CLINICAL EVALUATION CRITERIA AND APPROACH TO MANAGEMENT OF OCULAR ALLERGY BY OPHTHALMOLOGISTS IN KENYA

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DECLARATION

THIS DISSERTATION IS MY ORIGINAL WORK AND HAS NOT BEEN PRESENTED FOR A DEGREE IN ANY OTHER UNIVERSITY.

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DEDICATION

This work is dedicated to my family for their continued support and encouragement in my every endeavour.

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LIST OF ABBREVIATIONS

AKC- Atopic Keratoconjunctivitis

AOD-Allergic Ocular Diseases

CsA- Cyclosporine A

EACO- Eastern Africa College of Ophthalmologists

ENT- Ear Nose and Throat

FGD- Focus Group Discussion

GPC- Giant Papillary Conjunctivitis

HDM- House Dust Mites

KAP- Knowledge Attitude and Practice

KEU- Kikuyu Eye Unit

KNH- Kenyatta National Hospital

MCJ- Mucocutaneous Junction

MGD- Meibomian Gland Disease

MMed- Master of Medicine

NSAIDs- Non-Steroidal Anti-inflammatory Drugs

OA- Ocular Allergy

OSEA- Ophthalmological Society of Eastern Africa

PAC- Perennial Allergic Conjunctivitis

SAC- Seasonal Allergic Conjunctivitis

SPK- Superficial Punctate Keratitis

STGs- Standard Treatment Guidelines

UON- University of Nairobi

VKC- Vernal Keratoconjunctivitis

ABSTRACT

Background: Despite the high prevalence (20% of the population worldwide) of ocular allergy (OA), its definition, a standard classification and staging as well as the guidelines to diagnosis and treatment are not globally accepted. Clinical evaluation criteria would allow appropriated evaluation of progression, the establishment of algorithms of treatment, as well as objective assessment for analysis of treatment efficacy.

Aims: To determine the clinical evaluation of OA by ophthalmologists in Kenya and also to describe their practices regarding the clinical grading and approach to management of ocular allergy.

Methods: The study was a descriptive (Knowledge, Attitude and Practice) cross-sectional study carried out in the Republic of Kenya from 1st December 2012- 31st May 2013. All qualified and practising ophthalmologists in Kenya were included in the study. Primary data was collected using self-administered questionnaires. Focus Group discussions were used as a secondary data collection tool for triangulation and to get detailed information on the attitudes and practices of the ophthalmologists regarding OA. Quantitative data analysis was undertaken using Stata version 11.0. Qualitative data was imported into NVivo 10 software for coding and data analysed through content analysis.

Results: A total of 58 ophthalmologists were included in the study (69% response rate). All the participants reported diagnosing OA based on clinical findings. Majority, 82.8% (48/54 reported grading ocular allergies with 63.8% (37/58) grading OA according to the level of severity. 50% (29/58) felt that grading of OA was very important. The rational use of topical steroids was advised so as to avoid their overuse. Surgical intervention was suggested only in the management of complications of OA or conditions associated with OA. There is no national standard treatment guideline for the management of OA. Counselling was seen to form a major part of the management of a patient with OA though it is inadequate in our setting.

Conclusion: Despite the high number of ophthalmologists reporting grading OA, there is no standardised grading system followed. Its establishment would allow for better documentation and assessment of treatment response during patient follow-up. Patient counselling needs to be emphasized so as to improve compliance to treatment and follow up appointments. There is a need to come up with a national guideline so as to harmonise the diagnosis, grading and treatment of ocular allergy.

1. INTRODUCTION TO OCULAR ALLERGY

1.1 DEFINITION

Ocular allergy (OA) is an inflammatory disease of the ocular surface, frequently recurrent, whose basic pathophysiological mechanism is the type I hypersensitivity, associated with other types of hypersensitivity reactions[1-2]. OA seems to be a broad and more appropriate term to describe this group of heterogeneous diseases, whose basic mechanism is allergic, including conjunctivitis and keratoconjunctivitis[1]. The term ocular allergy encompasses a group of diseases in which there is a high frequency of atopy, ocular itching, stringy discharge and a papillary conjunctival reaction[3].

1.2 EPIDEMIOLOGY

There are few epidemiological data on allergic conjunctivitis, probably because of lack of criteria, under-diagnosis of the condition, and the fact that the disease is often associated with allergic rhinitis, which draws scant attention[2]. According to Rosario *et al.* (2011) one of the major problems associated in the provision of a 'current opinion' evaluating the epidemiology of ocular disorders from the various studies is the lack of clinical 'criteria' for the variety of ocular disorders[7].

OA affects 20% of the population worldwide and is usually associated with a type I hypersensitivity reaction and the spectrum of clinical expression varies according to individual cases[1, 8]. Recent studies according to Rosario *et al.* (2011) imply rates as high as 40%[7]. The prevalence of the different forms of ocular allergy has not been well established, though the serious forms are believed to represent only 2% of all eye allergies. In contrast, mild allergic conjunctivitis (acute, seasonal and perennial) is much more common, representing up to 98% of all cases of ocular allergy, and its incidence moreover is increasing[2].

A study by Waweru *et al.* (1991) in Kenyatta National Hospital (KNH), Kenya, found that the age and sex structure of VKC in the Kenyan population parallels that of other populations elsewhere. Majority of the patients had the limbal form of the disease. Approximately 55% of the patients studied had a related history of allergy, the commonest

association being allergic rhinitis. In this study, 3% of the patients with VKC suffered from keratoconus[9]. In a study by Wade *et al.* (2012) to assess the prevalence of allergic conjunctivitis in Gambia, 7.9% of the patients were diagnosed with various forms of ocular allergies making it one of the most common disorders at the clinic[10].

In the Alergológica 2005 study, allergic rhinoconjunctivitis was found to have been the main reason for consulting the allergologist, in 55.5% of all cases. In turn, 15.3% of the patients consulting in allergic rhinoconjunctivitis already had a history of allergic conjunctivitis. A full 60.3% of the patients considered the eye symptoms to have been one of the main reasons for seeking medical help[2]. While VKC tends to have a good prognosis and eventually subsides as the patient grows older, it should be recognized as a potentially blinding disease[9].

1.3 PATHOLOGY

The pathogenesis of ocular allergy is complex and multifactorial, and can be regarded as the result of environmental interaction with a group of predisposing genes. Few studies have explored the genetic associations of allergic conjunctivitis, though a clear familial predisposition to develop the disease has been demonstrated. An association has been found between allergic conjunctivitis and chromosomes 5, 16 and 17, and also chromosome 6 when considering specific allergens. This suggests that there may be organ-specific susceptibility genes in allergic diseases, since the genes identified for conjunctivitis differ from those established for atopic asthma[2].

In general, allergic conditions involve mast cell degranulation that leads to release of inflammatory mediators and activation of enzymatic cascades generating pro-inflammatory mediators. In chronic ocular inflammatory disorders associated with mast cell activation such as VKC and AKC constant inflammatory response is observed due to the predominance of inflammatory mediators such as eosinophils and Th2-generated cytokines[11].

A study done to describe the pathology of vernal keratoconjunctivitis in children from Kenya found that the features are similar to those in reports of VKC in temperate regions, although the degree of B-lymphocyte clustering is greater in tropical patients with VKC. Although

none of the patients had other symptoms of atopy, the authors' findings are consistent with those for an allergic basis for this disease[12].

2. LITERATURE REVIEW

2.1 CLASSIFICATION

Allergic eye disease is commonly encountered in clinical practice because the external eye is exposed to a host of environmental, cosmetic, and pharmacologic antigens. Although individual responses show a wide range of variability, a number of distinctive syndromes have emerged to define the spectrum of allergic eye disease. They consist of seasonal allergic conjunctivitis (SAC), perennial allergic conjunctivitis (PAC), atopic keratoconjunctivitis (AKC), vernal keratoconjunctivitis (VKC), giant papillary conjunctivitis (GPC), and contact allergies involving the conjunctiva[4].

Of these ocular allergy types, SAC and PAC are the most common. The most striking difference within this group of ocular diseases is that SAC and PAC remain self-limited without ocular surface damage, while AKC and VKC can compromise the cornea, causing ulcers and scarring and can ultimately lead to vision loss[3, 5-6]. Ocular allergy may also be classified in terms of duration. This includes acute, chronic and recurrent forms[1].

2.1 DIAGNOSIS

The diagnosis of ocular allergy is mainly clinical, and the medical treatment is based on these clinical findings which are usually varied. A number of tests can be performed in patients suspected of having allergic conjunctivitis, although these are usually limited to academic or confirmatory purposes[6].

The previously mentioned study by Waweru *et al.* (1991) at KNH Kenya, found that a conjunctival scraping is useful in cases where the diagnosis is in doubt. It also showed that the commonest symptoms encountered among VKC patients was itching(99%), tearing(85%) and gritty foreign body sensation (77%). 17% of the patients had palpebral vernal disease while 83% had both palpebral and limbal forms. There was no patient with

exclusively the limbal form of the disease. Corneal signs encountered included superficial punctuate keratopathy (4 patients), corneal ulcers (3 patients) and keratoconus in 3 patients[9].

In a study in Gambia at Sheikh Zayed Regional hospital (2012), the diagnosis of allergic conjunctivitis was similar to other eye centres in African countries, that is by meticulous questioning, emphasizing on the existence of ocular itching and looking for tarsal papillae, follicles and conjunctival pigmentation[10]. PAC in the United Kingdom is most commonly caused by the house-dust mite (HDM); diagnosis is confirmed by skin-prick tests, eosinophils in the conjunctival smear, and raised tear or serum total IgE[20].

2.2 EVALUATION OF GRADE OF SEVERITY FOR OCULAR ALLERGY

Despite the high prevalence, its definition, a standard classification and staging as well as the guidelines to diagnosis and treatment are not globally accepted. Agreement regarding the classification of ocular allergies is limited. Syndromically, a distinction can be made between mild presentations (acute, seasonal and perennial according to the time of exposure to the allergen) and more serious conditions such as VKC, AKC, GPC and contact dermatoconjunctivitis[1-2]. The clinical features of allergic ocular diseases are characterized by their wide variety. Clinical evaluation criteria would allow appropriated evaluation of progression, the establishment of algorithms of treatment, as well as objective assessment in clinical trials for analysis of treatment efficacy[13].

Uchio *et al.* (2007) established criteria for classifying and clinically evaluating the severity of allergic ocular diseases (Appendix VI: B). The researchers then evaluated the effectiveness of the criteria in the diagnosis of 1,079 patients, according to the study. The researchers diagnosed and classified allergic conjunctivitis, atopic keratoconjunctivitis and vernal keratoconjunctivitis based on local and systemic clinical findings. Specifically, 10 objective conjunctival, limbal and corneal lesion findings were graded on a 4-point scale. The total score was used as the clinical score, with the highest value of 30. The results suggested that allergic ocular diseases (AOD) can be classified by their new clinical grading system, and that the system would be sensitive enough for clinical evaluation of AOD[13].

Robles-Contreras *et al.* (2011) proposed an objective grading system to recognize the progress of allergic ocular disease (Appendix VI: A). The authors recommended a grading

system of conjunctival, palpebral and corneal inflammation based on a scale of 0 to 4 according to severity. They also took into consideration the frequency of symptoms (itching, tearing, light sensitivity, gritty sensation, and burning sensation) and repercussion of signs implicated on alterations accompanying the inflammation at the ocular surface, such as eyelid position and skin aspect, eyelid margin state of mucocutaneous junction (MCJ) with involvement of meibomian gland disease (MGD), discharge aspect, implication of limbal stem cell deficiency and even keratoconus involvement. The score of the more severe side in bilateral cases was used as the clinical score[14].

In situations where unanimity of opinions does not exist because of lack of or contradictory scientific evidences, consensus methods can be useful. A panel of experts may be an appropriate method to obtain a consensus based on current knowledge. In the Ocular allergy Latin American consensus (2011), agreement was reached on the significance of establishing a staging of ocular allergic diseases based on levels of severity (>66.67% agreed on the importance). This was especially to follow patients and to determine algorithms of treatment. However, they did not reach consensus regarding this topic. Merely illustrative, Table 3 in Appendix VI: C presents the chosen staging by less than half of panellists (4/10)[1].

Sacchetti *et al.* (2010) proposed a decision tree for VKC treatment and a new clinical grading system. It allows for the identification of the more severe VKC forms that are at a higher risk of recurrences, corneal ulceration, and a worse final visual outcome[15]. Most of the criteria take into consideration, subjective frequency of symptoms such as itching, tearing, light sensitivity, gritty sensation, and burning sensation, and objective ocular clinical findings of conjunctival, limbal and corneal lesions. Other authors have also proposed various grading systems, including: Takamura *et al.* (2011) in the Japanese Guideline for Allergic Conjunctival Diseases[16], Cuvillo *et al.* (2009)[2] Bonini *et al.* (2007)[17] Calonge *et al.* (2007)[18] and Shoji *et al.* (2009)[19].

2.3 MANAGEMENT

Advances in the understanding of ocular allergic disorder mechanisms have provided a foundation for more rational guidelines of treatment of these diseases. The goals of therapy

should include not only the control of signs and symptoms, but also improvement of the ocular health of patients with allergies[1, 21-22].

First Line treatment involves non-specific measures:

- Environmental control and avoidance of allergens, which might be achieved by removing allergen sources or changing occupational venue.
- Application of cold dressings.
- Use of artificial tears for all cases of ocular allergies, aiming at either the removal and dilution of allergens or the re-establishment of the tear film, which can be compromised by ocular surface inflammation produced by the allergic response. (1) (3) (6)

However, these measures are typically ineffective or not very practical, and pharmacological treatment normally proves necessary[2]. Since the conjunctiva is an accessible mucosa, topical drug application logically appears as the ideal approach for the treatment of allergic conjunctivitis, since rapid action is assured, with improvement in eye hydration[2]. Therefore, secondary treatment should include the use of topical anti-histamines, mast cell stabilizers and multi-action drugs, as measures of symptomatic control[1]. Topical antihistamines – preferably those with established dual action- are very effective in treating allergic conjunctivitis, and outperform other groups of drugs such as mast cell stabilizers or topical Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) [2]. These combination medications act as both mast cell stabilizers and H1-specific antihistamines, such as olopatadine, ketotifen fumarate, and azelastine, and have become a mainstay of treatment. Studies have shown the dual mechanism medications to be effective in acute and chronic treatment[23].

Oral antihistamines are also a treatment option to be taken into account, particularly when considering that the isolated presentation of allergic conjunctivitis without associated rhinitis is rare. Furthermore, although the topical treatment of allergic conjunctivitis has been shown to improve the nasal symptoms of allergic rhinoconjunctivitis, systemic antihistamines are more potent in securing relief from symptoms of this kind. However, some studies have demonstrated an adverse effect on the part of oral antihistamines, causing dry eye, compared with topical antihistamines, which do not produce this effect[2]. VKC and AKC are chronic

allergic disorders with physiopathogenic mechanisms that are more complex than in the case of allergic conjunctivitis. As a result, the role of antihistamines (both oral and topical) is very limited in such situations, and is confined to attempting control of the most bothersome clinical manifestations (especially itching) during the symptomatic periods[2].

The third line of treatment should be indicated for the most severe cases of keratoconjunctivitis, (vernal keratoconjunctivitis and atopic keratoconjunctivitis) when topical medications have failed in controlling allergic signs and symptoms. This includes the rational use of topical corticosteroids for treating some chronic cases and acute crises, considering a short time course of treatment and its ocular side effects[1, 3]. This is commonly used in addition to antihistamines and mast cell stabilizers in order to acutely control the inflammation[23].

Immunosuppressive agents such as cyclosporine A (CsA), azathioprine may be effective at relatively low doses in AKC unresponsive to other measures. Ozcan *et al.* (2007) investigated the efficacy of topical CsA 0.05%, a less concentrated and commercially available novel preparation, in patients with severe VKC or AKC refractory to topical steroid treatment. The study showed that topical cyclosporine A is an effective treatment in the management of severe allergic conjunctivitis with a benefit as a steroid-sparing agent[24-25]. A Japanese study evaluated cyclosporine 0.1% ophthalmic solution and found that 30% of topical corticosteroid users were able to discontinue their use when using adjunctive topical cyclosporine 0.1%[25]. It is not used routinely to treat ocular allergies. Monoclonal antibodies against T cells have also shown some promise in refractory cases[1, 26].

For cases where symptoms are not alleviated by drug treatment and conjunctival papillary hyperplasia progresses to cause worsened corneal epithelium disorder, a tarsal conjunctival resection, including the papillae may be performed. While the treatment effect is immediate, it may recur in some cases. Although corneal plaques may be removed by surgical curettage, the treatment is performed only when the pathologic condition has been alleviated[16].

Superficial keratectomy may be required to remove plaques or debride shield ulcers and allow epithelialisation. Medical treatment must be maintained until the cornea has reepithelialised in order to prevent recurrences. Excimer laser phototherapeutic keratectomy

is an alternative. Surface maintenance-restoration surgery such as amniotic membrane overlay grafting or lamellar keratoplasty, or eyelid procedures such as botulinium toxin-induced ptosis or lateral tarsorrhaphy, may be required for severe persistent epithelia defects or ulceration. Gluing may be appropriate for focal ('punched-out') corneal perforations[26].

The management of VKC in tropical countries is controversial and is often determined by availability of medications, safety, and cost[12]. Frequency of follow-up visits is based on the severity of disease presentation, aetiology, and treatment. Consultation with a dermatologist is often helpful. A follow-up visit should include an interval history, measurement of visual acuity, and slit-lamp biomicroscopy. If corticosteroids are prescribed, baseline and periodic measurement of intraocular pressure and pupillary dilation should be performed to evaluate for glaucoma and cataract[25-26].

2.4 STANDARD TREATMENT GUIDELINES

The development and implementation of standard treatment guidelines (STGs) is a necessary task in a health care system where numerous treatments may be available. Doctors, nurses, pharmacists, community health workers, and other health care providers learn about all of the treatments that could be used, instead of focusing on the best treatment that should be used. Casual observation, as well as more systematic study of prescribing practices, frequently reveals a pattern of tremendous diversity among prescribers in the treatment of even the most common conditions[28].

2.5 LITERATURE REVIEW SUMMARY

Knowledge, attitude and practice (KAP) studies serve as an educational diagnosis of the community being studied. The main purpose of this study is to explore changes in KAP of practising ophthalmologists in Kenya on ocular allergy. This study will provide information on the current management of OA and the perceived importance of a grading system by ophthalmologists in Kenya. The literature cited has indicated the importance of grading ocular allergy, especially in patient follow-up and to determine algorithms of treatment. By conducting a KAP study I will be able to assess the environment and create awareness on the need for severity grading, and the need to generate a standardized protocol so as to guide clinicians on the management of ocular allergy.

3. JUSTIFICATION

Currently the classification and management of OA is not standardized and there appear to be several approaches to management depending on the understanding of severity. The results from this study will be useful in creating awareness on the importance of clinical grading. This may help clinicians and researchers classify disease activity and establish a common agreement for treatment of ocular allergy. Additionally, it is anticipated that the findings will also help in the establishment of set guidelines in Kenya on the management of OA. Finally, no studies have been done on the assessment and approach to management of allergic ocular diseases in Kenya

4. STUDY OBJECTIVES

4.1 Broad Objectives:

1. To determine the clinical evaluation of ocular allergy by ophthalmologists in Kenya.
2. To describe the practices of ophthalmologists in Kenya regarding the clinical grading and approach to management of ocular allergy.

4.2 Specific Objectives:

1. To determine the criteria for diagnosis of ocular allergy used by ophthalmologists in Kenya.
2. To determine the clinical grading of ocular allergy by ophthalmologists in Kenya.
3. To determine the importance of severity grading and its impact on clinical decision making.
4. To describe the approach to treatment of ocular allergy and factors affecting the choice of treatment.
5. To determine the factors used to evaluate response to treatment.

5. METHODOLOGY

5.1 Study design

A descriptive (KAP) study was employed as it would adequately address the explorative nature of the objectives of this study.

5.2 Study area

This study was carried out in The Republic of Kenya.

5.3 Study population

All qualified ophthalmologists practising in Kenya covering public, private and faith based hospitals/clinics. This includes all ophthalmologists who have attained a Master of Medicine (MMed) degree in ophthalmology from a recognized institution.

5.4 Study period

The study period was six months from 1st December 2012- 31st May 2013.

5.5 Sampling size

Since there are no previous studies on prevalence (how often ophthalmologists' grade OA) of grading of ocular allergy in the region, the maximum sample size was determined using the prevalence assumption of 50% grading by ophthalmologists'.

Adopted from Fishers et al 2003 method;

Where $n = \frac{z^2 \times p(1-p)}{d^2}$

n = required sample size

z = confidence level at 95% (standard value of 1.96)

p = proposed percentage of grading by ophthalmologist (50%).

d = margin of error at 8% (standard value of 0.08)

$n = \frac{1.96^2 \times 0.5(1-0.5)}{0.08^2} = 150$

However, the number of registered and practising ophthalmologists in Kenya is 84 (N), therefore there was need to correct the sample size for finite population using the finite population correction factor using the sample size below.

$$n_0 = n \times \frac{N}{N+n}$$

$$= 150 \times \frac{84}{84+150}$$

$$= 53$$

Therefore a minimum of **53** ophthalmologists were interviewed.

5.6 Sampling method

All qualified ophthalmologists practising in Kenya during the study period were included.

5.7 Inclusion criteria

1. All qualified ophthalmologists practising in Kenya.
2. Ophthalmologists who gave informed consent to participate in the study.

5.8 Exclusion criteria

Ophthalmologists who were not co-operative and were not willing to provide information even after being provided with full details of the study and intended use of output, and after assurance of confidentiality and ethical approval were excluded from the study.

5.9 Tools

Data Collection Tools:

The data collection tools that were used in this study were both quantitative and qualitative in nature. The self-administered questionnaires (Appendix III) served as both a qualitative/quantitative tool. Moderated focus group discussions were used to complement data collected from the questionnaires especially in the attitude section and this was exclusively qualitative.

Materials:

- Digital Tape Recorder
- Stationery
- Telephone Services
- Mailing Services
- Flash disk

5.10 Ethical Considerations

Ethical approval was sought from the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee.

All the study participants received information sheets giving them necessary details on the research and an assurance that the information collected will be used solely for educational purposes and to improve health care services offered to the public.

Confidentiality was maintained throughout the study by avoiding use of ophthalmologists' names in the questionnaires and during the FGDs; they were allocated codes instead to ensure anonymity. The data was only available to the statistician and social scientist strictly for analysis and was not shared with any other people.

The results of this study will be shared with the relevant stake-holders including the University of Nairobi (UON), Kenyatta National Hospital (KNH), Kikuyu Eye Unit (KEU) and the Division of Ophthalmic Services in the Ministry of Public Health and Sanitation so as to improve service delivery.

5.11 Procedure

5.11.1 Quantitative Methods

Participants

An updated list of all practising ophthalmologists in Kenya, including their contacts, was collected from the Division of Ophthalmic Services, Ministry of Medical Services and Eastern Africa College of Ophthalmologists (EACO). The Division of Ophthalmic Services is charged with the co-ordination of eye care services in Kenya and has an updated register of the

ophthalmologists practising in the country. All identified ophthalmologists were recruited and information letters and self-administered questionnaires were sent to them.

Process

The self-administered questionnaires were generated on Google docs as an online survey. The survey was pre-tested on colleagues so as to find glitches and unexpected question interpretations and as a result find ways of improving it.

The actual survey was anonymous and each recipient filled in the questionnaire online and submitted it. All the questions were marked as a required field so that a participant would not be able to submit an incomplete questionnaire. This reduced the chances of receiving questionnaires with missing data unless the participant actively chose to ignore the question. Questionnaires collected from participants who could not fill in the online survey were cross-checked for any erroneous or missing data during collection. The data was then transferred to the Google docs file and stored in a password protected Google drive.

Quantitative Data Analysis

All analysis was undertaken using Stata version 11.0 (Stata Corporation, College Station, TX, USA). Proportions were calculated and where appropriate 95% binomial confidence intervals are reported. The confidence intervals were corrected using a finite population correction factor assuming a finite population of 84.

To assess the importance of symptoms and signs in the grading of ocular allergy severity, proportions were calculated for each level of importance for each symptom and sign. A cumulative score was then generated to assess the importance of each sign or symptom relative to the other. To generate the cumulative score, an ordinal scale of 1-5 depending on the level of importance was assigned (1=not important, 2=slightly important, 3=moderately important, 4=very important and 5=extremely important). The scores were summed up to generate a cumulative score. The magnitude of the cumulative score was assumed to be a reflection of the importance of the sign or symptom in the grading of the ocular allergy severity. Similar analysis was used to assess the importance of the following factors in treatment selection; severity of symptoms, tolerability, the patients' preference, time of action, cost and availability of drugs.

5.11.2 Qualitative methods

Participants

I conveniently and purposively sampled ophthalmologists who receive the greatest volume of eye patients in the country and these were located in three main sites-KNH, KEU and department of ophthalmology UON. The other informed assumption was that these participants because of their high exposure to eye patients had a higher likelihood of high frequency of ocular allergy patients and would therefore be able to speak from experience. This would fulfil the aim of a qualitative sample in it being informative. A request was sent to the heads of departments at the institutions requesting participation of department members in the discussions at suggested times and venues that were acceptable and convenient to the invited participants. A minimum of 6 participants was expected for each FGD as the recommended size of a group is of 6 – 10 people [28].

The invitation to the focus group discussion provided the background and objectives of the study and provided an opportunity to collect the demographic information on the participants (Appendix IV: FGD invitation/consent form). The invitations were sent via email and through hand delivery where applicable a week before the proposed date of the discussion and follow up phone calls made two days before the agreed on date to remind the participants.

Initially, I intended to conduct a focus group discussion with ophthalmologists in private practice during the monthly Ophthalmological Society of Eastern Africa (OSEA) meeting but due to logistical and time limiting factors this was not possible. I am however confident that this exclusion did not affect the credibility of the results of this study as the three prior discussions were conducted to point of saturation and most of the participants (14/15) in these focus group discussions were also in private practice during the study period.

Process

The proposal was reviewed with a social scientist and the feedback was used to refine a discussion guide for the proposed focus group discussion. Initially, a pilot survey was conducted to test the self-administered questionnaire on ophthalmology registrars at UON, after which the discussion guide was fine-tuned in consultation with the social scientist to match and compliment the questionnaire. Given the qualitative nature of the discussions there was concern

that the ophthalmologists might not understand or value the necessity of obtaining rich explanations of their experiences, and I therefore invited the social scientist to act as a moderator and note-taker during the discussions.

Participants provided an audio recorded verbal consent to the discussion after the study objectives were explained to them and issues of the voluntary nature of the study and confidentiality were assured to them. The participants were then assigned codes to avoid use of names during the discussion and to maintain anonymity. They were also reminded of their right to withdraw from the discussion at any time that they wished. Dialogue was encouraged to ensure that there was mutual understanding and adequate interaction with the research topic.

Once informed consent was given for tape recording the conversation, I moved the participants from general observations regarding their attitude and practice of OA diagnoses, into detailed perceived important signs and symptoms used in diagnosing OA, guidelines used and standard treatment of OA and concluded by providing two suggested OA grading systems and asking the participants their perceptions and suggestions about the grading. They were also asked about their perceptions about other ophthalmologists' attitude and practice to grading OA which provide invaluable "shadowed data" [29]. The discussion guide contained suggestions for the interviewer to probe beyond the formal question protocol and it was designed to allow the interviewer to accommodate the interviewee's style and responses (Appendix V).

Qualitative Data Analysis

All the audio taped discussions were transcribed into word 2007. The discussions were generally audible and where there was poor clarity, hand written notes taken during the discussions were used to address the discrepancies. These transcripts and qualitative information collected from the open-ended questions in the questionnaire were then imported into NVivo 10 software (QSR International Pty Ltd 1999 to 2012). In the first instance, these data were then independently coded into themes felt to emerge from the data (content analysis) by the social scientist after which we compared and discussed the results before arriving at an agreed set of themes for coding and final analysis using NVivo 10 software (QSR International Pty Ltd 1999 to 2012).

Unanticipated themes arising from the data were incorporated into a second round of coding with free nodes representing broad categories. Further nodes were then created by grouping some of

the free nodes into tree nodes by making logical connections and incorporating any emerging themes. Thus, while we attempted to allow themes to emerge from the data, my prior beliefs and understanding of the literature are likely to have influenced the final themes identified. The final stage was a layered analysis that entailed the identification of the main and then the underlying causes of reported experiences, practices and attitudes.

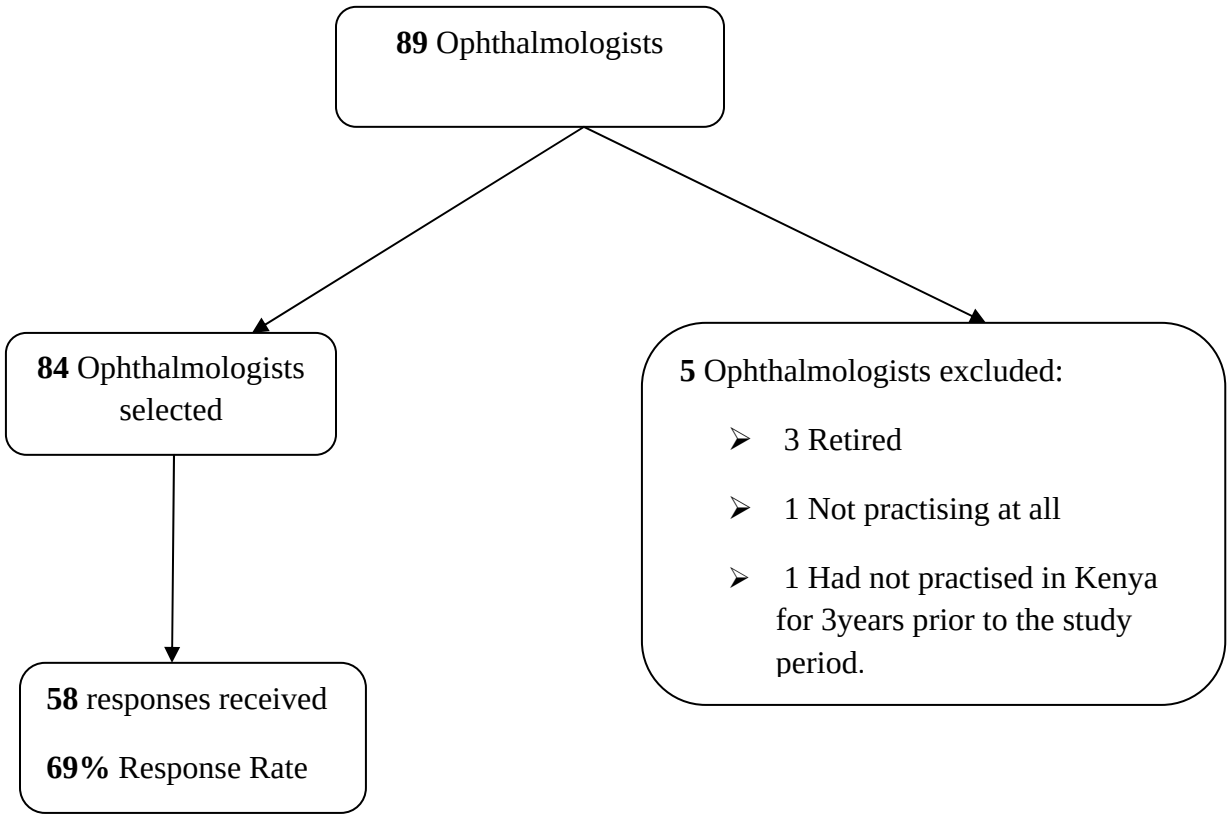
The relevant quotes from the open-ended questions in the questionnaire and the discussions are presented in the results section in italicized font.

6. RESULTS

Demographics

A total of 58 ophthalmologists were included in the study.

Figure 1: Flowchart for online survey participants



The median age was 39 (range: 32 - 66 years) and 41/58 were male, Table 1. The majority (65.5%) practised in government hospitals (26=government facility only, 11=government and private practice, 2=government and others, see Table 1). 24.1% of the ophthalmologists had practised for less than two years while only 5 had practised for more than 20 years.

Table 1: Characteristics of the study participants (n=58)

Characteristics	**n (%)**
Age group	**n=58**
30 – 34 years	12 (20.7)
35 – 39 years	18 (31.0)
40 – 49 years	18 (31.0)
50 years and above	9 (15.5)
Missing	1 (1.7)
Sex	**n=58**
Male	41 (70.7)
Female	17 (29.3)
Duration of practice	**n=58**
3 months – 2 years	14 (24.1)
3 – 5 years	10 (17.2)
6 – 10 years	15 (25.9)
11 – 20 years	13 (22.4)
Over 20 years	5 (8.6)
Missing	1 (1.7)
Place of practice	**n=58**
Government facility	26 (44.8)
Government and private practice	11 (18.9)
Private hospital	4 (6.9)
Faith-based hospital	9 (15.5)
Private practice	4 (6.9)
Multiple places[1]	4 (6.9)

[1] Other practised in multiple places: (government, private practice and faith-based hospital=1, government, private practice and private hospital=1, Private practice and faith-based=1, and private practice and private hospital=1)

Ocular allergy diagnosis

All respondents 58/58 (100%) reported that the diagnosis of OA is clinical, based on patients' symptoms/signs. 2 respondents (3.4%) suggested '*swabs and/or allergy testing for severe cases.'*

The table below shows some of the signs and symptoms listed by the ophthalmologists as being important for the diagnosis of OA.

Table 2: Important symptoms and signs for diagnosis of ocular allergies

Symptoms	**Signs**
Itchy eyes	*Papillae/cobblestones*
Foreign body sensation	*Limbal infiltrates/trantas dots*
Tearing	*Mucoid/stringy discharge*
Redness	*Hyperpigmentation of lids/conjunctiva*

Ocular allergy classification

The majority (86.2%, 95% confidence interval: 74.6 – 93.9%) of ophthalmologists reported classifying ocular allergies. Out of the ones who classified, most classified the allergies as mild, moderate or severe (MMS) only (n=10) or MMS and something else (n=8). Other forms of classification included atopic keratoconjuctivitis (AKC), seasonal allergic conjunctivitis (SAC), perennial allergic conjunctivitis (PAC), vernal keratoconjuctivitis (VKC), giant papillary conjunctivitis (GPC) and others.

Table 3: Classification and grading of ocular allergies (n=58)

	n (%)	**95% confidence interval**
Classified ocular allergies	**n=58**	
No	8 (13.8)	7.7 – 19.9
Yes	50 (86.2)	74.6 – 93.9
Graded ocular allergy severity	**n=58**	
No	10 (17.2)	10.6 – 23.9
Yes	48 (82.8)	76.1 – 89.4
Grading criteria	**n=58**	
Mild, moderate, severe	37 (63.8)	
Papillae size	2 (3.5)	
Mild, moderate, severe and Acute or chronic	1 (1.7)	
Papillae size and others	3 (5.2)	
Others[1]	5 (8.6)	
Do not grade	10 (17.2)	

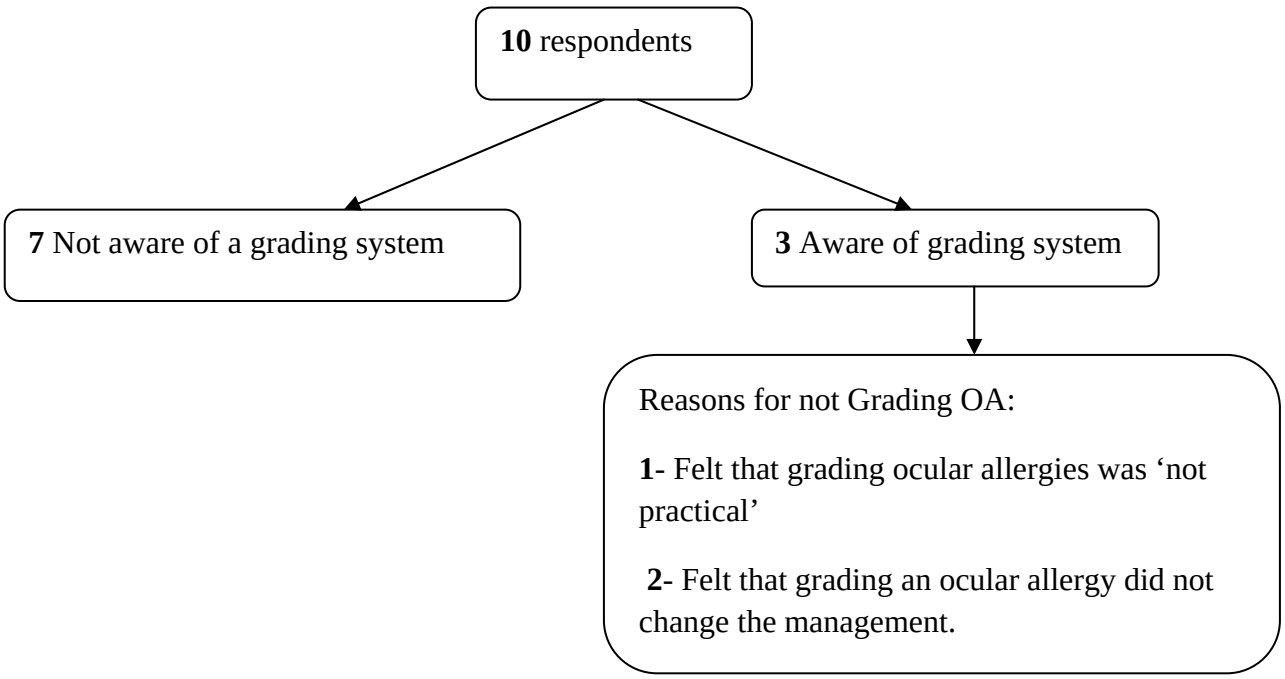
[1]Others included: appearance of conjunctiva and limbus, VKC, seasonal/perennial, vision threatening/non-vision threatening, conjunctival hyperaemia, follicular hypertrophy and depending on the frequency and intensity of reaction

Ocular allergy grading

Majority (82.8% (95% CI: 76.1 – 89.4%) of the ophthalmologists also reported grading ocular allergies, Table 3. Most (63.3%) graded the allergies depending on whether they were mild, moderate or severe, while the others graded them depending on the papillae size, whether acute or chronic, or depending on symptoms, Table 3.

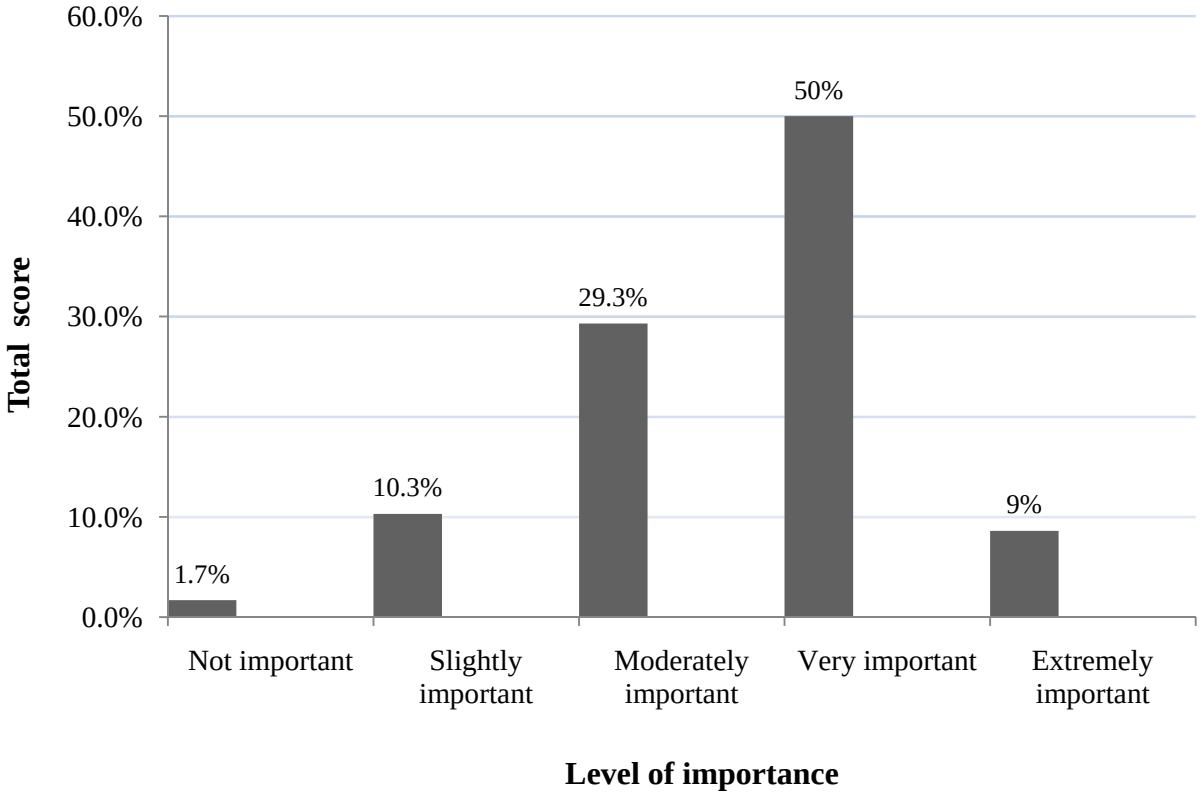
Out of the ones who did not grade OA, 7 of 10 were not aware of a grading system. For the other three who did not grade but were aware of a grading system, one felt that grading ocular allergies was *'not practical'* while the other two felt that grading an ocular allergy did not change the management, Figure 2.

Figure 2: Flowchart showing respondents not grading OA (n=10)



When they were asked if grading ocular allergies was important, 50% (29/58) of the ophthalmologists felt that grading was very important while one ophthalmologist felt that grading was not important, Figure 3.

Figure 3: Perceived importance of grading OA (n=58)



Important symptoms and signs for the grading ocular allergy severity

In terms of importance of symptoms in grading of ocular allergy, 36.2% (21/58) of the ophthalmologists felt that ocular itch was extremely important and over half thought that hyperaemia and foreign body sensation were extremely or very important, Table 4.

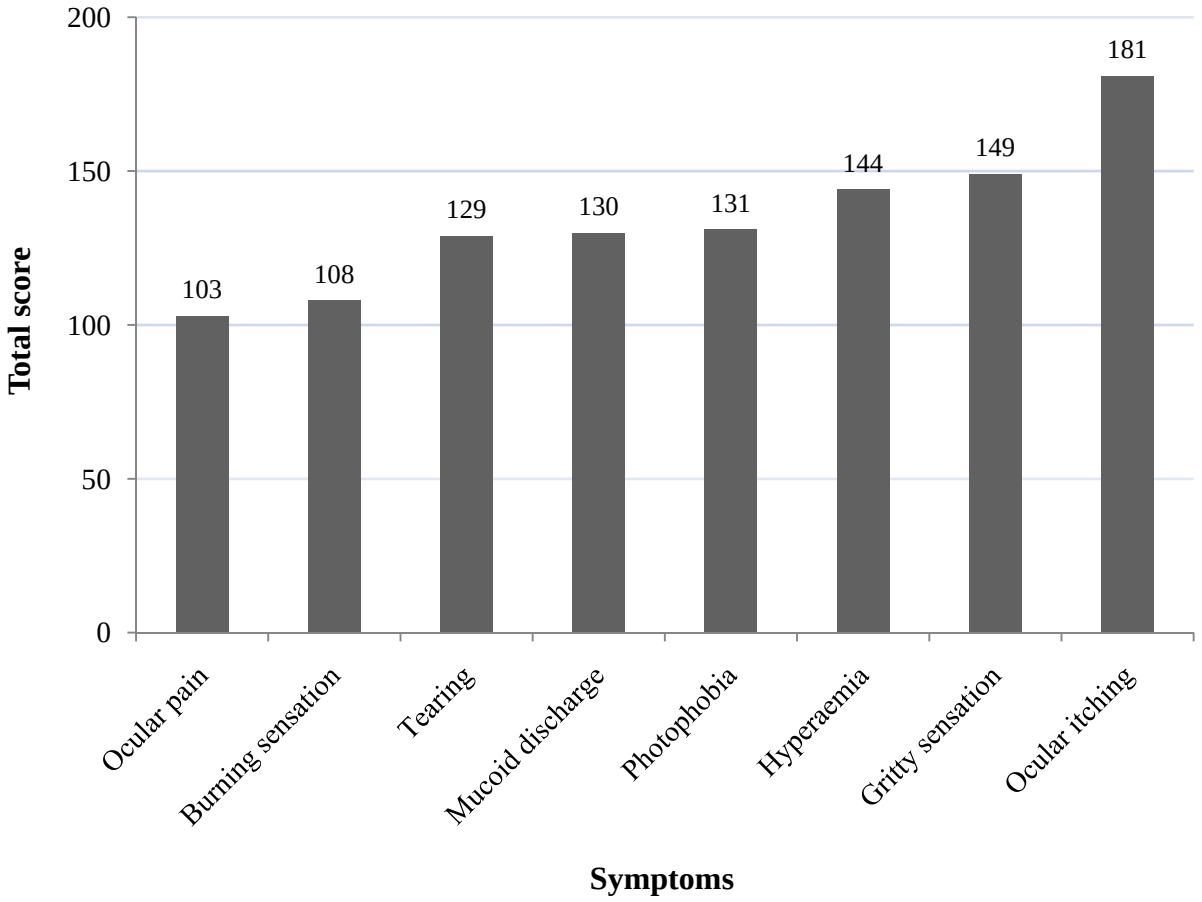
Table 4: Perceived importance of symptoms in OA diagnosis (n=58)

	Not important n (%)	**Slightly important n (%)**	**Moderately important n (%)**	**Very important n (%)**	**Extremely important n (%)**
Symptoms for grading ocular allergy					
Ocular itching	1 (1.7)	1 (1.7)	9 (15.2)	**26 (44.8)**	21 (36.2)
Hyperaemia	1 (1.7)	9 (15.2)	15 (25.9)	**27 (46.6)**	6 (10.3)
Tearing	4 (6.9)	7 (12.1)	**24 (41.4)**	18 (31.0)	5 (8.6)
Photophobia	2 (3.5)	8 (13.8)	**26 (44.8)**	17 (29.3)	5 (8.6)
Foreign body (Gritty) sensation	0	8 (13.8)	**20 (34.5)**	19 (32.8)	11 (19.0)
Ocular pain	6 (10.3)	**22 (37.9)**	16 (27.6)	7 (12.1)	7 (12.1)
Mucoid discharge	3 (5.2)	6 (10.3)	**26 (44.8)**	20 (34.5)	3 (5.2)
Burning sensation	3 (5.2)	15 (25.9)	**29 (50.0)**	9 (15.2)	2 (3.5)

Conversely, about half of the ophthalmologists (28/58) felt that ocular pain was not an important symptom or was slightly important in the grading of ocular allergy severity.

The following figure (Figure 4) represents the cumulative scores from the reported level of importance for each symptom listed in the table above (Table 4).

Figure 4: Perceived importance of symptoms in the grading of ocular allergy severity



Overall, ocular itch, foreign body sensation and hyperaemia had the highest cumulative score. (Figure 4)

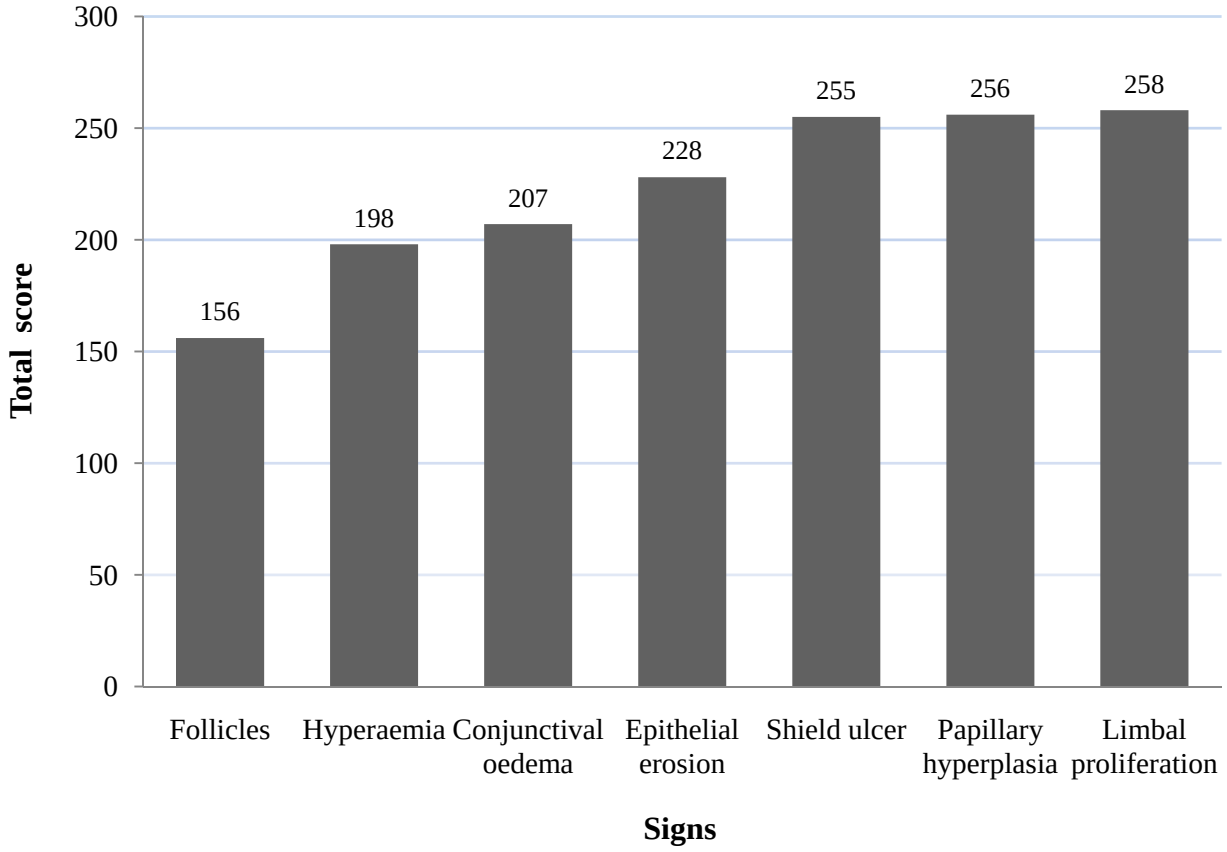
Table 5: Perceived importance of signs for grading severity of OA (n=58)

	Not important n (%)	**Slightly important n (%)**	**Moderately important n (%)**	**Very important n (%)**	**Extremely important n (%)**
Importance of signs for grading ocular allergy					
Hyperaemia	0	11 (19.0)	18 (31.0)	**23 (39.7)**	6 (10.3)
Limbal proliferation/ Horner-Trantas dot	0	0	4 (6.9)	24 (41.4)	**30 (51.7)**
Papillary hyperplasia	0	0	5 (8.6)	24 (41.4)	**29 (50.0)**
Conjunctival oedema	2 (3.5)	7 (12.1)	**18 (31.0)**	**18 (31.0)**	13 (22.4)
Follicles	13 (22.4)	12 (20.7)	**17 (29.3)**	12 (20.7)	4 (6.9)
Shield ulcer	1 (1.7)	2 (3.5)	3 (5.2)	19 (32.8)	**33 (56.9)**
Corneal Epithelial Erosions & SPKs	2 (3.5)	4 (6.9)	10 (17.2)	**22 (37.9)**	20 (34.5)

Majority of the ophthalmologists considered limbal proliferation or Horner-Trantas dot (30/58), papillary hyperplasia (29/58) and shield ulcer (33/58) as extremely important signs in the grading of ocular allergy severity, Table 5. However the presence of follicles was not regarded as an important sign in the diagnosis of ocular allergy.

Figure 5 below shows the cumulative totals of the perceived importance of signs shown in the above table (Table 5).

Figure 5: Perceived importance of signs in the grading ocular allergy severity



The presence of follicles was not regarded as an important sign in the grading of ocular allergy severity and had the least cumulative score compared to the other signs, Figure 5.

Treatment

Table 6 presents factors that are important in treatment selection.

Table 6: Factors of importance in treatment selection (n=58)

	Not important	**Slightly important**	**Moderately important**	**Very important**	**Extremely important**
Goals of treatment					
Severity of symptoms	0	0	5 (8.6)	25 (43.1)	**28 (48.3)**
Tolerability	0	3 (5.2)	9 (15.5)	**32 (55.2)**	14 (24.1)
Patient preference	1 (1.7)	18 (31.0)	**25 (43.1)**	13 (22.4)	1 (1.7)
Time of action	1 (1.7)	4 (6.9)	**19 (32.8)**	16 (27.6)	18 (31.0)
Cost of drugs	2 (3.5)	2 (3.5)	15 (25.9)	**24 (41.4)**	15 (25.9)
Availability of drugs	0	2 (3.5)	5 (8.6)	25 (43.1)	**26 (44.8)**

The majority, >70%, of ophthalmologists considered symptom severity, availability of drugs, and treatment tolerability as extremely important and very important factors in the selection of treatment offered to the patient.

The figure below represents cumulative scores from the reported level of importance for each factor listed in table 6 above.

Figure 6: Important factors in the selection of treatment offered

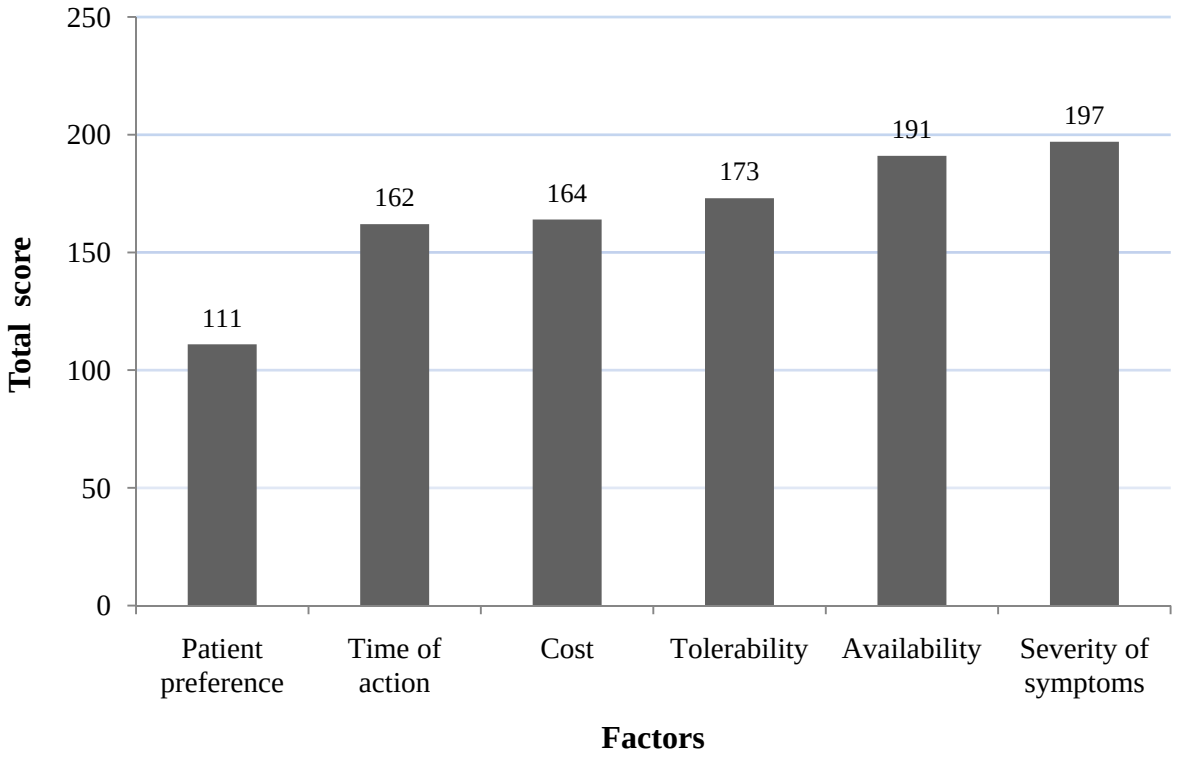


Table 7: Mode of treatment and category used (n=58)

Treatment options	1st line n (%)	2nd line n (%)	3rd line n (%)	Not used n (%)
Artificial tears	**28 (48.3)**	10 (17.2)	12 (26.7)	8 (13.8)
Mast cell stabilizers	**33 (56.9)**	21 (36.2)	3 (5.2)	1 (1.7)
Topical antihistamines	**36 (62.1)**	11 (19.0)	4 (6.9)	7 (12.1)
Multiple action drugs (antihistamine + mast cell stabilizer)	24 (41.4)	**25 (43.1)**	4 (6.9)	5 (8.6)
Topical steroids	**25 (43.1)**	23 (39.7)	10 (17.2)	0
Topical vasoconstrictors	9 (15.2)	4 (6.9)	5 (8.6)	**40 (69.0)**
Topical NSAIDs	11 (19.0)	9 (15.5)	11 (19.0)	**27 (46.6)**
Immunomodulators/Systemic steroids	1 (1.7)	3 (3.5)	**44 (75.9)**	11 (19.0)
Oral antihistamines	10 (17.2)	**23 (39.7)**	21 (36.2)	4 (6.9)
Periocular steroids	0	4 (6.9)	**42 (72.4)**	12 (20.7)

In terms of treatment category, over half of the ophthalmologists considered topical antihistamines and mast cell stabilizers (62.1% and 56.9% respectively) as first line treatment, Table 7. In contrast, majority (69.0%) of the ophthalmologists did not use topical vasoconstrictors for the treatment of ocular allergies.

Evaluating response to treatment

All the respondents, 58/58 (100%) reported assessing response to treatment based on clinical assessment.

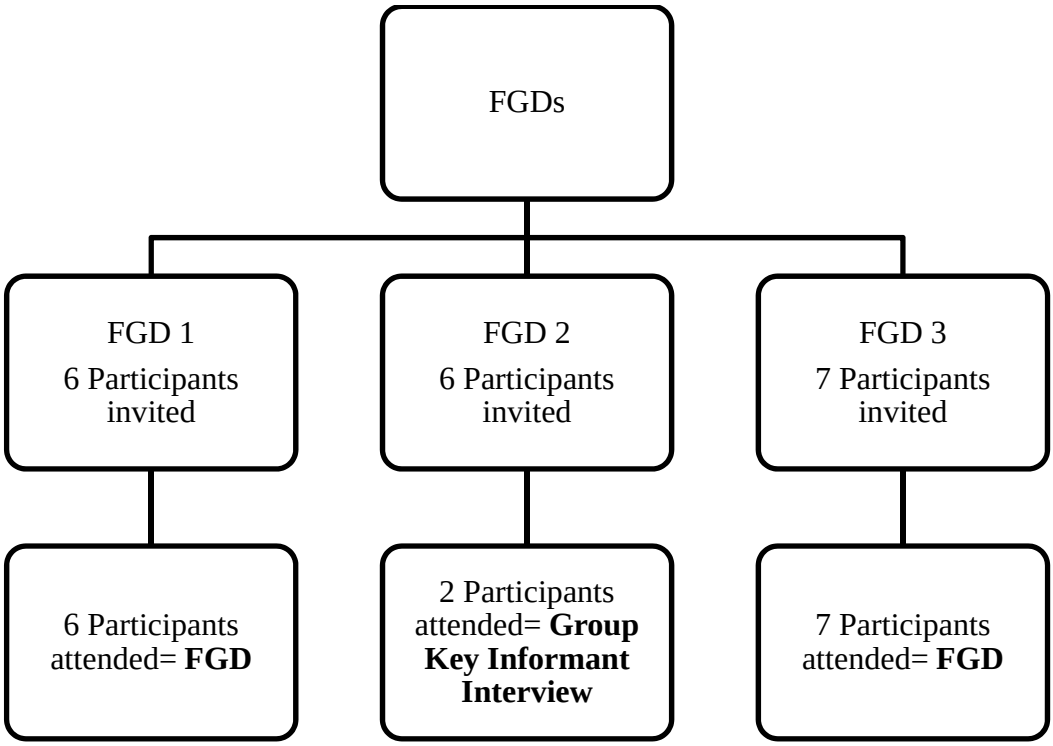
'Improvement in symptoms and signs (Regression)'

'…report from the patient that he or she feels better clinical improvement i.e. less redness, less papillae etc'

Focus group discussions and Key Informant interview results

The focus group discussions were held in the month of January 2013 at the University of Nairobi (6 participants) and the Kikuyu Eye Unit (7 participants), Figure 7. The Kenyatta National hospital FGD was planned but as it took place with only 2 participants it was then considered as a group key informant interview. A total of 14 participants who were part of the FGDs and key informant interviews also practice in the private sector, representing many views of the ophthalmologists in that area.

Figure 7: FGD participants' flowchart



The discussions/interviews sought to explore the ophthalmologists' views on the clinical evaluation and management of patients with ocular allergy. The key areas that arose from the discussions are summarized below.

Grading of Severity

This area of discussion was broad and it included a description of the grading systems used by the participants. The respondents generally agreed that grading of ocular allergy is important. A view shared by the majority was that it determines the kind of treatment you would need to give a patient and how frequent and intense the follow up would need to be.

Though majority felt that it was beneficial, one respondent felt that grading of OA is of benefit to the practitioner because *'the morbidity of the condition and the way it affects the patients, to them [the patient what is important is relief of the symptoms. So no matter how you grade it, to them [the patient] its relief and alleviating any complications that may come from it.'*

The most common response on how the participants grade OA, was grading based on the patients' symptoms and clinical findings into mild, moderate and severe according to the level of severity.

'In terms of severity I put it as mild, moderate and severe depending on how they present, in terms of how they d*eem it affects their activities of daily living…'*

Minority of the participants felt that it is important to distinguish between the blinding and non-blinding allergies due to presence of limbal stem cell deficiency in the blinding cases and the difference in counseling and follow up of the patients. They also felt that blinding allergies may not be that symptomatic until they reach a severe stage.

'*VKC and AKC are blinding, PAC and SAC are irritating but visual acuity is not affected. The patient with Seasonal has no need to recall for an appointment, but with the blinding cases, appointments should be scheduled*.'

A differing opinion was from a participant who pointed out that in spite of categorizing it as such, there is still need to grade the severity of the disease into mild, moderate and severe '*because at the end of the day I find that is the one that will determine my kind of treatment, it might be non-blinding but it is severe. I will still do mild moderate and severe and I will still decide if it is vernal or not vernal*.'

Effect of grading on clinical decision making

The grading of OA was viewed by the respondents as a means to impact on the clinical decision making because it influences the type of medication prescribed to the patient, the dosage, follow-up and counseling.

'…it influences what medication you give the patients and how often you give them, how soon you see them back and how often you see them thereafter…'

Despite this, it was clear from the respondents that there is no standardized grading system used and the participants felt that it would be good to come up with one as it will help in giving an objective assessment of the patients' condition. This is especially for better documentation and assessment of treatment response during patient follow-up.

'*What I can say is that if you are in a setting where you are not the only one seeing the patient, it's good to write the details on how you arrived at a particular grade so that if a different doctor sees the patient they are able to follow up from that and know if the patient is getting better or worse but if it's a patient that you are seeing most of the time, fine, it's good to record it so that you know where you are*.'

Patient Follow up

'…you need to educate the patient about their illness, and they need to know how serious it is so that they can take their follow up seriously because that very often is the problem.'

Most of the respondents linked the follow up of patients to the severity of the patients' signs and symptoms. Few of the participants based their follow up on whether the patient has a blinding or non-blinding condition.

'*For mild, I don't follow up, I just say PRN when you come back. For moderate, because of recurrence, I tell them I will not give them a date but once they finish the medication and you feel quiet, just stay on if it's not disturbing you. But for severe cases I see them two-weekly because I have put them on steroids or a month later depending on the severity. Moderate is PRN and they should come as soon as they develop symptoms*.'

For minority of the participants, follow up would be determined by the patients' response to the medication. This would be dependent on '*…whether they are improving or not because…if they are improving you take longer to follow them up. But if they are not improving you see them often so that you are changing the medication they are using and intervening so that you don't get to complications.'*

Surgical Intervention

Regarding the surgical intervention, all participants in the discussions suggested its use in complications of OA and conditions associated with OA. During the discussions, the following were the procedures mentioned: subtarsal steroid injections for refractory cases with severe allergies e.g. those with cobble stone papillae; debridement and superficial keratectomy for patients with shield ulcers and chronic keratitis arising from the allergy; surgical removal of giant papillae and keratoplasty for end-stage keratoconus.

Tables highlighting symptoms/signs, treatment and follow-up options suggested per grade

Table 8: Mild ocular allergy

Symptoms and signs	Treatment options	Follow-up Options
Mild papillae, first timers, most of them with tearing itching, photophobia, gritty sensation. *Complaining of foreign body sensation and itching with a bit of tearing and redness but nothing major* *If they say 'occasionally I itch' or sometimes they feel like they have something in their eye, they rub their eyes that one I will put it as a mild form* *some papillae, a bit of conjunctival hyperpigmentation papillae that are minute* *few papillae, no corneal or limbal disease*	*mild anti-histamine and mild steroid* *mast cell stabilizers or artificial tears* *oculast/one of the mast cell stabilizers or just tell them to wash their eyes with cold water (cold water technique)* *short term anti-histamines + non-steroidal + a topical lubricant* *mast cell stabilizers only, if they complain of foreign body sensation... artificial tears* *very mild steroid like fluoromethalone or a combination of a mast cell stabilizer + an anti-histamine like Relastat or Patanol*	*PRN* *I don't follow up, I just say PRN when you come back.*

Table 9: Moderate ocular allergy

Symptoms and Signs	Treatment Options	Follow-up Options
Moderate will have long, recurrent histories, and from far with conjunctival discoloration. The papillae are small; there is no corneal disease and probably just small melanosis of the conjunctiva. *Cobblestones in the moderate and a little bit of limbal disease and SPK* *A little bit of cobblestones but I will also be looking at whether they have limbal disease or not and they rarely have any corneal involvement.* *large papillae*	*mast cell stabilizer, a steroid* *Short course of steroid drops for a week or two and mast cell stabilizers.* *Course of steroids and long term mast cell stabilizers or other anti-inflammatories non-steroidals but for longer periods a monthly treatment of non-steroidal* *Oral anti-histamines because of a lot of itching at night especially sub-consciously.* *Steroid ointment because it seems to clear the papillae faster and during the night, if you put a drop its out in the next two minutes so put the ointment at night.*	*Because of recurrence, I tell them I will not give them a date but once they finish the medication and you feel quiet, just stay on if it's not disturbing you, PRN* *More regular*

Table 10: Severe ocular allergy

Symptoms and signs	Treatment options	Follow-up Options
Long, recurrent histories, large papillae, corneal complications of whatever type and SPKs (Superficial punctuate keratopathy), pannus, limbal scarring, trantas dots, large cobbling, corneal ulcers, SPK and bad limbal disease with tear film problems and vision will be affected *giant papillae, limbal involvement and have corneal problems sometimes they will have shield ulcers, a lot of SPKs and sometimes the vision is affected* *always photophobic, scratching their eyes, tearing and eyes most of the time are red* *cobblestones, SPKS or corneal ulcers, corneal infiltration and limbal hypertrophy which is almost blinding them.* *Visually endangering disease such as shields ulcers, keratoconus, pseudogerontoxon or scars encroaching on optical axis corneal complications huge cobblestones*	*mast cell stabilizer, a steroid, artificial tears, +/_ oral steroids* *Generous with the steroids and sometimes I will give injectables if I feel the vision is threatened especially the ones with shield ulcers that have are not healing, I might even take them to theatre for scraping.* *Course of steroids and long term mast cell stabilizers or other anti-inflammatories steroidal for two weeks and then 1 month for non-steroidal or anti-histamines* *Combination of a mast cell stabilizer and an anti-histamine, artificial tears and some form of steroid, preferably in the ointment form as it will last longer.* *Stronger steroid like predforte in addition to a mast cell stabilizer, preservative free like, allergocomod, treat them for a longer time* *If they have papillae and any other complications like shield ulcers then I would opt to inject them with sub-tarsal long acting steroids like triamcinolone and depo-medrol.* *Oral anti-histamines because of a lot of itching at night especially sub-consciously.* *Steroid ointment because it seems to clear the papillae faster and during the night, if you put a drop its out in the next two minutes so put the ointment at night.* *Sometimes though rarely I might advise for subtarsal injections of steroids, for those who are very refractory*	*increase the frequency of the visits, after the first time I see them I will then see them again in maybe 2-3 weeks then after that if they are doing well I see them in a month then after depending on how they are doing I see them in 2-3 months.* *every month initially to see how they are doing and if they stabilize then every 2-3 months but initially at least every month.* *two-weekly because I have put them on steroids or a month later depending on the severity* *more regular* *more frequently*

Counselling

'Counselling is more important than giving the drugs.'

There was a strong feeling amongst all of the groups that counselling forms a major part of the management of a patient with OA as represented by the statement below.

'I think it's extremely important because in my experience that is what they have been lacking; that this treatment is long term, it may be intermittent but it's a long term treatment, it's not a one off…counselling them about the causative factors because most of the time this disease is environmental…The other thing is that patients go hoping from one clinical centre to the other and just going round in circles, so when you counsel them they have faith in you and stick to one person and they are more compliant to the treatment prescribed.'

The general feeling was that the counselling given is inadequate, possibly because of the busy set-ups, therefore not giving the patient a chance to internalize what is being said. *'…patients need more time to hear more and ask more questions which I think most of us are unfortunately not able to give.'* A suggestion given to counter this was the establishment of health talks which would give the patients more time to get the necessary information and ask questions.

The participants' further pointed out that counselling was especially important for mothers/caregivers taking care of their children so that they may be more observant so as to notice symptoms. *'Sometimes the child just itches and that is all the mother sees, the mother doesn't know about vision and things like that, so it [counselling] is a major part of management.'* Another participant also mentioned a sad experience he had with three children going blind in high school due to VKC and he uses this as an example to emphasize to patients on the importance of follow up especially in the blinding conditions.

During the discussions the following were mentioned as important points during counselling:

1. Tell the patient what ocular allergy is.
2. Patients with blinding disease should be aware that it is blinding and the importance of proper follow up. (Honouring their appointments)
3. Make the patient aware of recurrences and to expect them.
4. Supportive management:

- Advice on hand washing after playing outside.
- Cold compress/cold water technique:
    - Avoid rubbing the eyes, just press with a cold compress.
    - Apply Plain cold water.

5. Advise the patient not to have things like carpets, pets, dusting under the bed, on the curtain boxes.
6. Leave rooms open to air and dry for good aeration to avoid mould. Counsel Matrons in boarding schools on the same.

It was also felt that patient education on their condition is wanting unlike in other general diseases such as asthma. The reason given was because '*when you see the patients who have other general body allergies…you find that the paediatrician or whoever is seeing them for the general things has explained to them and they understand about the disease and the management; when they should have the inhalers and all that but you find that the education on how to manage the [ocular] allergy lacks in patients.*'

Majority of the participants mentioned that counselling is also important so as to avoid patients moving from one doctor to another hoping to be cured when what they are experiencing are recurrences which they had not been counselled on.

'*So if you do not take that extra time to counsel the patient, they will keep running around and at the end of the day they will end up at the pharmacy with self- medication and we all know the famous Probeta-N (Neomycin:0.5%w/v, Betamethasone:0.1%w/v).*'

Standard management guidelines and challenges in developing guidelines

'…having protocols for different allergies, for management of different severity is important because one, allergies are very prevalent and they are being managed almost by everybody, at all levels of health care.'

Most participants felt it was worth investing time in coming up with treatment protocols but it would be pertinent to take into account that the private set-up is very different from the public set-up in terms of the resources available.

'Unlike the private where they can afford or are under insurance the topical anti-histamine would not be an issue for them, so it's good, academically and theoretically to have a protocol but we have to look at

the different institutions in the different set ups in terms of accessibility, affordability and availability of these medications… are these medicines going to be available in the government set ups because this is where most of the patients are being seen.'

Majority of the participants were of the opinion that coming up with standard guidelines would be challenging for various reasons, that it may be very subjective and that there is also the need to change the perception that allergic conjunctivitis is not a major disease. This is because at times a patient may have a *'severe form of allergy and people are told that it's "just an allergy" so they think it will come and go… I think that such issues should be addressed and raise awareness because most of those patients will not be seen by us they will be seen by the junior cadres especially the clinical officers. And I wonder if they have that knowledge especially of the classification and the treatment options and availability of medication.'*

Coming up with standard guidelines for the management of OA will help in creating awareness on how to treat the different grades of severity of OA. *'… But without a protocol people might forget what to do, always referring small things to the eye clinic for treatment; minor allergies and there are even safe medicines which can even be used by the nurses at the community level.'*

It was also agreed by most of the participants that with the introduction of standard guidelines and with practitioners prescribing medication according to the guidelines, the government will buy the medication so as to meet the generated need. *'… if you don't have a protocol, they [medication] will not be bought because it is from the guidelines of the ministry of health, that they make the essential drugs list, so it will not be an essential drug until we prove that it can be used. The only way to create demand for that is to teach the people who treat that and to remind them, to give them guidelines and protocols which they can refer and treat.'*

One of the institutions, KEU, was in the process of coming up with a treatment guideline especially to promote rational use of steroids.

Suggested grading system: Preferences and suggestions for improvement

Two grading systems were presented to the participants for discussion on preferences and suggestions for improvement. Grading system 1 incorporated both symptoms and signs, with the frequency/severity of symptoms being graded on a Likert scale. The clinician would then total up the findings and the score of the more severe eye would indicate the level of severity. Grading

system 2 took into consideration the signs which are picked by the clinician. All the signs are assessed and the grade is determined by the most severe sign present in the more severe eye.

It appeared that the participants present for the discussions preferred grading system 2 with the recurring reason being that '*the simpler the grading system the easier it is to be used by people who see patients in a crowded clinic*.' It was suggested that the two grading systems would also be beneficial in that grading system 1 can be used as the simplified grading system used in the field and grading system 2 can be used as the expanded grading system for research and educational purposes.

'I would go for the 2nd one too because sometimes you may want to break something into very small details like system 1 but it doesn't change your management so for me to waste time on it, I need to get the benefit that the patient also needs to get the benefit. So, if you want somebody to use something, make it simple and to the point.'

Discussions identified the following suggestions for improvement: simplifying the grading system by reducing the categories to mild, moderate and severe, re-organising the areas to be assessed to follow the usual examination pattern, mild cases should not have any corneal changes, and use of a pictorial flow chart including the drug options and follow up for each level of severity.

Few participants suggested a separate grading system that will highlight AKC and VKC ('*to avoid mixing oranges and apples')* this is because they were of the opinion that they should not be grouped together with allergic conjunctivitis.

Few participants felt that there should be a separate grading system that will highlight AKC and VKC. They were of the opinion that they should not be grouped together with allergic conjunctivitis because the.'… *it's like mixing oranges and apples, and then trying to sort them out, you can't, you can only discuss oranges and then apples so I see that you will get into a lot of problems if you try to bring VKC into this category. Probably you need to leave VKC out of this, the management is quite different, and its level of severity is different, considering that is the blinding part, so I would think about VKC hard before putting it in OA.*'

Grey area in ocular allergy: Keratoconus

This was an emerging theme from the discussion, it was an area that was explored explicitly but

During the discussions a debate emerged among the ophthalmologists, on whether keratoconus is a *'different condition all together'*, if it is an association or if it is a complication of ocular allergy.

Majority of the participants agreed that if keratoconus is present, the patient should be placed in the severe category. *'If you think it's going to affect the way you manage a patient, you just need to be more careful with it and you can get with it putting here. Because you need to pick up those allergic patients with keratoconus and treat them more carefully, so you put them in the severe category.'*

7. DISCUSSION

The purpose of this study was to determine the clinical evaluation of ocular allergy by ophthalmologists in Kenya and to describe the practices of ophthalmologists with regard to the clinical grading and approach to management of ocular allergy. This will then influence the preparation of a clinical grading system and treatment guidelines for the management of OA. The end result will be an improvement of services offered to patients with OA. In this study, both self-administered questionnaires and focus group discussions were used for data collection. The reason for using both of these tools was so as to get more in-depth information from a smaller group of people in focus groups. This helped in understanding the context behind the answers given in the written survey; explore topics in more detail.

Ocular allergy is a condition encountered almost daily in the outpatient clinic and its diagnosis is based on clinical findings as shown in the online survey responses with all the respondents reporting that the diagnosis of OA is clinical, based on patients' symptoms/signs. This in keeping with the findings by Wade *et al.* in Gambia[10], and by Santos *et al*. at the ocular Latin American consensus[1]. 2 respondents (3.4%) suggested the use of swabs and/or allergy testing for severe/refractory cases.

Ocular allergy may be classified into various sub-groups, and as mentioned by Uchio *et al.* there are numerous classifications for OA according to the underlying pathophysiology and clinical findings [13]. There was a lot of overlap between the classification of OA and its grading according to levels of severity. The majority (86.2%) of ophthalmologists reported classifying OA with majority classifying it into Mild, moderate and severe and/or OA according to the syndromes (AKC, VKC, GPA, SAC, PAC).This may explain the similarity in the percentages of the ophthalmologists classifying and those grading ocular allergy. Grading the severity of OA presents various challenges because of the diverse signs and symptoms. 50% (29/58) of the ophthalmologists felt that grading was very important and 29% felt that it was moderately important. At the ocular allergy Latin American consensus, majority of the panellists agreed on the significance of establishing a staging of ocular allergic diseases based on

levels of severity[1]. In our setup, 63.3% of the participants of the online survey and majority of the ophthalmologists in the face to face discussions stated that they grade the signs/symptoms of OA patients according to the levels of severity. It was further stressed at the discussions on the importance of classifying patients into blinding and non-blinding conditions mainly due to the limbal stem cell deficiency and the difference in counselling offered between the two categories. Majority of the ophthalmologists agreed that grading of OA severity impacts on the clinical decision making. This is because it determines the choice of treatment; timing and frequency of follow up, better documentation and assessment of treatment response during patient follow up. Uchio *et al.* and Santos *et al.* further stressed that such staging would allow the establishment of algorithms of treatment, as well as objective assessment in clinical trials for analysis of treatment efficacy[1, 13].

Two clinical grading systems (Appendix V) were designed with reference to suggested grading systems by Santos *et al.* [1], Cuvillo *et al* .[2] and Uchio *et al* .[13]. All the clinicians present for the discussions preferred grading system 2 with the main reason being that it is simpler to use especially in busy clinics. This grading system takes into consideration the signs of OA picked by the clinician with the most severe sign present in the more severe eye determining the grade. It was suggested that the two grading systems would also be beneficial in that grading system 2 can be used as the simplified grading system used in the field and grading system 1 which incorporated both symptoms and signs, with the frequency/severity of symptoms being graded on a likert scale can be used as the expanded grading system for research and educational purposes. Uchio *et al.* stated that a grading system with a small number of categories is easy to use; however, a large number of categories are necessary to recognize variations over time with changes in season and patient responsiveness to medication [13].

The goals of therapy should include not only the control of signs and symptoms, but also improvement of the ocular health of patients with allergies [1, 21-22]. The majority, >70%, of ophthalmologists considered symptom severity, availability of drugs, and treatment tolerability as extremely important factors in the selection of treatment. This was further emphasized in the discussions where the grade of severity and availability of drugs were

seen as the key factors influencing treatment selection. Tuft *et al.* found that the management of VKC in tropical countries is controversial and is often determined by availability of medications, safety, and cost[12].

Non-pharmacological treatment including allergen avoidance, cold compresses, and artificial tears were mentioned as being important for providing short-term relief for allergy symptoms. This is by advising patients to control their environment where possible and to avoid activities that have been noted to make their symptoms worse. Use of cold compresses to reduce vasodilatation and provide temporary symptomatic relief was also mentioned as being important. The non-specific measures were similar to those mentioned in other studies [1, 3, 6].

The use of tear supplements in all grades of severity to provide ocular lubrication and also for dilution of allergens was mentioned by the majority. This was similar to the majority of panellists in the ocular allergy Latin American consensus who answered that they always use topical lubricants (preferably preservative free) for treating OA indefinitely [1]. In terms of treatment category, over half of the ophthalmologists considered topical antihistamines and mast cell stabilizers (62.1% and 56.9% respectively) as first line treatment. Mast cell stabilizers require a loading period of up to 2 weeks in order to achieve maximal efficacy, therefore participants in the discussions stressed on the importance of making patients aware of this and giving the patient topical antihistamines which provide faster relief but do not have a long duration of action. Another option raised was the use of mild topical steroids such as fluoromethalone during the two week period. 49/58 respondents considered multiple action drugs as first or second line medication (41.4% and 43.1% respectively). A review by Cuvillo *et al.* implied that topical antihistamines – preferably those with established dual action – are very effective in treating allergic conjunctivitis, and outperform other groups of drugs such as mast cell stabilizers or topical NSAIDs [2].

In contrast, majority (69.0%) of the ophthalmologists did not use topical vasoconstrictors for the treatment of ocular allergies this may be because they are effective at reducing redness, but they have no direct effect on the allergic response itself. Santos *et al.* found

that majority of panellists (80%) did not report topical vasoconstrictors for the treatment of ocular allergic patients [1]. The rational use of topical steroids was also recommended with the majority agreeing that mild topical steroids should be used in acute crises for short periods of time-less than 2 weeks, this was similar to the findings by Santos *et al.* where panellists indicated the rational use of topical corticosteroids for treating some chronic cases and acute crises, considering a short time course of treatment and its ocular side effects[1]. At the discussions, the use of steroid ointments' was also recommended because it was thought to clear the papillae faster. Topical ocular steroids are effective (probably the most effective of all options), but pose the important risk of frequent side effects (glaucoma, cataracts, corneal ulcers) [2].

Oral antihistamines (preferentially second generation drugs) can also play an important role, since they are of established efficacy and offer adequate treatment of the nasal symptoms that tend to accompany the ocular manifestations of allergic rhinoconjunctivitis. It was selected for use as a 2nd line measure by 39.7% of the respondents. Participants at the discussions recommended its use by patients with moderate and severe OA to relieve intense itching especially at night subconsciously and also for patients with rhinoconjunctivitis. Although the topical treatment of allergic conjunctivitis has been shown to improve the nasal symptoms of allergic rhinoconjunctivitis, systemic antihistamines are more potent in securing relief from symptoms of this kind but may also cause dry eye [2].

Majority of the participants of the online survey indicated the use of topical immunomodulators/systemic steroids (75.9%) and periocular steroids (72.4%) only for severe cases though during the discussions, the use of topical immunomodulators and systemic corticosteroids was not mentioned. Use of periocular steroids was indicated where topical medication does not control symptoms or disease progression (refractory cases). Regarding surgical intervention, participants in the discussions suggested it to manage complications of OA and conditions associated with OA. The panellists in the ocular allergy Latin American consensus contraindicated use of surgery for any case of ocular allergy. However they suggested considering such treatment in extremely severe cases for treating corneal complications, such as persistent and unresponsive to

conventional treatment keratitis and very recurrent shield ulcer [1]. The assessment of patient response to treatment was reported to be based on clinical assessment i.e. improvement in symptoms and signs (regression) and this was assessed during the follow-up sessions.

The frequency of patient follow up was linked to the severity of the patients' signs and symptoms, whether the patient has a blinding or non-blinding condition and/or the patients' response to the medication prescribed. This was similar to the AAO Preferred practice guidelines which suggest that the frequency of follow-up visits is based on the severity of disease presentation, aetiology and treatment [25]. It was further stressed on the need for making patients with blinding OA (especially VKC) aware of the need to honour appointments. Despite agreeing on the importance of following up patients, the frequency of follow up suggested was unclear, with terms such as "more frequently" and "more often" used to denote follow-up of moderate and severe cases. There was a general agreement on the follow up of mild cases as being *pro re nata* (PRN). Involvement of Low vision and outreach programmes were also suggested as a way of following up patients, especially those who were lost to follow-up and also as a way to reach potential allergy patients.

Counselling of patients with OA helps to provide effective management. This was stressed during the discussions as being more important than giving drugs as it would improve patient compliance to the use of medication and follow up. Patients often use trial-and-error techniques and settle for partial resolution of symptoms; they may also see a financial incentive to self-medicating so as to reduce the clinic visits. Counselling would also reduce the cases of self-medication especially in the abuse of steroids leading to corneal thinning and other complications. Compliance with medication improves if patients are well informed [27]. Establishment of health talks was also suggested as a forum for patients to ask questions which they might not get a chance to ask the clinician especially in busy set-ups. Distribution of take-home leaflets with basic information on what ocular allergy is and non-specific measures for relief of symptoms to be issued to patients with OA during clinic visits was recommended. This would increase disease state awareness and may also make significant impressions on patients.

Despite the high prevalence of OA there are no globally accepted guidelines to treatment [1,2] . The ophthalmologists followed their knowledge base, training, and preconceived ideas on the treatment rationale for each patient with OA. They did not follow any standard treatment guidelines (STGs) though the establishment of STGs was seen to be important and worth investing time in. The guidelines would orientate the clinicians because there are numerous treatment options available for the treatment of OA and it would list the preferred pharmacological and non-pharmacological treatment options [28]. The participants also agreed that the guidelines would lead to provision of optimal care to the patients and to promoting therapeutic effective and economically efficient prescribing. A vacuum would also be created when the practitioners are aware of what to prescribe and therefore demonstrate a need for which the government would have to fill by supplying the medication. This is because the pharmaceutical supply in government hospitals is based on an essential drugs list which would be derived from a standard treatment guideline.

The discussants also emphasized on the need to consider the prevailing medicine cost and affordability of the medication when coming up with guidelines because most patients are seen in the government institutions where some of the medication may not be available. Another benefit is that provision of standard treatment guidelines would also reduce the need for referral, as patients with OA are seen by almost everyone at all levels of healthcare and with STGs treatment of mild allergies will be clear therefore reducing the need for referral to the eye clinic, because even nurses at the community level will know how to manage it. The establishment of the STGs was thought to be challenging and this was similar to findings by Santos et al who stated that the task of creating guidelines for OA showed to very complex due to the need for a larger consensus including experts from different groups around the world on controversial topics especially an internationally acceptable classification and staging and a more rationale algorithm of treatment for this challenger group of diseases [1].

8. CONCLUSION

1. Ocular allergy is a condition seen daily in the ophthalmology outpatient clinics and its diagnosis is based on clinical findings.
2. Despite the high number of ophthalmologists grading OA (82.6%), there is no standardised clinical grading system followed. There is need to adopt one so as to allow for objective assessment and better documentation of the patients' clinical grade.
3. 50% of the ophthalmologists felt that grading of OA is very important and greatly impacts clinical decision making as it determines the choice of treatment, timing and frequency of follow up, allows for better documentation and assessment of treatment response during patient follow up.
4. The development of STGs would be beneficial to harmonise the diagnosis, grading and treatment of OA and doing so would promote effective therapeutic and economically efficient prescribing. The key factors affecting treatment selection include the severity of symptoms/signs and availability of drugs.
5. The importance of counselling as the basis for management of patients with ocular allergies should be emphasized so as to improve compliance to treatment and follow up appointments.
6. The assessment of response to treatment is based on clinical assessment and feedback from the patient.

9. RECOMMENDATIONS

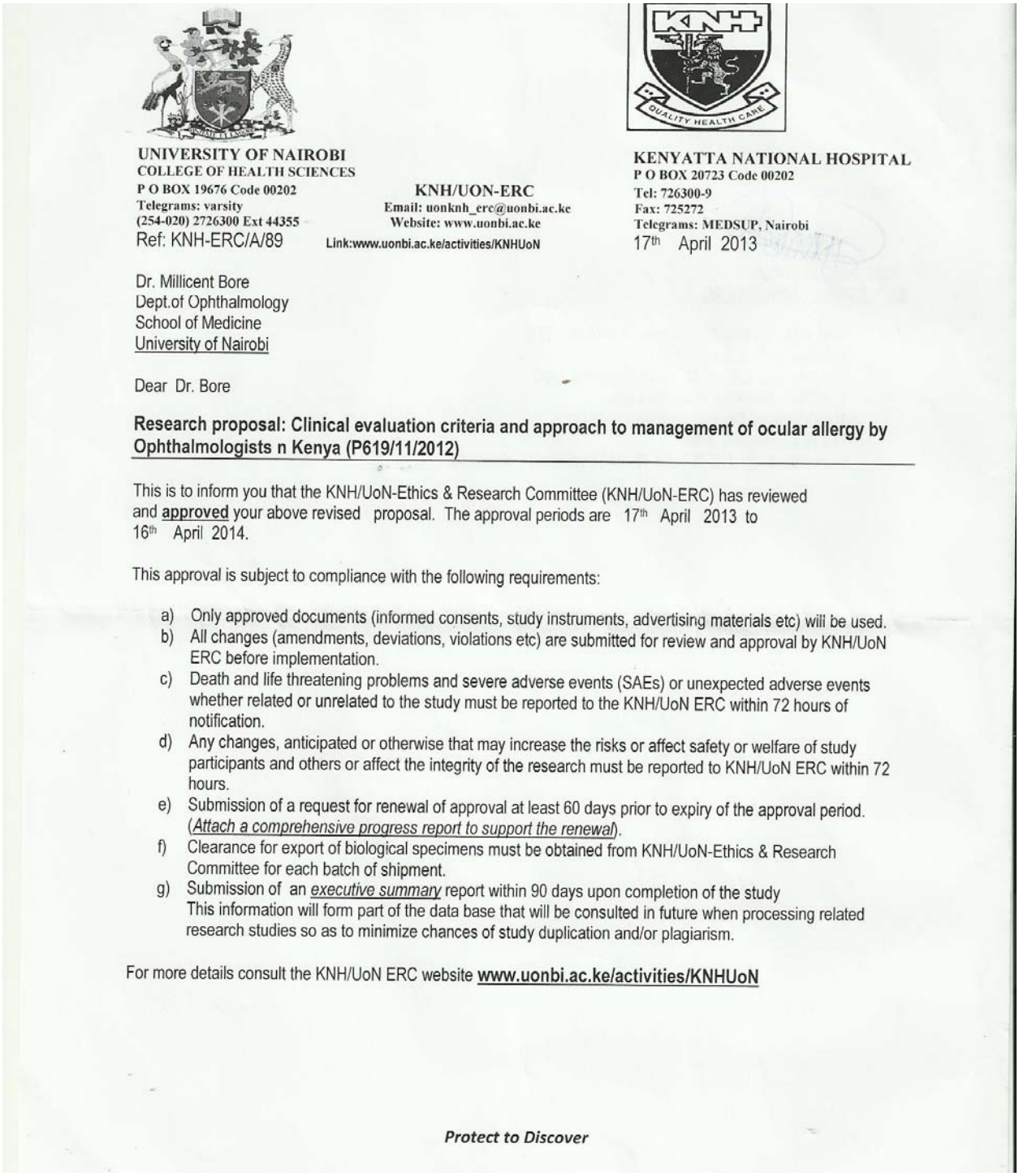
1. Establishment of a standardised grading system as it impacts on clinical decision making. A prospective study to assess if OA can be graded using the suggested clinical grading system would be a step in that direction.
2. There is also the need to come up with national guidelines for the management of OA as this study as well as prior studies have shown that it can greatly improve the services offered to patients with OA and reduce the need for referral of minor cases of OA, therefore promoting effective therapeutic and economically efficient prescribing.
3. Counselling/ patient education should be more aggressive as it directly influences compliance to treatment and patient follow-up and it is the mainstay of management of patients with OA.
4. A similar study to be done with ophthalmic clinical officers (OCO's) as it would give a more complete picture of how OA is managed at the grass-root level as they are the first line managers.

10. LIMITATIONS

1. There was difficulty in ascertaining if the participants' email addresses were in use during the study period and this may have influenced the response rate. The participants whose phone numbers were available were contacted on telephone and requested to provide alternative email addresses if the email address provided was not in use, or if they would prefer a hard copy to be delivered to them.
2. Being an online self administered online survey may have also influenced the response rate as there is a tendency of some individuals to respond to an invitation to participate in an online survey, while others ignore it, leading to a systematic bias. Several reminders were sent out, both on email and through telecommunication services, encouraging the participants to respond and that the online questionnaire was short and would take a few minutes of their time.
3. It was also difficult to assemble groups of ophthalmologists for the FGDs due to the nature of duties/busy schedules. As a result one FGD was converted to a group key informant interview as only 2 participants were available. It would also have been better to carry out several FGD sessions with the same groups so as to make them more comprehensive but this was not possible due to time constraints.

11. APPENDICES

11.1 APPENDIX I: Approval letter from Ethics and Research Committee



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17th April 2013

Dr. Millicent Bore
Dept.of Ophthalmology
School of Medicine
University of Nairobi

Dear Dr. Bore

Research proposal: Clinical evaluation criteria and approach to management of ocular allergy by Ophthalmologists n Kenya (P619/11/2012)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above revised proposal. The approval periods are 17th April 2013 to 16th April 2014.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN**

Protect to Discover

Yours sincerely

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. Prof. A.N. Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
The Principal, College of Health Sciences, UoN
The Dean, School of Medicine,UoN
The Chairman, Dept.of Ophthalmology,UoN
The HOD, Records, KNH
Supervisors: Prof. D.R. Ilako, Dr. Millicent Kariuki-Wanyoike

11.2 APPENDIX 11: Information Sheet

My name is **Dr Millicent Bore**. I am a postgraduate student at the Department of Ophthalmology, University of Nairobi.

I am conducting a study on the **Clinical evaluation criteria and approach to management of ocular allergy by ophthalmologists in Kenya**.

I am kindly requesting you to read and carefully fill this questionnaire, and participate in a follow up telephone interview if necessary. Participation in this study is voluntary and the information gathered will be used solely for academic and intended purposes. You do not have to write your name or identify yourself in any way in the questionnaires. All information obtained will be treated with confidentiality and will not be used to reflect on the respondent in any way.

Thank you for your co-operation.

11.3 APPENDIX III: Questionnaire

Baseline Survey – For Ophthalmologists

Clinical evaluation criteria and approach to management of ocular allergy questionnaire

Date of filling questionnaire: ☐☐☐

PART 1

Age: ☐☐

Gender: M ☐ F ☐

Duration of Practise as an ophthalmologist ☐☐

Other Qualifications (e.g. fellowship) ……..……

Place of Practice: Government ☐ Private Practice ☐ Faith based ☐ Private Hospital ☐

Other ……...

PART 2

Kindly go through and answer the questions below. The information collected will help in improvement of provision of services. Thank you.

1. Do you classify Ocular Allergy (OA)?
   .....
   If yes above, how do you classify it?
   ……
   ……

2. Do you grade/stage OA level of severity?
   ……
   a. If yes, how do you grade it?
      ……
      ……
      ……
   b. If No
      i. Are you aware of a system for the grading of OA severity?
         ……
      ii. What is/are your reason(s) for not grading OA severity?
         ……
         ……

3. How do you make the diagnosis of OA?

……
……
……

4. What is/are the most important symptom(s) for OA **diagnosis**?

……
……...
……

5. What is/are the most important sign(s) for OA **diagnosis**?

……
……
……

6. How do you assess response to treatment in patients with OA?

……
……
……

7. Do you think staging of OA severity is important?
   a. Not at all important ☐
   b. Slightly important ☐
   c. Moderately important ☐
   d. Very important ☐
   e. Extremely important ☐

8. How important do you think the following symptoms are for **grading** of ocular allergy severity?

Subjective Symptoms	Not at all important	Slightly Important	Moderately Important	Very Important	Extremely Important
Ocular itching					
Hyperaemia					
Tearing					
Photophobia					
Foreign body (Gritty) sensation					
Ocular pain					
Mucoid discharge					
Burning sensation					

9. How important are the following signs for **grading** of ocular allergy severity?

Objective Symptoms	Not at all important	Slightly important	Moderately important	Very important	Extremely important
Hyperaemia					
Limbal proliferation/ Horner-Trantas dot					
Papillary hyperplasia					
Conjunctival oedema					
Follicles					
Shield ulcer					
Corneal Epithelial Erosions & SPKs					

10. How important are the following in the selection of treatment offered?

Goals	Not at all important	Slightly Important	Moderately Important	Very important	Extremely important
Severity of symptoms					
Tolerability					
Patient preference					
Time of action					
Cost of drugs					
Availability of drugs					

11. Kindly indicate the mode of treatment and category used.

Medication	1st Line	2nd Line	3rd Line	Not used
Artificial Tears				
Mast Cell Stabilizers				
Topical Antihistamines				
Multiple Action Drugs(Antihistamine + Mast cell stabilizer)				
Topical Steroids				
Topical Vasoconstrictors				
Topical NSAIDs				
Immunomodulators/Systemic steroids				
Oral Antihistamines				
Periocular steroids				

11.4 APPENDIX IV: FGD Invitation/Consent Form

You have been requested to participate in a focus group by Dr Millicent Bore, a postgraduate student at the University of Nairobi. The purpose of the group is to try collect information with regards to the grading and management of Ocular allergy. The information collected in the focus group will be used solely for academic purposes.

You can choose whether or not to participate in the focus group and stop at any time. Although the focus group will be tape recorded, your responses will remain anonymous and no names will be mentioned in the report.

There is no right or wrong answer to the focus group questions. We would like to hear many different viewpoints and would like to hear from everyone. We hope you can be honest even when your responses may not be in agreement with the rest of the group. In respect for each other, we ask that only one individual speak at a time in the group and that responses made by all participants be kept confidential.

I understand this information and agree to participate fully under the conditions stated above:

Print Name of Participant: _____

Signature of Participant: _____

Date: _____

Participant Demographics:

How long have you been in practice?
- Less than 5 years
- 5 to 10 years
- More than 10 years

Age:
- 30 to 40
- 41 to 50
- 51 to 60
- Over 60

Your gender:
- Male
- Female

11.5 APPENDIX V: Discussion Guide

Introduction, assurance of confidentiality, informed consent.

1. How long have you been an ophthalmologist?
2. How often do you see patients with ocular allergy?
3. Do you classify ocular allergy? If yes how?
4. Do you grade level of OA severity?
    a. If yes, how?
    b. If no, why not?
5. Do you think it is important to grade OA severity?
    a. If no, why not?
    b. Does it impact clinical decision making?
        i. If yes, how?
        ii. If no, why not?
6. Which subjective symptoms do you think are important for **grading** of ocular allergy severity?
7. Which objective symptoms do you think are important for **grading** of ocular allergy severity?
8. Do you have standard management guidelines (protocol) for OA?
    a. If yes,
        i. Do you follow them?
        ii. The challenges of using them?
        iii. The benefits?
    b. If no, why not?
9. How do you treat ocular allergy?
    a. Do you categorize your patients?
    b. If yes how?
    c. Kindly discuss the treatment offered for each category.
10. Which factors are important in assessment of a patients' response to therapy?

11. Is there room for surgical intervention in patients with OA?

    a. If yes, kindly let us know the procedure(s) performed and the indications.

    b. If not, why not?

12. Kindly look through the suggested grading system 1

    a. Do you think it can be used in the assessment of OA?

        i. If yes, why?

        ii. If no, why not?

    b. Do have any suggestions for improvement?

        i. If yes, which ones?

13. Kindly look through the suggested grading system 2

    c. Do you think it can be used in the assessment of OA?

        i. If yes, why?

        ii. If no, why not?

    d. Do have any suggestions for improvement?

        i. If yes, which ones?

Suggested grading system 1

Evaluation of Grade of Subjective Symptoms Severity for Ocular Allergy

	0 None of the time	1 Some of the time	2 Half of the time	3 Most of the time	4 All of the time
Itching					
Tearing					
Light sensitivity					
Gritty Sensation					
Burning sensation					

Evaluation of Grade of Objective Symptoms Severity for Ocular Allergy

Grade/Level	0 None	1 Mild	2 Moderate	3 Moderately Severe	4 Severe
Papillae	No manifestations	Micro: <0.5mm	Macro: >0.5-1mm	Cobblestone Papillae<1mm +/-fibrosis	Giant: > 1mm
Conjunctiva	No manifestations	Hyperaemia	Hyperaemia & partial conjunctival swelling	Hyperaemia & diffuse thin chemosis	Hyperaemia, cyst like chemosis & scar
Cornea	No manifestations	Sectoral SPK	Diffuse SPK	Shield Ulcer or epithelial erosion	Keratoconus +/- central leucoma
Limbus (Limbal oedema/trantas dots)	No manifestations	1 quadrant	2 quadrants	3 quadrants	4 quadrants

Mild: 1-9 **Moderate: 10-18** **Moderately Severe: 19-27** **Severe: 28-36**

Suggested grading system 2

Evaluation of Grade of Objective Symptoms Severity for Ocular Allergy

Grade	None	Mild	Moderate	Severe
Papillae	No manifestations	Micro: <0.5mm	Cobblestone Papillae 0.5-<1mm, +/- fibrosis	Giant: > 1mm
Conjunctiva	No manifestations	Hyperaemia	Hyperaemia Diffuse thin chemosis	Hyperaemia Cyst like chemosis scar
Cornea	No manifestations	Sectoral SPK	Diffuse SPK Or epithelial erosion	Shield Ulcer, Keratoconus +/- central leucoma
Limbus (Limbal oedema/ trantas dots)	No manifestations	1 quadrant	2 quadrants	3-4 quadrants

All the above signs are assessed and the grade is determined by the most severe sign present in the more severe eye.

11.6 APPENDIX VI: Studies on Evaluation of Grade of Severity for Ocular Allergy

A. Allergic Conjunctivitis: An Immunological Point of View, Robles-Contreras *et al (2011)* (14)

The authors propose here, besides to take all recommendations mentioned above, a grading system based on a scale of 0 to 4, when 0=absent, 1=mild, 2=moderate, 3=moderately severe, and 4=severe, for both signs and symptoms.

Taking in consideration, frequency in symptoms (itching, tearing, light sensitivity, gritty sensation, and burning sensation), (Table 1) and repercussion of signs implicated on alterations accompanying the inflammation at the Allergic Conjunctivitis: An Immunological Point of View 37 ocular surface, such as eyelid position and skin aspect, eyelid margin state of mucocutaneous junction (MCJ) with involvement of meibomian gland disease (MGD), discharge aspect, implication of limbal stem cell deficiency and even keratoconus involvement. (Figure 1 and Table 2)

The total score of signs and symptoms following grade of severity scale would give a total amount of 48 points, twenty of them corresponding to symptoms, and twenty eight of them corresponding to signs. According to this statement, they propose an objective grading system to recognize progress of allergic ocular disease, which could be defined as follows: 0 points= Absent, 1-12 points (mild), 13-24 points (moderate), 25-36 points (moderately severe) and 36-48 points (severe). The score of the more severe side in bilateral cases could be used as a clinical score.

Table 1: Allergic Conjunctivitis: An Immunological Point of View, Robles-Contreras *et al*, pg 37. [14]

Evaluation of Grade of Symptoms Severity for Allergic Ocular Diseases					
	0 None of the time	1 Some of the time	2 Half of the time	3 Most of the time	4 All of the time
Itching					
Tearing					
Light Sensitivity					
Gritty Sensation					
Burning Sensation					

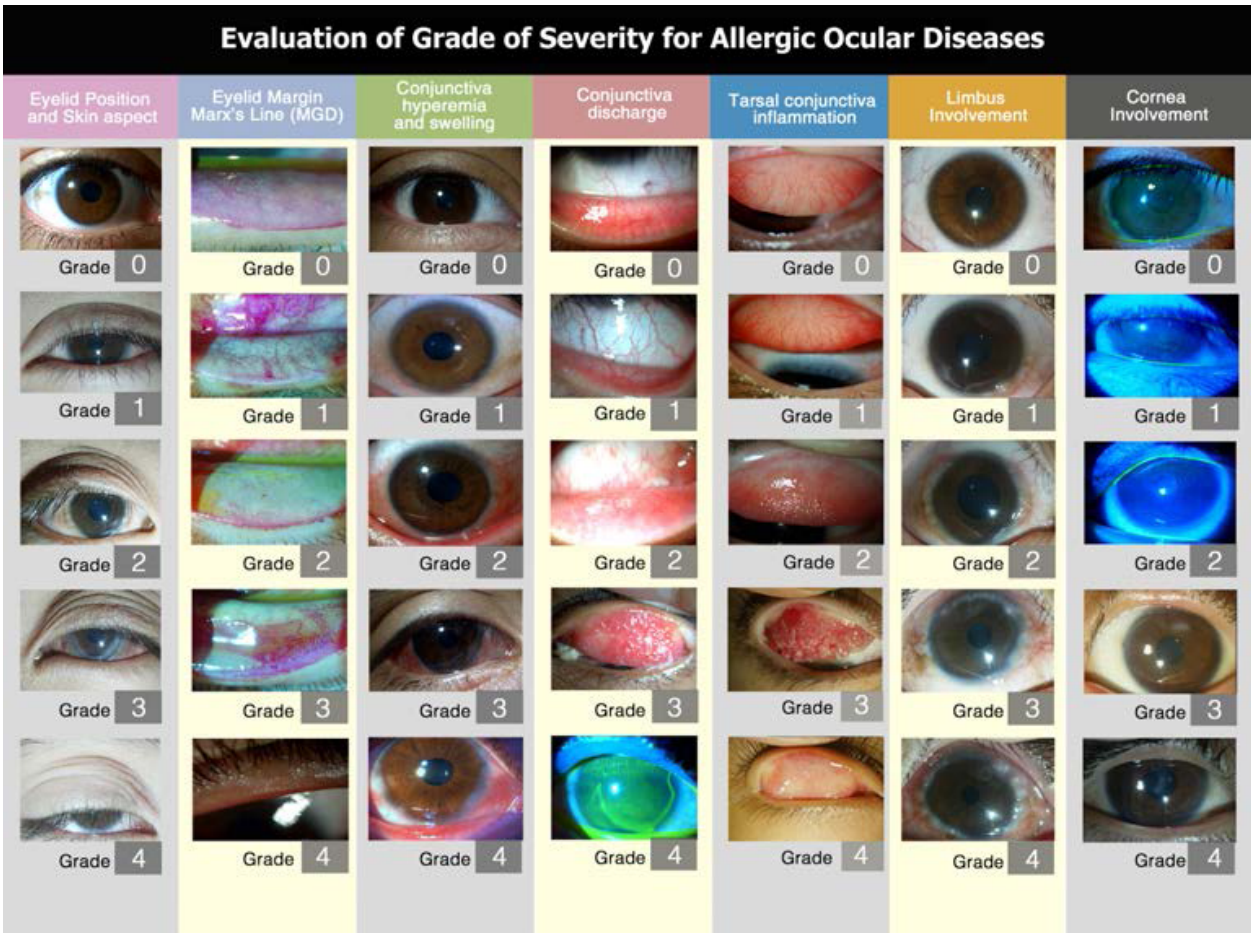
Table 2: Allergic Conjunctivitis: An Immunological Point of View, Robles-Contreras *et al*, page 38. [14]

Evaluation of Grade of Severity for Allergic Ocular Diseases

Signs / Grades	Eyelid Position and Skin aspect	Eyelid Margin Marx's Line (MGD)	Conjunctiva hyperemia and swelling	Conjunctiva discharge	Tarsal conjunctiva Inflammation Response	Limbus Involvement	Cornea Involvement
0	No eyelid edema	No displacement of MCJ	No hyperemia or edema	No discharge	No papillary hyperplasia or visible follicles	No visible limbus nodules or dots	No SPK
1	Localized superior or inferior eyelid margin edema without Dennie Lines.	1/3 displacement of MCJ inferior or superior eyelid margin	hyperemia 1+ - 2 + with 1/3 pink edema aspect in conjunctiva. No conjunctiva plica formation in sac fundus	Clear watery discharge and/or slight debris within	Less than 1/3 tarsal papillae size 0.3 with visible uniform conjunctiva tarsal vessels	Less than one quadrant with dot Trantas	Slight SPK without central involvement
2	Generalized superior and/or inferior eyelid edema with slight pseudoptosis and Dennie Lines	2/3 displacement of MCJ inferior or superior eyelid margin	Hyperemia 2+ - 3+ with 2/3 redness edema aspect in conjuctiva, and/ or slight conjunctiva plica formation in sac fundus	White-gray mucoid discharge in sac fundus or adherent 1/3 to limbus or tarsal conjunctiva	1/3 to 2/3 moderate tarsal papillae 0.3-0.5 size with thin visible tarsal conjunctiva vessels.	One ¼ to one half of dot trantas on limbus with slight pigment	One quarter to one half of SPK without compromise of visual axis.
3	Unilateral or bilateral moderate pseudoptosis and several Dennie Lines	Generalized displacement of MCJ	Hyperemia > 3+ with more than 2/3 conjuctiva edema with localized engorgement of ciliary vessels Moderate plica formation in sac fundus	White, gray or yellow thick copious mucoid strands in sac fundus or adherent 2/3 to limbus or tarsal conjunctiva	Cobblestone papillae presentation. More than 2/3 tarsal papillae 0,75 size.with or without fibrosis. fairly irregular tarsal vessels.	More than one half of dot trantas on limbus with slight to moderate pigment or¼ to one half of LSCD	Generalized SPK with compromise of visual axis, or epithelial defects. Indolent corneal Ulcer on superior quadrants.
4	Uni or Bilateral severe Pseudoptosis with Dennie Lines and changes on skin texture and pigmentation. Hertoghe´s sign present.	Scarring or keratinized changes	Same as grade 3 + generalized engorgement of ciliary vessels. Severe plica or conjunctiva folding formation in sac fundus	Thin copious farely strands adherent mainly to cornea surface	Few tarsal papillae > 0.75 with fibrosis or Macro Papillae extrusion and possible fornix foreshortening (symblefaron) or Generalized pale tarsal conjunctiva aspect without normal visible tarsal vessels.	Generalized dot trantas on limbus with fibrosis and pigment or more than one half of LSCD	Keratoconus with or without central leucoma

Hyperemia Grading: 0 = Absence of hyperemia. 1+ = mild (1/3 localized sector engorgement of bulbar conjunctival vessels). 2+ = moderate (2/3 diffuse engorgement of bulbar conjunctival vessels), and 3+ = severe (significant generalized engorgement of bulbar conjunctival vessels)
SPK (Superficial punctuate Keratopathy)
LSCD (Limbal Stem Cell Deficiency)
MGD (Meibomian Gland Disease)
MCJ (Mucocutaneous junction)

Figure 1: Allergic Conjunctivitis: An Immunological Point of View, Atzin Robles-Contreras *et al*, page 39. [14]



B. Demographic aspects of allergic ocular diseases and evaluation of new criteria for clinical assessment of ocular allergy, Uchio *et al*, 2007:293. [13]

Table 1 Criteria for clinical evaluation of allergic ocular findings

Descriptions			
Palpebral conjunctiva	Hyperemia	Severe	Impossible to distinguish individual blood vessels
		Moderate	Dilatation of many vessels
		Mild	Dilatation of several vessels
		None	No manifestations
	Edema	Severe	Diffuse marked edema
		Moderate	Diffuse mild edema
		Mild	Localized edema
		None	No manifestations
	Follicles	Severe	20 or more follicles
		Moderate	10–19 follicles
		Mild	1–9 follicles
		None	No manifestations
	Papillae	Severe	Diameter ≥0.6 mm
		Moderate	Diameter 0.3–0.5 mm
		Mild	Diameter 0.1–0.2 mm
		None	No manifestations
	Giant papillae	Severe	Elevated papillae in 1/2 or more of upper palpebral conjunctiva
		Moderate	Elevated papillae in less than 1/2 of upper palpebral conjunctiva
		Mild	Flat giant papillae
		None	No manifestations
Bulbar conjunctiva	Hyperemia	Severe	Vasodilatation of all vessels
		Moderate	Dilation of many vessels
		Mild	Dilation of several vessels
		None	No manifestations
	Chemosis	Severe	Cyst-like chemosis of entire conjunctiva
		Moderate	Diffuse thin chemosis
		Mild	Partial conjunctival swelling
		None	No manifestations
Limbus	Limbal edema	Severe	In ≥ 2/3 of circumference
		Moderate	In 1/3 to 2/3 of circumference
		Mild	In less than 1/3 of circumference
		None	No manifestations
	Trantas' dots	Severe	≥ 9 dots
		Moderate	5–8 dots
		Mild	1–4 dots
		None	No manifestations
Cornea	Epithelial lesions	Severe	Shield ulcer or epithelial erosion
		Moderate	Superficial punctate keratitis with filamentary debris
		Mild	Superficial punctate keratitis
		None	No manifestations

In cases having giant papillae, papillae and giant papillae should be graded simultaneously

C. Ocular allergy Latin American consensus, Santos *et al*, 2011:454. [1]

Table 3: Staging of ocular allergy severity

Grade/Level	**Papilla**	**Conjunctiva**	**Cornea**	**Limbus**
1	Micro: < 0,5 mm	Hyperemia	(-)	(-)
2	Micro: < 0,5 mm	Hyperemia	Sectoral SPK	Limbitis in 1 quadrant
3	Macro: > 0,5 mm - 1 mm	Hyperemia and edema	Diffuse SPK	Limbitis in 2 quadrants
4	Giants: > 1 mm	Hyperemia, edema and scar	Ulcer	Limbitis in 3 or more quadrants

SPK= superficial punctate keratitis

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