STANDARD TREATMENT GUIDELINES

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MANAGEMENT OF DRY EYE DISEASE IN INDIA

AUGUST 2017

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health & Family Welfare
Government of India

NHSRC

STANDARD TREATMENT GUIDELINES

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Ministry of Health & Family Welfare
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TABLE OF CONTENTS

INTRODUCTION

The term dry eye syndrome or dry eye disease has been described as a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbances and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface (Dry Eye Work Shop –DEWS,2007). Dry eye represents a disturbance of the lacrimal functional unit, an integrated system composed of the lacrimal glands, ocular surface (cornea, conjunctiva, eye lids and the meibomian glands) with the sensory and motor nerves that connect these structures. The overall function of the lacrimal functional unit is to preserve tear film integrity, ocular surface health, maintaining corneal transparency and surface stem cell population, thereby significantly influencing the quality of images projected onto the retina. Decreased tear secretion, delayed tear clearance from the ocular surface and altered tear composition may compromise tear film stability, sometimes accompanied by ocular inflammation. Disturbances integral to the lacrimal functioning unit are considered to pay an important role in evolution of different forms of dry eye.

DISEASE DEFINITION

Dry Eye Syndrome or Dry Eye Disease refers to a group of disorders of the ocular tear film attributed to reduced tear production or excessive tear evaporation, associated with ocular discomfort and /or visual symptoms with possible disease of the ocular surface.

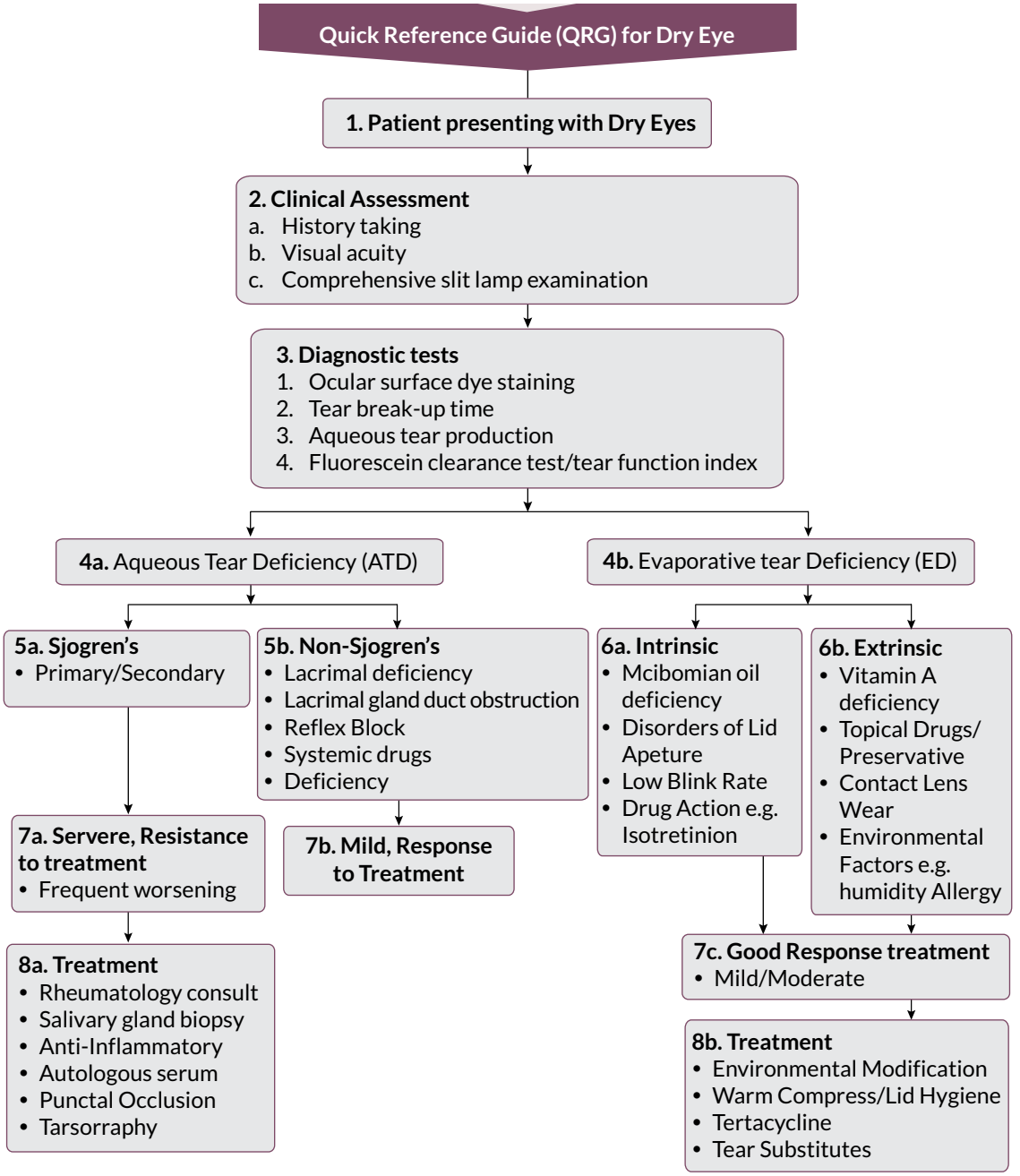
EPIDEMIOLOGY & PREVALENCE OF DRY EYE DISEASE

Epidemiological information on dry eye syndrome has been limited by lack of uniformity in its definition and the inability of any single diagnostic test or set of diagnostic tests to confirm or rule out the condition. Dry eye syndrome is a common condition that causes varying degrees of discomfort and disability. While clinic-based studies confirm its frequency (17% of 2127 consecutive new outpatients were diagnosed with dry eye following comprehensive examination), such studies may not reflect the overall population. In a population-based sample of 2520 elderly (65 or older) residents of Salisbury, Maryland, USA, 14.6% were symptomatic, which was defined as reporting one or more dry eye symptoms often or all the time. The combination of being symptomatic and having a low Schirmer test (≤5 mm with anesthesia) or a high rose bengal score (≥5) was seen in 3.5% of the residents. A population-based study of dry eye conducted in Melbourne, Australia, using different diagnostic criteria reported higher percentages of the 926 participants aged 40 to 97 who had a low Schirmer test (16.3% ≤8 mm)or a high rose bengal score (10.8% ≥ 4).There is no population-based study in relation to dry eye disease in India. However, there are three published reports on prevalence of dry eye among hospital-based population from North and Eastern India and the prevalence varies between 18.4% and 40.8%. A study from higher altitudes reported a higher prevalence of 54%. Since these data are hospital based, they are likely to overestimate the prevalence of dry eye.

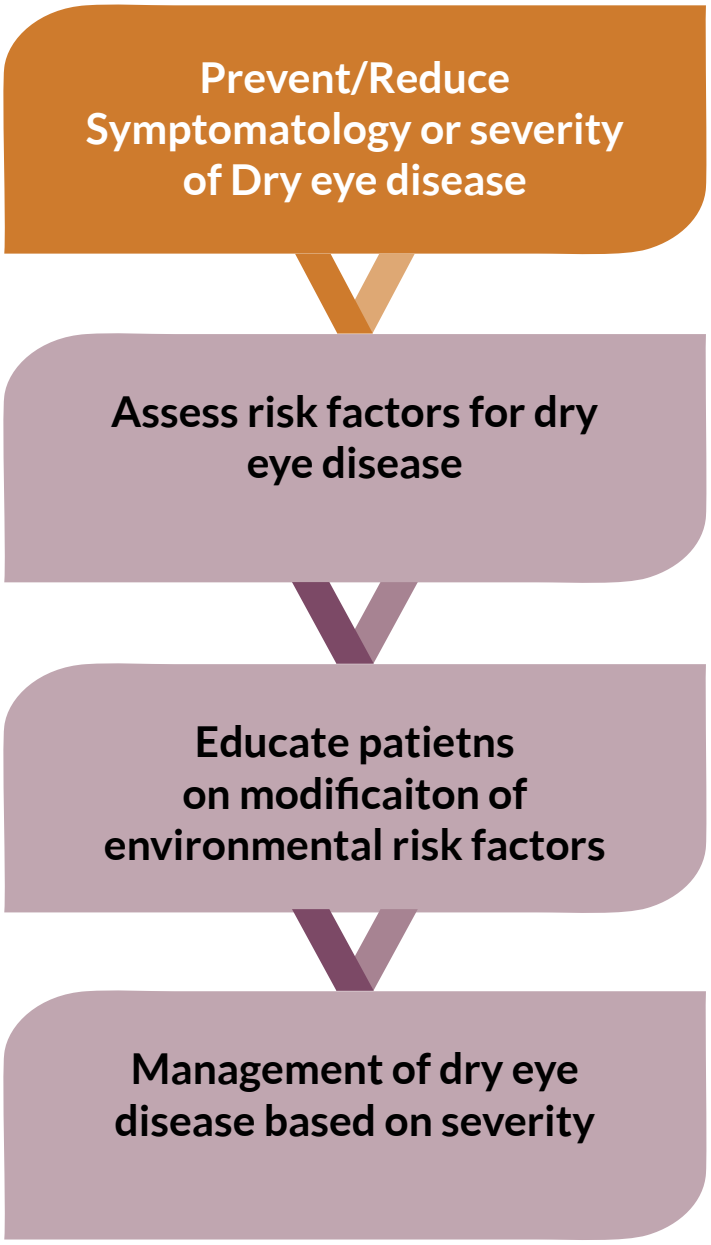
RECOMMENDATIONS

1. Diagnosis
2. Management
3. Provider & Setting
4. Counseling & Referral
5. Prevention

CLINICAL PATHWAY 1:
OVERVIEW OF DRY EYE DISEASE MANAGEMENT



CLINICAL PATHWAY 2: PREVENTION OF DRY EYE DISEASE



4.1 DIAGNOSIS OF DRY EYE SYNDROME

Table 1: Risk Factors for Dry eye Disease

High level of evidence	Moderate level of evidence	Low level of evidence Age
• Age • Female Sex • Postmenopausal estrogen therapy • Antihistamines • Collagen vascular disease • Corneal refractive surgery • Irradiation • Hematopoietic stem cell transplantation • Vitamin A deficiency • hepatitis C • Androgen deficiency	• Medications- Tricyclic antidepressants, selective serotonin reuptake inhibitors, diuretics, beta blockers. • Diabetes mellitus • HIV/HTLV1 infections • Systemic chemotherapy • Cataract surgery with a large incision • Keratoplasty • Isotretinoin • Low air humidity • Sarcoidosis • Ovarian dysfunction	• Smoking • Hispanic ethnicity • Anti cholinergic drugs- anxiolytics & antipsychotics • Alcohol • Menopause • Botulinum toxin injection • Acne • Gout • Oral contraceptives • Pregnancy

(The definition and classification of dry eye disease: report of the Definition and Classification Sub Committee of the International Dry Eye Workshop. Ocul Surf 2007; 5:75-92)

4.1.1. Identify characteristics of the causative factors, such as adverse environments, prolonged visual efforts, or ameliorating circumstances, which is helpful in diagnosing dry eye

4.1.2. Use supporting clinical observations and tests to confirm diagnosis of dry eye

4.1.3. Question about patient symptoms and signs, exacerbating conditions, duration of symptoms and ocular history to elicit helpful information

4.1.4. Pay particular attention to the skin, eyelids, adnexa, proptosis, cranial nerve functions, mouth, skeletal system and hands

4.1.5. On slit lamp biomicroscopy evaluation, focus on the tear film, eye lashes, anterior and posterior eyelid margins, puncta, conjunctiva and cornea. Pay particular attention to Meibomian gland dysfunction in evaluation of tear film

4.1.6. Test for anti-thyroid and anti-thyroglobulin antibody in dry eye patients suspected of thyroid eye disease

4.1.7. Order a B-Scan sonogram or other imaging study to assess extra ocular muscle thickness in patients with dry eye who have suspected thyroid eye disease

4.1.8. Recommend/ Perform conjunctival biopsy for dry eye patients who have significant chronic conjunctivitis with a nodular appearance or cicatrisation

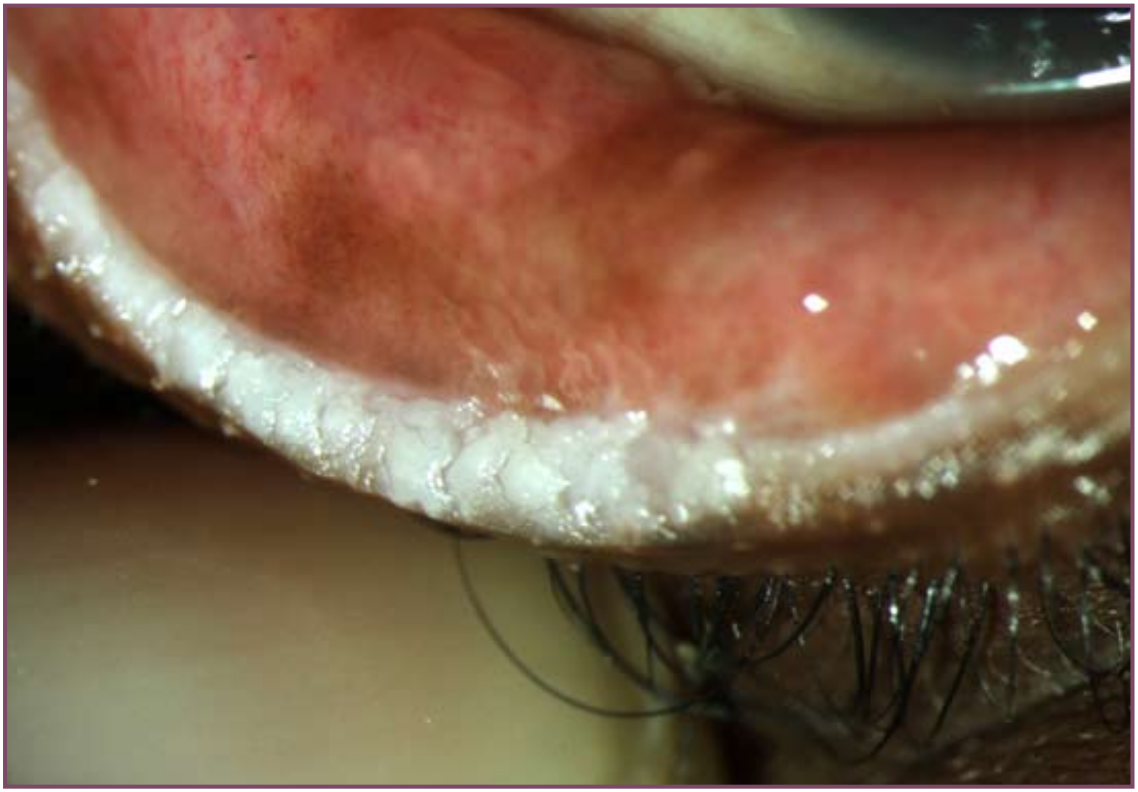


Figure 1: Severe Blepharitis is a major risk factor for Dry eye disease (See Recommendations 4.1.4 and 4.1.5)

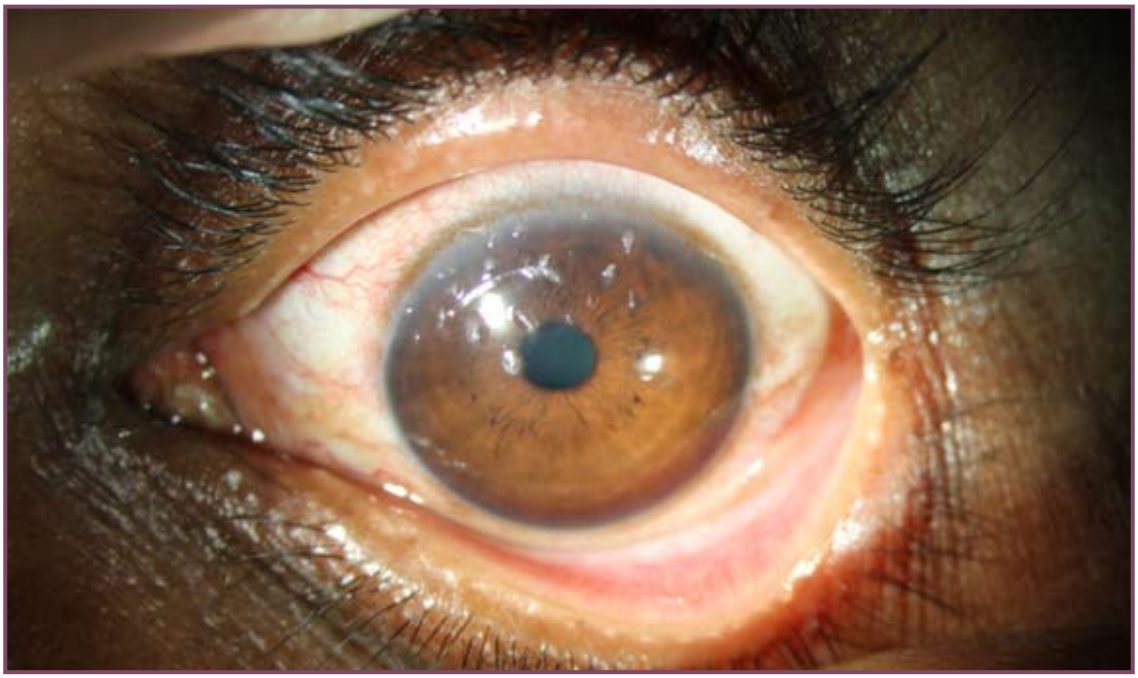


Figure 2: Filamentary Keratitis in Recurrent Dry Eye Disease

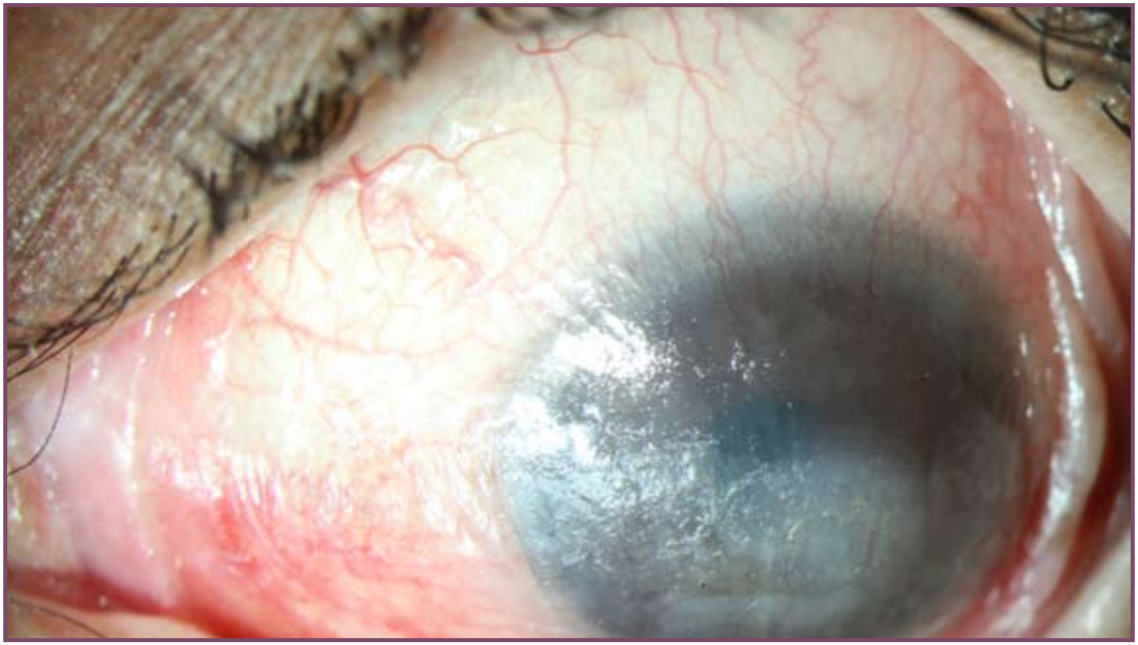
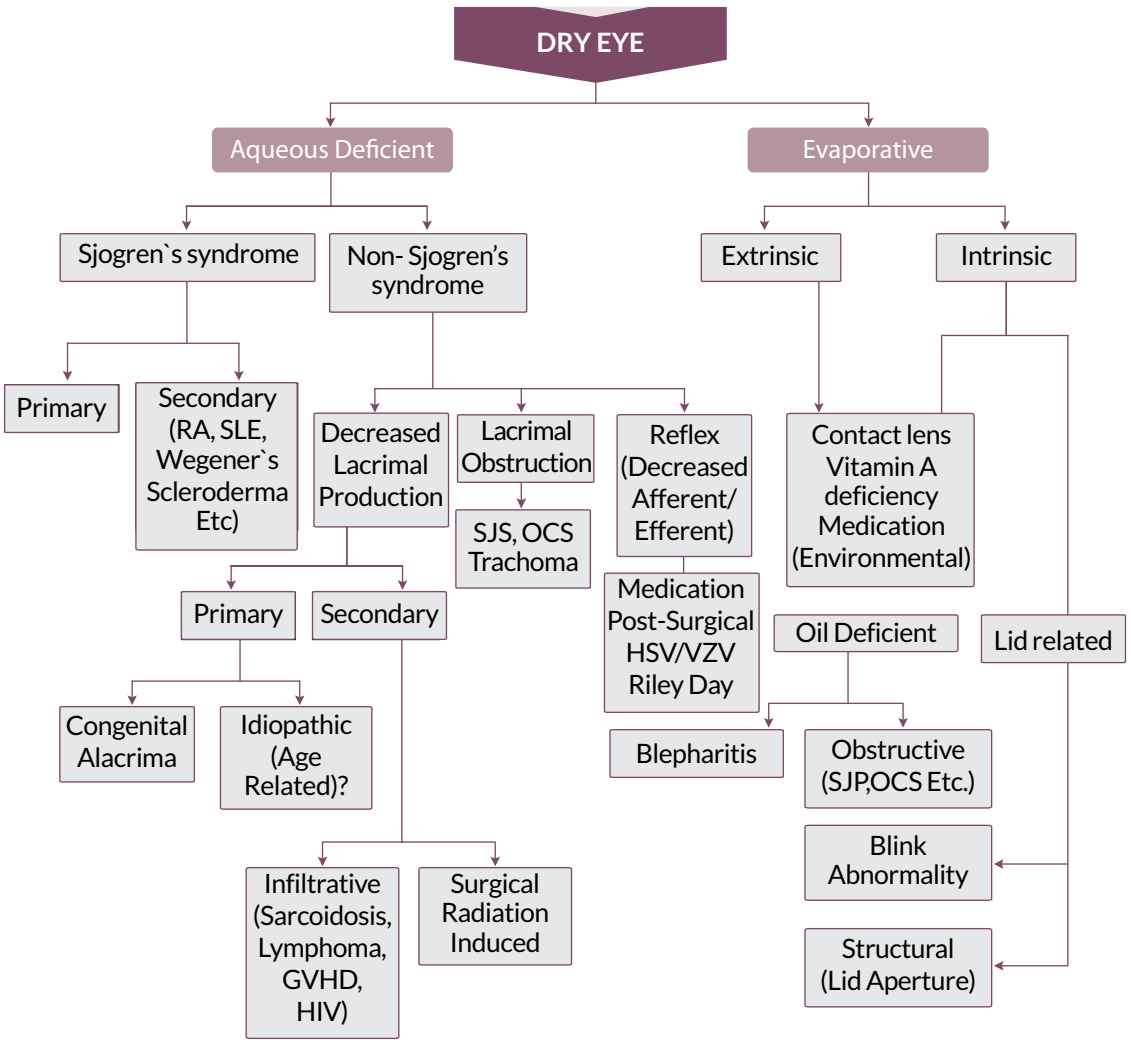


Figure 3: Severe Dry eye with corneal scarring, vascularization and characteristic Conjunctival folds with significant reduction in tear film

CLINICAL PATHWAY 3 :
DIAGNOSTIC CLASSIFICATION OF DRY EYE DISEASE

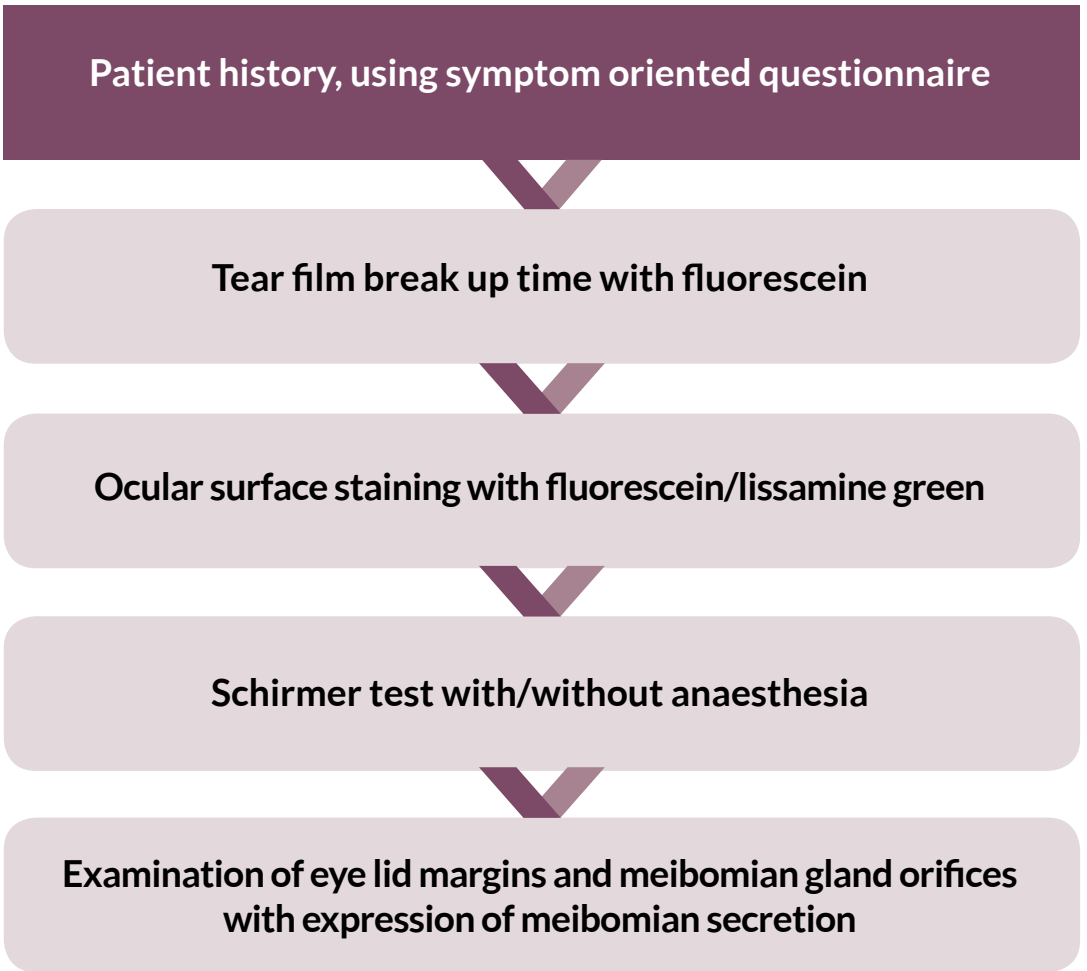
Major etiological factors for dry eye disease Source: Lemp MA (chair). Definition and classification of dry eye disease: report of the definition and classification subcommittee of the International Dry Eye Work Shop (DEWS - 2007). Ocul Surf 2007; 5: 77



4.1.9. For patients with moderate to severe aqueous tear deficiency, establish the diagnosis by using one or more of the following tests: Tear break-up time test, ocular surface dye staining and Schirmer test

4.1.10. Perform these tests in this sequence because the Schirmer test can disrupt tear film stability and cause false positive ocular surface dye staining

CLINICAL PATHWAY 4: PRACTICAL SEQUENCE OF DRY EYE TESTS



(The definition and classification of dry eye disease: report of the Definition and Classification Sub Committee of the International Dry Eye Workshop. Ocul Surf 2007; 5:75-92)

Figure 4: Schirmer's Test to assess Tear film. Results less than 10 mm without anaesthesia considered abnormal. Consistently low Schirmer test readings are suggestive of aqueous tear deficiency

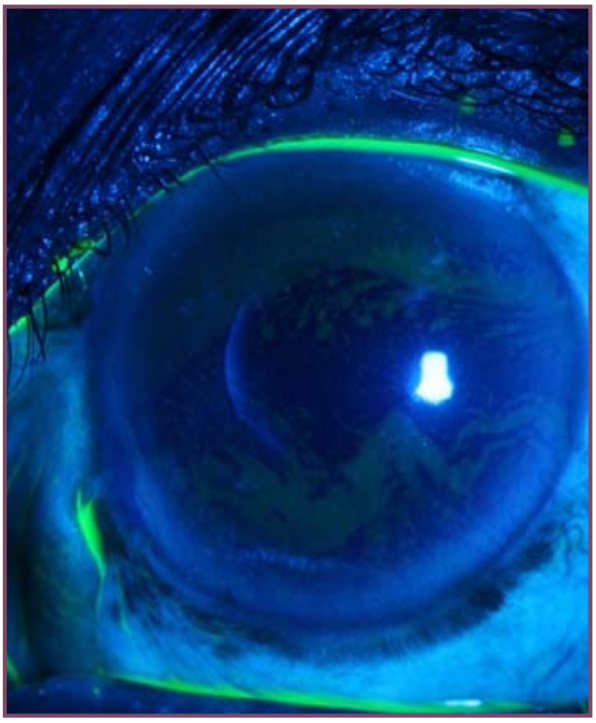


Figure 5: Fluorescein Dye staining of cornea and Conjunctiva in mild to moderate Dry eye disease

4.1.11. Allow several minutes between the dye testing and the Schirmer test

4.1.12. Assess corneal sensation when trigeminal nerve dysfunction is suspected

4.1.13. Consider a laboratory and clinical evaluation for autoimmune disorders for patients with significant dry eye, other signs and symptoms of an autoimmune disorder or a family history of an autoimmune disorder

4.1.14. Consider testing for an underlying Sjogren Syndrome in patients with moderate punctate staining of the cornea and /or conjunctiva as these patients will require a multi- disciplinary approach.

4.1.15. Evaluate aqueous tear production with the Schirmer test. It gives variable results and do not use as the sole criterion for diagnosing dry eye.

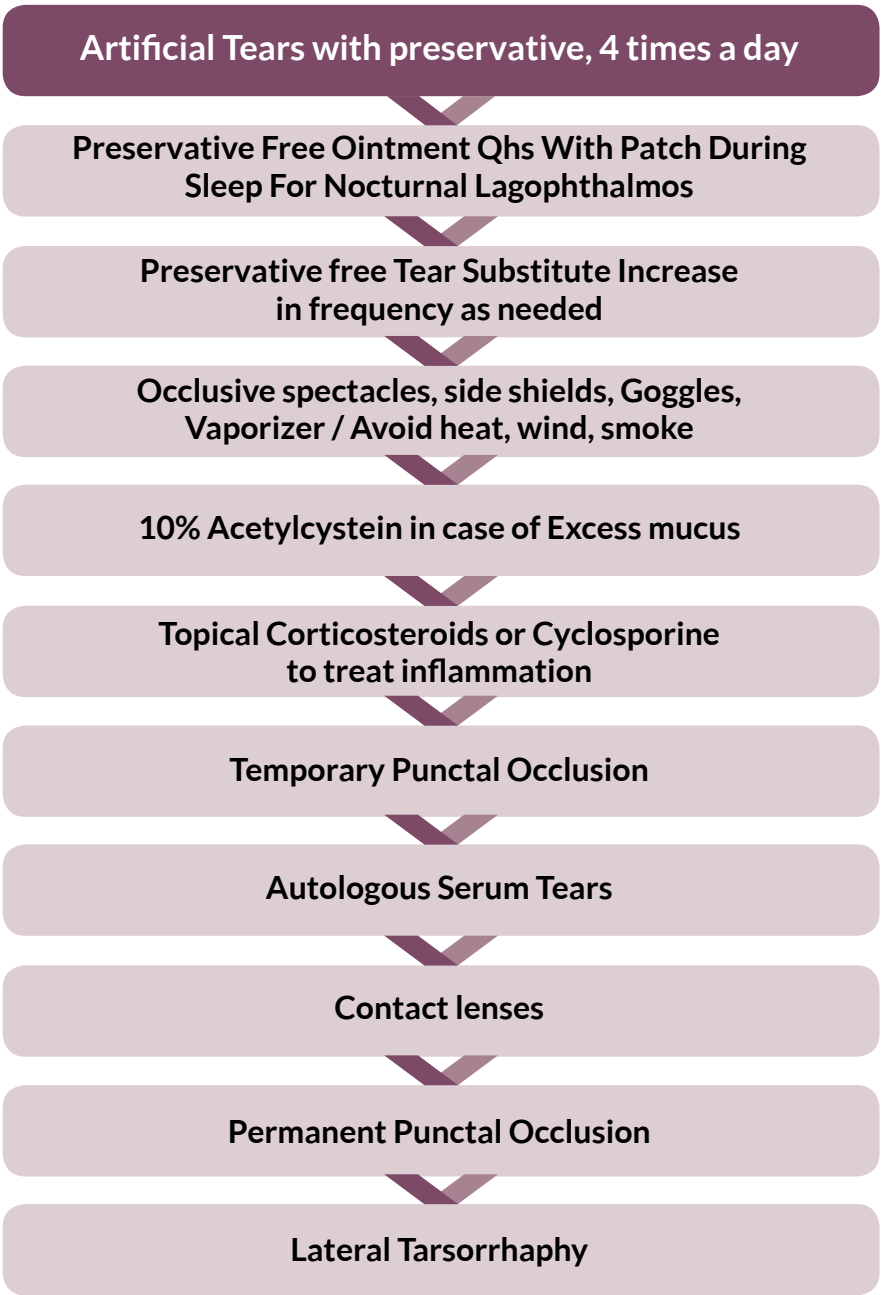
Table 2: Classification of Dry Eye Severity

	1	2	3	4
Discomfort	Mild/ Episodic Occurs under environmental stress	Moderate, episodic or chronic with or without stress	Severe, frequent, or constant withour stress	Severe and/or disabling and cosntant
Visual Symptoms	None or episodic Mild fatigue	Annoying and/or limiting activity episodic	Annoying, chronic/ constant Limiting activity	Constant, possibly disabling
Clinical Signs	None to mild	None to mild, may or may not have staining, reduced tear meniscus, TBUT < 10	Moderate to marked conjunctival staining, marked central corneal staining, filamentary keratitis, TBUT < 5, Schirmer score < 5	Conjunctival injection & marked staining, severe punctate erosions, scarirng, almost immediate TBUT, Schirmer Score < 2

Based on 2007 International Dry Eye Workshop (DEWS) Report

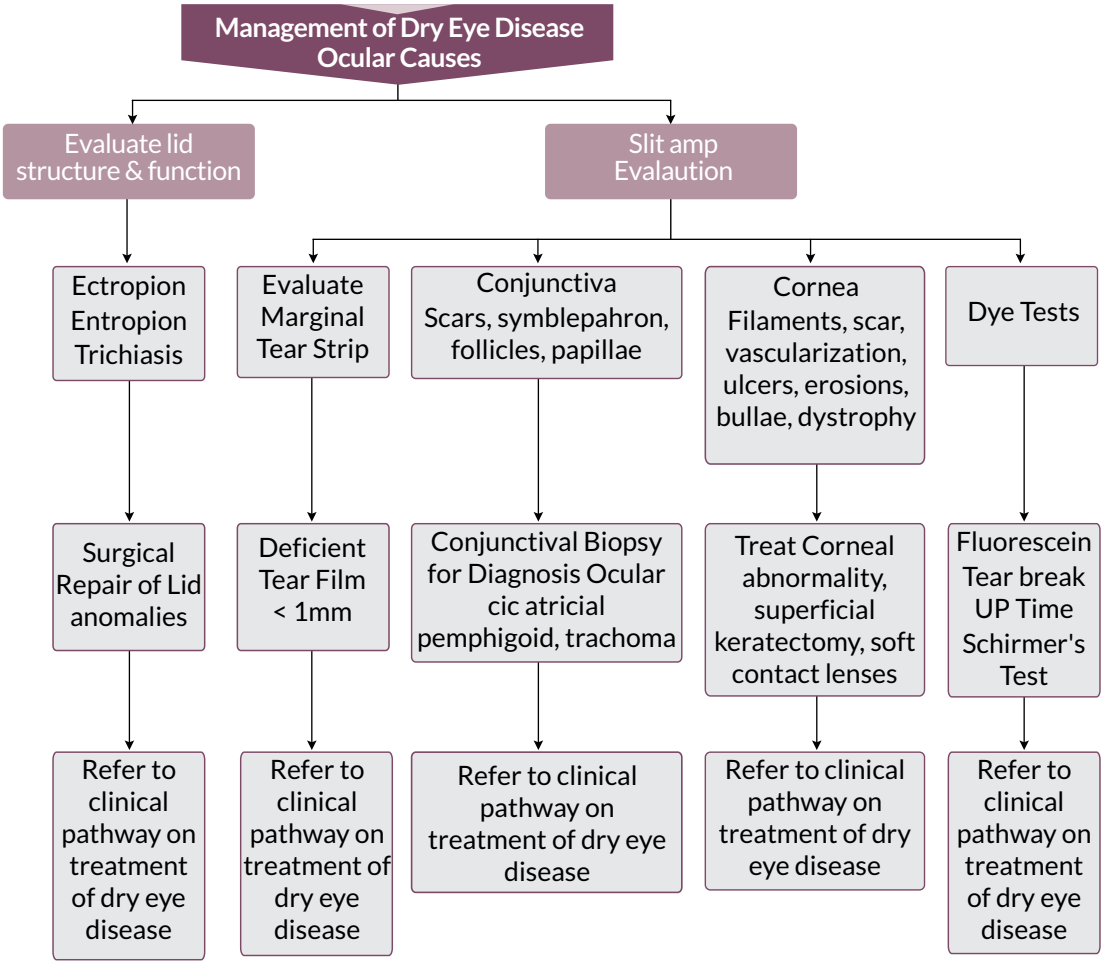
Behrens et al, Cornea 2008, International Task Force (ITF) Guidleines

CLINICAL PATHWAY 5: TREATMENT ALGORITHM FOR DRY EYE SYNDROME MANAGEMENT



4.2. MANAGEMENT OF DRY EYE

CLINICAL PATHWAY 6: OVERVIEW OF DRY EYE MANAGEMENT



Treatment of Mild Dry Eye

4.2.1. Place patients who have suggestive symptoms without signs on trial treatments with artificial tears when other potential causes of ocular irritation have been eliminated

4.2.2. For patients with a clinical diagnosis of mild dry eye, address potentially exacerbating exogenous factors such as anti histamine or diuretic use, cigarette smoking and exposure to second hand smoke, and environmental factors such as air drafts and low humidity environments

4.2.3. Suggest measures such as lowering the computer screen to below eye level to decrease lid aperture, scheduling regular breaks, and increasing blink frequency to decrease the discomfort associated with computer and reading activities

4.2.4. Prescribe emulsions, gels and ointments to treat dry eye symptoms

4.2.5. Increase use of artificial tears as required, but recommend frequent tear instillation depending on the lifestyle or manual dexterity of the patient

4.2.6. Prefer Nonpreserved tear substitutes; however, you may recommend tears with preservatives for patients with mild dry eye and otherwise healthy ocular surface

4.2.7. Prescribe non preserved tears when tear substitutes are frequently and chronically used

4.2.8. Use Systemic Doxycycline in patients with evidence of Meibomian gland dysfunction

4.2.9. Correct eye lid abnormalities resulting from blepharitis

4.2.10. Correct eye lid abnormalities resulting from trichiasis

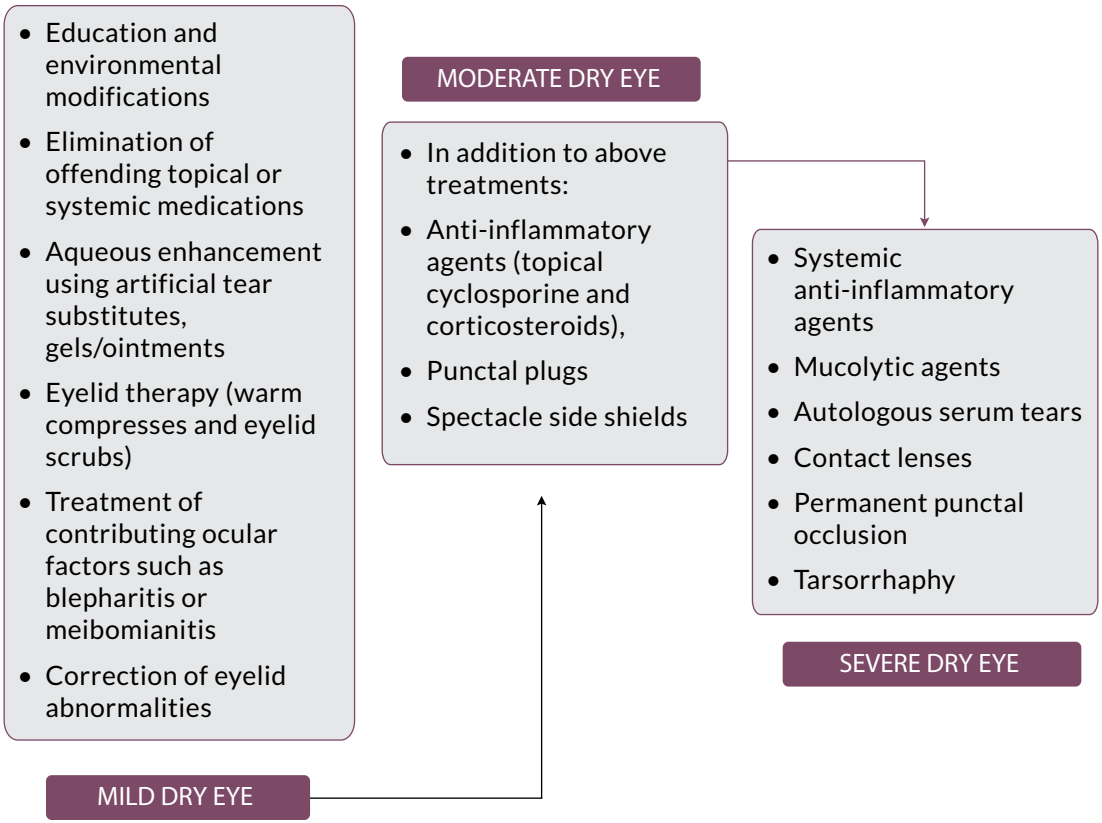
4.2.11. Correct eyelid abnormalities resulting from lid malposition

CLINICAL PATHWAY 7: TREATMENT RECOMMENDATIONS FOR DRY EYE SYNDROME BY DISEASE SEVERITY LEVEL

(Adopted From Aao Preferred Practice Pattern 2013, Dry Eye Syndrome

Clinical Pathway: TREATMENT RECOMMENDATIONS FOR DRY EYE SYNDROME BY DISEASE SEVERITY LEVEL (Adopted from AAO Preferred Practice Pattern 2013, Dry Eye Syndrome

Reference: Pflugfelder. Management and Therapy Subcommittee of the International Dry Eye Workshop. Management and therapy of dry eye disease: report of the Management and Therapy Subcommittee of the International Dry Eye Workshop (2007). Ocul Surf 2007;5:174



Reference: Pflugfelder. Management and Therapy Subcommittee of the International Dry Eye Workshop. Management and therapy of dry eye disease: report of the Management and Therapy Subcommittee of the International Dry Eye Workshop (2007). Ocul Surf 2007;5:174

Treatment of Moderate Eye Disease

4.2.12. Use low dose topical corticosteroid therapy at infrequent intervals for short period of time (i.e., several weeks) to suppress ocular inflammation

4.2.13. Monitor patients prescribed corticosteroids for dry eye for adverse effects such as increased intraocular pressure and cataract formation

4.2.14. Do not routinely recommend omega-3 fatty acid supplements for dry eye treatment since there is no evidence of their efficacy

CLINICAL PATHWAY 8: ARTIFICIAL TEAR SUBSTITUTES IN MANAGEMENT OF DRY EYE DISEASE

Mild Dry Eye Stage I	• Low viscosity eye drops based on Polyvinyl Alcohol (PVA), Polyvinyl Pyrrolidine (PVP) with Preservative • Frequency of application < 4 times daily • Hyaluronic Acid 0.1%
Moderate Dry Eye Stage IIa	• Low viscosity eye drops with PVA withour preservatives • PVP without preservatives • low viscosity cellulose derivatives • Hyaluronic Acid 0/1% • Osmoprotection
Moderately Severe Dry Eye Stage IIb	• Higher viscosity cellulose derivatives without preservatives, frequency of application >4 times daily • Hydrogels (Carbomers), with preservative, frequency < 4 times daily • Hyaluronic Acid 0.3% • Osmoprotection
Severe Dry Eye Stage III	• Hydogels without preservatives • combined with unpreserved PVA, PVP • Combined with Hyaluronic Acid 0.3%

4.2.15. Consider punctual occlusion for patients with aqueous tear deficiency when medical means of aqueous enhancement are ineffective or impractical

4.2.16. Punctal plugs are not routinely recommended for dry eye management in India owing to their relatively high cost. Punctal occlusion by thermal cauterization is preferred for patients with aqueous tear deficiency resistant to medical and conservative measures of treatment

4.2.17. Use non invasive therapies like Eye glass side shields and moisture chambers

Treatment of Severe Dry Eye

4.2.18. Hydroxy Propyl Cellulose eye drops, emulsions, gels are frequently used in moderate to severe dry eye. Punctal occlusion may be attempted in patients who are unable to use frequent artificial tears

4.2.19. Prescribe autologous serum drops to improve ocular irritation symptoms a well as conjunctival and corneal dye staining in patients with Sjogren syndrome and Graft versus host disease

4.2.20. Treat filamentary keratitis with debridement of the filaments or application of topical mucolytic agents, such as acetylcysteine 10 % four times a day

4.2.21. Perform debridement of filaments with a cotton-tip applicator, dry cellulose sponge, or a non -toothed forceps

4.2.22. Avoid treatment with contact lenses in patients with associated neurotrophic keratopathy

4.2.23. Perform thermal cautery if permanent punctal occlusion is to be accomplished.

4.2.24. Perform a stepwise punctal occlusion so that no more than one punctum is cauterized in each eye at a treatment session

4.2.25. Perform a limited tarsorraphy to decrease tear evaporation in patients with severe dry eye who have not responded to other therapies

4.2.26. Recommend Boston Scleral Contact lenses in treatment of severe dry eye

4.3. PROVIDER & SETTING

4.3.1. If you are a health care provider other than an ophthalmologist, refer patients with dry eye who have moderate or severe pain, lack of response to therapy, corneal infiltration or ulceration, or visual loss to an ophthalmologist

4.4. COUNSELING & REFERRAL

4.4.1. Educate patients with dry eye about the chronic nature of the disease process and provide specific instructions for therapeutic regimens

4.4.2. Periodically reassess the patients' compliance and understanding of the disease, the risks for associated structural changes and re inform the patient as necessary

CLINICAL PATHWAY 9: TREATMENT OF DRY EYE DISEASE BASED ON LEVEL OF CARE

Primary Care Providers – Primary health centres, Optometrists, Ophthalmic Assistansts, Non Ophthalmologist Primary care Providers

Treratment of mild dry eyes Guide & Counsel patients.

Refer to secondary level care in case of exacerbation of dry eye symptoms, blurring of vision, presence of lid abnormalities or No response to treatment with Tear Substitutes.

Secondary Care- Comprehensive Ophthalmologists

Treatment of Mild to Moderate Dry Eyes

In instances of visual loss, pain non responsive to conservative treatment, lack of response to therapy, presence of corneal infiltration or ulceration, refer to tertiary level of care

Tertiary Care Providers: medical Colleges, Tertiary eye care Institutes, Specialist Ophthalmologists

Diagnose and treat etiological factors of dry eyes

Treat Complications in severe dry eye disease

Lid correction/other major surgeries for dry eye management

Refer to medical Specialist or Rheumatologist for dry eye patients with systemicimmune dysfunction/ connective tissue diseas/RA or those requiring immunosuppression

4.4.3. Caution patients with pre-existing dry eye that kerato-refractive surgery, particularly LASIK may worsen their dry eye condition

4.4.4. Treat dry eye, when present, prior to considering kerato-refractive surgery

4.4.5. Refer patients with moderate to severe dry eye unresponsive to treatment or when systemic disease is suspected to an ophthalmologist who is experienced in management of these entities

4.4.6. Refer patients with systemic immune dysfunction or those who require immunosuppressive therapy to an internist or rheumatologist

4.5 RECOMMENDATIONS FOR PREVENTION OF DRY EYE DISEASE

Suggest the following recommendations to those at risk of dry eye disease:

4.5.1. Avoid excessive movement and windy conditions

4.5.2. Avoid hot, dry environments since both heating and air conditioning can worsen dry eye disease

4.5.3. Use humidifier to keep the air moist. Adding moisture to the air reduces dry eye symptoms

4.5.4. Wear wrap around glasses to reduce effect of wind on ocular surface to reduce evaporative dry eye symptoms.

4.5.5. Recommend taking frequent breaks while reading, seeing television and using mobile phone or computer devices.

4.5.6. Position computer screen below eye level to reduce lid aperture and minimize tear evaporation

4.5.7. Recommend refraining from smoking and exposure to secondary smoke

4.5.8. Recommend use of hot compresses and eye massage

4.5.9. Recommend use of artificial tears and lubricating gels as soon as symptoms of dry eye disease appear

HOW THIS STG WAS DEVELOPED

BACKGROUND

A Task Force was constituted by the National Health Systems ResourcesCentre under the aegis of the Ministry of Health & Family Welfare to guide the development of Standard Treatment Guidelines (STG) in India. The Task Force subsequently approved the draft STG development manual of India (Part 1) for development of adapted guidelines. In addition, it approved a list of 14 topics recommended by a subgroup of the task force appointed to select prioritized topics for STG development. These 14 topics are from 10 clinical specialties for which the first set of STGs will be developed. The topic of Dry Eye management in India is included in this first list and the task of developing STG on Dry eye was delegated to the Clinical Sub Group on Ophthalmology.

OVERVIEW

The STG on Dry Eye management was developed by a team of ophthalmologists specialised in treatment of Cornea & External eye diseases experienced in management of dry eye syndrome in India. The recommendations in the STG were adopted/adapted from the American Academy of Ophthalmology 22 (2013) Preferred Practice Pattern on Dry Eye as the principal source guideline, which is available from and full reference provided in the following reference:

American Academy of Ophthalmology Cornea/External Disease Panel.Preferred Practice Pattern® Guidelines. Dry Eye Syndrome. San Francisco, CA: American Academy of Ophthalmology; 201322. Available at: www.aao.org/ppp.

The processes and methods used in developing this STG draw on those outlined in the STG development manual of India for development of adapted guidelines and summarized in the Stepwise guide on STG development. The figure below contains a schematic of the process followed and each of the steps are detailed in subsequent sections below.

Steps followed during the development of the STG on Dry Eye Management are as follows:

Dry Eye Treatment STG Subgroup established

A multi-disciplinary group consisting of health professionals, subject matter experts in various fields and a patient representative undertook the development of this evidence-based STG on dry eye treatment. Once the Ophthalmology Sub Group co-ordinator in collaboration with the Task Group members constituted and recommended the multi disciplinary expert members, Official letters of invitation were sent from the NHSRC head office.

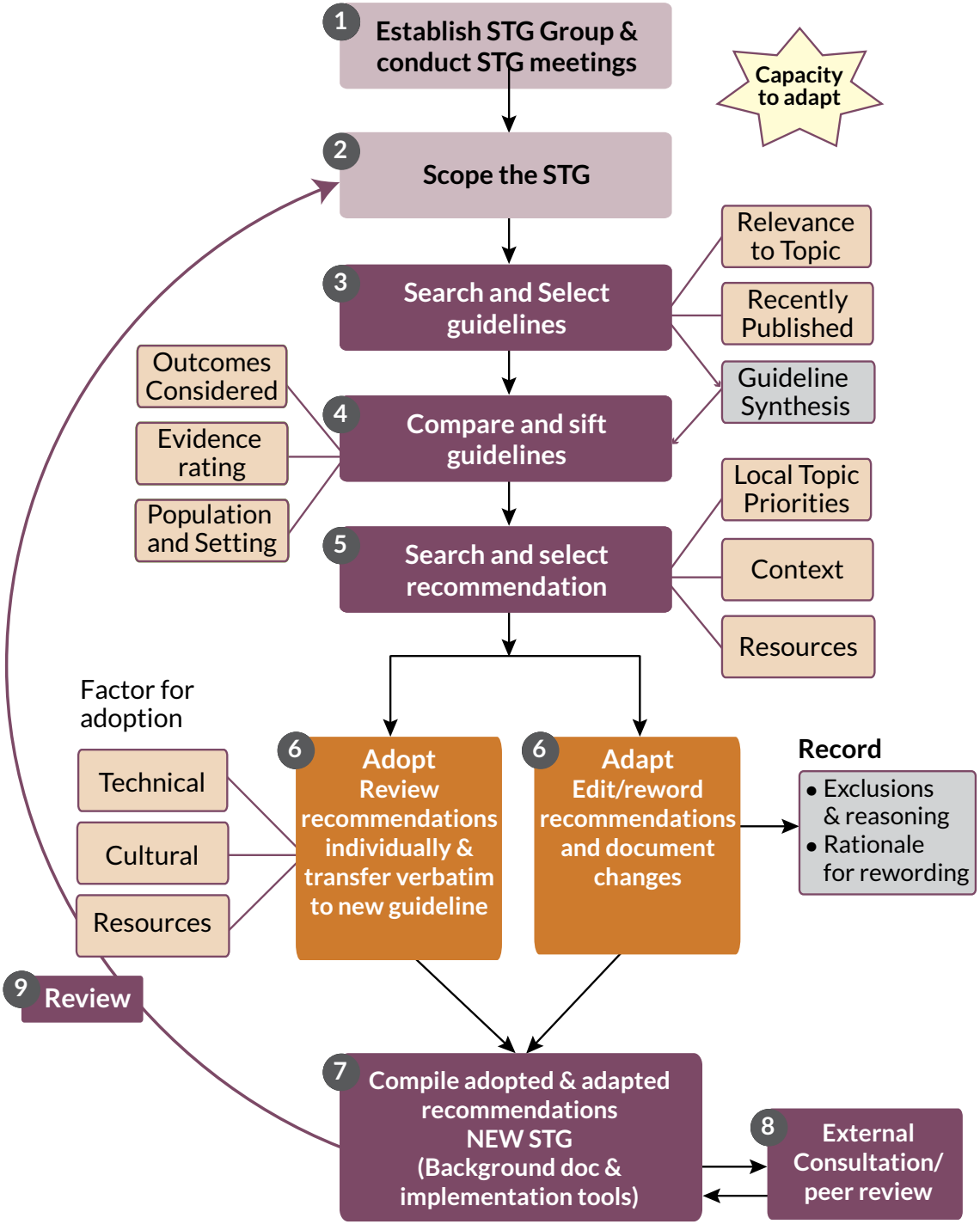
The names of the Ophthalmology Sub group members in the STG on Dry Eye management, their specialities and organization affiliation are listed here:

Taskforce member: Dr. R. D. Ravindran, Chairman, Aravind Eye Care System

Coordinator Dr. Krishna Das, Medical Consultant- Glaucoma Services & Director, Human Resources, Aravind Eye Care System

Experts

1. Dr. N. V. Prajna, Chief,Cornea Services, Aravind Eye Hospital, Madurai
2. Dr. Parveen Sen, Vitreo Retina Specialist SankaraNethralaya, Chennai, India.
3. Dr.Virender S Sangwan, MS , L V Prasad Eye Institute, Hyderabad
4. Dr. ParthaBiswas B B Eye Foundation, Kolkatta
5. Dr. Revathy, Consultant, Cornea Services, Aravind Eye Hospital, Coimbatore
6. Dr. Vikram, Consultant, Cornea Services, Aravind Eye Hospital, Coimbatore
7. Dr. Ashish, Consultant, Cornea Services, Aravind Eye Hospital, Madurai
8. Dr Lukshey Dudeja, ophthalmologist, Cornea Services, Aravind Eye Hospital, Madurai


1 Establish STG Group & conduct STG meetings
Capacity to adapt
2 Scope the STG
3 Search and Select guidelines
Relevance to Topic
Recently Published
Guideline Synthesis
Outcomes Considered
Evidence rating
Population and Setting
4 Compare and sift guidelines
5 Search and select recommendation
Local Topic Priorities
Context
Resources
Factor for adoption
Technical
Cultural
Resources
6 Adopt
Review recommendations individually & transfer verbatim to new guideline
6 Adapt
Edit/reword recommendations and document changes
Record
• Exclusions & reasoning
• Rationale for rewording
9 Review
7 Compile adopted & adapted recommendations NEW STG (Background doc & implementation tools)
8 External Consultation/ peer review

Physician/Private Practitioner/Paramedical personnel and Patient Right Group/NGO:

1. Dr. Sangumani, Physician, Asst Professor of Medicine in Madurai Medical College, Madurai 20
2. Dr. Ramesh Dorairajan, Private Practitioner, Sundar eye Hospital, Chennai
3. Dr. Valluvan, Primary care practitioner, Vriddhachalam, Tamil nadu
4. Mrs. Alees Mary, Staff Tutor, Aravind Eye Hospital, Madurai
5. Mr. Nan Narayanan, Freelance Faculty on soft skills and HR consultant, Madurai

Rapporteur:

1. Mr. V. Vijayakumar, Faculty, LAICO, Aravind Eye Care System, Madurai
2. Mr. D. Yesunesan, Faculty Associate, LAICO, Aravind Eye Care System, Madurai

A smaller writing group was formed from the above listed multi-disciplinary team along with Rappotaeurssupporting the writing of the STG document/s. The members of the working group were:

1. Dr R Krishnadas (Ophthalmology Sub Group Co ordinator)
2. Dr R Revathy (Chief Consultant, Cornea Services, Aravind Eye Hospital, Coimbatore)
3. Dr Vikram (Consultant, Cornea Services, Aravind Eye Hospital, Coimbatore)
4. Dr Ashish (Consultant, Cornea Services, Aravind Eye Hospital,Madurai)
5. Mr. V. Vijayakumar (Faculty, LAICO, Aravind Eye Care System, Madurai
6. Mr. D. Yesunesan (Faculty Associate, LAICO, Aravind Eye Care System, Madurai

All the members of the writing group consisted of chiefly faculty from the Aravind eye hospital, the institution to which the Sub group facilitator was affiliated, principally to facilitate frequent discussions and face to face meetings which would be logistically easier. The recommendations/guidelines and the entire document on STG of Dry eye management, however was finalized by consensus by repeated discussions with all the Sub group members.

The Dry Eye Syndrome STG Sub Group (ophthalmology) members wrote the Dry Eye Syndrome STG for practice in India. The members of the Sub Group in Ophthalmology elaborately reviewed the available source documents for the treatment guidelines on dry eye management, and evolved the STG by meeting in person once and conducting other reviews by e mail discussion to develop a consensus over the final version of the treatment guidelines. Information for the STG clinical Sub Group members on the details of the processes and methods enumerated and elaborately delineated in the STG development draft manual and the role of the STG clinical sub group members were shared with all the members to understand their role and responsibilities in evolving the STG on dry eye syndrome. After a brief deliberation to individual members over telephonic conversation on the purpose of the STG, the standard set of slides on the detailed process of STG development provided by the NHSRC were shared with all the members of the Ophthalmology Sub Group.

The draft scope of the Dry eye management STG and the search terms for identifying and compiling the existing relevant guidelines compiled by the facilitator after receiving multiple input from the constituent sub group domain experts (Cornea experts) were shared with all the members and adopted after several rounds of discussion and consensus by e mail. Subsequently a detailed work plan to search and select available guidelines, compare and select recommendations was also formulated by the Sub Group facilitator in consultation with the members of the Sub Group.

The STG Subgroup met once face to face in December 2015 in Madurai (Add minutes of the meeting, photographs of attendees, list of those who attended, reasons for those who could not attend). The members of the Working Group met weekly before the face to face meeting of the Sub Group in December 2015 since the orientation discussion with the working group members in June 2015. The orientation of the working group members briefed on the rules of operation based on the STG development manual, consistent use of terminology and definitions, with assistance of the structured power-point presentations provided to the Ophthalmology Sub Group Co Ordinator by the NHSRC / NICE during the Induction & training meeting held in New Delhi on 25-27 May, 2015. The STG development manual and the various structured presentations provided by NHSRC were once again discussed with the members of the sub group These presentations earlier had been shared by e mail prior to formulating the guidelines on dry eye management.

Scoping the STG

Dry Eye Management guidelines proposed to be evolved by the Sub Group on Ophthalmology was translated into a scope prior to detailed discussion on the treatment recommendations. Scoping of Dry Eye management was drafted by the Sub group facilitator in consultation with the members and finalized by consensus on discussion by e mail. The purpose of the Scope was to ensure key clinical issues in dry eye management are covered by the STG, set the boundaries of the development work and provide a clear framework to enable the entire guidelines/recommendations and the methodology employed to evolve STG were within the priorities agreed with NHSRC and to be conducted within the specified, agreed timelines and ensure compilation of the existing guidelines relevant to the scope of the chosen area of the STG. The Scope defines the population that will and will not be covered by the recommended guidelines on dry eye management, key clinical issues and clinical management that will be included and various types of intervention and management strategies to be included or excluded including clinical evaluation, diagnostic tests, medical and surgical therapies and intervention, patient counselling and education, lifestyle advice and rehabilitation. The Scoping document is also expected to cover the health care setting relevant to the STG as well as the expected outcomes and any relevant adverse effects of recommendations/ interventions covered in the STG. The Scoping of dry eye guideline, based on this broad framework, was subject to multiple revisions based on the opinion and feedback from the Sub-Group members before it was finalized. The Scope of the STG on Dry eye management, initially drafted by the facilitator with the assistance of the writing group in July 2015,was reviewed, discussed and finally approved by the STG Sub Group (Ophthalmology) in August 2015. The final version of the Scope on Dry eye management is provided in detail in Section 3 of this document on page 3.

Briefly, the Scope of the document on dry eye treatment guidelines includes:

1. The guidelines will cover all persons with signs and symptoms suggestive of dry eye disease at primary, secondary and tertiary levels of eye care.
2. Establishing diagnosis by clinical evaluation and diagnostic tests and treatment recommendations based on severity
3. Recommendations on prevention of dry eye disease, patient counselling
4. Provision of Evidence based treatment guidelines of dry eye for eye care providers at every level of care

5. Patient comfort & relief of symptomatology from dry eye disease
6. Limiting ocular morbidity from dry eye disease& prevention of complications such as visual loss, infection and ocular surface structural damage

The guidelines will not include cost evaluation and cost impact analysis of dry eye treatment, although all recommendations and guidelines have been considered with cost effectiveness of intervention as a major consideration. Recommendations from the Source guidelines which are expensive and lack sufficient evidence of efficacy have been adapted to suit the clinical care practice and processes widely followed by eye care practitioners in India experienced in management of dry eye syndrome after substantive discussion with the Sub group members and domain experts and evolving a consensus based approach. Details of drugs used in dry eye management, interventions and surgical procedures and the adverse effects of the treatment approaches to dry eye and any rehabilitative procedures is also not covered in detail. The STG will be reviewed by the Sub Group members once in three years for any major changes in recommendations of dry eye management which will be submitted to NHSRC task force on STG for approval.

Search & Select Guidelines

The STG Working group search for published evidence based guidelines on dry eye syndrome management. The National Guidelines Clearinghouse (NGC), NICE, WHO websites were accessed and a google search was also performed to obtain available guidleines, especially since many evidence based guidelines on dry eye management were not listed in the guidline.gov / NGC websites. Some of the available guidelines on dry eye treatment included the 2007 report of the International Dry Eye Workshop, the American Academy of Ophthalmology Preferred Practice Pattern Guidelines on Dry Eye Syndrome[22], 2013 (www.aao.org/ppp), and the All India Ophthalmological Society (AIOS) Preferred Practice Pattern Series (2013) on dry eye syndrome. Some of the additional guidelines considered by the Working group included the American Optometry Association Dry eye guidelines, Canadian Optometry dry eye guidelines, NHS Dry eye treatment guidelines, and the Korean guidelines for diagnosis and management of dry eyes. The AIOS Preferred pattern Series on Dry eye was evolved by the Indian Ophthalmologists and was completely adapted from the AAO preferred practice pattern on dry eye syndrome. The STG Working group on dry eye management decided to consider the AAO dry eye guidelines as the principle source document since this was the only dry eye management guideline which had

graded evidence at least partially acceptable to AGREE 2 method (Appraisal of Guidelines Research and Evaluation). AAO guidelines on dry eye treatment was widely perused by the working group of STG to recommend guidelines for treatment of dry eye in India based on the Adopt/ Adapt method as described in this document subsequently.

Compare & Sift Guidelines

After sifting through all the available guidelines, the working group selected two guidelines as the primary source guidelines for evolving dry eye treatment guidelines for STG in India: the AAO Preferred Practice Pattern guidelines for dry eye (2013) and the AIOS Preferred Practice Series on Dry Eye Disease (2014) following a review of all the selected guidelines. The selected guidelines were compared in terms of relevance to the topic and key clinical issues listed in the Scoping document of the dry eye, evidence ratings, target population and their applicability and relevance to management of dry eye disease in Indian context. Most recently published guidelines were preferred owing to the necessity to include the most updated, evidence based recommendations. The selected guidelines were subsequently approved by the STG Sub Group on Ophthalmology as the primary source guidelines for reference to evolve India specific recommendations for management of dry eye for the STG. Before the face to face meeting of the Sub group members, the working group had prepared a draft scope for the STG (step 2), performed background research on available evidence based source guidelines (refer step 3 above), compared and sifted the guidelines to select evidence based recommendations developed according to internationally accepted methodology for guideline development with subsequent draft of proposed recommendations (adopted / adapted) from the source guideline. The first draft of guidelines adopted or adapted from the source document were submitted for review and final adoption by the Ophthalmology STG Sub group in September 2015

Search & Select Recommendations

Each of the key clinical issue identified in the Scoping document of the STG was revisited and relevant recommendations were searched for in the AAO Dry eye treatment Source Guidelines. All the major recommendations from the AAO Preferred Practice Pattern on dry eye were studied and reviewed by the experts group of the STG sub group with relevance to their application and clinical practice in the Indian context, with specific consideration to the cost, safety, efficacy, availability, accessibility and practical

application of the various recommendations on diagnosis and management of dry eye syndrome. All evidence based recommendations provided in the source document guideline were critically considered by the expert ophthalmologists in the light of their clinical experience of management of dry eye in India, as well as the available expertise, and resources for implementation in clinical practice. While most recommendations from AAO source guidelines were adopted in the STG on dry eye management in India, some of the recommendations were adapted. The reasons for adaptation and the evidence based support for adapted recommendations have also been provided as references from peer reviewed literature. Each recommendation listed in the draft was circulated to all subgroup members prior to the face to face meeting and subsequently discussed in the Sub group meeting held in Madurai *(provide date and details of the meeting held, with members attended including details of signing of conflict of interest forms)*

Adopt/Adapt Recommendations

An earnest attempt was made by the Working Group while adopting recommendations from the Source Guidelines to strictly maintain the standards (evidence) used in the original statement of recommendations. A systematic approach was followed to ensure quality and standards of original recommendations were retained. The STG clinical sub group was required to make a series of judgments on the new STG recommendations formulated by the Working group. These consultations with the Sub Group members was entirely done over e mail communications and the finalized draft of recommendations were evolved over consensus between the experts group. The final draft of recommendations developed after review and consensus within the experts group was re circulated by e mail to all the Sub Group members for careful consideration, critical review and analysis and any further recommendations. The entire list of draft recommendations agreed over e mail were presented to the Sub Group members in the face to face meeting held in Madurai for final approval and signing of declaration of conflict of Interest. Reasons for each recommendation being adapted were documented to ensure quality assurance. The various options followed by the Working Group in drafting the STG recommendations included:

Adopted Recommendation: this step comprised of transferring a recommendations from the source guideline verbatim to the new STG. In deference to the requirements of the STG task force recommendations, however, the recommendations from the source guideline, even those adopted were transferred to active voice format.

Adapted recommendations : this step comprised of editions / additions / deletion or other suitable modifications in the original source guideline recommendations to ensure their suitability and compatibility or practical application for clinical practice of dry eye management in India. Every attempt has been made by the Working group to ensure when adapting original guidelines, evidence underlying the recommendations is preserved. Additional, evidence based support form peer reviewed literature was actively sought and has been provided to support any adaptations considered in the STG recommendations.

Implementation challenges for eye care providers and patients were considered by the Sub group members when conclusions were made to adopt or adapt recommendations. Factors considered included public/private health care infrastructure available across various levels of eye care, accessibility of the various facilities and resources in the primary, secondary and tertiary level of eye care. Discussions had begun with segregation of recommendations across various levels of eye care in the community to suit primary, secondary, and tertiary eye care providers. Owing to a consensus in the STG task group that recommendations may be combined to reflect the guidelines to be suitably applied by all levels of health care providers, with clear recommendations to refer the patient to a higher level of care provider if initial line of management tends to be refractory to treatment. The Clinical Sub Group has therefore collated all recommendations as a single list of guidelines for all care providers.

The working group compiled a list of the proposed recommendations which was reviewed by the STG sub-group. Each proposed recommendation was discussed and debated before a decision was taken on whether it can be adopted or needed adapting to the Indian context. Few recommendations were excluded as they were considered inappropriate in view of the required resources/ cost and/ or feasibility. There was significant debate about use of systemic azithromycin, omega -3 Essential Fatty Acids, Oral Pilocarrpine, Cevimiline and punctal plugs for management of dry eyes in India. Many of the recommendations on the use of these drugs/ devices provided in the AAO source document have been eliminated from recommendations by the Sub group members by discussion and consensus owing to either their cost, non-availability or lack of sufficient evidence to support their recommendation in the literature. Use of lasers in punctal occlusion suggested in the original source guideline have also been eliminated to adapt in the STG recommendations, since equally efficacious alternative of thermal cauterization has been supported in the peer reviewed literature. The details of adopted and adapted

recommendations and the rationale for adaptation are available in the Annexure names "Adopt/Adapt guidelines".

Review by Internal harmonization Group

The initial draft of recommendations of Standard treatment guidelines for management of Dry eye disease in India was submitted to the Internal harmonization Group for review and revision on October 20, 2015. The Internal Harmonization group had critically reviewed the initial draft on Dry eye treatment guidelines and had provided the following recommendations in its communication dated 16th January, 2016. The Working Group on Ophthalmology Clinical Sub Group substantively worked on the recommendations and suggestions to have all the feedback incorporated in their revised draft and submitted to the broader Experts Group for consensus. The Experts Group, by consultation and discussion by series of e mails, agreed to incorporate all the recommendations of the Internal harmonization Group, except:

1. The recommendation of the IHG on including the Stem cell transplantation as a modality of treatment of Dry eye disease was not accepted by the Experts Group. All the experts were unanimously of the opinion that limbal stem cell transplantation, currently has little role in management of dry eye disease and there was no evidence based consensus in the published literature to support the role of limbal stem cell transplantation in dry eye management. This recommendation has not been accepted by the Experts Group.
2. The IHG was of the opinion that Autologous serum had no role in management of dry eye disease in India. The Experts Group was of the opinion that autologous serum could be prepared by most laboratories in the teriary eye care centres and Centres of excellence in management of Corneal disease and that autologous serum could be employed in management of moderate to severe dry eye disease, which otherwise is poorly responsive to other conservative methods of therapy.

The final draft of the STG on Dry eye management, with the suggestions of IHG incorporated was submitted for review by the Ministryof Health on 12th May, 2016.

NOTE

MINISTRY OF HEALTH AND FAMILY WELFARE
Government of India
Nirman Bhawan, New Delhi