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Identification of Diabetic Retinopathy and Ungradable Image Rate with Ultrawide Field Imaging in a National Teleophthalmology Program

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Purpose: To compare diabetic retinopathy (DR) identification and ungradable image rates between nonmydriatic ultrawide field (UWF) imaging and nonmydriatic multifield fundus photography (NMFP) in a large multistate population-based DR teleophthalmology program.

Design: Multiple-site, nonrandomized, consecutive, cross-sectional, retrospective, uncontrolled imaging device evaluation.

Participants: Thirty-five thousand fifty-two eyes (17 526 patients) imaged using NMFP and 16 218 eyes (8109 patients) imaged using UWF imaging.

Methods: All patients undergoing Joslin Vision Network (JVN) imaging with either NMFP or UWF imaging from May 1, 2014, through August 30, 2015, within the Indian Health Service–JVN program, which serves American Indian and Alaska Native communities at 97 sites across 25 states, were evaluated. All retinal images were graded using a standardized validated protocol in a centralized reading center.

Main Outcome Measures: Ungradable rate for DR and diabetic macular edema (DME).

Results: The ungradable rate per patient for DR and DME was significantly lower with UWF imaging compared with NMFP (DR, 2.8% vs. 26.9% [$P < 0.0001$]; DME, 3.8% vs. 26.2% [$P < 0.0001$]). Identification of eyes with either DR or referable DR (moderate nonproliferative DR or DME or worse) was increased using UWF imaging from 11.7% to 24.2% ($P < 0.0001$) and from 6.2% to 13.6% ($P < 0.0001$), respectively. In eyes with DR imaged with UWF imaging (n = 3926 eyes of 2402 patients), the presence of predominantly peripheral lesions suggested a more severe level of DR in 7.2% of eyes (9.6% of patients).

Conclusions: In a large, widely distributed DR ocular telehealth program, as compared with NMFP, nonmydriatic UWF imaging reduced the number of ungradable eyes by 81%, increased the identification of DR nearly 2-fold, and identified peripheral lesions suggesting more severe DR in almost 10% of patients, thus demonstrating significant benefits of this imaging method for large DR teleophthalmology programs. *Ophthalmology 2016;■:1–8 © 2016 by the American Academy of Ophthalmology.*

Remote retinal imaging to evaluate diabetic retinopathy (DR) has the potential to lower barriers to eye examination and to expand care opportunities to a large population of diabetic individuals who otherwise may not receive traditional care.[1,2] Central to DR teleophthalmology programs is an imaging device that is usable in diverse settings, accurately identifies eyes with DR, and appropriately stratifies the risk for visual loss. Speed of image acquisition and reduced image evaluation time also are important, especially to large programs.

The Indian Health Service (IHS) is a United States government agency that provides health care to 2.2 million persons of American Indian (AI) and Alaska Native (AN) ethnicity. Because the AI and AN population has a 42% rural distribution, there is limited access to specialty care in some areas served by the IHS. The IHS–Joslin Vision Network (JVN) Teleophthalmology Program has been in continuous clinical operation since 2001, providing DR evaluation to the AI and AN population. The IHS–JVN Teleophthalmology Program currently is deployed in 97 health care facilities in 25 states and evaluates approximately 18 000 patients annually (geographic distribution of IHS–JVN Teleophthalmology Program sites is shown in Fig 1). The IHS–JVN Teleophthalmology Program follows a clinically validated protocol and work flow using stereoscopic retinal imaging by nonmydriatic multifield fundus photography (NMFP) at remote sites to determine DR and diabetic macular edema (DME). Retinopathy assessment based on protocol grading of the retinal images is performed at the IHS–JVN Teleophthalmology Program National Reading Center located at the Phoenix Indian Medical Center. Ultrawide field (UWF) retinal imaging using scanning laser ophthalmoscopy was introduced in selected IHS–JVN Teleophthalmology

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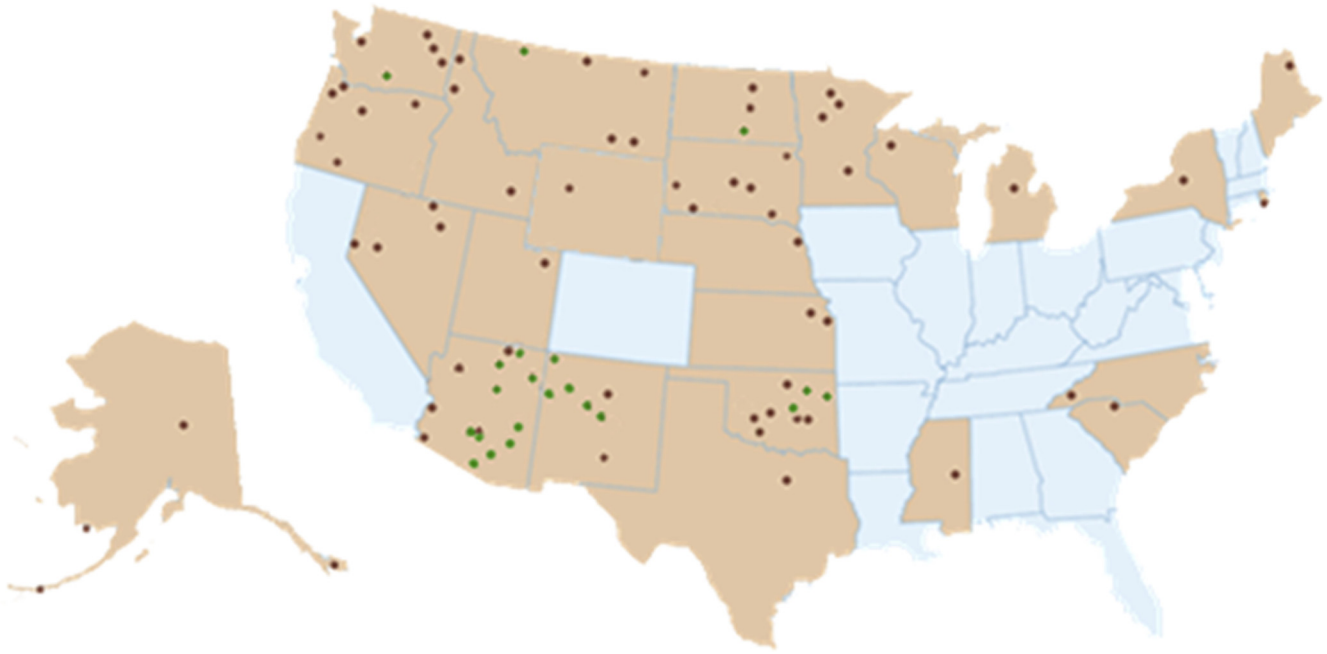

Figure 1. Location of IHS-JVN imaging sites by state (shaded red) and city (diamond bullets). Sites where ultrawide field imaging devices were deployed are marked as green.

Program sites in October 2014, given its favorable comparison with gold standard stereoscopic 7-field Early Treatment Diabetic Retinopathy (ETDRS) photography,[3,4] its potential benefits of reduced image acquisition time,[4] and its ability to image more than twice the total retinal surface area.[5] The purpose of this study was to evaluate the effect of implementing UWF imaging within this large multistate population-based DR ocular telehealth program in terms of DR identification and ungradable image rates as compared with the program's standard NMFP.

Methods

This was a multiple-site, nonrandomized, consecutive, cross-sectional, retrospective, uncontrolled imaging device evaluation. We reviewed the electronic medical records of all patients who underwent IHS−JVN Teleophthalmology Program retinal imaging from May 1, 2014, through August 30, 2015, across all 97 sites. During the study period, UWF imaging was deployed in 21 sites with the geographic distribution shown in Figure 1. Patients underwent standardized imaging either with NMFP (NW6S; Topcon Medical Systems, Inc., Paramus, NJ; stereoscopic pairs of three 45° and two 30° retinal fields and one external image) or UWF imaging (Daytona, Optos, plc, Dunfermline, United Kingdom; single 200° stereoscopic image pair). The deployment of UWF imaging began on October 1, 2014, and was staged incrementally across 21 sites, with the remaining sites continuing to use NMFP. Both NMFP and UWF imaging were acquired using corresponding standardized protocol by certified imagers. All imagers were trained to identify ungradable images at the time of imaging, and images were reobtained up to 3 times if the imager considered image quality to be poor. Licensed optometrists (D.C.) certified for image grading within the program evaluated all images in a centralized reading center under direct supervision of an ophthalmologist (M.B.H.) experienced in grading retinal images for diabetic retinal disease. Grading was conducted according to protocols for NMFP[6,7] and UWF imaging[4] that have been validated previously to compare favorably with mydriatic ETDRS 7-field standard imaging.

Graders evaluated all images on identical color-calibrated liquid crystal display high-resolution monitors with identical reading station configurations for both imaging types. Detailed protocols for evaluating UWF and NMFP images have been described previously and have shown substantial agreement with grading of dilated 7-field ETDRS standard photography.[4,6] Both protocols are based on the ETDRS classification and evaluate extent and severity of individual retinal lesions in comparison with ETDRS standard photographs to determine the severity of DR and DME.

All images were acquired through undilated pupils. An eye was considered ungradable if there was inadequate photographic quality or if media opacity made it impossible to determine whether DR lesions were present in the images of that eye. If one or more disc areas of retina were visible in each ETDRS-defined photographic field in either NMFP or UWF imaging and that area was free of the characteristic lesion, it was graded as "no evidence" rather than "ungradable." If the characteristic lesion was present in the unobscured part of the field, it was estimated for the entire field. In the absence of definable lesions in the macula, no macular edema was entered, even if one image of the stereo pair prevented stereoscopic reading of the macula area.

Additionally, each UWF image was evaluated specifically for the distribution of hemorrhages or microaneurysms, or both, venous beading, intraretinal microvascular abnormalities, and new vessels elsewhere on the retina, as previously described.[8] Each DR lesion type was considered predominantly peripheral if more than 50% of the lesion being graded was located outside the ETDRS fields based on a standardized ETDRS grid.[5] Severity grading took into account both number and extent of the lesions being graded within the field. Any DR lesion type that was present