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THE ROLE OF RETINAL IMAGING AND COMPREHENSIVE EYE EXAMINATIONS IN THE CARE OF THE PATIENT WITH DIABETES

BACKGROUND

Diabetes mellitus (DM) is a chronic, multi-system disease. Diabetes complications in the eye include diabetic retinopathy (DR), dry eye, cataracts, optic disc disease, as well as eye muscle, pupil, and eyelid involvement. DR is the leading cause of new-onset blindness in working-aged Americans, despite proven methods of care and treatment. The value of comprehensive eye examinations by an optometrist or ophthalmologist and appropriate treatment is well documented.¹⁻³, The American Optometric Association Optometric Clinical Practice Guideline on Care of the Patient With Diabetes Mellitus⁴ and the American Academy of Ophthalmology Preferred Practice Pattern for Patients with Diabetes⁵ currently recommend an annual dilated comprehensive eye examination for patients with DM. The American Diabetes Association (ADA) Clinical Practice Recommendations⁶ support annual follow-up evaluations for persons with diabetes by “an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management.” The ADA makes allowance for less frequent exams (at intervals of 2-3 years) “after one or more normal eye exams” and conducting retinal assessment “with retinal photographs (with or without dilation of the pupils) read by experienced experts.”

The value of a comprehensive eye examination by an optometrist or ophthalmologist is well established. Through a comprehensive examination, an optometrist or ophthalmologist not only detects and diagnoses possible ocular complications of DM, including cataracts, glaucoma, retinopathy, and refractive error, but also establishes a recommended treatment plan for each patient. The examination also provides another opportunity to educate the patient and reinforce the importance of appropriate blood glucose control, blood pressure control, and discussion of other risk factors for onset and progression of DR. Currently, 62% of patients with DM receive an annual dilated eye examination by an optometrist or ophthalmologist.⁷ Issues of access, cost, lack of education, and denial may contribute to these compliance rates.

Advances in technology provide an opportunity to extend timely diabetes eye care to the growing number of persons with diabetes. Retinal imaging to assess the presence or level of diabetic retinopathy has become more prevalent and is accepted in various clinical and research settings. Such assessment is likely to become more prevalent as

technology and programs advance and become more sophisticated. Digital retinal imaging systems may be a useful tool to increase access and adherence to demonstrated standards of care among individuals with DM. This imaging does not replace a comprehensive eye examination by an optometrist or ophthalmologist, but offers an opportunity to assess the presence and degree of diabetic retinopathy and diabetic macular edema.

THE ISSUES

1. What is the role of telemedicine for diabetic retinopathy (DR) and diabetes mellitus (DM)?
2. What criteria should present and future technologies meet to be approved for telemedicine for DR?
3. How does a telemedicine program for DR define expectations for patients and care providers?

RESPONSE RATIONALE

The American Optometric Association (AOA) recognizes the potential benefits of telemedicine programs for screening, diagnosis, and management of DR. These potential benefits have been well-elucidated in the ophthalmic literature⁹⁻¹³. Some of the benefits include early identification of sight threatening DR, improving access to diabetes eye care, annual assessment for presence or progression of retinopathy in defined circumstances, and maintaining a consistent quality of care. Potential shortcomings of telemedicine programs for DR include unrealistic or undefined expectations of patients or care providers, and technological challenges such as interoperability, failure of a system to meet minimal HIPAA, DICOM, and other standards, or lack of stability or sustainability of a program.

The American Telemedicine Association (ATA) has prepared and promulgated Clinical Practice Recommendations for Telehealth and Telemedicine programs for DR¹⁴. These recommendations address clinical, technological, and administrative components of such programs. Clinically, the recommendations suggest that the accuracy of a telemedicine program to identify DR be measured against Early Treatment Diabetic Retinopathy Study seven standard field, stereoscopic, color 35-mm film photos (ETDRS photos), a universally accepted standard for diagnosing level of DR and diabetic macular edema.¹⁵ Clinically, the ATA defines 4 categories of care: (1) category 1—the program identifies no or very minimal DR vs. the presence of DR; (2) category 2—the program distinguishes between the presence or absence of sight-threatening retinopathy; (3) category 3—the program identifies clinical level of DR (mild, moderate, severe nonproliferative DR; proliferative DR; DME) to match clinical dilated retinal examination and recommended treatment follow-up, and (4) category 4—a program meets or exceeds the ability of ETDRS photos to diagnose DR in any clinical or research setting.

RESPONSE TO THE ISSUES

1. The AOA and other professional organizations have historically recommended annual comprehensive dilated eye examinations by an optometrist or ophthalmologist for persons with DM. Telemedicine utilizing seven standard field stereoscopic photos and interpreted by an optometrist or ophthalmologist or imaging validated to match diagnosis from these photos may serve to increase adherence to demonstrated standards of care for persons with DM and increase the number of DM patients being evaluated.

The AOA recognizes that properly designed and executed retinal imaging programs have a role in providing scheduled assessment of presence and level of DR in defined circumstances.

2. The AOA recognizes and endorses the ATA Practice Recommendations for validating telemedicine for DR. The AOA endorses appropriate validated telemedicine programs using remote digital imaging for detecting and monitoring DR when such programs demonstrate ability to match dilated retinal examination or the accepted standard of Early Treatment Diabetic Retinopathy Study seven standard field 35-mm stereoscopic slides. Furthermore, the AOA recommends that the telemedicine program must clearly define patient and providers' expectations for the programs, be operationally sound, and meet appropriate technical standards.
3. Approved telemedicine programs should clearly define the expectations for patients and health care providers. Validated digital retinal imaging systems only identify retinopathy and do not replace the other important elements of a comprehensive eye examination. Timely and appropriate comprehensive dilated eye examinations by an optometrist or ophthalmologist should continue to be clearly stated as the recommended standard for persons with DM.

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