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ASSESSMENT OF UTILIZATION PATTERN OF TOPICAL STEROIDS IN ALERT HOSPITAL

BY

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This is to certify that the thesis prepared by Hanna Negussie, entitled "Assessment of Utilization Pattern of Topical Steroids in ALERT HOSPITAL" and submitted in partial fulfillment of the requirements for the Degree of Master of Science (Pharmacoepidemiology and Social Pharmacy) complies with the regulations of the university and meets accepted standards with respect to originality and quality.

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List of abbreviations/acronyms

ALERT	All Africa Leprosy, TB and HIV, Research, Rehabilitation and Training Center
AAERC	AHRI/ALERT Ethics Review Committee
AMF	ALERT Medicines Formulary
BNF	British National Formulary
HPA	Hypothalamic-Pituitary-Adrenal
OTC	Over the Counter
OPD	Out Patient Department
NSTG	National Standard Treatment Guideline
WHO	World Health Organization

Abstract

Topical steroids comprise the mainstay treatment of skin diseases. However, irrational prescription of topical steroids is a common occurrence in clinical practice and they are being abused by health professionals and patients alike. This study was performed to assess the utilization pattern of topical steroids in ALERT Hospital, Addis Ababa. The study employed a descriptive, cross sectional study design, using both quantitative and qualitative methods between August and November, 2013. Data abstraction format was used to collect the data from a total of 660 patient records and an interview guide was employed to collect data qualitatively. The quantitative data was analyzed using SPSS version 16 and the qualitative data was analyzed thematically. The majority of patients were females 380(60.9%) and their mean age was 24.2 years. Eczematous dermatitis 211(30.0%) was the single most common skin diseases observed. However, infectious skin diseases were the most common skin dermatoses 230(33.8%) when combined. The most commonly prescribed classes of drugs were topical steroids and its combination 315(28.4%) followed by anti-fungal drugs 245(22.1%). There were a total of 1108 drugs prescribed, with an average of 1.77 drugs per prescription. Topical steroids and its combination were found to be the most commonly prescribed drugs. A total of 315 topical steroids were prescribed and brand name was used in 307(97.5%) of them. The most commonly prescribed topical corticosteroids were betamethasone dipropionate 77(24.4%) and clobetasol propionate 73(23.2%), which are potent and very potent topical corticosteroids, respectively. Out of all the topical corticosteroids prescribed, the majority were potent 174(55.2%) and very potent 73(23.2%). Prescribers' adherence is to the ALERT Medicines Formulary and National Standard Treatment Guideline was found to be 100% and 58.1%, respectively. In most prescriptions, site of application, duration of treatment and quantity to be dispensed was inadequate; a practice that should be improved.

Key words: Prescription pattern, Topical steroids/corticosteroids, Skin diseases

1. Introduction

Skin diseases are a significant problem all over the world (Bezie *et al*., 2005). The substantial costs of skin diseases are generated by physician visits, hospital care, prescription drugs, and over-the-counter (OTC) products for treating or managing these conditions, as well as indirect costs due to productivity losses (The Lewin Group Inc., 2006). However, their importance is often overlooked (Bezie *et al*., 2005; van Hees and Naafs, 2001). Although most of the dermatological conditions do not result in death, they lead to misery and incapacitations. The quality of life in this group of patients is compromised in different ways. Patients also face a lot of distress from social stigma and low self-esteem due to deformities and disabilities of various degrees (Bezie *et al*., 2005; The Lewin Group Inc., 2006).

Dermatological conditions account for up to 2% of consultations in general practice worldwide (Saravanakumar *et al*., 2012). These skin problems are generally among the most common diseases seen in primary care settings in tropical areas. For instance, the World Health Organization's (WHO) 2001 report on the global burden of disease indicated that skin diseases were associated with mortality rates of 20,000 in Sub-Saharan Africa in 2001(Hay *et al*., 2006). This burden was comparable to mortality rates attributed to meningitis, hepatitis B, obstructed labor, and rheumatic heart disease in the same region (Hay *et al*., 2006).

With the skin being the largest and most accessible organ to treat, topical steroid therapy comprises the mainstay treatment of many dermatologic conditions since they were first introduced in early 1950s (AOCD, 2012; Padma *et al*., 2013; Usatine, 1998). For successful treatment with topical corticosteroid, accurate diagnosis, selecting the correct drug, the potency, delivery vehicle, frequency of application, duration of treatment and adverse effects, and proper patient profiling are decisive factors. To achieve this, monitoring, evaluating and therapeutically analyzing the prescribing pattern of dermatological drugs is important. Such analysis will not only improve the standards of medical treatment at all levels in the health system, but will also help in the identification of problems related to drug use such as polypharmacy, drug–drug interaction and adverse drug reactions (Padma *et al*., 2013).

On the other hand, OTC use of topical steroids is common for dermatological conditions. This is because; these products represent an important component of prevention and treatment of dermatologic conditions (Nolan *et al*., 2012). However, their use as skin lighteners is also widespread. Consequently, topical steroids produced for other purposes are being utilized for the purpose of skin lightening in the African setting which is directed toward attempting to lighten or tone one's skin color, and this has been a longstanding practice in this setting (Nnoruka and Okoye, 2006). This can cause a wide range of side effects depending on the strength of the steroid used, the length of time it is used, and the area of skin treated.

The purpose of this study is to describe utilization patterns of topical steroids in ALERT Hospital. Periodic reviewing of utilization patterns of commonly prescribed drugs is essential to increase the therapeutic efficacy, decrease adverse effects, provide feedback to prescribers and analyze the observance of standards of medical treatment (Padma *et al*., 2013). Therefore, the output of the finding is helpful to promote rational drug use of topical steroids and improves the standards of medical treatment.

1.1. Statement of the problem

Topical corticosteroids have greatly contributed to the dermatologist's ability to effectively treat several difficult dermatoses. The available range of formulations and potency gives flexibility to treat all groups of patients, different phases of disease and different anatomic sites. However, the rapid rise in incidence of improper use of these drugs by dermatologists, general physicians, and patients threatens to bring disgrace to the entire group of these remarkable drugs (Rathi and d'Souza, 2012). The cost of such irrational drug use is enormous in developing countries in terms of both scarce resources and the adverse clinical consequences of therapies that may have real risks, other than the side effects these classes of drugs cause (Bijoy *et al*., 2012; Narwane *et al*., 2011; Saravanakumar *et al*., 2012).

Irrational drug use is common with topical steroid use as they are important in the treatment of wide range of dermatologic conditions. Problems associated with topical steroid use includes: prescribing inappropriate quantities, inappropriate strength of steroid and length of treatment, prescribing emollients inadequately and prescribing generally with inadequate instructions in the use of both emollients and topical steroids (Bewley, 2008; Draper, 2011). This irrational use of topical steroids causes complications in the patient's health since topical steroids are associated with a number of side effects, both superficial and systemic (Al Shaikh, 2005; Lee and Arriola, 1999; Lim Fat and Leslie, 2011; Tempark *et al*., 2010; Woodson, 2009).

A Prescription Survey conducted in dermatology outpatient department (OPD) of an Indian Tertiary Care Hospital, showed steroids were one of the most frequently prescribed drugs. Among the steroids prescribed, topical steroid formulation Clobetasol, class I topical steroid which is associated with a number of adverse effects, was commonly prescribed as it was available in the hospital pharmacy (Narwane *et al*., 2011).

Despite the fact that use of topical steroids is associated with a number of side effects and related health complications, topical steroids are readily obtained OTC at affordable prices from non-pharmaceutical stores in most African countries (Nnoruka and Okoye, 2006). This has led to the misuse of topical steroids for skin lightening, which has constituted a public health concern in many African countries since 1980s and is a frequent practice (25-96%) in women from sub-Saharan Africa (Kpanake *et al*., 2010; Ly *et al*., 2007). Specifically, it was found to be practiced

by 25% of women in Bamako, Mali, 52% of women and 28% of men in Dakar, Senegal, 66% of the inhabitants of Brazzaville, Congo, and by more than 75% of both women and men in Lagos, Nigeria (Kpanake *et al*., 2010). Furthermore, the abuse of topical steroids is worsened when some general practitioners prescribe topical steroids for all skin rashes and for protracted periods (Nnoruka and Okoye, 2006).

In a study undertaken in southeast Nigeria in consecutive new patients attending a dermatology clinic, topical steroids were utilized by 313 (57.2%) patients for cosmetic purposes as depigmenting agents. There were more than 21 different steroid-containing products utilized, mostly class-I steroid in 89.6% of cases which were often compounded with other bleaching products. Disorders observed included steroid-induced acne (45.3%), macular hyperpigmentation of face (37.2%), mycoses (40.4%), striae (28.3%), telangiectasis (21.3%), hypertrichosis (13.9%) and diabetes mellitus (2.1%). Duration of utilization of these topical steroids was significantly associated with severe local and systemic consequences, while withdrawal of the offending steroids usually resulted in severe withdrawal dermatitis (Nnoruka and Okoye, 2006).

In Ethiopia, the use of topical steroids for cosmetic use is common although these classes of drugs are not to be sold OTC (FMHACA, 2012). Even though the practice of using topical steroids is not documented in Ethiopia, it can be seen that there is a widespread use of these drugs for cosmetic use and are sold in pharmacies, drug stores, rural drug vendors and even in cosmetic shops.

The utilization pattern of topical steroids in clinical settings is also not documented in Ethiopia. As irrational drug use associated with topical steroids is a common occurrence in clinical practice (Bijoy *et al*., 2012; Narwane *et al*., 2011), studying the utilization pattern of these classes of drugs will enable and effect suitable modifications in prescribing pattern to increase the therapeutic benefits and reduce adverse effects (Kumar *et al*., 2011). Also addressing the OTC use of these classes of drugs will give an insight for policy makers to what magnitude these drugs are being abused so that an intervention program could be designed. The study was conducted in ALERT Hospital, which is the specialized hospital for dermatological conditions and process large number of patients.

2. Literature review

2.1. Prevalence of skin diseases

The skin is the largest organ of the human body, a major interface between a person and the environment and the most diverse organ (Karn *et al*., 2010). It provides important functions, including protection from external insults and microorganisms, temperature modulation and synthesis of vitamin D. The importance of healthy intact skin is, without a doubt, decisive in the optimal physical functioning of the human body. A healthy and attractive skin also plays a major role in most persons' self-confidence as it is a key component of the image they present to the outside world (Karn *et al*., 2010). However, the skin is susceptible to a spectrum of insults including disorders caused by chemical and microbial agents, thermal and electromagnetic radiation, and mechanical trauma (Robert and Kupper, 1999).

Due to its exposure to the outside world and involvement in almost all of the systemic diseases, skin diseases are one of the most common health issues (Karn *et al*., 2010). They comprise a wide variety of diagnoses ranging from pure cosmetic conditions to tumors, genetic disturbances, autoimmune diseases and inflammatory skin diseases. Although a significant fraction of the population suffers from skin conditions, little is known on how this affects the everyday life of the individual's concerned (Bingefors *et al*., 2002).

In developing countries, skin diseases represent the greatest public health care problem and are a major cause of morbidity. They also represent a considerable financial burden in these resource poor countries (Paek *et al*., 2012). However, they have not been regarded as a significant problem that could benefit from public health measures. This attitude is due to the assumption that skin diseases are a benign, not life-threatening minor nuisance, and that they do not worth measures that may appear out of proportion to their low priority (WHO, 2005).

Generally, the information available on the prevalence and incidence of common skin diseases is scarce. This is even more so in Sub-Saharan Africa (Bissek *et al*., 2012). Nevertheless, it has been reported worldwide the prevalence of skin diseases ranges from 14% to 87% (Karn *et al*., 2010). The overall prevalence of skin diseases ranging between 62 % and 34.7% has been reported in a community based study conducted in some part of Africa (Bissek *et al*., 2012; Satimia *et al*., 1998).

In the case of Ethiopia, skin disease is considered a common problem in both urban and rural areas and is also among the leading causes of outpatient attendance (Accorsi *et al*., 2008). Studies conducted on skin diseases by the ministry of health indicated that skin diseases were the eighth cause of outpatient visits in Ethiopia, in both 2004/05 and 2006/07 (FMOH, 2005; FMOH 2007). From the very few studies conducted on the prevalence of skin diseases in Ethiopia, an overall prevalence of 80.4% and 3.3% has been documented (Accorsi *et al*., 2008; Figueroa *et al*., 1996; Figueroa *et al*., 1998). The literature concerning the prevalence of skin diseases is sparse. However, there are few studies done assessing patterns of skin diseases (Accorsi *et al*., 2008; Figueroa *et al*., 1996; Gimbel and Legesse, 2013; Shibeshi, 2000a; Shibeshi, 2000b).

2.2. Overview of topical steroids

Steroids are natural occurring hormones made by the body. In response to stress or disease, the body releases these hormones into the blood stream to control the immune response. Steroids work by penetrating the membrane of a cell and binding to a receptor. This can increase the production of anti-inflammatory proteins or inhibit the production of inflammatory ones. Synthetic derivatives of steroids have been formulated specifically for use on the skin (AOCD, 2012). Topical steroids were introduced to medicine in 1952 (Alavi and Sibbald, 2007). It began when the first controlled test of topical hydrocortisone for dermatological diseases was reported. The development of topical corticosteroids went on from that by adding functional substituent groups to the cortisone molecule to provide functionality and improve activity and/or reduce side effects (Katz and Gans, 2008).

The effects of topical corticosteroids are related to four main mechanisms of action: anti-inflammatory, immunosuppressive, anti-proliferative and vasoconstrictive effects. Together, the effects of these medications make them instrumental in treating a wide variety of disorders. The anti-inflammatory effect of topical corticosteroids is mediated by the inhibition of phospholipaseA2 release and also by inhibiting transcription factors involved in activating pro-inflammatory genes. The immunosuppressive effect of topical corticosteroids is mediated by their ability to significantly suppress the production and action of humoral factors involved in the inflammatory response. The anti-proliferative effect of topical corticosteroids is mediated by their ability to interfere with DNA synthesis and mitosis. The vasoconstrictive effect of topical corticosteroids is not yet completely understood. However, it is believed that the effect on

superficial dermal vessels may be mediated via inhibition of natural vasodilators (Chabassol and Green, 2012).

Topical steroids are best known for their powerful anti-inflammatory properties and their effectiveness of a topical therapy depends first on the inherent potency and second on its ability to penetrate into the skin (AOCD, 2012). The human vasoconstrictor assay, developed by McKenzie and Stoughton, has become one of the most valuable methods for precise evaluation of topical corticosteroid potency (Katz and Gans, 2008). Vasoconstrictor assay classifies steroids based on the extent to which the agent causes cutaneous vasoconstriction ("blanching effect") in normal, healthy persons (Ference and Last, 2009; Katz and Gans, 2008).

Depending on potency, topical steroids are generally grouped into four categories according to the British National Formulary (BNF), mild (weak = hydrocortisone), moderately potent (2.5 times stronger), potent (10 times stronger), and very potent (50 times stronger) (Bianchi *et al*., 2011). While the American system classifies topical steroids into seven classes, with class I corresponding to the very potent, super potent or ultrahigh potency approximately 600-1000 times stronger than the common OTC preparation of hydrocortisone 1% which is a class VII (AOCD, 2012; Ference and Last, 2009; Nnoruka and Okoye, 2006).

The choice of potency, for a specific skin condition, is dependent on the severity of the reaction (Cameron, 2007). The greater the potency, the more effect it has on reducing inflammation, but the greater the risk of side-effects with continued use (Cameron, 2007; Draper, 2011; National Eczema Society, 2005). When choosing a topical corticosteroid, it is crucial to consider the area of the body to which the therapy will be applied and to be cautious to the qualities of the underlying skin. Penetration varies greatly between sites as a result of the thickness of the stratum corneum, as well as vascular supply to the area. The side effects also vary according to the area treated (Chabassol and Green, 2012).

As a general rule, low potency steroids are the safest agents for long-term use (Rathi and d'Souza, 2012). They are also the potency of choice for application to a large area. Low potency steroids are preferred for areas with high penetration, including the axillae, groin, genitals, and face. They are preferred for infants, children, and the elderly due to the increased susceptibility of these populations to side effects. High potency and very high potency topical corticosteroids

should be reserved for areas with low penetration, including palms, soles, elbows, knees, as well as areas of lichenification. Additionally, when using these agents, it is recommended that, once control is obtained, the patient should be put on a lower potency agent for maintenance. High and very high potency therapies should only be used for short periods of time or intermittently to avoid adverse effects (Chabassol and Green, 2012; Ference and Last, 2009). Application of topical steroids is usually recommended once or twice daily depending on the condition being treated (Ference and Last, 2009; Oakley, 2009).

The amount of topical steroid dispensed and applied should be considered carefully because; too little steroid can lead to a poor response, and too much can increase side effects (Ference and Last, 2009). However, it is difficult to advice patients how to use a topical skin preparation correctly and often the advice given is inadequate, with the result that the patient is left confused. Few attempts have been made to rationalize advice on applying topical therapy (Bewley, 2008). The method that has gained widest acceptance has been the fingertip unit, which is the amount of cream or ointment expressed from a 5-mm diameter nozzle, applied from the distal skin-crease to the tip of the patient's index finger (Bewley, 2008; Chabassol and Green, 2012).

2.3. Adverse effects caused by topical steroids

The use of topical corticosteroids is associated with a number of side effects. The most significant adverse effect of corticosteroids is immunuosuppresant action which may increase the susceptibility to bacterial and fungal infection (Saravanakumar *et al*., 2012). The other most common side effect associated with prolonged use is skin atrophy (Schoepe *et al*., 2006). With long-term use of topical steroid, the skin may develop permanent striae (like 'stretch' marks), bruising, discoloration, or thin spidery blood vessels (telangiectasia). They may trigger or worsen other skin disorders such as acne, rosacea and perioral dermatitis (for eczema). It can also cause atrophic changes, more fragile skin, more easily bruised skin, masked infection, secondary infection, contact dermatitis, delayed wound healing, hyperpigmentation, hypopigmentation and photosensitization (Ference and Last, 2009; Woodson, 2009).

A major concern associated with topical corticosteroid therapy is the risk of systemic absorption. Although they are rare, systemic complications have manifested as a result of topical corticosteroid use, such as suppression of the hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, hyperglycemia, growth suppression in children, and femoral head osteonecrosis (Al Shaikh, 2005; AOCD, 2012; Lee and Arriola, 1999). Glaucoma has also been evidenced as a side effect from an excessive use of topical steroid in eczema (Lim Fat and Leslie, 2011).

A systemic side effect associated with hypothalamic–pituitary–adrenal (HPA) axis suppression, decreased cortisol response, in those using potent or very potent topical corticosteroids were evidenced in retrospective cohort study of children of corticosteroid treatment for atopic eczema (Bewley, 2008). Cushing's syndrome was also evidenced in a case report after misuse Clobetasol cream for diaper dermatitis for 4 months (Tempark *et al.*, 2010).

Using topical steroids for a very long time can result in steroid addiction syndrome. This syndrome occurs as a result of chronic daily application for greater than a 1-month period of a potent or moderately potent glucocorticosteroid preparation to the facial skin, neck, scrotum or vulva. These tissues become "addicted" to the topical steroid, so that withdrawing the topical steroid results in severe burning which is only relieved by further steroid applications. As application continues, the patient experiences a rebound vasodilatation. Permanent redness of the facial skin eventuates, with thinning and fine wrinkling of the skin (Olumide *et al*., 2008; Rapaport and Lebwohl, 2003).

2.4.Irrational use of topical steroids in clinical settings

According to 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. As more than 40% of therapeutic costs are pharmaceutical costs, this implies a significant waste of health resources in the world (Yousefi *et al*., 2012). Topical corticosteroids have greatly contributed to the dermatologist's ability to effectively treat several difficult skin diseases conditions since they were first introduced in early 1950s. The available range of formulations and potency gives flexibility to treat all groups of patients, different phases of disease, and different anatomic sites (Rathi and d'Souza, 2012).

Topical steroids are the cornerstones of therapy for a wide variety of dermatoses, such as atopic dermatitis, eczema, contact dermatitis, psoriasis, seborrheic dermatitis, vitiligo, lichen sclerosus and intertrigo (Lee and Arriola, 1999; Woodson, 2009). However, the rapid rise in incidence of improper use of these drugs by dermatologists, general physicians, and patients threatens to bring disgrace to the entire group of these remarkable drugs (Rathi and d'Souza, 2012). From the several studies that have addressed the issue of dermatological drug prescribing patterns, some have indicated inappropriate utilization or over-utilization of topical corticosteroids.

A study conducted in an ambulatory medical care services in the United States revealed that of all the topical corticosteroid drug mentions, 5.0% were for high-potency agents, 56.3% were for low-potency agents, and 38.7% were for medium-potency agents. Of the clotrimazole-betamethasone dipropionate prescribed, 56.4% were for children aged newborn to 4 years indicating that clotrimazole-betamethasone dipropionate is prescribed inappropriately by pediatricians, especially in the treatment of young children. Pediatricians rarely use high-potency topical corticosteroid agents, but most of their use of clotrimazole-betamethasone dipropionate is in the youngest children as the authors noted, in whom such corticosteroid use is least appropriate. The writers concluded that the prescription pattern suggested that some pediatricians may be unaware that clotrimazole-betamethasone dipropionate has a high-potency corticosteroid component (Fleischer and Feldman, 1999).

A study conducted in an Indian Tertiary Care Teaching Hospital shows that anti-fungals (23.15%) were the most commonly prescribed class of drugs followed by steroids (19.61%) and antibiotics (16.72%). Major combination preparations prescribed were steroids in combination with antibiotics, anti-fungals and keratolytics. The maximum numbers of steroids prescribed were of high potency (43.47%), which are associated with severe side effects, while mild potency was least prescribed (15.22%) (Bijoy *et al*., 2012).

Another study conducted in India, in North Gujarat, from 521 randomly selected participants shows that majority of drug prescribed are the antihistaminics (66%), topical steroids (29%), tetracycline (26%), erythromycins family antibiotics (20%) and fluconazole (23%) and other anti-fungal agents (19%). From the patients that received topical steroid treatment, 22% patients were under treatment for 12 months, while 37% patients were under treatment for one month and 30% patients were under treatment for two months at the time of the study. The rest of the

patients were under treatment from duration more than 12 months, despite potential health complications associated with long term use of topical steroids (Patel and Patel, 2010).

An audit of prescribing practices of topical corticosteroids in outpatient dermatology clinics in north Palestine indicated that topical corticosteroids are commonly prescribed (51.6%). The prescription analysis showed that prescribing information was inadequate in the majority of cases: the quantity of the corticosteroid to be applied was not mentioned in 87.7% of prescriptions and duration of use not mentioned in 71.6%. It was found out that none of the topical corticosteroids were prescribed by their generic names (Sweileh, 2006).

2.5. Practice of use of topical steroids for self medication and its consequences

Prescription drug abuse is the intentional use of a medication without a prescription; in a way other than as prescribed. Abusing prescription drugs can have negative short- and long-term health consequences (NIDA, 2011). OTC topical steroids, in most instances, are used for the side effect of depigmentation in conditions such as melasma, cosmetic ochronosis, acne vulgaris and post-inflammatory hyperpigmentation, and in several instances for cosmetic practices as a depigmenting agent in combination with hydroquinone (Nnoruka and Okoye, 2006).

Skin bleaching is currently a widespread global phenomenon (Blay, 2011) and has constituted a public health concern in many African countries since the 1980s and is a frequent practice (25-96%) in women from sub-Saharan Africa (Kpanake *et al*., 2010; Ly *et al*., 2007). Specifically, it was found to be practiced by 25% of women in Bamako, Mali, 52% of women and 28% of men in Dakar, Senegal, 66% of the inhabitants of Brazzaville, Congo, and by more than 75% of both women and men in Lagos, Nigeria (Kpanake *et al*., 2010). Most depigmenting agents contain topical steroids (Raynaud *et al*., 2001) which are associated with a number of health risks and problems. The net effect is an array of skin disturbances and disorders, ranging from skin burns, uneven and patchy skin, thinning and wrinkling of skin and contagious fungal infections (López *et al*., 2011; Olumide *et al*., 2008).

The extensive use of illegal clobetasol-containing agents is responsible for most of the severe side-effects associated with skin bleaching in Francophone countries (Dadzie and Petit, 2009). Consumers cannot stop skin bleaching after obtaining a lighter skin because of a paradoxical increase in skin pigmentation, called exogenous ochronosis. Because of this repigmentation, they are often compelled to continue using bleaching creams to maintain the newly acquired light colored skin, thereby, creating complications from prolonged use (Kpanake *et al*., 2010).

Interestingly, studies reveal that individuals often continue their practice of skin bleaching even throughout pregnancy and lactation. A study by Mahé *et al*. demonstrated that 68.7% of selected women between 6 and 9 months gestation, attending a maternity centre in Dakar, Senegal, used skin lighteners for cosmetic purpose during their pregnancy which included agents containing highly potent corticosteroids and products of unknown composition (Dadzie and Petit, 2009). This practice in pregnant women can cause complications on the baby since use of potent topical steroids during pregnancy is associated with low birth weight (Mahe´ *et al*., 2007), orofacial cleft (Edwards *et al*., 2003) and fetal growth restriction by affecting the insulin-like growth factor system (Chi *et al*., 2011).

A study conducted in Dakar, the capital of Senegal, shows that from a sample of 368 adult women presenting at a dermatological centre, 52.7% were using of bleaching products at the time of the investigation. The products were applied on the whole body in 92% of users, with a median duration of use of 4 years. The active principles used included hydroquinone (89%), glucocorticoids (70%), mercury iodide (10%) and caustic agents (17%); 13% of users used products of unknown composition. From sample analysis, superpotent (class 1) glucocorticoids predominated from the steroids used. The main skin complaints in bleaching products users included dermatophyte infections and scabies, both often unusually extensive and severe; acne, often severe; eczema; irritant dermatitis; and dyschromia (including cases of exogenous ochronosis). The skin examination noted features apparently disregarded by users: striae, and macular hyperchromia involving the face, mainly the periocular area. The statistical analysis showed that glucocorticoids were the main agents responsible for the observed complications. Their use was associated with the presence and severity of infectious skin diseases, and of acne (Mahé *et al*., 2003).

Another study was performed in Senegal in eighty-six female patients, with a mean age of 29.34 years and with a level of education: primary (48.8%), secondary (18.3%), higher (8.5%) education and 22% had not attended school. The initial skin tone before using skin bleaching products was black in 41.5% of patients, light in 32.9%, and intermediate in 25.6%. The mean duration of exposure was 6.7 +/- 5 years (range, 1-30 years). The breakdown by skin bleaching products showed that topical corticosteroids were the most frequently used (78%), followed by hydroquinone (56%), products based on vegetable extracts (31.7%), caustic products (8.5%), and, finally, products of unknown composition (41.4%). Two components or more were frequently combined (86.5%). Nineteen types of aesthetic complication were reported in the sample. Hyperpigmentation of the joints was the most frequently found complication (85.4%), followed by striae atrophicae (72%) and skin atrophy (59.8%). Patients frequently presented (71.9%) with other complications associated with artificial depigmentation (Ly *et al*., 2007).

2.6.Factors associated with the use of topical steroid for self medication

There are many reasons why black, dark-skinned people resort to skin lightening and these reasons may be grouped in two kinds. The first are personal reasons - beauty and its pursuit are universal (Dadzie and Petit, 2009). Ignorance is also one of the factors that contribute to this phenomenon since the lack of adequate information is an omnipresent prejudice in all choice-situations. Society also has a significant impact on the misuse of skin lightening agents. Studies have indicated that the majority of black men prefer light-skinned women as partners, girlfriends or wives. Even the cosmetic industry promotes products that are designed to help dark-skinned women look "lighter". It is also reported, for instance, that facial attractiveness is associated with positive evaluation by others and that many African Americans believe that their lighter skinned fellows are more competent. Still, in the USA, studies have shown that for the same level of education, dark-skinned people earn much less than their peers with lighter skin and thus reinforcing the perception that a lighter skin tone is associated with better economic status (Kpanake *et al*., 2010; López *et al*., 2011).

Studies in patients presenting with steroid-related eruptions have shown that there are several nonmedical advisers like friends, neighbors, beauticians and barbers telling them to use it as fairness/cosmetic creams, anti-acne, anti-fungal therapy and for that matter any skin eruptions.

There is also a tendency to reuse old prescription for a recurrent or new rash (Rathi and d'Souza, 2012).

In a survey conducted in Lomé, Togo, from 300 (219 women and 81 men, aged 15-50), four motives appeared as clearly dominant. Participants admitted to bleaching their skin on a regular basis, mainly to appear important, to look attractive, because they enjoyed their light skin, and because skin bleaching was fashionable. They did not practice skin bleaching as a demonstration of opposition towards African culture or to their relatives or as a demonstration of compliance with others' wishes. They sometimes practiced skin bleaching to secure a job (Kpanake and Mullet, 2011).

In a study of four hundred and fifty Nigerians who confessed the use of bleaching creams, 73.3% women and 27.6% men, various reasons were given for using the bleaching creams. The use of bleaching creams cuts across all socio-demographic characteristics, people of all religious groups, single or married, rich and poor, literate and illiterate, low, middle and upper classes. Some of the reasons given for using the products are to look more attractive; to go with existing fashion trend; to treat skin blemishes like acne or melasma; to cleanse or "tone" the face and body; or to satisfy the taste of one's spouse. Although the men also use the products for the above reasons, some of them claimed they use the creams because their wives use them; and some male marketers of female cosmetics and toiletries claim they use the products to advertise their wares. In Nigeria, all corticosteroid preparations can be purchased OTC, which makes them one of the most used drugs for bleaching purpose (Olumide *et al*., 2008).

A survey conducted in Pretoria, South Africa, among patrons of pharmacies shows that 64.5% participants used the topical steroids for therapeutic reasons, while 35.5% used them as skin lighteners. The majority of participants were black female Africans, employed, 20-40 years old, and unmarried. A total of 50.2% had a high school level of education. The majority of participants (69.9%) were advised to use topical steroid products by their doctors and pharmacists, while the others were advised by friends (20.4%) and nurses (9.7%). In terms of duration of use, 40% of the participants had used topical steroid products for more than six months. The majority of participants applied the product once or twice a day, but 18.7% applied it three times or more a day. In terms of awareness of side effects, only 19.1% of the participants were aware of these side effects. Participants mentioned acne, moon face, and changes in skin

pigmentation as side effects encountered. The odds ratios calculated showed being black female African, as well as being advised by a friend, and unaware of the side effects suggested a strong association with the misuse of topical steroid products (Malangu and Ogunbanjo, 2006).

A prospective multicenter questionnaire-based clinical study conducted at 12 dermatology centers in India on patients with relevant facial dermatoses reporting to the investigator shows from a total of 2926 patients with facial dermatoses screened, 14.8% were using topical corticosteroids. And it was used as a fairness/general purpose cream or aftershave in 29% and in 24% for acne. Steroid combinations were used by 59.6%. Potent and super-potent topical corticosteroids were significantly ($P = 0.05$) more frequently used by the rural/suburban population. The younger age groups used more potent formulations. A non-physician recommendation for topical corticosteroids use was obtainable in 59.3% patients. Of these, 90.3% were for potent/super-potent steroids. Among 176 physician prescriptions, 44.3% were from non-dermatologists. All non-physician prescriptions and 83% physician prescriptions for topical corticosteroids were inappropriately refilled. Adverse effects were seen in 90.5% topical corticosteroids users. Acne/exacerbation of acne was the most common adverse effect (Saraswat *et al*., 2011).

3. Objective of the study

3.1. General objective

To assess the pattern of topical steroid utilization in ALERT Hospital, Addis Ababa

3.2. Specific objectives

- To describe the type of topical steroids commonly prescribed in ALERT Hospital
- To determine the extent of use of topical steroids in ALERT Hospital
- To assess the prescribers' prescribing practice in the dermatology clinic of ALERT Hospital

4. Methodology

4.1. Study design

A descriptive, cross sectional study was conducted between August and November, 2013. The study employed both qualitative and quantitative methods of data collection to gather the required information. Retrospective analysis of the records of dermatological outpatients was conducted to study the utilization pattern of topical steroids.

4.2. Description of the study setting

The study was conducted in ALERT Hospital which is one of the specialized tertiary referral hospitals in the country. It is located in Addis Ababa at 7 km southwest on the way to Jimma. It was established in 1934 with the objective of serving persons affected by leprosy. It was to fulfill this objective the training division was established within the hospital compound and it was named ALERT on December 11, 1965 (ALERT, 2008). The hospital currently provides a wide range of services in the various departments. These include emergency, gynecology, general OPD, ART & TB, Psychiatry and counseling, dermatology and venereology, red medical (the department where leprosy patients are treated), general reconstructive and plastic surgery, minor operation room and ulcer clinic, dental, ophthalmology, pediatric, surgical and orthopedic, laboratory, pharmacy, radiology, anesthesia, environmental health education and promotion, rehabilitation and physiotherapy, prostatic orthotics, occupational therapy and research center. Daily about 600-700 patients are treated and these patients come from all over the country. Currently, there are five dermato-venereologists and 17 resident dermato-venereologists working in the dermatology clinic of the hospital.

4.3. Source population

All outpatients treated in the dermatology clinic of ALERT hospital were used as source population in this study. The study also used all physicians working in the hospital for the key informant interview, as a source, to collect data qualitatively.

4.4. Study population

Outpatients that visited the dermatology clinic in ALERT hospital in the year 2011/12 were used as study population. For the key informant interview, dermato-venereologists and resident dermato-venereologists working in the hospital were part of the study population.

4.5. Inclusion and exclusion criteria

All patients who visited the OPD of the dermatology clinic in ALERT Hospital in the year 2011/2012 were included in the study. A total of 36 patient records that did not have any drug prescribed were excluded from the analysis.

Sampling and sample size calculation

For the quantitative study, records of patients with skin diseases that were treated in the OPD of the dermatology clinic during the period 2011/2012 were taken as a study population and patient cards were the sampling units. Sample size was taken as 600, which is the standard required for drug utilization study in health facilities (WHO, 1993).

The sample size was determined using the single proportion formula:

$$\mathbf{n = \frac{(z_{\alpha/2})^2 p(1-p)}{d^2} = \frac{(1.96)^2\ 0.5*0.5}{0.04^2} = \frac{0.96}{0.0016} = 600}$$

Where: n = the required sample size

$Z_{\alpha/2}$ = (Z critical value at $\alpha = 0.05$) = 1.96

p = Extent of steroid utilization = 50% (chosen to get maximum sample size)

d = the margin of error (precision) = 0.04

n = 600

Then adding 10% contingency for incomplete records, the total sample size was 660 patient records.

From the hospital registration book of records, it was found out that a total of 63,038 new patients were treated at the OPD of the dermatology clinic in ALERT Hospital in the year 2011/2012. Dividing the total number of patients by the required sample size (660) and using systematic random sampling, the sample to be used for the data collection was chosen at regular intervals of 96 by drawing a random starting card until the total sample size was reached. When a selected patient record was missing, the next patient record was selected and then moved from that at a regular interval of 96.

For the key informant interviews, dermato-venereologists and resident dermato-venereologists working in the hospital were selected employing purposive sampling technique. A total of 6 key informants, 4 dermato-venereologists and 2 resident dermato-venereologists, were interviewed.

4.6. Study Variables

- Independent variables:
  - Demographic characteristics of the patients: Sex, age
  - Drug characteristics (dosage form)
  - Presence of/ absence STG, formulary (institutional)
- Dependent variables:
  - Types and potency of topical steroids utilized
  - Extent of topical steroid use
  - Adherence of prescribers to national treatment guideline (done by simply checking it with the NSTG)

4.7. Data collection and management

4.7.1. Data Collection

A combination of both quantitative (data abstraction format) and qualitative data (key informant interview) collection techniques were used to gather information for this study.

4.7.2. Data collection instruments

A data abstraction format (Annex I) was prepared and used to collect data regarding socio-demographic characteristics, the type of disease condition, previous history self prescribed steroid use, number of drugs prescribed, qualification of the prescriber, class of drugs prescribed, whether a topical steroid preparation was prescribed, name of the topical steroid prescribed, the dosage forms and strength of topical steroids prescribed, frequency of application, the duration of treatment, site of application and whether or not there was a treatment shift in patients receiving topical corticosteroids.

Key informant interviews were also conducted with dermatologists and resident dermatologists working in ALERT hospital using an interview guide (Annex II) to complement the quantitative data and to describe the use of topical corticosteroids OTC and its consequences.

4.7.3. Data collectors

Two nurses working in the OPD of the dermatology clinic in ALERT hospital were recruited to review patient records, in order to take advantage of their experience on the clinical record system, of diseases and diagnosis and ability to interpret medicine names and dosage. The key informant interviews with the dermatologists and resident dermatologists were conducted by the principal investigator.

4.7.4. Data quality assurance

The data abstraction format was pretested to ensure any relevant information was not missed out and to make sure there was no difficulty of understanding. After pre-testing, all the necessary modification such as qualification of the prescriber and information on the last visit were incorporated. Data collectors were given appropriate training prior to data collection. Supervision was made by the principal investigator during the data collection process and inconsistencies were corrected on time. With the permission of the interviewees, the interviews were tape recorded and the interviews were transcribed immediately after the interview so any information would not be left out.

4.7.5. Data entry and analysis

The quantitative data was cleaned, coded and entered into EPI Info Version 6.0. Then, the data was exported to excel spreadsheet and then to SPSS version 16 for further analyses. The data was analyzed using simple descriptive statistics including tables and figures. Whereas the qualitative data obtained from the key informant interviews were grouped, coded and analyzed thematically.

Skin diseases were classified in different categories, as reported in previous studies (Shibeshi, 2000a; Ukonu and Eze, 2012) and the potency of the topical corticosteroids was categorized according to the BNF (British Medical Association, 2009) and as reported in a previous study (Schoepe *et al*., 2006). Adherence of prescribers to national treatment protocol was analyzed by checking it with the national standard treatment guideline (NSTG) and also with ALERT Medicines Formulary (AMF) was used to assess the prescribers' adherence to an institutional guideline.

4.7.6. Operational definitions

Topical steroid refers to the preparation intended only for a dermatological condition but excludes topical steroids in the form of inhalers, drops and nasal sprays.

Topical steroid and topical corticosteroids are used interchangeably.

Combined drug: drugs that are prepared together with the topical steroid prescribed (Mohamed Saleem *et al*., 2012; Sweileh, 2006).

Concomitant drugs: drugs that are prescribed to be taken along with the topical steroid but not prepared together with the topical steroid (Sweileh, 2006).

Fixed drug combination: a topical steroid combined with other classes of drugs like anti-fungal and anti-bacterial which is already made and not prepared extemporaneously (Tikoo *et al*., 2011).

Treatment shift: a medication shift from one topical to another type or strength topical steroid or other drug class.

4.7.7. Ethical considerations

Ethical approval was obtained from the ethics review committee of School of Pharmacy, Addis Ababa University (Annex III) and the study was conducted in ALERT Hospital after obtaining the permission from the hospital. AHRI/ALERT Ethics Review Committee (AAERC) reviewed the proposal and the data collection was started after the final approval from the committee was issued (Annex IV). To keep the confidentiality, nurses working in the hospital extracted the data from the patient records and no personal identifiers were used on the data collection format. The dermatologists and resident dermatologists that were included in the interview were asked for their consent prior to the interview by providing an information sheet (Annex V) and written informed consent (Annex VI). During the consent process, they were provided with the information regarding the purpose of the study, why and how they were selected to be involved in the study, and what is expected of them and that they can withdraw from the study at any time. They were also informed that after the completion of the study, the interview recorded would be erased.

5. Results

5.1. Socio-demographic characteristics of patients

There were reportedly 95,292 new outpatients who visited ALERT Hospital in the year 2011/2012; out of whom 63,038 visited the OPD of the Dermatology Department. From these patients that visited the OPD of the dermatology clinic, a total of 660 patient records were sampled using systematic random sampling and then reviewed. Out of the 660 patient records, 624 (94.5%) patients were treated with drugs.

From the 36 patients that did not receive any drug treatment, 15(41.7%) of them received a physical therapy and 5(13.9%) were referred to a plastic surgeon. The prescribed physical therapies included cryotherapy 12 (80%), electrocoutery 2(13.3%) and elastic bandage 1(6.7%). From remaining 16 patients that did not receive any drug treatment, 10(62.5%) patients were reassured of normal skin, and 6(37.5%) were given consultation only. The skin conditions that were treated employing cryotherapy were wart 10(83.3%), alopecia areata 1(8.35%) and solar keratosis 1(8.35%). Two electrocoutery therapy and elastic bandage were prescribed for the conditions wart and varicose vein, respectively. Patients who were referred to a plastic surgeon were with skin conditions keloid, infected wound, excessive scar and lentigo melanoma.

These 36 patient records, which account for 5.5% of the total sample size, were not included in subsequent analysis since there were no drugs prescribed for these patients.

As shown in table 1, of the 624 patients, 447(71.6%) were from Addis Ababa and 177(28.4%) were from other regions of Ethiopia. The majority of patients were females accounting for 380(60.9%) and the males accounted for 244(39.1%). The minimum age observed was 2 months and the maximum was 86 years, with a mean of 24.23 years and a standard deviation of 16.1. Majority 192(30.7%) of patients were in the age group of 21-30 years followed by 139(22.3%) from the age group of 0-10 years and 126(20.2%) from the age group 11-20 years.

The drugs for 437(70%) of the patients were prescribed by dermato-venereologists and 187(30%) of them were prescribed by resident dermato-venereologists.

Table 1. Socio-demographic characteristics of patients in ALERT Hospital, Ethiopia, 2013.

Characteristics	Frequency (n=624)	Percent
Sex		
Female	380	60.9
Male	244	39.1
Age		
0-10	139	22.3
11-20	126	20.2
21-30	192	30.7
31-40	78	12.5
41-50	51	8.2
51-60	21	3.4
>60	17	2.7
Address		
Addis Ababa	447	71.6
Out of Addis Ababa	177	28.4

5.2. Pattern of skin diseases in ALERT Hospital

Out of the 624 patients included in the study, 568(91.03%) patients were diagnosed with a single skin disease and 56(8.97%) patients were diagnosed with two skin conditions and hence 680 dermatoses were documented. Out of all skin diseases documented during the study period, the most single common skin diseases observed were eczema/dermatitis 211(30.0%), tinea (dermatophytosis) 136(20.0%), pigmentary disorder 77(11.3%), acne 38(5.6%), rosacea 20(3.0%), tinea versicolor 20(3.0%), urticaria 19(2.8%) and lichen planus 18(2.6%), all together accounting for about 539(78.3%) (Table 2).

Table 2. Skin disease patterns and frequency among the study population in ALERT Hospital, Ethiopia, 2013.

Diseases	Frequency (n=680)	Percent
Eczema and dermatitis	211	30.0
Tinea (dermatophytosis)	136	20.0
Pigmentary disorder	77	11.3
Acne	38	5.6
Rosacea	20	3.0
Tinea versicolor	20	3.0
Urticaria	19	2.8
Lichen planus	18	2.6
Hair disorder	15	2.2
Hyperkeratosis	10	1.5
Wart	9	1.3
Others*	107	16.7

Others* include vasculitis, candidiasis, herpes zoster, molluscum contagiosum, pityriasis rosae, discoid lupus erythematous, postherpetic neuralgia, sweating disorder, scar, benign skin tumor, leishmaniasis, psoriasis, prurigo, lymphoedema, dandruff, pityriasis, pitriasporum folliculitis, scabies, sexually transmitted infection, xerosis, exfoliative chelitis, actinic chelitis, drug induced skin disease, erythema, apthous ulcer, pityriasis lichenoides chronica, pyoderma, impetigo, folliculitis, furunclosis, erythrasma, ecthyma, carbuncle, cellulitis and leprosy.

Among eczema and dermatitis, the most common skin diseases were atopic dermatitis 59(28.0%) followed by seborrheic dermatitis 39(18.5%) and lichen simplex chronicus 26(12.3%). The others were contact dermatitis 23(10.9%), pityriasis alba 19(9.0%), nummular eczema 11(5.2%), unspecified eczema 12(5.7%), photo dermatitis 8(3.8%), pityriasis sicca 4(2%), atopic diathesis 3(1.4%), statis eczema 2(0.9%), perioral dermatitis 2(0.9%), discoid eczema 1(0.5%), follicular eczema 1(0.5%) and xerotic eczema 1(0.5%).

When all the infectious and parasitic skin diseases were combined, they accounted for 230(33.8%) of all the skin diseases documented in the study period. The most common infective dermatoses were fungal skin diseases 166(72.2%) followed by bacterial skin infections 30(13.0%). The rest were viral skin infections 23(10.0%) and parasitic skin infestations 11(4.8%). The result shows that fungal skin infections were the most common cause of the infectious skin diseases (Figure 1).

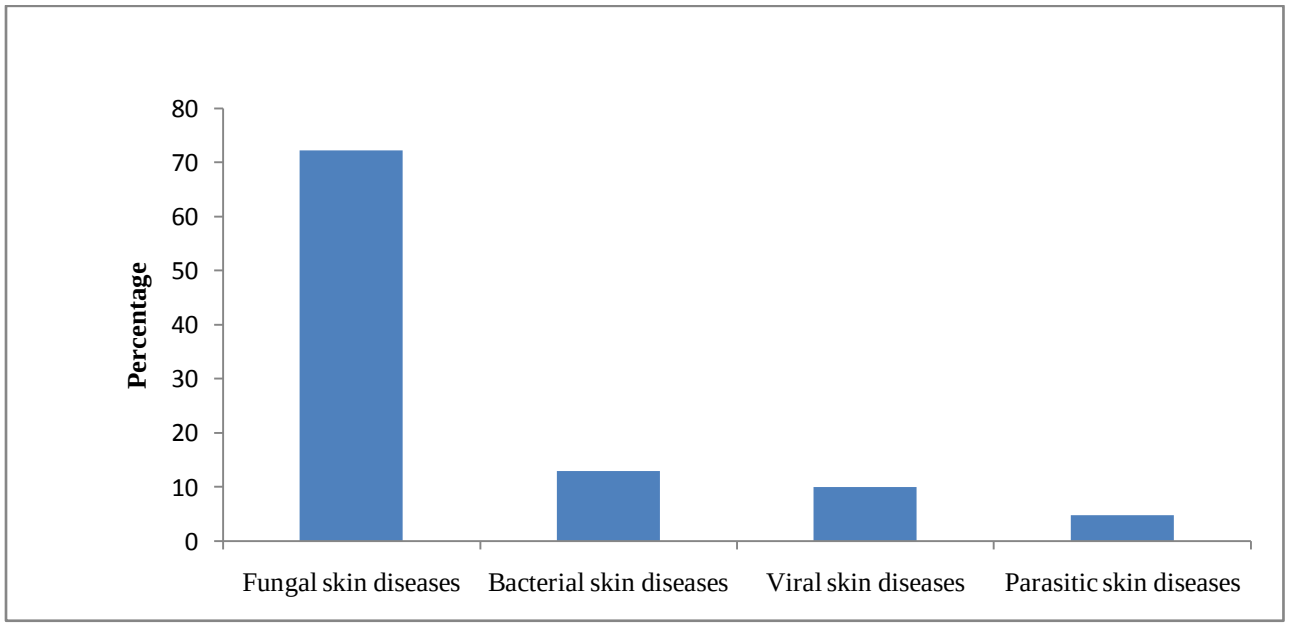


Figure 1. Distribution of infectious skin diseases in ALERT Hospital, Ethiopia, 2013.

Among the fungal skin diseases documented, tinea (dermatophytosis) was the most common fungal infection 136(81.9%) in the outpatient dermatology clinic, followed by pityriasis versicolor 20(12.0%) and candidiasis 5(3.0%). From the bacterial skin infections, impetigo 8(26.7%) was commonly observed, followed by folliculitis decalvans (20%), pyoderma (16.7%), folliculitis (10%) and furunculosis(6.7%). Wart was the most common viral infection 9(39.19%), followed by pityriasis rosae 7(30.4%), molluscum contagiosum 3(13.0%) and herpes zoster 3(13.0%). Scabies (45.6%) was the commonly observed parasitic skin infestation, followed by leishmaniasis (27.2%) and lymphoedema (27.2%).

5.3. Prescribing pattern of dermatological drugs in ALERT Hospital

The total number of drugs prescribed for the patients included in the study was 1108, with an average of 1.77 drugs per prescription and a standard deviation of 0.72. From these, 236(37.8%), 305(48.9%), 71(11.4%), 11(1.8%) and 1(0.2%) patients were prescribed 1, 2, 3, 4 and 5 drugs, respectively.

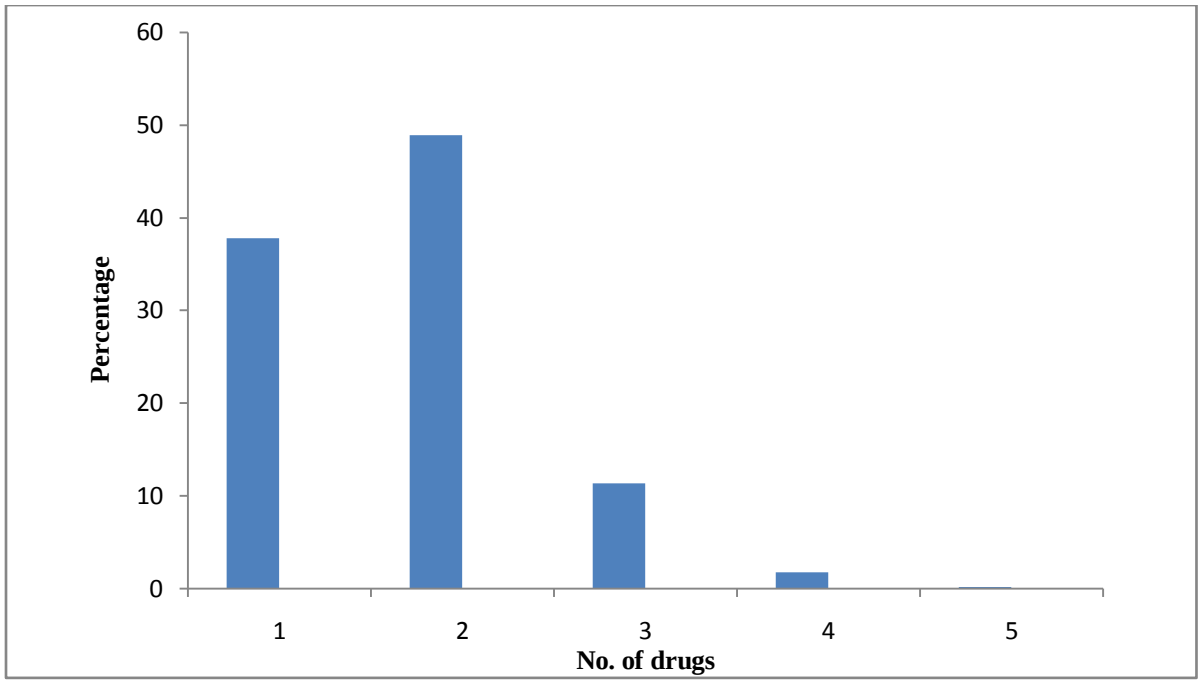


Figure 2. Number of drugs per prescription in ALERT Hospital, Ethiopia, 2013.

Out of all the drugs prescribed, 801(72.3%) were prescribed to be administered by the topical route, 296(26.7%) by the oral route and 11(1%) by parentral route (Table 3).

Table 3. Routes of administration in ALERT Hospital, Ethiopia, 2013.

Route of administration	Frequency (N=1108)	Percent
Topical	801	72.3
Oral	296	26.7
Parenteral	11	1.0

As shown in table 4, from the total of 1108 drugs, the commonly prescribed drugs were topical corticosteroids (alone and combined) 315(28.4%) followed by anti-fungals 245(22.1%), anti-bacterials 186(16.8%), emollients and moisturizers 101(9.1%), protectants and astringents 87(7.9%), anti-histamines 43(3.9%) and bleaching agents 38(3.4%).

Table 4. Pattern of dermatological drugs prescribed in ALERT Hospital, Ethiopia, 2013.

Drug group	**Frequency (N=1108)**	**Percent**
Topical steroids	315	28.4
Anti-fungal	245	22.1
Anti-bacterial	186	16.8
Emollients/moisturizers	101	9.1
Protectants and astringents	87	7.9
Anti-histamine	43	3.9
Bleaching agents	38	3.4
Others*	93	8.4

Others* include keratolytics 26(2.3%), vitamin A derivative 23(2.1%), systemic steroids 11(01.0%), analgesics 6(0.5%), scabicides 5(0.4%), cleansing agents 3(0.3%), supplements 5(0.4%), anti-helmentic 2(0.2%), anti-virals 4(0.4%), anti-depressant 3(0.3%), anti-hypertensive 1(0.1%), anti-pruritic 3(0.3%) and $AlCl_3$ solution(drug for sweating disorder) 1(0.1%).

Among the anti-fungals, the most commonly prescribed drug was ketoconazole 98(40%) followed by griseofulvin 59(24.1%) and fluconazole 57(23.3%). The other anti-fungal prescribed were clotrimazole and miconazole constituting 21(8.5%) and 10(4.1%) of all anti-fungal prescribed, respectively. From the antibiotics the most commonly prescribed drug was cephalexin 43(23.2%) followed by doxycycline 39(21.1%), metronidazole 20(10.8%), clindamycin 16(8.6%) and cloxacillin 13(7.0%).

5.4. Prescribing pattern of topical steroids in ALERT Hospital

Out of the 624 patients included in the study, 302 (48.4%) patients were treated with topical corticosteroids. Out of all the topical steroids prescribed (315), more than half 180(57.1%) of the topical steroids were prescribed to female patients and the rest 135(42.9%) were prescribed to male patients. Of the 302 patients that received topical corticosteroid treatment, 289(95.7%) were prescribed only one topical corticosteroid and the remaining 13(4.3%) were prescribed 2 topical corticosteroids. There were no patients that received more than two topical steroids on one prescription. Hence, the total number of topical corticosteroids prescribed was 315, accounting for 28.4% of all the drugs prescribed in the dermatology clinic. Out of all the topical steroids prescribed, 229(72.7%) were prescribed by dermato-venereologists and 86(27.3%) by resident dermato-venereologists.

Out of all the patient records that had topical corticosteroids prescribed, the frequency of application was indicated in 308(97.8%). However, the site of application and duration was mentioned in only 141(44.8%) and 93(29.5%) of the patient records, respectively. The quantity of the topical steroid to be dispensed was specified in 140(44.4%) patient records. Almost all 307(97.5%) of the topical steroids were prescribed using brand names and 8(2.5%) were prescribed using generic names of the drugs (Table 5). From all the topical corticosteroids prescribed, 177(56.2%) were ointments, 116(36.8%) were creams, 18(5.7%) were in lotion form and 4(1.3%) was in powder form to be prepared extemporaneously with other drugs.

Table 5. Information included on prescriptions for topical steroids in ALERT Hospital, Ethiopia, 2013.

Parameter	**Frequency (N=315)**	**Percent**
Generic	8	2.5
Site of application	141	44.8
Frequency of application	308	97.8
Duration of application	93	29.5
Quantity to be dispensed	140	44.4

5.4.1. Types and potency of the topical corticosteroids

The most commonly prescribed topical corticosteroids were betamethasone dipropionate 0.05% 77(24.4%) and clobetasol propionate 0.05% 73(23.2%), which are potent and very potent topical corticosteroids, respectively. These were followed by mometasone furoate 0.1% 45(14.3%) and hydrocortisone acetate 36(11.4%), which are potent and mild topical corticosteroids, respectively. The other topical corticosteroids prescribed were fluocinolone acetonide 0.025% 20(6.4%), methylprednisolone aceponate 0.1% 20(6.4%), betamethasone valerate 0.1% 17(5.4%), triamcinolone acetonide 0.1% 12(3.8%), clobetasone butyrate 0.05% 12(3.8%) and diflucortolone valerate 3(0.9%) (Table 6).

Table 6. Distribution of types the topical steroids and combination prescribed in ALERT Hospital, Ethiopia, 2013.

Topical steroid	**Frequency (N=315)**	**Percent**	**Potency**
Betamethasone dipropionate 0.05%	77	24.4	Potent
Clobetasol propionate 0.05%	73	23.2	Very potent
Mometasone furoate 0.1%	45	14.3	Potent
Hydrocortisone acetate	36	11.4	Mild
Fluocinolone acetonide 0.025%	20	6.4	Potent
Methylprednisolone aceponate 0.1%	20	6.4	Moderate
Betamethasone valerate 0.1%	17	5.4	Potent
Triamcinolone acetonide 0.1%	12	3.8	Potent
Clobetasone butyrate 0.05%	12	3.8	Moderate
Diflucortolone valerate	3	0.9	Potent

Out of the 315 topical corticosteroids prescribed, 174(55.2%) were potent, 73(23.2%) were very potent, 36(11.4%) were of mild potency and 32(10.2%) were moderately potent. This result shows that the potent class was the most commonly prescribed topical corticosteroids. Most of the very potent topical steroids 53(72.6%) and 126(70.4%) of the potent topical steroids were prescribed by the dermato-venereologists.

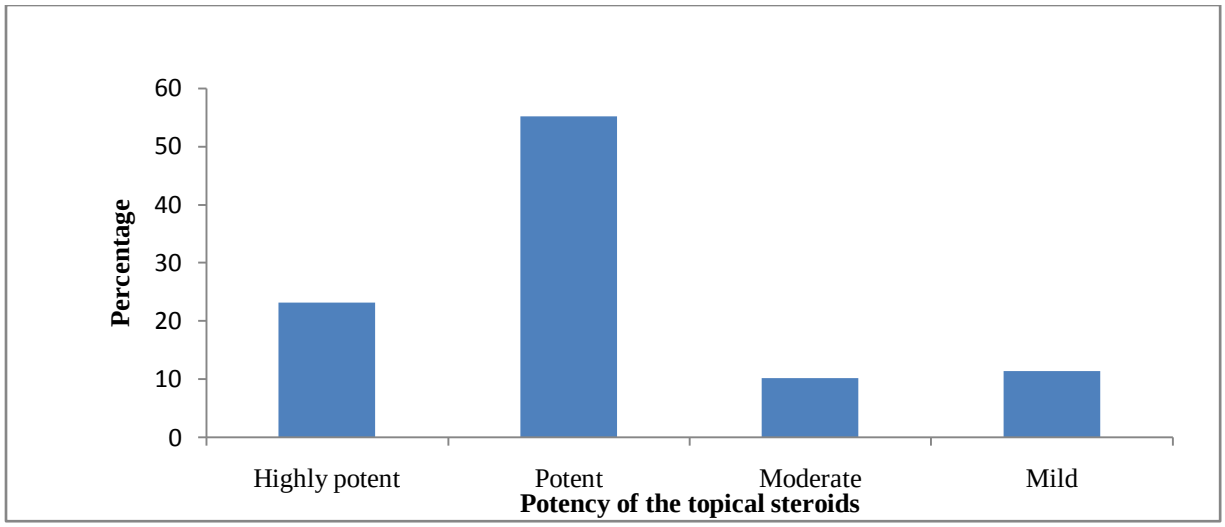


Figure 3. Percentage of the potency of the topical steroids prescribed in ALERT Hospital, Ethiopia, 2013.

Out of all the topical steroids prescribed, 93(29.5%) was prescribed within the age group 21-30 years followed by 0-10 years 71(22.5%) (Table 7). Most of the very potent and potent topical steroids, together, were prescribed for the age group of 21-30 years 81(32.8%) followed by 11-20 years 44(17.8%) and 0-10 years 41(16.6%).

Table 7. Potency of the topical corticosteroids prescribed by age group of patients in ALERT Hospital, Ethiopia, 2013.

Age group	Very potent	Potent	Moderate	Mild	Total	Percent (%)
0-10	2	39	17	13	71	22.5
11-20	12	32	3	8	55	17.5
21-30	30	51	4	8	93	29.5
31-40	10	27	2	6	45	14.3
41-50	10	12	3	0	25	7.9
51-60	6	6	2	1	15	4.8
> 60	3	7	1	0	11	3.5
Total	**73**	**174**	**32**	**36**	**315**	**100**

5.4.2. Combined and concomitantly prescribed drugs with the topical steroids

Out of all the topical corticosteroids prescribed, 229(72.7%) were prescribed alone and the rest 86(27.3%) were prescribed in combination with other classes of drugs (Table 8). The result shows that from the topical corticosteroids prescribed in combination with other drugs, 35(40.7%) drugs were prescribed as fixed drug combination and the rest 51(59.3%) were prescribed to be prepared extemporaneously.

Table 8. Form of the topical steroids prescribed in ALERT Hospital, Ethiopia, 2013.

Form	**Frequency**	**Percent (%)**
Alone	229	72.7
Combined	86	27.3
Total	**315**	**100**

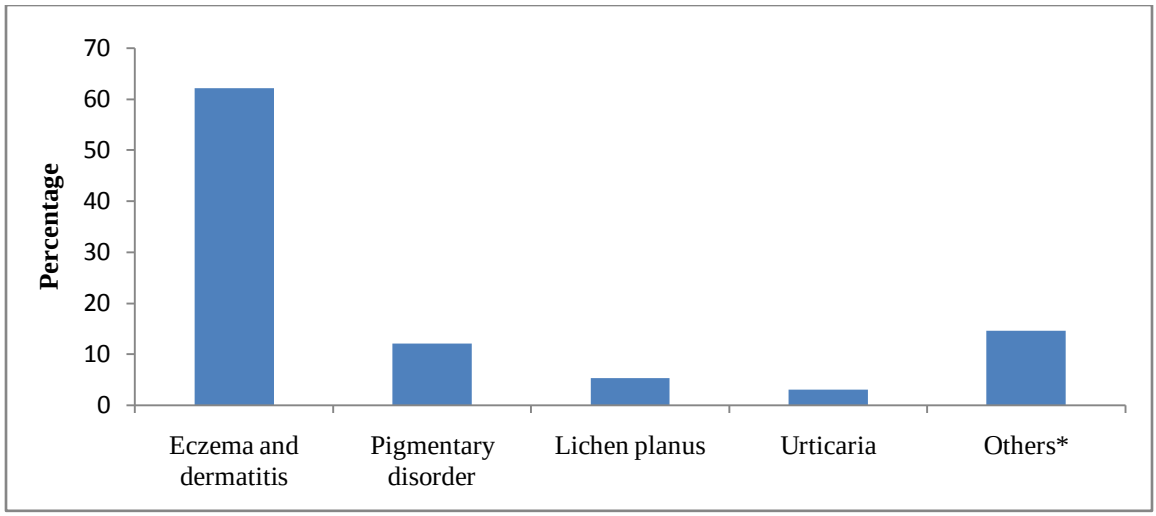
There were a total of 94 drugs that were prescribed in combination with topical steroids. The groups of drugs prescribed combined with the topical steroids were keratolytics 46(48.9%) followed by antibacterial 26(27.7%), anti-fungals 13(13.8%), bleaching agents 5(5.3%) and emollients 4(4.3%). All together there were 195 concomitantly prescribed drugs with the topical corticosteroids. The most commonly prescribed concomitant drugs were emollients 81(41.5%) followed by anti-histamines 32(16.4%), protectants and astringents 25(12.8%), antibiotics 19(9.7%) and anti-fungals 17(8.7%) (Table 9).

Table 9. Frequency of combined and concomitantly prescribed drugs with topical steroids in ALERT Hospital, Ethiopia, 2013.

Drug group	Combined	Concomitant
Antibacterials	26(27.7%)	19(9.7%)
Keratolytics	46(48.9%)	6(3.1%)
Emollients	4(4.3%)	81(41.5%)
Anti-fungals	13(13.8)	17(8.7%),
Anti-histamines	-	32(16.4%)
Supplements	-	6(3.1%)
Protectant and astringents	-	25(12.8%)
Bleaching agents	5(5.3%)	3(1.5%)
Vitamin A derivative	-	2(1.0%)
Cleansing agents	-	3(1.5%)
Anti-hypertensive	-	1(0.5%)
Total	**94(100%)**	**195(100%)**

5.4.3. Skin conditions topical steroids were prescribed for in ALERT Hospital

There were a total of 302 skin conditions in which topical steroids were prescribed for in the study period. The most common skin conditions of these were eczema/dermatitis 187(62.1%), pigmentary disorder 36(12.0%), lichen planus 16(5.3%), urticaria 9(3.0%) and psoriasis 9(3.0%), accounting for 86.6% of all the skin diseases topical corticosteroids were prescribed for (Figure 4).



Others* include pityriasis rosae 7(2.3%), hair disorder 6(2.0%), prurigo 4(1.3%), discoid lupus erythematous 4(1.3%), rosacea 2(0.7%), pityriasis versicolor 2(0.7%), tinea 3(1%), benign skin tumor 2(0.7%), scar (fibrous skin tumour) 4(1.3%), vasculitis 2(0.7%), keratoderma 2(0.7%), chelitis 2(0.7%), pyoderma 1(0.3%), drug induced skin disease 1(0.3%), pityriasis 1(0.3%) and pityriasis lichenoides chronica 1(0.3%).

Figure 4. Pattern of skin diseases topical steroids were prescribed for in ALERT Hospital Ethiopia, 2013.

5.4.4. Adherence of prescribers to AMF and NSTG

All the topical corticosteroids prescribed were found to be included in the AMF and hence the prescribers' adherence is 100%. The total number of diagnosis in which topical steroids were prescribed for in this study were 97. Of all the skin conditions topical steroids were prescribed for, only 8 skin conditions are found in the NSTG. These are atopic dermatitis, contact dermatitis (both atopic contact dermatitis and irritant contact dermatitis), urticaria, psoriasis, pityriasis versicolor, prurigo, tinea manuum and tinea capitis. These skin conditions make up 32.12% of all the skin diseases topical steroids were prescribed for in this study. There were a total of 105 topical steroids prescribed for the skin conditions that are found in the NSTG, indicating that there were two topical steroids prescribed for some cases. In the NSTG topical steroids are indicated in only atopic dermatitis, contact dermatitis (both allergic contact dermatitis and irritant contact dermatitis) and psoriasis. With regard to this, the adherence of the prescribers' to the NSTG was found to be 58.1%.

5.4.5. Treatment shift observed in the topical steroids

From the 302 patients that received topical corticosteroid treatment on the first visit, 96(31.8%) of them visited the dermatology clinic multiple times. There was no treatment shift in 19(19.8%) of those patients and treatment shift was observed in 77(80.2%) of the patients. Out of the patients that treatment shift was made, 54(70.1%) visited the clinic with the same skin condition but in 23(29.9%) of the patients there was a change in the skin condition. The treatment shift in the patients who were diagnosed with a different skin condition in the second visit, 11(47.8%) were prescribed a topical steroid and 12(52.2%) of them were prescribed drugs from another drug group. From the patients that visited multiple times with the same condition, the reason for the treatment shift in the type of the topical steroid was not indicated in 15(27.8%) of the patient records but in the other 39(72.2%) an assessment was made.

From the 39 patient records where an assessment was made, in 29 of the patients treatment shift was made due to improvement of the skin condition. From these that showed improvement in their condition, 44.6% patients were advised to discontinue applying the topical corticosteroid and in 27.2% of the patients the strength of the topical steroid was decreased. However, potency of the topical steroid was increased in 20.4% of the patients and there was no change in potency in 7.7% of the patients.

5.4.6. Topical steroid induced skin diseases documented in ALERT Hospital

There were four cases of topical steroid induced skin diseases documented from the patient records reviewed. Out of the four cases, two were steroid induced acne caused by use of Elocom® (mometasone furoate 0.1%) and Beprosone® (betamethasone dipropanoate 0.05%), potent topical steroids. It was indicated the Elocom® was prescribed by health professional, however it was not specified whether the Beprosone® was prescribed by a health professional or if it was bought OTC. The other steroid induced skin disease documented was dermatitis and it was caused by use of Beprosone®, which was bought OTC. Steroid induced rosacea is the fourth steroid induced skin disease, which was caused by the use of a topical corticosteroid but the name and source of the drug was not indicated in the patient history record.

5.5. Findings of key informant interviews

There were a total of 5 dermato-venereologists and 17 resident dermato-venereologists working in ALERT Hospital during the data collection period, which was from September 20-November 12, 2013. From these, a total number of 6 key informants were interviewed, 4 dermato-venereologists and 2 resident dermato-venereologists. Five of the key informants were male and one female. Their ages ranged from 28 to 51 years with the mean age of 37.5 years and their range of experience were from 3 years to 23 years for dermatologist. The residents were a second and third year dermato-venereology students.

5.5.1. Utilization of topical steroids

Most of the key informants replied that topical steroids are the main treatment for a wide range of skin conditions and that these classes of drugs are being prescribed by both dermatologists and other health professionals, including pharmacists. They claimed that the use of these drugs by dermatologists is rational; topical steroids are prescribed when appropriate and that the prescribed strength of the topical steroids depends on the age of the patient, severity of the skin condition and site of the skin disease. One key informant added that topical steroids are also prescribed considering cost, availability, accessibility, efficacy, and duration of application and also by considering the profile effects and side effects the drugs have on different skin conditions based on experience. Nonetheless, one of the respondents believed that there might be mistakes even when prescribed by a dermatologist.

However, they described the use of these classes of drugs by other health professionals as inappropriate. They highlighted the use by pharmacists as follows:

> *"Pharmacists dispense these products without prescriptions although it is known that topical steroids are prescription only drugs and have a wide range of side effects" (Senior dermato-venereologist 2).*

They also noted that patients or clients of pharmacies and other stores can go and buy the products without consulting a dermatologist or use one prescription over and over again to buy the same product without the knowledge of the side effects from prolonged use.

As all the key informants confirmed that topical corticosteroids are generally appropriate for inflammatory skin conditions and are mainly used in treatment of all types of eczemas. Most of them added that these classes of drugs are also used in pigmentary disorders (particularly in vitiligo); photo allergies (lupus erythematous, particularly for discoid lupus erythematous); autoimmune conditions (like alopecia araeta and lichen planus); and sometimes in psoriasis, in combination with other classes of drugs.

All key informants attested that topical steroids from mild potency to very high potency are prescribed in the hospital depending on the intensity and site of the skin condition. They classified the potency into mild, moderate, potent and very potent. Hydrocortisone is the commonly prescribed mild topical steroid. Mometasone furoate (Eloson®, Elocom®), triamcinolone and flucinolone acetonide are the moderate topical steroids. Betamethasone and clobetasol are the potent and very potent topical steroids commonly prescribed topical steroids, respectively.

If the dermatose is on thin skin like face and joints, mild topical steroids are usually prescribed and for conditions on thick skin like scalp, moderately potent to high potent topical steroids are used, according to most of the respondents.

> *"I personally prefer using potent steroids for sites other than the face and joints, like betamethasone, on trunks and extremities. And if the lesion is on the scalp, palm or sole, I prefer very potent steroids; clobetasol propionate and diprosone ointment" (Senior dermato-venereologist 2).*

But two of the key informants pointed out that there are times when moderate to very high potent strength topical steroids are used on thin skin depending on the skin condition.

> *"Sometimes for conditions like vitiligo highly potent topical corticosteroids are used wherever the location is. There are allergies caused by photosensitivity on face like actinic lichen planus and discoid lupus erythematous and for these conditions we use moderately potent or sometimes potent steroids, and these are exceptions" (Senior dermato-venereologist 3).*

The choice of potency also depends on the age of the patient, as one of the dermatologists responded. For children, mild to moderate topical steroids are prescribed. One respondent noted that overall moderately potent topical steroids are the ones that are mostly prescribed in the hospital. Another key informant also revealed that availability is considered when prescribing these drugs and that the recent brands of topical corticosteroids are chosen to be prescribed because they are more effective although not documented.

Half of the key informants claimed that brand names are usually used to prescribe topical corticosteroids because some brands are found to be more effective although their efficacy is not documented. A key informant believed that patients better adhere to the medication when they spend a lot of money on it. The other point raised was the influence of promotion and since availability is taken into consideration, topical steroids that are known to be on the market are prescribed. Two respondents also mentioned that the brand names are easy to memorize and write unlike the generic names, which are long and take up a lot of space.

5.5.2. Average duration of application of topical steroids

All key informants said that there is no defined average duration in prescribing topical steroids. The duration depends on the severity of the condition. For chronic and severe conditions, they require longer period and that the drugs are prescribed to be applied intermittently. Most of the respondents gave the example of vitiligo where a topical steroid is prescribed for a period of a year and that patients are put on pulse therapy: the topical steroids are applied intermittently, two weeks on and one week off. One of the respondents added that body surface area of the skin disease also determines the duration a topical steroid is prescribed, if the condition is generalized it requires longer period to treat.

5.5.3. Adverse effects caused by topical steroids

The most common side effects from topical steroid use are skin atrophy, acne form eruptions, telangiectasis, hypertrichosis, reddish discoloration and photosensitivity of the face, rosacea, skin wrinkling and tinea incognito, when these classes of drugs are used for a long period of time according to the key informants. Two of the key informants pointed out that from long term use,

they can also cause tachyphylaxis i.e., the body becomes used to the steroid and becomes resistant or unresponsive to topical steroids and in children, the steroid may get absorbed and cause a systemic side effect.

All key informants said that the side effects are related to the age of the patient, site of application and strength of the topical steroid used. In children, the side effects are easily manifested since their skin is thin and absorption is high and hence mild topical steroids are prescribed. In adults, side effects are more manifested when these drugs are used on the face. All the dermatologists responded that there are systemic side effects that occur due to prolonged use of topical steroids like HPA axis suppression, hypertension, cushingoid appearance and bone necrosis and that this phenomenon is rare.

However, all the key informants, except two, replied that they have not had patients with a complaint of systemic side effect from topical steroid use. Stunting of growth due to HPA axis suppression, which was caused by the use of topical steroid for a prolonged time for generalized eczema and bullous pemphegoid were the two systemic side effects witnessed by the two key informants. But most of the key informants pointed out that the reason systemic side effects are not observed may be because such patients do not come and visit the dermatology clinic for such conditions.

5.5.4. Source of prescription of topical steroids in ALERT Hospital

All the dermatologists said that they use standard dermatology textbooks as a primary source. Published articles and efficacy-side effect profile gained from experience were also stated as a source of information for therapeutic decisions. When asked about the current national standard treatment guideline, they replied that it has a very limited range of skin diseases and that it does not comply with the current treatment strategies.

5.5.5. OTC use of topical steroids and their consequences

All key informants were of the opinion that the use of topical steroids is a very common practice in the community and in the patients they encounter. They also pointed out that it is the young female in urban areas, within the reproductive age group that commonly use these products without prescription. The most commonly used topical steroids used on OTC basis are

Betnovate® (betamethasone valerate 0.1%) and Dermalar®. In addition, Dermovate® (clobetasol propionate 0.05%), Betaderm® (betamethasone valerate 0.1%) and Cloderm® ® (clobetasol propionate 0.05%) are also used without consulting a dermatologist.

The main factor for OTC use of topical steroids in the community, according to the key informants, is for cosmetic purpose. However, they said that there are some people who use these products for therapeutic purpose due to the fact that these classes of drugs give quick relief for every skin diseases condition. The key informants also noted that because dermatology clinics are few and patients have to come a long way and then wait in line for hours, patients use one prescription over and over again. The main reason, people use these products for cosmetic purpose, is because there is a misconception that these products make the skin lighter and fair and are mostly used on the face. Some of the driving factors for the use of these products are peer pressure and accessibility of the products in pharmacies, drug stores, super markets and even in shops. One respondent added that even pharmaceutical companies play role in the inappropriate use of topical steroids by the community.

"Dermalar is popular for acne in the community. The Dermalar produced by EPHARM says medicine for acne on the packing material, which is deadly wrong (Senior dermato-venereologist 2)."

Skin atrophy, allergic reactions, steroid-induced acne, steroid-induced rosacea, striae, hypopigmentation, skin infections, steroid dependency from prolonged use, perioral dermatitis, photosensitivity, and telangectasia are the common side effects from OTC use of topical steroids.

5.5.6. Measures that should be taken to improve the utilization of topical steroids

There were a number of suggested ideas by the key informants to improve the use of topical steroids by dermatologists, other health professionals, and the community. All of the respondents emphasized and suggested that pharmacists should not prescribe and dispense these classes of drugs without a prescription. They also stressed that awareness should be created by educating the community about the consequences of use of these drugs without consulting a dermatologist and that every professional should take part in it.

Two of the respondents proposed that the dermatology service should be improved to increase access and also that patients should use the currently expanding dermatology service. Some of them believed that dermatologists should also prescribe topical steroids appropriately.

Some of the respondents implied that there should be a regulatory body that can control the market since the situation has a huge economic impact. They also suggested that a standard treatment guideline should be prepared and also that developing a formulary could help. One of the dermatologists recommended a committee should be established at a national level consisting of health professionals including pharmacists in order to bridge the gap between pharmacists and dermatologists because pharmacists sometimes insist that topical steroids should not be prescribed for a period longer than a month.

6. Discussion

The study attempted to shed light on the utilization pattern of topical corticosteroids in ALERT Hospital. In doing so, it described the commonly prescribed topical steroid agents, their potency and prescribing practice in the dermatology clinic of the hospital. In addition, the study tried to describe the common skin diseases encountered and the commonly prescribed dermatological drugs. It has used qualitative method to complement the quantitative data. The commonly used topical steroids without consulting a dermatologist and its health consequences were addressed through the qualitative method.

Despite representing the greatest public health care problem and being a major cause of morbidity in developing countries, skin diseases have not been regarded as a significant problem (Morrone, 2008). The ratio of dermatologist to patient in most developing countries is low due to scarcity of specialists in this area. Many of the dermatologists involved in daily clinical work in these parts of the world are in the big cities and cases in rural areas need to be referred to the cities before they can access skin care (Olasode *et al*., 2011). Similarly, it was found out from the key informants that there is a very high work load due to inadequate number of dermatologists.

In this study, it was found out that female to male ratio was 1.56:1. This finding is consistent with the study conducted in Black lion Hospital, Ethiopia (Shibeshi, 2000a) and many other studies conducted in different countries (Atraide *et al*., 2011; Gutierrez *et al*., 2010; Larsen and Sand, 2005; Paek *et al*., 2012; Raddadi *et al*., 1999; Sarkar *et al*., 2001; Souissi *et al*., 2007; Ukonu and Eze, 2012;). The higher rate of females in the clinic may be due to the greater sensitivity of women to health related issues (Abd Al Hassan, 2011).

Knowing the patterns of skin diseases is necessary to provide adequate therapeutic services to those suffering from these diseases (Abd Al Hassan, 2011). Although eczema and dermatitis was the single most skin disease commonly encountered, it was discovered that infectious and parasitic infestation was the most common dermatose, when they were combined. This finding was similar to studies done elsewhere in other regions of Ethiopia, Tigray, Illubabor and Jimma (Accorsi *et al*., 2008; Figueroa *et al*., 1996; Figueroa *et al*., 1998). Similar results were found in studies conducted different countries (Kumar *et al*., 2011; Abd Al Hassan, 2011; Atraide *et al*., 2011; Bissek *et al*., 2012; Devi and Zamzachin, 2006; Gutierrez *et al*., 2010; Narwane *et al*.,

2011; Onayemi *et al*., 2005; Souissi *et al*., 2007). The predominance of infectious skin diseases might be explained by overcrowding and poor environmental hygiene. In addition, the hot, humid environment is considered to be a predisposing factor and the disease is therefore very common in tropical countries (Bissek *et al*., 2012; Shibeshi, 2000a).

In contrast, studies conducted in ALERT Hospital, Black Lion Hospital and Ethio-Swedish Pediatric Hospital reported eczema and dermatitis to be the most common skin disease followed by infectious skin diseases (Gimbel and Legesse, 2013; Shibeshi, 2000a; Shibeshi, 2000b). Similar results, where eczema and dermatitis is the leading skin disease, have been found in studies conducted in different countries (Raddadi *et al*., 1999; Ukonu and Eze, 2012; Zamanian and Mahjub, 2005). Although they were the second most commonly observed skin diseases next to infectious skin diseases, eczema and dermatitis represented the single most encountered dermatoses. Lifestyle factors linked to urbanization (like the use of modern housing construction methods, sleeping on synthetic foam mattresses, brick (rather than mud) walls and corrugated iron (rather than thatched) roofs) were associated with an increased risk of eczema and dermatitis in a study conducted in Jimma, Ethiopia (Yemaneberhan *et al*., 2004). Other than life style changes, nutrition and other environmental factors are reported to contribute to the high prevalence of this groups of skin diseases (Haileamlak *et al*., 2005).

In this study, cryotherapy was identified to be the most commonly advised physical therapy. There were also patients that were referred to a plastic surgeon. Physical therapies were also observed to be prescribed in a study conducted in India as dermato-surgical techniques are becoming a very integral part of the dermatological workload since they help in reducing the overall cost and give better results by avoiding the risk of adverse drug reactions by systemic or local drug administration (Tikoo *et al*., 2011). Cryotherapy involves tissue destruction under controlled freezing and is advantageous since it is less invasive and has lower morbidity compared with surgical resection (Yiu *et al*., 2007). Warts were the most skin conditions that cryotherapy was prescribed for in this study. As warts resistant to topical agents commonly are treated with cryosurgery. The other skin disease was keratosis which is also a condition cryotherapy is appropriate for (Andrews, 2004). Alopecia areata was the other condition cryotherapy was prescribed for and studies have shown effectiveness of this therapy (Gita and Mohammadreza, 2013; Lei *et al*., 1991; Morita *et al*., 2002).

The extent of the use of drugs can be used to study the incidence and prevalence of dermatological problems to some extent (Bingefors *et al*., 2002). The most commonly prescribed drug group in this study was topical steroids and its combinations followed by anti-fungals and anti-bacterials. A similar finding was documented in north Palestine (Sweileh, 2006). Analysis of the patient record data revealed that inflammatory skin conditions, mainly eczema and dermatitis, were the single most common diagnosis (30.0%). This explains the greater use of topical steroids, as topical corticosteroids are a first line anti-inflammatory treatment for eczema/dermatitis (Darsow *et al*., 2013). Anti-fungal was also the second most prescribed drug class as fungal skin infections were the second single prevalent skin conditions documented in the present study.

It has been recommended that the limit of number of drugs per prescription should be two otherwise there will be increased risk of drug interactions (Narwane *et al*., 2011). In the current study, the average number of drugs per prescription was found to be 1.77. This number is lower than studies conducted in western Nepal (Sarkar *et al*., 2001), north Palestine (Sweileh, 2006) and different parts of India (Kumar *et al*., 2011; Mohamed Saleem *et al*., 2012; Narwane *et al*., 2011; Rathod *et al*., 2013; Tikoo *et al*., 2011). It shows that there is a better practice in ALERT dermatology clinic with regard to limiting the number of drugs per prescription to the minimum which in turn minimizes risk of side effects from drug interactions.

Among the total number of drugs prescribed in this study, most of them were prescribed by the topical route followed by oral and injectable routes. Similar data was reported by a study conducted in India (Tikoo *et al*., 2011). The reason for high percentage of topical drugs being prescribed is that topical route offers several advantages, including the avoidance of systemic toxicity and side effects and hence it is the preferred route of administration in dermatology (Schwartz *et al*., 2010; Tikoo *et al*., 2011).

The results of this study indicate that topical corticosteroids are the most commonly prescribed drugs for outpatients attending dermatology clinic in ALERT Hospital (28.4%). The key informants also explained that topical steroids are widely prescribed in the dermatology clinic of the hospital. Study conducted in S.R.T.R Medical College, India showed that topical steroids accounted the 28.4% of the prescription from all the drugs prescribed although they were not the first most commonly prescribed drug groups (Rathod *et al*., 2013). The plausible explanation

could be the difference in duration of study period as seasonal variation affects the pattern of skin diseases observed which in turn change the drugs that are prescribed (El-Kichaoi, 2006; Hancoux *et al*., 2004). This India study was conducted for duration of two months while ours was conducted for a duration of 12 months. It was also reported that none of the prescriptions contained more than one topical steroid unlike the finding in this study where there were 13 prescriptions that contained two topical steroids. There are studies that showed a lower prevalence of topical steroids being prescribed like in western Nepal (16.9%) (Sarkar *et al*., 2001) and the two other studies done in Ludhiana Hospital, India (13.4% & 8.8%) (Minocha *et al*., 2000; Tikoo *et al*., 2011). In contrast, a study conducted in north Palestine (56.5%) and Tamil Nadu, India (32.2%) showed a higher prevalence of topical steroids being prescribed for outpatients visiting dermatology clinics although the studies were conducted in a shorter period for 3 and 8 months, respectively (Kumar *et al*., 2011; Sweileh, 2006).

Out of all the topical steroids prescribed in this study, 97.5% were prescribed by brand name. This trend of prescribing large number of drugs in brand name could possibly result in prescribing errors due to similar brand names leading to increase in side effects in turn increasing the cost of the treatment (Rataboli and Garg, 2005). The common reason given for prescribing brand drugs, by the key informants, was related to the efficacy of some of the brands. The same reason regarding doubt about efficacy of generic formulations was also given in the Tamil Nadu, India study where all the topical steroids were prescribed using brand names (Kumar *et al*., 2011) which is similar to the finding in north Palestine (Sweileh, 2006). Although it is known prescribing drugs by their generic names is known to increases accessibility and prescription compliance due to lower cost of generic products (Sheppard, 2010), one respondent noted that some patients adhere to the medication when they spend a lot of money on it.

It was found out that frequency of application of the topical steroids prescribed was mentioned in 97.8% all of the patient records. This number is higher than the findings in Ambajogai, India (0%), the north Palestine (92.7%) and Tamil Nadu, India (90%) (Rathod *et al*., 2013; Sweileh, 2006; Kumar *et al*., 2011). The prescription analysis shows that prescribing information was inadequate in the majority of cases. Duration of application was mentioned in only 29.5% of the records reviewed, which is higher than the study in north Palestine (28.4%) and in Ambajogai, India (13.4%) but very lower than the study in Tamil Nadu (87.8%) and in Kerala, India (93%)

(Kumar *et al*., 2011; Mirshad *et al*., 2013). Of all the topical corticosteroids prescribed, the site of application was indicated in 44.8%. Our finding was found to be lower when compared to the north Palestine (63%) and the Tamil Nadu, India study (94.4%) but higher than the Ambajogai, India study (0%). Quantity of the prescribed topical steroids to be dispensed was mentioned in only 44.4% of the patient records. Nevertheless, it was indicated during the interview the quantity to be dispensed is written on the prescription and usually not on the patient records due to the work load in the clinic.

Once- or twice-daily application is recommended for most topical steroid preparations as more frequent administration does not provide better results and associated is with side effects (Ference and Last, 2009). In this study, out of all the patients records with topical steroids where frequency of application was mentioned, there were only 2 patients that were advised to apply the topical steroids twice a day but the rest (99.7%) were advised to apply once a day. Although chronic application of topical steroids can induce tolerance and tachyphylaxis (Olumide *et al*., 2008; Rapaport and Lebwohl, 2003), there was one case where betamethasone dipropionate 0.05% ointment was prescribed to be applied for 8 weeks straight and then discontinue for a week and then continue the application.

In this study, topical steroids from the four potency category were prescribed which is consistent with the key informants' response. Nonetheless, potent (55.3%) and very potent (23.2%) topical steroids were found to be the most commonly prescribed topical corticosteroids. Of all the topical steroids betamethasone dipropionate 0.05% was the most commonly prescribed drug (24.4%), which is a potent topical steroid, followed by clobetasol propionate (23.2%), a very potent topical steroid. This result is different from studies conducted in India where clobetasol (ranging from 27.7% - 91%) was the most commonly prescribed drug among the topical steroids (Kumar *et al*., 2011; Bijoy *et al*., 2012; Mohamed Saleem *et al*., 2012; Narwane *et al*., 2011). Although tendency of prescribing very potent topical steroids is lower when compared to the studies in India, it shows that there is a tendency of using potent topical corticosteroids in the dermatology clinic. The result found in this study is also different from the north Palestine study, where betamethasone-17 valerate 0.1% was the main therapeutic agent (22%). But, similarly clobetasol propionate was the second most prescribed topical steroid agent (Sweileh, 2006).

The topical steroids were categorized into four classes (very potent, potent, moderate and mild) based on the BNF classification and based on a previously conducted study, for this particular study. However, inconsistencies were encountered on the classification of triamcinolone acetonide 0.1%, mometasone furoate 0.1% and fluocinolone acetonide 0.025%, which are categorized under moderate classes from the key informants' response. On the other hand, these three topical steroids were classified under potent class in the analysis of this study. This might have affected the results found since one of the dermato-venereologists noted that moderately potent topical steroids are the commonly prescribed drugs in the OPD of the dermatology clinic. There were also some discrepancies with the results found in other studies where fluocinolone acetonide is categorized under very potent class together with clobetasol propionate (Rathod *et al*., 2013) and also betamethasone valerate is classified in moderate potency in the north Palestine study (Sweileh, 2006).

Most of the potent (70.4%) and very potent (72.6%) topical corticosteroids were prescribed by the dermato-venereologists. This is consistent with what one of the dermato-venereologist indicated in the interview, that the residents are usually reluctant to prescribe potent and very potent topical steroids and that they refer the cases to senior dermato-venereologists.

As it was also confirmed by the interviewees, topical corticosteroids are appropriate for the vast majority of patients, and the potency of the corticosteroid chosen should be individualized based on the severity of the dermatitis, the location of the affected skin, the surface area of the affected skin, and the age of the patient (Schneider *et al*., 2012). Although majority of the potent and very potent topical steroids were prescribed for patients aged 21 and over, the analysis of the result within age groups showed that children aged 10 and less were prescribed 16.6% of the potent and very potent topical steroids.

Majority (72.7%) of the topical steroids was found to be prescribed alone and the rest were prescribed in combination with other drugs. Keratolytics were the most commonly combined drug groups (48.9%) since they reduce hyperkeratosis and increase the absorption of other medications (Chiricozzi and Chimenti, 2012). This was also confirmed by one of the key informants that salicylic acid is usually prescribed in conditions that produce scales so as to shed the scales formed. The key informant added that for combinations that are prescribed to be

prepared extemporaneously, the appropriate pH and composition should be considered otherwise the medication will not be effective.

Emollients were found to be the most common concomitantly prescribed agents (46.7%) with the topical steroids in this study. This high use of emollients can be explained by the fact that the topical steroids were majorly prescribed for the conditions eczema and dermatitis, where the concomitant application of emollients and moisturizers significantly an improved barrier function and stratum corneum hydration makes the epidermis more resistant to external stressors (Fluhr *et al*., 2008) and reduces the risk of relapse and improves overall patient status (Schneider *et al*., 2012; Watson and Kapur, 2011). Anti-histamines were the second most concomitantly prescribed drug groups together with the topical steroids, which help to manage sleep disturbances caused by the inflammatory skin conditions since they control pruritus. The other commonly concomitantly prescribed agents were protectants/sun screens, which is also important since topical steroids cause skin burning and irritation. Anti-bacterials and anti-fungals were also prescribed together with the topical steroids, since the use of topical steroids increases the risk of infection. (Radley, 2004; Saravanakumar *et al*., 2012; Schneider *et al*., 2012; Watson and Kapur, 2011).

The principles of optimal use of topical corticosteroids includes controlling the skin condition by either continuing with a less potent preparation, reducing the frequency of application after sufficient clinical response and tapering off the treatment upon complete remission of skin diseases (Lo, 2006). This was also reported by the key informant. However, the finding of this study shows that potency of the topical steroid was increased in 20.4% in patients that showed improvement when the rest 44.6% of the patients were advised to discontinue applying the topical corticosteroid and in 27.2% of the patients the strength of the topical steroid was decreased.

The prescribers' adherence to the NSTG was only 58.1%, with regard to topical steroids, from the disease conditions that are found in the NSTG. This may be because the NSTG is prepared for general hospitals and as ALERT Hospital is a specialized hospital especially for dermatologic conditions, the drugs that are prescribed can be outside the NSTG. The NSTG also contains very limited type of dermatologic conditions and limited type of drugs indicated for various types of

skin diseases. The adherence of the prescribers to the AMF was found to be 100%. It showed that all the topical steroid agents prescribed are included in the AMF.

Several studies have reported topical steroid induced skin diseases (Al-Dhalimi and Aljawahiry, 2006; Fisher, 1995; López *et al*., 2011; Ly *et al*., 2007; Mahé *et al*., 2003; Nnoruka and Okoye, 2006; Olumide *et al*., 2008). In this particular study, topical steroid induced skin conditions were observed in four patients, two acne, rosacea and dermatitis, which were induced by the use of potent topical steroids. Although the dermato-venereologists noted that they encounter patients that visit the dermatology clinic often, there were only 4 cases observed due to a result of using topical steroids. The number found in the result is few may be because history of patients is not always written on the patient records however it shows, although few in number, that topical steroid plays role in causing skin diseases in patients that visit dermatology clinics. According to the key informants, the major factor that contributes to this situation is the availability these products in the market although they are prescription only drugs and also not being aware of the health consequences topical steroids cause.

Although not documented in the patient records, systemic side effects are also observed in patients that use topical steroids for a long period according to some of the key informants. Stunted growth due to the HPA axis suppression and cushing syndrome were the conditions that were witnessed. This result is consistent with other studies (Al Shaikh, 2005; Bewley, 2008; Tempark *et al*., 2010) since the use of topical steroids for a prolonged time is associated with systemic side effects.

7. Limitations of the study

- The study conducted was a retrospective study, which might have affected the completeness of the data
- The STG contains limited range of skin diseases making the analysis incomplete
- Nurses working in the dermatology clinic were employed for data collection which might have affected the validity of the data

8. Conclusion

From this study, it can be concluded that eczema and dermatitis are the single most common skin diseases observed in the dermatology clinic and that infectious skin diseases account for the majority of the skin dermatoses when combined. Topical steroids and its combination were found to be the most commonly prescribed drugs followed by anti-fungals.

Among the topical steroids prescribed adequate information was not written in most of the records with regard to the site of application, duration and quantity of the topical steroid to be dispensed and also brand names were also used almost in all the records. It was also found out that betamethasone dipropionate 0.05% and clobetasol propionate 0.05% were the two most commonly prescribed agents which are potent and very potent topical steroids, respectively.

Prescribing practice of potent and very potent topical steroids was found to be high. Keratolytics were the most commonly prescribed drug group to be combined with the topical steroids and emollients and anti-histamines were the most commonly prescribed concomitant drug groups. A treatment shift from higher potency to a lower potency topical steroid (27.2%) and discontinuation of the product (44.6%) was observed in patients who showed improvement in their condition. Prescribers' adherence to the AMF and NSTG was found to be 100% and 58.1%, respectively. According to the key informants, the OTC use of topical steroids is a common practice among the community despite the fact that their use is associated with a wide range of adverse effects.

9. Recommendations

Based on the findings of this study the following recommendations can be made:

- More than half of the diseases were allergic skin diseases and infections. Therefore, health professionals at all levels should emphasize on these groups of common skin diseases, such that correct diagnoses and treatment can be achieved at the peripheral centers, and only small number of patients need to be referred to specialized centers where dermatologists are available.

- Adequate information should be written on the patient records to have a complete picture of the condition and also generic names should be used to prescribe the drugs which in turn help to promote rational use of the topical corticosteroids and other dermatological preparations.

- A standard treatment guideline that matches the situation in the dermatology clinic should be developed since the current one contains very limited range of skin diseases and dermatological drugs for the respective skin conditions. It will help in minimizing the errors that occur during prescription of a certain dermatological drug.

- Health education should be given to the community to create awareness about the use of topical steroids without consulting a health professionals and the health consequences it causes by using both mass media and health workers

- Studies that assess the pattern of skin diseases should be conducted at different levels of health facilities

- Studies that assess the prescribing pattern of dermatological drugs and the use of topical corticosteroids in clinical settings should be conducted

- Studies should be conducted to determine the prevalence of the use of topical steroids without a prescription and its consequences

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Annexes

Annex I: Data abstraction format: patient records review in ALERT Hospital, 2013

1. **Patient information**

1.1.Card number _____

1.2.Age _____

1.3.Sex _____

1.4.Place of residence/address _____

1.5.Dermatological condition/Type of diagnosis _____

_____

1.6.Previous history of topical steroid use □ Yes □ No

If yes, Prescribed □

OTC □

Not specified □

2. **Treatment**

2.1.Date of visit _____

2.2.Qualification of prescriber _____

2.3.Number of drugs prescribed _____

Drug 1_____

Drug 2_____

Drug 3_____

Drug 4_____

Drug 5_____

2.4.Topical steroid prescribed _____

2.5.Dosage form _____

2.6.Dosage schedule _____

2.7.Frequency of application _____

2.8.Duration of treatment _____

2.9.Site (area) of application _____

2.10. Quantity of drug to be dispensed _____

2.11. Nature of concomitantly prescribed drugs _____

3. Last follow-up visit

3.1 Date _____

3.2. Diagnosis _____

3.3. Number of drugs prescribed _____

Drug 1_____

Drug 2_____

Drug 3_____

Drug 4_____

Drug 5_____

3.4.Topical steroid prescribed _____

3.5.Dosage form _____

3.6.Dosage schedule _____

3.7.Frequency of application _____

3.8.Duration of treatment _____

3.9.Site (area) of application _____

3.10. Quantity of drug to be dispensed _____

3.11. Nature of concomitantly prescribed drugs _____

Annex II: Interview Guide for key informant interviews with dermatologists and resident dermatologists working in ALERT Hospital

Age _____

Sex _____

Highest level of qualification/education_____

Work experience in your current qualification: _____

1. How do you describe the current utilization pattern of topical steroids in Ethiopia?
2. What dermatological conditions do you think are topical steroids appropriate for?
3. Which topical steroids are commonly prescribed in this hospital?
4. What is the average duration that you think topical steroids should be prescribed?

   Probe: What happens if these drugs are used for a longer than they are supposed to be used?
5. What are the most commonly encountered side effects from topical steroid use?

   Probe1: from short term and long term use

   Probe 2: Superficial as well as systemic complications
6. What sources do you use to prescribe topical steroids in this hospital? (STG, formulary)

   Probe: Do you think they comply with the current treatment strategies?
7. Do you think use of steroids on OTC basis is common among the community? among your patients?
8. Have you encountered any patients who used steroids OTC and visit the hospital as the result?

   Probe: How often do you encounter such patients?
9. What are the commonly used steroids OTC?

10. What factors do you think drives patients to use topical steroids without consulting a dermatologist?

    Probe: Therapeutic purpose, Cosmetic purpose (influence from the society, friends)

11. Which class of the society use these products most OTC?

    Probe: Age, sex, educational background, economic status

12. What are the most common consequences that are encountered in patients that use topical steroids for purposes other than therapeutic?

13. What do you think should be done to improve the use of topical steroids, at community and institution level?

Annex III: Ethical clearance from the Ethics Review Committee of School of Pharmacy, Addis Ababa University

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Addis Ababa University

School of Pharmacy
Ethical Review Board

ቀን Date: May 24, 2013

ቁጥር Ref. No.: ERB/SOP/05/05/2013

To: Hanna Negussie
School of Pharmacy

Re: Ethical Clearance

It is to be recalled that you submitted study proposal entitled, "ASSESSMENT OF UTILIZATION PATTERN OF TOPICAL STEROIDS IN ALERT HOSPITAL" for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the project 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 study is ethically approved for implementation

With best regards,

Daniel Bisrat (Dr.)
Secretary, ERB

ፋርማሲ ት/ቤት School of Pharmacy Addis Ababa University

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Annex IV: AHRI-ALERT Ethical Review Committee Approval Sheet

AHRI-ALERT ETHICAL REVIEW COMMITTEE APPROVAL SHEET

TITLE OF THE PROJECT

"Assessment of utilization pattern of topical steroids in ALERT hospital."

PI: Hanna Nigusie

Project Reg. No. PO40/13

Recommendation of the AHRI-ALERT Ethics Review Committee

The request for an initial review on the above mentioned research project was duly considered for expedited review and approved by the AHRI/ALERT Ethics Review Committee on August 06, 2013. The PI should submit progress report of the work every 6 months and the final report upon completion. The PI should also notify the AAERC ahead of any amendments or modifications in the protocol or premature suspension or termination of the study.

Signature: _____

CHAIRPERSON
Name: Prof. Getachew Tilahun

Signature: _____

SECRETARY
Name: Dr. Liya Wassie

Approval by Directors:

Director of AHRI

Signature: _____

Date: 8/13

Sponsored by the Government of Ethiopia, Norway & Sweden

Abraham Aseffa, MD. Ph.D
Scientific Director

Annex V: Information sheet (English and Amharic versions)

Dermatological conditions account for up to 2% of consultation in general practice worldwide. These skin problems are generally among the most common diseases seen in primary care settings in tropical areas. With the skin being the largest and most accessible organ to treat, topical steroid therapy comprises the mainstay treatment of many dermatologic conditions. However, irrational prescription of topical steroids is a common occurrence in clinical practice and they are being abused by physicians and patients alike. The cost of such irrational drug use is enormous in developing countries in terms of both scarce resources and the adverse clinical consequences of therapies that may have real risks.

The general purpose of this study is to assess the pattern of topical steroid utilization in ALERT Hospital, Addis Ababa.

The study will employ a descriptive, cross sectional study design employing both quantitative (retrospective analysis of records) and qualitative methods (key informant interviews with dermatologists). The study will be conducted in ALERT Hospital which is the most specialized hospital in Addis Ababa and a total of 660 patient cards from the year 2011/2012 will be reviewed.

Data will be collected employing a data abstraction format and an interview guide. Nurses working in ALERT Hospital will be recruited to review patient records and the interviews will be conducted by the principal investigator. The quantitative data will be inspected/cleaned, coded and entered into EPI Info Version 6.0. Then, the data will be exported to SPSS versions 16 for further analyses. The data will be analyzed using simple descriptive statistics, frequency tables, figure and bivariate and multivariate logistic regression. Whereas the qualitative data will be grouped, coded and analyzed thematically.

There are no direct risks to the participants. Nevertheless, there will be a sometime taken from their work 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 topical steroids. Participation of the interviewees is completely voluntary. They can refuse to answer any questions and/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 after the completion of the study, the interview recorded will be erased.

This study will contribute to the rational use of topical steroids and will give an insight to what extent these groups of drugs are being used without prescription, which will help take the appropriate intervention in order to minimize the associated risk following the use of topical steroids without the appropriate consultation with dermatologists.

After the completion of the study, the thesis will be printed and disseminated to the hospital and the participants of the study.

Contact address

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AHRI Tel: 0113481289

የመረጃ ገጽ

የቆዳ በሽታዎች በአለም አቀፍ ደረጃ 2 ከመቶ (2%) የሚሆነዉን የህክምና ጊዜ ይወስዳል፡፡ እነዚህ የቆዳ በሽታዎች በትሮፒካል አካባቢ ከሚከሰቱ የጤና ችግሮች አንዱና ዋነኛዉ ነዉ፡፡ እነዚህን የቆዳ በሽታዎች ለማከም ከሚታዘዙት መድሃኒቶች ቶፒካል ስቴሮይድስ ከፍተኛዉን ድርሻ ይወስዳሉ፡፡ ሆኖም ግን እነዚህን መድሃኒቶች በበሽተኞችና በህክምና ዶክተሮች አላግባብ ጥቅም ላይ የማዋል ሁኔታ የተለመደ ነዉ፡፡ ይህ የአለአግባብ የሆነ አጠቃቀም የሚያመጣዉ ጉዳት በታዳጊ አገሮች ካለዉ የመድሃኒት እጥረት ጋር ተያይዞ የሚያመጣዉ ጉዳት የከፋ ነዉ፡፡

የዚህ ጥናት አጠቃላይ አላማ በአለርጥ ሆስፒታል ያለዉን የቶፒካል ስቴሮይድስ አጠቃቀም ለመፈተሽ ነዉ፡፡ ከዚህም በተጨማሪ የነዚህን መድሀኒቶች ያለ ሃኪም ትእዛዝ ስለሚጠቀሙ ታካሚዎች እና ስለሚያስከትለዉ ዉጤት ይዳስሳል፡፡ የጥናቱ ዘዴዎች የታካሚዎችን መረጃ ከካርድ ላይ መዉሰድንና በቆዳ ህክምና ላይ ስፔሻላይዝ ያደረጉ ሃኪሞች ጋር ቃለ-መጠይቅ ማድረግን ያካትታል፡፡ ሆስፒታሉን በ2004 ዓ. ም ለመታከም ከመጡ ታካሚዎች ዉስጥ የ660ዎቹን ሆስፒታሉ በሚሰሩ ነርሶች አማካኝነት መረጃዎች በመረጃ መዉሰጃ ፎርማት እንዲሰባሰቡ ይደረጋል፡፡ 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 እንደየ ጭብጣቸዉ 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 ስቴሮይድስ አጠቃቀም እንዲመጣ አስተዋፆ ትልቅ ጥቅም አለዉ፡፡

ቃለ-መጠይቁ ላይ የሚሳተፉት የቆዳ ሃኪሞች በፍላጎታቸዉ ሲሆን ከቃለ-መጠይቁ የተገኙ ምላሾች እና ስማቸዉ በሙሉ በሚስጥር ይያዛል፡፡ ከጥናቱ ጋር ቀጥተኛ ግንኙነት ካላቸዉ ተሳታፊዎች በስተቀር ሁሉም መረጃዎች በሚስጥር ይያዛሉ፡፡ ጥናቱ ከተጠናቀቀ በኋላ በቴፕ መቅረጫ የተቀረጸዉ ቃለ-መጠይቅ እንዲደመሰስ ይደረጋል፡፡

ጥናቱ አግባብነት ላለዉ የቶፒካል ስቴሮይድስ አጠቃቀም አስተዋጽኦ ያደርጋል፡፡ ከዚህም በተጨማሪ ያለ ሃኪም ትእዛዝ እነዚህን መድሀኒቶች በሚጠቀሙ ታካሚዎች የሚደርሰዉን ጉዳት ያሳያል፡፡ ይሄም አስፈላጊዉን የማስተካከል እርምጃ እንዲወሰድ ይረዳል፡፡

ጥናቱ ሲጠናቀቅ የጥናቱ ጽሁፍ ለሆስፒታሉና በጥናት ዉስጥ ለሚሳተፉ ሰዎች ታትሞ እንዲሰራጭ ይደረጋል፡፡

አድራሻ

የጥናት መሪ ሀና ንጉሴ 0910026941

አርማዉር ሀንሰን የምርምር ኢንስትቲዉት 0113481289

Annex VI: Written informed consent (English and Amharic versions)

You are invited to participate in a research study conducted by Hanna Negussie, from Addis Ababa University, School of Pharmacy, Department of Pharmaceutics and Social Pharmacy. The research topic is "Assessment of utilization pattern of topical steroids in ALERT Hospital". The purpose of this study is to assess the utilization pattern of topical steroids in the hospital and it will also address the OTC use of these classes of drugs by patients and its consequences. This study will contribute to the rational use of topical steroids and will give an insight to what degree these groups of drugs are being used without prescription, which will help take the appropriate intervention in order to minimize the associated risk following the use of topical steroids without the appropriate consultation with dermatologists.

You were selected as a possible participant in this study because you are one of the dermatologists working in this hospital and the study is about the use of topical steroids. The interview will take 30-50 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 (will not be recorded), and your responses will not be linked to your identity at any time. And after the completion of the study, the interview recorded will be erased.

If you have any questions about the research, please contact the Principal Investigator, Hanna Negussie, via email at movsic@yahoo.com or telephone number 0910026941 or the faculty advisor Dr. Teferi Gedif via email at teferig@phar.aau.edu.et

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_____

የጽሁፍ ፍቃደኝነት ማረጋገጫ ቅጽ

ከአዲስ አበባ ዩኒቨርሲቲ የፋርማሲ ትምህርት ቤት ከፋርማሲዩቲክስ እና ሶሻል ፋርማሲ የትምህርት ክፍል በሀና ንጉሴ በሚደረገዉ ጥናት ላይ እንዲሳተፉ ተጋብዘዋል፡፡ የጥናቱ ርዕስ “Assessment of utilization pattern of topical steroids in ALERT Hospital“ ነዉ፡፡ ዓላማዉም በአለርጥ ሆስፒታል ያለዉን የቶፒካል ስቴሮይድስ አጠቃቀም ለመፈተሽ ነዉ፡፡ ከዚህም በተጨማሪ የነዚህን መድሀኒቶች ያለ ሃኪም ትእዛዝ ስለሚጠቀሙ ታካሚዎች እና ስለሚያስከትለዉ ዉጤት ይዳስሳል፡፡ ጥናቱ አግባብነት ላለዉ የቶፒካል ስቴሮይድስ አጠቃቀም አስተዋጽኦ ያደርጋል፡፡ ከዚህም በተጨማሪ ያለ ሃኪም ትእዛዝ እነዚህን መድሀኒቶች በሚጠቀሙ ታካሚዎች የሚደርሰዉን ጉዳት ያሳያል፡፡ ይሄም አስፈላጊዉን የማስተካከል እርምጃ እንዲወሰድ ይረዳል፡፡

በዚህ ቃለ-መጠይቅ ዉስጥ እንዲሳተፉ የተጠየቁት ጥናቱ ለቆዳ በሽታዎች ስለሚታዘዙት ቶፒካል ስቴሮይድስ ስለሆነና እርስዎ ደግሞ እዚህ ሆስፒታል ዉስጥ ካሉት የቆዳ ሀኪሞች መካከል አንዱ ስለሆኑ ነዉ፡፡ ቃለ-መጠይቁ ከ30 እስከ 40 ደቂቃ 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 በኋላ በቴፕ መቅረጫ የተቀረጸዉ ቃለ-መጠይቅ እንዲደመሰስ ይደረጋል፡፡

ስለ ጥናቱ ማንኛዉም ጥያቄ ካለዎት የጥናት መሪዋን ሀና ንጉሴ በኢ-ሜይል አድራሻ movsic@yahoo.com ወይም ሞባይል ቁጥር 0910269411 ወይም የጥናቱን አማካሪ ዶ/ር ተፈሪ ገድፍ በኢ-ሜይል አድራሻ teferig@phar.aau.edu.et አግኝተዉ መጠየቅ ይችላሉ፡፡

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

እስማማለሁ ☐ አልስማማም ☐

ፊርማ_____

ቀን_____