመረጡት መካከል አንዱ ነዎት፡፡ ቃለ-መጠይቁ ከ20 ደቂቃ የማይበልጥ ጊዜ የሚወስድ ሲሆን ተሳትፎዎት በሙሉ ፍቃደኝነት ሲሆን ያልፈለጉትን ጥያቄ አለመመለስ ይችላሉ እናም በማንኛዉም ሰአት ቃለ መጠይቁን ማቋረጥ ይችላሉ፡፡ መልሶቹ በሚስጥራዊነት የሚያዙ ይሆናል ማለትም ስምዎት ቃለ መጠይቁ ላይ አይጠቀስም እናም በማንኛዉም ጊዜ መልስዎት ከእርስዎ ጋር አይያያዝም፡፡ስለ ጥናቱ ማንኛዉም ጥያቄ ካለዎት የጥናቱ መሪ የሆኑትን ነጻነት ባንታየሁ በሞባይል ቁጥር 0911 976449 ወይም በኢ-ሜይል አድራሻ netsanetba@yahoo.com ማግኘት ይችላሉ፡፡

<u>የመጠይቁ መግለጫ</u>

ይህ መጠይቅ የሚከናወነዉ የፊት ቆዳ ችግር ላጋጠማቸዉ እና በመለያዉ ጥያቄ የቶፒካል ኮርቲኮስቴሮይድስ መጠቀማቸዉ ለተረጋገጡ ታካሚዎች ይሆናል፡፡

ከቅርብ ጊዜ ዉስጥ ለፊትዎ በመደበኛነት ከሚጠቅሙ የፊት ቅባቶች (እንደ ቫዝሊን፣ ኒቪያ ቅባት...) የተለየ ተጠቅመዋል?

የቆዳ ህክምና ማዕከሉ ስም----------መለያ ቁጥር----------

መጠይቁ የተካሄደበት፡- ቀን----------ወር-------ዓ.ም-------

መጠይቁ የተጀመረበት፡- ሠዓት-------ደቂቃ--------

መጠይቁ የተጠናቀቀበት፡- ሠዓት-------ደቂቃ--------

የጠያቂዉ ስም----------ሙያ----------ፊርማ----------

ተ.ቁ.	ጥያቄ	የመልሥ መሰጫ

ክፍል I. የታካሚዉ አጠቃላይ መረጃ

1.	ጾታ	1. ወንድ 2. ሴት
2.	ዕድሜ	----------ዓመት
3.	የጋብቻ ሁኔታ	1. ያላገባ 2. ያገባ 3. በፍች የተለያዩ/አብረዉ የማይኖሩ 4. በሞት የተለያዩ
4.	የመኖሪያ አድራሻ	2. አዲስ አበባ 3. ከአዲስ አበባ ዉጭ
5.	የሥራ ሁኔታ	1. ተማሪ 2. የመንግስት ድርጅት ተቀጣሪ 3. መንግስታዊ ያልሆነ ድርጅት ተቀጣሪ 4. የግል ድርጅት ተቀጣሪ 5. ተቀጣሪ ሰራተኛ ያልሆነ 6. ሌላ----------
6.	አማካኝ ወርታዊ የቤተሰብ ገቢ	1. ገቢ የሌለዉ 2. ከ 450 ብር በታች 3. በ 450 እና በ1000 ብር መካከል 4. በ 1000 እና በ1500 ብር መካከል 5. በ 1500 እና በ2000 ብር መካከል 6. በ 2000 እና በ2500 ብር መካከል 7. በ 2500 እና በ3000 ብር መካከል 8. በ 3000 እና በ3500 ብር መካከል 9. ከ 3500 ብር በላይ

10. አላዉቀዉም

7. የትምህርት ደረጃ

1. ማንበብ እና መጻፍ የማይችል
2. ማንበብ የሚችል ግን መጻፍ የማይችል
3. ማንበብ እና መጻፍ ብቻ የሚችል
4. የመጀመሪያ ደረጃ ትምህረት የመጀመሪያ ሳይክል (ከ1-4)
5. የመጀመሪያ ደረጃ ትምህረት የሁለተኛ ሳይክል (ከ5-8)
6. የሁለተኛ ደረጃ ትምህርት የመጀመሪያ ሳይክል (ከ9-10)
7. የሁለተኛ ደረጃ ትምህርት የሁለተኛ ሳይክል (ከ11-12)
8. ኮሌጅ፣ ዩኒቨርቲ ወይም ከዚያ በላይ

8. በፊት ላይ የታየዉ የቆዳ ችግር ዓይነት (ከታካሚዉ ካርድ ያረጋግጡ)

ክፍል II. የመድኃኒተት አጠቃቀምን የተመለከቱ ጥያቄዎች

9. የተጠቀሙትን የቅባት ዓይነት ከየት ሊያገኙት ቻሉ?

1. ከህዝብ መድኃኒትቤቶች
2. ከሆስፒታል መድኃኒትቤቶች
3. ከኮስሞቲክስ ወይም ከሽቀጣሽቀጥ መሸጫ ቤቶች
4. ከቤተሰብ ወይም ከቅርብ ጓደኛ
5. አላስታዉሰዉም
6. ከሌላ ከሆነ ይጠቀስ_____

10. የተጠቀሙትን የቅባት ዓይነት እንዴት አገኙት?

1. በመድኃኒት ማዘዣ
2. ያለመድኃኒት ማዘዣ

11. የተጠቀሙት የቶፒካል ኮርቲኮስቴሮይድስ የያዘዉ የቅባት ዓይነት መግለጫ (የመድኃኒቱ ሥም፣የዝግጅት ዓይነትና ይዘት

እና የንግድ ስም)

12. ፊትዎ ላይ እንዴት ነበር የተጠቀሙት?
    1. ሙሉ የፊት አካልን
    2. የተነዳዉን የፊት አካል ብቻ

13. ለምን አገልግሎት ነዉ የተጠቀሙት?
    1. እንደዉበት መጠበቂያ ቅባት
    2. ለህክምና አገልግሎት
    3. ሌላ----------

14. ለምን ያህል ጊዜ ነዉ የተጠቀሙት?
    1. ከ 6 ወር በላይ
    2. ከ 1 እስከ 6 ወር
    3. ከ 1 ወር በታች

15. በምን ያክል ጊዜ ልዩነት ነዉ የተጠቀሙት?
    1. በተከታታይ
    2. አልፎ አልፎ

16. በቀን ስንት ጊዜ ይጠቀሙት ነበር?
    1. ሦስት ጊዜ እና ከዚያ በላይ
    2. ሁለት ጊዜ
    3. አንድ ጊዜ

ሥለምላሽዎ እናመሰግናለን

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DEPARTMENT OF PHARMACEUTICS AND SOCIAL PHARMACY,
SCHOOL OF PHARMACY

III. <u>Observation checklist for availability of any TC in selected cosmetics shops and interview guide for cosmetics shop sales persons</u>

Questioner ID /...../...../...../

Questioner Information

Type of the shop…… identification number……

Address of the cosmetics shop: - Sub city……Local area……

Date of the interview /……/date /……/month /……./year

Start time /……/hour /……/minute

End time /……/hour /……/minute

Interviewer

name……Qualification……..Signature…….

1. Gender □ Male □ Female
2. Age in years: _____
3. Total years of professional experience as a cosmetics sales keeper _____ years
4. Educational status
   a. Cannot read or write
   b. Read but cannot write
   c. Read and write only
   d. Primary education first cycle (1-4)
   e. Primary education second cycle (5-8)
   f. Secondary education first cycle (9-10)
   g. Secondary education second cycle (11-12)
   h. College, University or higher
5. Check for availability of TC containing preparation by asking or by showing samples of popularly used brand preparations and check the generic name in the list below.

Ser. No.	**Check for the availability of the following TC**	**A**	**NA**	**Brand name if available**
1.	Betamethasone dipropionate 0.05% ointment			
2.	Clobetasol propionate 0.05% ointment			
3.	Betamethasone valerate 0.1% ointment			
4.	Mometasone furoate 0.1% ointment			
5.	Mometasone furoate 0.1% cream			
6.	Betamethasone dipropionate 0.05% cream			

7. Betamethasone dipropionate lotion
8. Betamethasone valerate 0.05% ointment
9. Betamethasone valerate 0.05% cream
10. Triamcinolone acetonide 0.1% cream
11. Methylprednisolone aceponate 0.1% ointment
12. Clobetasone 0.05% cream
13. Hydrocortisone or hydrocortisone acetate 0.5%
14. Hydrocortisone or hydrocortisone acetate 1%
15. Desonide 0.05%

6. If any TC preparation is available, where are the sources of these TC?

---

7. Is there any restriction to any product you want to sell? If there is any restriction, from which institute?

---

8. If there is anything you would like to add----------

THANK YOU FOR YOUR RESPONSE

ADDIS ABABA UNIVERSITY

SCHOOL OF GARDUATE STUDIES

DEPARTMENT OF PHARMACEUTICS AND SOCIAL PHARMACY,

SCHOOL OF PHARMACY

IV. Interview guide for dermatologists working in the selected dermatology centers

Questioner ID /...../...../...../

The aim of this study is to assess the associated factors, the most common types of facial dermatoses noted, and the extent of OTC utilization of TC on the face in the dermatology OPD attendees of the selected health facilities, and also to ascertain the extent of availability in selected cosmetics shops of Addis Ababa, Ethiopia. Your participation is encouraged as your feedback is vital for the successful completion of the study.

You are kindly requested to be honest in answering all question's as it will be solely used for research purpose. The interview will take around 20-25 minutes of your time and your responses will be confidential, anonymous and data will be analyzed in aggregates. If you have any questions, please contact the principal investigator Netsanet Bantayehu with a mobile phone number of +251 911 976 449 or e-mail: netsanetba@yahoo.com.

Questioner Information

Name of the dermatological center…… identification number……

Date of the interview /……/date /……/month /……./year

Start time /……/hour /……/minute

End time /……/hour /……/minute

Interviewer name……Qualification……..Signature…….

1. Gender □ Male □ Female
2. Age in years: _____
3. Total years of professional experience _____ years
4. What is the highest education level you completed?
5. What is your professional title?
6. How do you explain the irrational use of TC in Ethiopia?

---

7. How do you explain the extent of TC use without prescription?

---

8. Do you think use of TC on OTC basis is common among the community? Among your patients?

---

9. What do you think inappropriate use of TC result in?

---

10. How common do you think each the following factors are known to contribute to irrational use of TC? (Can choose more than one factor)

    i. The easy access by the people OTC in drug retail outlets
    ii. The easy access by the people OTC in cosmetics shops
    iii. The unregulated sales
    iv. Their use for cosmetics purpose
    v. Lack of awareness by the community

11. What possible methods do you recommend so that factors or practices which contribute to irrational use of TC could be addressed? ----------

---

---

12. If there is anything you would like to add----------

THANK YOU FOR YOUR RESPONSE

ADDIS ABABA UNIVERSITY

SCHOOL OF GARDUATE STUDIES

DEPARTMENT OF PHARMACEUTICS AND SOCIAL PHARMACY,

SCHOOL OF PHARMACY

V. Interview guide for FMHACA drug regulatory and inspection case team

Questioner ID /...../...../...../

The aim of this study is to assess the associated factors, the most common types of facial dermatoses noted, and the extent of OTC utilization of TC on the face in the dermatology OPD attendees of the selected health facilities, and also to ascertain the extent of availability in selected cosmetics shops of Addis Ababa, Ethiopia. Your participation is encouraged as your feedback is vital for the successful completion of the study.

You are kindly requested to be honest in answering all question's as it will be solely used for research purpose. The interview will take around 20-25 minutes of your time and your responses will be confidential, anonymous and data will be analyzed in aggregates. If you have any questions, please contact the principal investigator Netsanet Bantayehu with a mobile phone number of +251 911 976 449 or e-mail: netsanetba@yahoo.com.

Questioner Information

1. Gender □ Male □ Female
2. Age in years: _____
3. Total years of professional experience _____ years
4. Highest level of education you completed _____
5. Current position in FMHACA_____
6. Work experience in your current qualification: _____

7. How do you describe OTC utilization of prescription only drugs by the community in Ethiopia, Particularly in Addis Ababa? What are the commonest groups of drugs?

   --Probe, what about TC?----------

---

8. How do you describe the sources of prescription only drugs for OTC use?

Probe, what about TC?----------

---

9. What do you think inappropriate use of drugs particularly TC use without a medical prescription result in?

---

10. Is there any regulatory manual that govern sales practice of TC containing preparations?

□ Yes □ No

11. Is there any regulatory structure/mandate of your office for the regulation OTC selling practices of drugs in drug retail outlets and informal shops like cosmetics shops?

---

12. What methods does FMHACA utilize to improve the rational use of drugs, particularly TC?

    Probe, how effective each of the described methods at improving such practices?

    ---

13. What do you think the barriers to regulate the sales practice of TC as OTC in drug retail outlets as well as and cosmetic shops?

    ---

14. If there is anything you would like to add----------

THANK YOU FOR YOUR RESPONSE

VI. Patients with facial dermatoses screened among OPD attendees, in selected dermatology health facilities of Addis Ababa, February 2015 (N=927).

Types of facial dermatoses screened	Usage of TC	
	Yes	No
	N (%)	N (%)
Acne	58 (6.3)	216 (23.3)
Melasma	37 (4.0)	181 (19.5)
Atopic Dermatitis (AD)	7 (0.8)	79 (8.5)
Rosacea	31 (3.3)	50 (5.4)
Photocontact Dermatitis	9 (1.0)	34 (3.7)
Vitiligo	5 (0.5)	25 (2.7)
Seborrheic Dermatitis (SD)	7 (0.8)	22 (2.4)
Perioral Dermatitis (PD)	10 (1.1)	15 (1.6)
Hyperpigmentation	0 (0)	17 (1.8)
Acne and Melasma	8 (0.9)	7 (0.8)
Xerosis (Dry Skin)	1 (0.1)	12 (1.3)
Actinic Lichen Palinus (ALP)	5 (0.5)	8 (0.9)
Cutaneous Leshmaniasis	0 (0)	12 (1.3)
Discoid Lupus Erythromatus (DLE)	2 (0.2)	9 (1.0)

Steroid Dependent Face (SDF)	10 (1.1)	1 (0.1)
Mollescum Contagiosum (MC)	0 (0)	10 (1.1)
Irritant Contact Dermatitis (ICD)	2 (0.2)	7 (0.8)
Tinea Incognito (TI)	2 (0.2)	6 (0.6)
Tinea Faciei (TF)	2 (0.2)	5 (0.5)
Hyperhydrosis	0 (0)	6 (0.6)
Tinea Corporis (TC)	0 (0)	3 (0.3)
Telangiectasia	3 (0.3)	0 (0)
Impetigo	0 (0)	1 (0.1)
Ochronosis	1 (0.1)	0 (0)
Folliculitis	0 (0)	1 (0.1)
Total	**200 (21.6)**	**727 (78.4)**

VII. Information sheet

TC are the most commonly used drugs in dermatological practice. Over the last 60 years TC have become the cornerstones of treatment for many inflammatory skin conditions. However, it has become increasingly apparent that these groups of drugs are being abused by prescribers, dispensers and patients. Misuse of TC is found to cause different dermatological

complications worldwide and particularly in developing countries like to additional unplanned cost in terms of both scarce resources and the adverse drug effects. The easy access by the people OTC, the unregulated sale, their use for cosmetics purpose and poor dispensing practice by the pharmacies contributed to the irrational use of these groups of drugs.

The aim of this study is to assess the associated factors, the most common types of facial dermatoses noted, and the extent of OTC utilization of TC on the face in the dermatology OPD attendees of the selected health facilities, and also to ascertain the extent of availability in selected cosmetics shops of Addis Ababa, Ethiopia. The study will employ a descriptive, cross sectional study design using both qualitative and quantitative methods of data collection. Prospective data collection method in the selected dermatologic centers will be conducted with dermatological outpatients to assess the extent of OTC utilization of TC and the most common dermatological problems. Observation check list will also be employed to assess the extent of availability of TC in cosmetics shops and a key informant interview will be conducted to collect the qualitative data.

Before entry into the computer statistical program like Excel and EPI-INFO, the collected data will be checked and cleaned by the principal investigator. Quantitative data will be analyzed using SPSS for Windows software version 16. Descriptive statistics such as mean, frequencies and percentages will be used to describe the data and tables and figures will be used to summarize the data. Qualitative data obtained from the key informant interviews will be grouped based on similarities and differences of perspectives between different respondents and analysis will be conducted thematically.

Participation in the study is encouraged as their feedback is vital for the successful completion of the study. There are no direct risks to the participants. However, there will take their time while they are being interviewed. There are also no direct benefits to participants. However, it is hoped that their participation will ultimately contribute to the rational use of TC. Your responses will be confidential, anonymous and data will be analyzed in aggregates. Participation of the interviewees is completely voluntary. They can refuse to answer any questions or withdraw from the study at any time. All the responses will remain strictly confidential: their name will not appear on the interview guide (will not be recorded), and the responses will not be linked to your identity at any time. All data will be kept in a secure

location and only those directly involved with the research will have access to the data. And the interview recorded will be erased after the completion of the study.

This study will be important by determining the extent of TC use OTC, the most common dermatological problems resulting from misuse of TC and by showing the extent of availability in cosmetics shops for non prescribed use to these classes of drugs in Addis Ababa. This will help regulatory authorities for the curbing of the problem associated with misuse of TC. The study will be conducted in selected dermatological centers and cosmetics shops in Addis Ababa.

After the completion of the study, It will be presented to AAU, SOP and printed and disseminated to the dermatological centers, FMHACA and FMoH.

For any questions, please contact the principal investigator Netsanet Bantayehu with a mobile phone number of +251 911 976 449 or e-mail: netsanetba@yahoo.com or the advisor Dr. Teferi Gedif via email at tgedif@gmail.com

የመረጃ ቅጽ

ለቆዳ በሽታዎች ህክምና ከሚጠቅሙ መድሃኒቶች መካከል ቶፒካል ኮርቲኮስቴሮይድስ ዋነኞቹ ሲሆኑ ከአለፉት 60 አመታት ጀምሮ ለተለያዩ አይነት የቆዳ በሽታ ህክምና እየገለገሉ ይገኛሉ፡፡ ሆኖም ግን በአለም አቀፍ ደረጃ እነዚህን

መድሃኒቶች ያለአግባብ መጠቀም በህክምና ባለሙያዎችና በታካሚዎች አካባቢ በመጨመሩ ለአላስፈላጊ ጉዳት እየዳረጉ ሲሆን በተለይም በታዳጊ አገራት ለተጨማሪ ወጪና ጉዳት እያጋለጡ ይገኛሉ፡፡ ያለማዘዣ መድሃኒቶችን በቀላሉ ማግኘት መቻል፣ ለኮስሞቲክስነት መጠቀም እንዲሁም የሽያጭ ቁጥጥር ማነስ እነኝህን መድኃኒቶች ያለአግባብ ለመጠቀም እንደምክንያትነት የሚጠቀሱ ናቸዉ፡፡

የዚህ ጥናት አጠቃላይ አላማ በአዲስ አበባ ያለዉን የቶፒካል ኮርቲኮስቴሮይድስ ያለ ኃኪም ማዘዣ አጠቃቀም እና እነዚህን መድሀኒቶች ያለ ሃኪም ትዕዛዝ በተጠቀሙ ታካሚዎች ላይ የሚያደርሰዉን ጉዳት ለመፈተሽ ነዉ፡፡ ከዚህም በተጨማሪም በተመረጡ የኮስሞቲክስ መደብሮች መገኘት አለመገኘታቸዉን ይዳስሳል፡፡ የጥናቱ ዘዴዎች ታካሚዎችን በቀጥታ በመጠዬቅ መረጃ መሰብሰብ፣ የኮስሞቲክስ መደብሮችን መጎብኘትና ከመድኃኒት ተቆጣጣሪ ባለሙያዎች፣ በቆዳ ህክምና ላይ ስፔሻላይዝ ያደረጉ ሃኪሞች እንዲሁም ከኮስሞቲክስ መደብር ሽያጭ ሰራተኞች ጋር ቃለ-መጠይቅ ማድረግን ያካትታል፡፡ ጥናቱ በሚሰራበት የህክምና ማዕከላት በሚሰሩ ነርሶች አማካኝነት መረጃዎች በመጠይቅ እንዲሰባሰቡ ይደረጋል በተጨማሪም በተመረጡ የኮስሞቲክስ መደብሮች መገኘት አለመገኘታቸዉን ማየት፡፡ የተሰባሰበዉም መረጃ ኮድ እየተሰጠዉ EPI Info Version 6.0 ሶፍት ዌር ዉስጥ እንዲገባ ይደረጋል፡፡ በመቀጠልም በSPSS version 16 ፕሮግራም የተለያዩ የስታቲክስ ዘዴዎችን በመጠቀም ይጠናቀራሉ፡፡ እንዲሁም ከቃለ-መጠይቁ የሚገኙትን መረጃዎች እንደየሃሳባቸዉ ተመሳሳይነት ተከፋፍለዉ ይጠናቀራሉ፡፡

መረጃዎችን በማሰባሰብ ሂደት ዉስጥ ቀጥተኛ ጉዳት የሚደርስበት ሁኔታ የለም፡፡ ነገር ግን ቃለ-መጠይቅ በሚካሄድበት ሰዓት የሚባክን ጊዜ ይኖራል፡፡ ይህ በእንዲህ እያለ ተሳታፊዎቹ የሚያገኙት የተለየ ጥቅም ባይኖርም ትክክለኛ ወይም አግባብነት ያለዉ የቶፒካል ኮርቲኮስቴሮይድስ አጠቃቀም እንዲመጣ ይረዳል፡፡

በጥናቱ ላይ የሚሳተፉት በሙሉ በፍላጎታቸዉ ሲሆን ከጥናቱ የተገኙ ምላሾች እና ስማቸዉ በሙሉ በሚስጥር ይያዛል፡፡ ከጥናቱ ጋር ቀጥተኛ ግንኙነት ካላቸዉ ተሳታፊዎች በስተቀር ሁሉም መረጃዎች በሚስጥር ይያዛሉ፡፡ጥናቱ ከተጠናቀቀ በ|ላ በቴፕ መቅረጫ የተቀረጸዉ ቃለ-መጠይቅ እንዲደመሰስ ይደረጋል፡፡

ጥናቱ አግባብነት ላለዉ የቶፒካል ኮርቲኮስቴሮይድስ አጠቃቀም አስተዋጽኦ ያደርጋል፡፡ ይሄም ለተቆጣጣሪ አካላት አስፈላጊዉን የማስተካከል እርምጃ እንዲወሰድ ይረዳል፡፡

ጥናቱ ሲጠናቀቅ የጥናቱ ጽሁፍ አግባብነት ላላቸዉ አካላት የሚቀርብና ታትሞ የሚሰራጭ ይሆናል፡፡

አድራሻ

የጥናት መሪ፡ ነጻነት ባንታየሁ

ሞባይል ቁጥር 0911 976449፣ ኢ-ሜይል netsanetba@yahoo.com

VIII. Written informed consent

You are kindly invited to participate in a research study conducted by Netsanet Bantayehu, from Addis Ababa University, School of Pharmacy, Department of Pharmaceutics and Social

Pharmacy. The research topic is "Assessment of over-the-counter utilization of topical corticosteroids in Addis Ababa".

The aim of this study is to assess the associated factors, the most common types of facial dermatoses noted, and the extent of OTC utilization of TC on the face in the dermatology OPD attendees of the selected health facilities, and also to ascertain the extent of availability in selected cosmetics shops of Addis Ababa, Ethiopia. So that it will be important by determining the magnitude of the extent of TC use OTC, the most common dermatological problems resulting from misuse of TC and by showing the extent of availability in cosmetics shops for non prescribed use to these classes of drugs in Addis Ababa. This will help regulatory authorities for the curbing of the problem associated with misuse of TC.

You were selected as a possible participant in this study because you fit for this topic and the study is about OTC utilization of TC. The interview will take around 20-25 minutes of your time and the interview will be tape recorded. Your participation is completely voluntary. You can refuse to answer any questions and/or withdraw from the interview at any time. All your responses will remain strictly confidential: your name will not appear on the interview guide, and your responses will not be linked to your identity at any time. And the interview recorded will be erased after the completion of the study.

You are kindly requested to be honest in answering all question's as it will be solely used for research purpose. Your responses will be confidential, anonymous and data will be analyzed in aggregates. If you have any questions, please contact the principal investigator Netsanet Bantayehu with a mobile phone number of +251 911 976 449 or e-mail: netsanetba@yahoo.com or the advisor Dr. Teferi Gedif via email at tgedif@gmail.com

Your signature indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation without any consequences.

Yes I agree ☐ No, I don't agree ☐

Signature _____

Date_____

<u>የጽሁፍ ፍቃደኝነት ማረጋገጫ ቅጽ</u>

ከአዲስ አበባ ዩኒቨርሲቲ የፋርማሲ ትምህርት ቤት ከፋርማሲዩቲክስ እና ሶሻል ፋርማሲ የትምህርት ክፍል በነጻነት ባንታየሁ በሚደረገዉ ጥናት ላይ እንዲሳተፉ ተጋብዘዋል፡፡ የጥናቱ ርዕስ "Assessment of over-the-counter utilization of topical corticosteroids: a cross-sectional facility level study in Addis Ababa" ነዉ::

አላማዉም በአዲስ አበባ ያለዉን የቶፒካል ኮርቲኮስቴሮይድስ ያለ ኃኪም ማዘዣ አጠቃቀም እና እነዚህን መድሀኒቶች ያለ ሃኪም ትዕዛዝ በተጠቀሙ ታካሚዎች ላይ የሚያደርሰዉን ጉዳት ለመፈተሽ ነዉ። ከዚህም በተጨማሪም በተመረጡ የኮስሞቲክስ መደብሮች መገኘት አለመገኘታቸዉን ይዳስሳል። ጥናቱ አግባብነት ላለዉ የቶፒካል ኮርቲኮስቴሮይድስ አጠቃቀም አስተዋጽኦ ያደርጋል። ይሄም ለተቆጣጣሪ አካላት አስፈላጊዉን የማስተካከል እርምጃ እንዲወሰድ ይረዳል።

በዚህ ቃለ-መጠይቅ ዉስጥ እንዲሳተፉ የተጠየቁት ጥናቱ ለቆዳ በሽታዎች ስለሚታዘዙት ቶፒካል ኮርቲኮስቴሮይድስ ስለሆነና እርስዎ ደግሞ ለዚህ ጥናት ከተመረጡት መካከል አንዱ ነዎት። ቃለ-መጠይቁ ከ20-25 ደቂቃ የማይበልጥ ጊዜ የሚወስድ ሲሆን ተሳትፎዎት በሙሉ ፍቃደኝነት ሲሆን ያልፈለጉትን ጥያቄ አለመመለስ ይችላሉ እናም በማንኛዉም ሰአት ቃለ መጠይቁን መተዉ ይችላሉ። መልሶቹ በሚስጥራዊነት የሚያዙ ይሆናል ማለትም ስምዎት ቃለ መጠይቁ ላይ አይጠቀስም እናም በማንኛዉም ጊዜ መልስዎት ከእርስዎ ጋር አይያያዝም። ጥናቱ ከተጠናቀቀ በ|ላ በቴፕ መቅረጫ የተቀረጸዉ ቃለ-መጠይቅ እንዲደመሰስ ይደረጋል።

ስለ ጥናቱ ማንኛዉም ጥያቄ ካለዎት የጥናቱን መሪ ነጻነት ባንታየሁ በሞባይል ቁጥር 0911 976449 ወይም በኢ-ሜይል አድራሻ netsanetba@yahoo.com ወይም የጥናቱን አማካሪ ዶ/ር ተፈሪ ገድፍ በኢ-ሜይል tgedif@gmail.com አግኝተዉ መጠየቅ ይችላሉ።

ፊርማዎ መረጃዉን አንብበዉ እንደተረዱና በፍቃደኝነት እንደሚሳተፉ እንዲሁም ፍቃደኝነትዎን በማንኛዉም ጊዜ መተዉ እንደሚችሉ ያረጋግጣል።

እስማማለሁ ☐ አልስማማም ☐

ፊርማ_____

ቀን_____

በ ፋርማሲ ት/ቤት
የኢቲክስ ሪቪው ቦርድ

አዲስ አበባ ዩኒቨርሲቲ
Addis Ababa University

School of Pharmacy
Ethical Review Board

ቀን Date: December 31, 2014

ቁጥር Ref. No: ERB/SOP/42/12/2014

To: Netsanet Bantayehu
School of Pharmacy

Subject: **Ethical Clearance**

It is to be recalled that you submitted a study proposal entitled, "Assessment of Over-The-Counter Utilization of Topical Corticosteroids: A Cross-sectional Facility Level Study in Addis Ababa " for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Esubalew Adugna (BPharm, MSc)
Secretary, ERB

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