TELEMEDICINE JOURNAL AND e-HEALTH
Volume 10, Supplement 2, 2004

Online Continuous Quality Improvement for Diabetic Retinopathy Tele-screening

STEVEN H. STUMPF, Ed.D.,[1] DINESH VERMA, M.D., F.R.C.S.,[1]
ROD ZALUNARDO, Ed.D.,[1] TRACY ALY, C.R.A.,[2] ROBERT CHEN, M.H.A.,[1]
and LAURIE LABREE, M.S.[3]

ABSTRACT

Non-mydriatic digital fundus cameras constitute the key component for diabetic retinopathy tele-screening. This study investigated whether image capture skills acquired by non-professional photographers in a 1-day seminar and applied in a community setting may be reinforced and strengthened over time using an online continuous quality improvement (CQI) protocol. Approximately 20 amateur photographers from 13 independent sites were trained to capture images according to the recommended protocol: one 45° image per eye, centered between the macula and the optic nerve, without dilation. In total, over the 19-month project period, 58 non-professional photographers captured and submitted 2,917 images. A professional photographer evaluated each image online assigning a CQI score. CQI scores indicated acquisition, and maintenance of skills was sustained over the study period. Over 93% of the images were scored as sufficient for clinical grading. Exposure and focus proved to be the most difficult skills. Skills needed to operate the digital cameras were acquired with relative ease. The online CQI protocol reinforced photographer skills over a significant period of time even when considerable turnover was experienced. The use of digital fundus cameras is easy to learn for the non-professional photographer. Their use saves the cost of a professional photographer. An online CQI protocol is also an effective tool for reinforcing and ensuring skill transfer, especially when considerable turnover in photographers can be expected.

INTRODUCTION

DIABETIC RETINOPATHY requires acute care, but it may be preventable with effective screening programs. It is the major cause of visual impairment and blindness, to which underserved populations are especially vulnerable.[1–3] Effective preventive treatment with timely photocoagulation has been available for 2 decades.[4] Obstacles to stemming the tide of vision loss from diabetic retinopathy in the United States include the persistence of an established standard that relies upon a complete eye examination with dilation or, as an alternative, dozens of 35-mm photographs captured by a professional photographer for patients with diabetes[5,6] despite research that demonstrates the advantages of tele-screening.[7–10]

[1]Advanced BioTelecommunications and BioInformatics Center and [3]Department of Preventive Medicine, University of Southern California Keck School of Medicine, Los Angeles, California.
[2]Department of Ophthalmology and Visual Sciences, University of Iowa Roy J. and Lucille A. Carver College of Medicine, Iowa City, Iowa.

With the widespread implementation of tele-screening programs for diabetic retinopathy in European countries[11–13] and the failure of state-side screening programs to have impact on the most vulnerable populations at high risk for vision impairment,[14] it may be only a matter of time before tele-screening programs are deployed widely in this country.

The Early Treatment Diabetic Retinopathy Study (ETDRS) established the gold standard for photographic assessment of severity of diabetic retinopathy.[15] The ETDRS protocol involves the use of seven standard field 35-mm stereoscopic color fundus photography, requiring the services of a professional ophthalmic photographer. With the advent of digital image resolution rivaling that of 35-mm film, the obvious benefits of remote transmission, and the ability to assess the photographs, digital fundus imaging may be most appropriate for screening diabetic retinopathy. A centralized digital reading center complete with online image evaluation tools and remote web-based access for primary care clinics completes the operational technological requirements for patients and clinicians.

Recent studies have demonstrated substantial agreement between 45° non-mydriatic three-field digital color imaging and the ETDRS gold standard.[16] In another study, two-field, 50° non-stereo digital images compared favorably to the live examination in the detection of retinopathy and macular edema.[17] Digital monochromatic imaging may even be better than an eye examination with dilated pupils by board-certified ophthalmologists.[9] In most studies, the extra cost and the availability of a trained certified photographer at each primary care setting have not been addressed adequately. Previous research has challenged the suitability of digital images for clinical evaluation,[18] finding 99% of images captured (n = 108) as unsuitable for clinical review. The authors indicated the importance of error related to photographer skills in capturing images sufficient for clinical evaluation. Meanwhile, the number of tele-screening programs continues to grow, especially in Southern California.[19]

The use of the digital camera as a plug-and-play device is an attractive feature in tele-screening. Certain systems obviate the need for a photographer by increasing the automation of image capture and review. Many screening programs typically use mid-levels as photographers.

We developed a web-based continuous quality improvement (CQI) protocol to instruct and reinforce the training of novice photographers. This study assessed the impact of implementing the CQI protocol on the quality of photographs in a multiple-site, remote digital screening program for diabetic retinopathy. We addressed the following key questions:

1. Was there an improvement in skills over time?
2. Did amateur photographers acquire image capture skills?
3. What were the most frequently cited skills for improvement?
4. Was any relationship observed between CQI scores and other factors such as number of images captured or photographer variance?

MATERIALS AND METHODS

The Topcon TRC NW6S digital non-mydriatic fundus camera (1,024 × 768 digital image) was deployed in 13 sites distributed throughout California for a diabetic retinopathy tele-screening program. Approximately 20 designated photographers, mostly recruited from clinic staff, were trained on four separate occasions during a 19-month period from August 2001 through February 2003. The designated photographers were trained to capture one 45° image per eye, centered between the macula and the optic nerve, without dilation. There was significant turnover, resulting in 58 amateur photographers capturing images across the 13 independent healthcare sites over the 19-month period.

In total, 2,917 images were captured and evaluated using a CQI protocol developed in collaboration with a professional ophthalmic photographer. The photographer reviewed the images online via a secure website using an online grading tool. She scored each image according to explicit criteria. Photographers received specific feedback in an electronic report, and they made adjustments in their technique accordingly. We analyzed CQI scores over the period of the study to address the study questions.

RESULTS

Changes in photographer skills over time

Clinical sites submitted images in batches reflecting two significant (and logical) epochs within the study period. Cycle 1 included 1,553 images over the first 8 months, reflecting the original training sessions and the 18 original sites. Cycle 2 included 1,364 images reflecting a refresher course for the original sites plus three new ones.

A CQI score approaching zero indicated fewer areas for improvement. The actual scores were generally low. Improvement was observed over time for all photographers across all sites over both cycles. Figure 1 shows the declining trend for both grant cycles. The overall CQI mean score for the entire project period was 0.651 (SD 1.122). The overall CQI scores for Cycles 1 and 2 were 0.695 (SD 1.121) and 0.601 (SD 1.123), respectively.

Seven sites received training in both cycles. A 29% reduction was observed in the aggregate mean scores from Cycle 1 to Cycle 2 (Table 1). Even though this change was not statistically significant ($p = 0.17$), it suggests improvement in skills over time.

Acquisition of image capture skills

The trend in image capture skills was generally positive. The unsuitable image rate (also referred to as technical failure) was extremely low. An unsuitable image was defined as one that did not have the correct field orientation, or was scored sufficiently high on the CQI grading tool to prevent clinical grading. Only 196 images (6.72%) were judged as unsuitable for reading. Conversely, 93.28% of them were judged suitable for clinical review.

Skills for improvement

Exposure and focus were cited most often as needing improvement ($p < 0.001$). Exposure was cited as needing improvement in 16.22% of the images, and focus was cited in 9.67% of images. Distribution of recommendations for improvement for all eight elements is presented in Table 2.

Relationship between CQI scores and other factors

The number of images submitted and the number of photographers varied widely by clinical site. For example, Site B submitted 425 images, while Site I submitted only 47. The mean number of images per site was 225.46. By contrast, Site C had the most photographers (10), who collectively submitted 320 images, while four other sites had as few as three photographers. Every site used at least three photographers. Typically, one photographer at

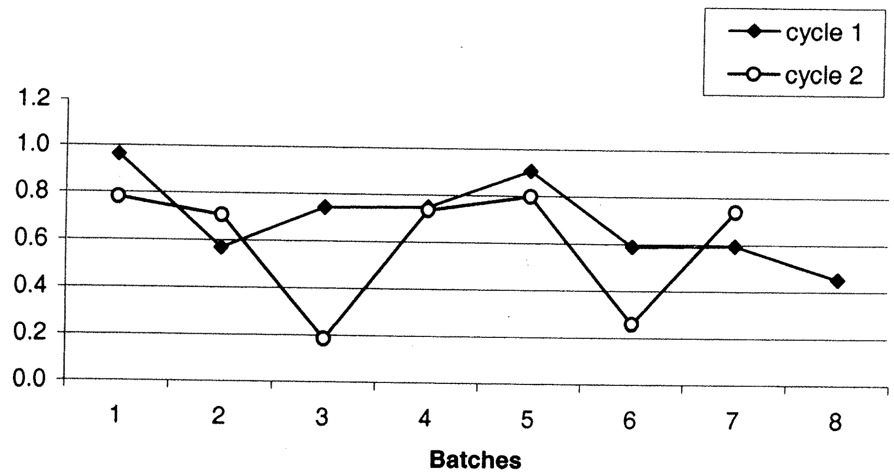

FIG. 1. CQI scores by batch for Cycles 1 and 2.

TABLE 1. COMPARISON OF CQI SCORES FOR SEVEN SITES RECEIVING BOTH TRAININGS

	Mean (SD) score
Cycle 1	0.804 (0.234)
Cycle 2	0.568 (0.249)
Decrease in score	0.236 (0.403)

each site submitted the majority of the images. The difference in scores between the photographer who captured the most images (Photographer 1) and the other photographers (Photographer *n*) was analyzed.

A negative mean difference indicates that Photographer 1 (the principal photographer) scored worse (lower score is better) than the other photographers. Except for Site C, there was no difference in score between Photographer 1 and the other photographers ($p > 0.05$). At site C the other photographers had lower (better) scores ($p = 0.002$).

DISCUSSION

The online CQI protocol developed for this study helped amateur photographers acquire and maintain skills necessary for capturing images for clinical grading by trained readers. CQI scores were generally low (lower is better), on average below 1.0, across the two cycles. The number of images that were judged insufficient for clinical grading was exceptionally low, consistent with earlier research identifying photographer training as the principal source of error.

The most difficult skills were exposure and focus, much like with taking any photograph. The professional photographer noted that exposure adjustments generally favored increasing the flash setting to accommodate small pupils. Patients with darker pigment often require a brighter flash. One way to compensate is to ensure that image capture occurs in a dimly lighted room and that the patient waits in a dimly lighted room ("dark adaptation") prior to image capture. Focus is a function of mastering the camera fine motor movements and recognizing the visual cues required to focus the image.

Tele-screening programs for diabetic retinopathy are likely to proliferate. Diabetic retinopathy can be controlled with effective screening. Traditional screening with a complete eye examination cannot meet the existing demand for patients with diabetes.

The validity of using digital images for screening purposes under controlled conditions is well documented in the literature. As programs proliferate, we can anticipate that predictable barriers to telemedicine will threaten to undermine successful implementation in this application.[20] One such barrier is the ability of photographers to capture sufficient images suitable for clinical review. These results are encouraging for the utility of the CQI protocol in supporting the tele-screening approach.

A web-based CQI program can strengthen tele-screening. Future research might examine photographer characteristics to determine if prior experience with, interest in, or familiarity with commercial digital technologies influences skill acquisition. This study demonstrates that amateur camera operators can readily learn to use the cameras to capture images sufficient for clinical evaluation.

ACKNOWLEDGMENTS

This study was performed at the USC Keck School of Medicine under a project funded by

TABLE 2. MOST COMMON PHOTOGRAPHER IMAGE ACQUISITION ERRORS

Type of error	*Percent of total images (95% confidence)*[a]
Exposure	16.22 (14.88, 17.55)
Focus	9.67 (8.6, 10.7)
Eyelash	6.68 (5.78, 7.59)
Dirty lens	5.73 (4.88, 6.57)
Field determination	4.53 (3.77, 5.28)
Camera distance	3.91 (3.20, 4.61)
Peripheral crescent	2.37 (1.81, 2.92)
Other	0.82 (0.49, 1.15)

[a]95% confidence interval using the normal approximation to the binomial distribution.

The California Endowment. A preliminary presentation was made at the 2003 America Telemedicine Association Annual Meeting and Exposition. Research was supported in part by NIH Vision Research Grant EY03040.

REFERENCES

1. Seddon JM. The differential burden of blindness in the United States. *N Engl J Med* **1991;**325:1440–1442.
2. Tielsch JM, Sommer A, Katz J, Quigley H, Ezrine S. Socioeconomic status and visual impairment among urban Americans. *Arch Ophthalmol* **1991;**109:637–641.
3. Sommer A, Tielsch JM, Katz J, Quigley HA, Gottsch JD, Javitt JC, Martone JF, Royall RM, Witt KA, Ezrine S. Racial differences in the cause-specific prevalence of blindness in east Baltimore. *N Engl J Med* **1991;**325: 1412–1417.
4. Ferris FL III. How effective are treatments for diabetic retinopathy? *JAMA* **1993;**269:1290–1291.
5. Verma D. Teleophthalmology meets Hollywood. *Healthcare Inform* **2003;**3:50–52.
6. Moss SE, Meuer SM, Klein R, Hubbard LD, Brothers RJ, Klein BE. Are seven standard photographic fields necessary for classification of diabetic retinopathy? *Invest Ophthalmol Vis Sci* **1989;**30:823–828.
7. Davis, RM, Pockl J, Bellis K. Improved diabetic eye care utilizing telemedicine: a randomized controlled trial. Poster presented at the Association for Research in Vision and Ophthalmology meeting, May **2003.**
8. Tennant MTS, Greve MDJ, Rudnisky CJ, Hillson TR, Hinz BJ. Identification of diabetic retinopathy by stereoscopic digital imaging via teleophthalmology: a comparison to slide film. *Can J Ophthalmol* **2001;**36: 187–196.
9. Lin DY, Blumenkrantz MS, Brothers RJ, Grosvenor DM. The sensitivity and specificity of single-field nonmydriatic monochromatic digital fundus photography with remote image interpretation for diabetic retinopathy screening: a comparison with ophthalmoscopy and standardized mydriatic color photography. *Am J Ophthalmol* **2002;**134:204–213.
10. Gomez-Ulla F, Fernandez MI, Gonzalez F, Rey P, Rodriguez M, Rodriguez-Cid MJ, Casanuera FF, Tome MA, Garcia-Tobio J, Gude F. Digital retinal images and teleophthalmology for detecting and grading diabetic retinopathy. *Diabetes Care* **2002;**25:1384–1389.
11. Lamminen J, Salminen L, Uusitalo H. Teleconsultations between general practitioners and ophthalmologists in Finland. *J Telemed Telecare* **1999;**5:118–121.
12. Stefansson E, Bek T, Porta M, Kristinsson JK, Agardh E. Screening and prevention of diabetic blindness. *Acta Ophthalmol Scand* **2000;**78:374–385.
13. Arun CS, Ngugi N, Lovelock L, Taylor R. Effectiveness of screening in preventing blindness due to diabetic retinopathy. *Diabet Med* **2003;**20:186–190.
14. Hahn SH, Torres M, Klein R, Azen SP, Varma R; LALES Group. Prevalence of diabetes and diabetic retinopathy in a population-based cohort of adult Latinos. The Los Angeles Latino Eye Study (LALES). Presented at the Association for Research in Vision and Ophthalmology meeting, May **2003.**
15. The Diabetic Retinopathy Study Research Group. Report 7. A modification of the Airlie House classification of diabetic retinopathy. *Invest Ophthalmol Vis Sci* **1981;**21(1 Pt 2):210–226.
16. Bursell SE, Cavallerano JD, Cavallerano AA, Clermont AC, Birkmire-Peters D, Aiello LP, Aiello LM; Joslin Vision Network Research Team. Stereo nonmydriatic digital-video color retinal imaging compared with Early Treatment Diabetic Retinopathy Study seven standard field 35-mm stereo color photos for determining level of diabetic retinopathy. *Ophthalmology* **2001;**108:572–585.
17. Liesenfeld B, Kohner E, Piehlmeier W, Kluthe S, Aldington S, Porta M, Bek T, Obermaier M, Mayer H, Mann G, Holle R, Hepp KD. A telemedical approach to the screening of diabetic retinopathy: digital fundus photography. *Diabetes Care* **2000;**23:345–348.
18. Lim JI, LaBree L, Nichols T, Cardenas I. A comparison of digital nonmydriatic fundus imaging with standard 35-millimeter slides for diabetic retinopathy. *Ophthalmology* **1998;**105:1907–1914.
19. Zalunardo R, Stumpf S. Shift to digital spurs reconsideration of image quality standards: six years and eight studies demonstrate need for shift in clinical practice. *Telemed Today* **2002;**9(2):25–26.
20. Stumpf S, Zalunardo R, Chen RJ. Barriers to telemedicine implementation. **Healthcare Inform 2002;**4: 45–48.

Address reprint requests to:
Steven H. Stumpf, Ed.D.
Advanced TeleDiagnosis
22201 Camay Court
Calabasas, CA 91302

E-mail: sstumpf@charter.net