Training retinal imagers for retinopathy of prematurity (ROP) screening

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PURPOSE To report the training/certification process of nonphysician imagers, image quality, and factors that affected image quality in the National Eye Institute sponsored multicentered e-ROP study.

METHODS Nonphysician imagers underwent rigorous training and certification in obtaining retinal images, with attention to clarity, focus, and optic disk placement. Image readers measured pupil size in pupil image and graded posterior pole, temporal, nasal, superior, and inferior retinal images and classified them as good, adequate, poor, or missing. Good and adequate images were deemed acceptable.

RESULTS In 4,003 image sessions of 1,257 infants, 3,453 (86.8%) were complete. Of 39,550 retinal images, 91.7% had acceptable quality, 5.6% poor, and 2.7% were missing. Inadequate pupil dilation negatively affected acceptable image quality: 54% acceptable images for pupil <5 mm versus 93% for >6 mm ($P < 0.0001$). When ventilatory equipment obstructed access to imaged infant, the percent of acceptable image quality decreased: 94% for no support versus 66.6% for oscillatory ventilation ($P < 0.0001$). Acceptable image quality rates improved from 87% to 90% ($P = 0.03$) from first 6 months to last 6 months at low patient volume centers, while high patient volume centers remained stable at 95%.

CONCLUSIONS Nonphysicians successfully obtained acceptable quality images for ROP evaluation. Skills improved with experience. Image quality was negatively affected by inadequate pupil dilation and the presence of obstructive ventilatory equipment. (J AAPOS 2016;20:214-219)

Retinopathy of prematurity (ROP), which remains a significant comorbidity of very-low-birth-weight (VLBW) infants, can lead to blindness. Worldwide, an estimated 20,000 to 30,000 premature infants go blind or are severely visually handicapped from ROP each year.[1] Although blindness from ROP can largely be prevented by timely treatment, ROP of any stage is associated with a poorer prognosis for child development.[2] In the US, approximately 14,000-16,000 preterm infants undergo ROP screening annually, with 1,100-1,500 who develop severe acute-phase ROP considered for treatment.[3]

Screening for ROP, based on the American Academy of Pediatrics (AAP)/American Academy of Ophthalmology (AAO)/American Association of Pediatric Ophthalmology and Strabismus (AAPOS) guidelines,[4] has traditionally been the responsibility of an ROP-trained ophthalmologist. With the mismatch between the limited number of ophthalmologists and the large number of at-risk infants, other methods, such as using retinal images for remote evaluation, are gaining currency for efficiently, effectively, and safely evaluating infants at risk for ROP. Telemedicine-based remote evaluation of digital fundus imaging is now recognized by the AAP[5] as a potential means of ROP screening, helping to fill a void left by lack of ROP-trained ophthalmologists. The use of digital imaging enables nonophthalmologists to obtain retinal images that can be reviewed by ophthalmologists or trained readers to identify infants with potentially severe ROP. Such projects are already underway on a large scale in India[6] and California,[7] using different models.[8] The training of nonophthalmologists to obtain quality images is a cornerstone to the widespread use of retinal imaging in ROP screening.

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**A complete listing of the members of the e-ROP Cooperative Group is provided online as e-Supplement 1.*

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The term referral-warranted ROP (RW-ROP)[9] describes morphology on retinal images that should activate an ophthalmic consultation. RW-ROP is defined as ROP in zone I, any stage 3 or worse ROP, or plus disease noted by the evaluation of retinal images. To evaluate the presence of RW-ROP reliably, image readers need to have diagnostic images of acceptable quality; therefore, a robust and reliable method for imager training and certification and maintenance of skills is required.

The protocol used to train nonphysician imagers to acquire and submit retinal images in the Telemedicine Approaches to Evaluating Acute Phase ROP (e-ROP) Study was rigorous and systematic and can be implemented in a nonresearch setting. The e-ROP study was the first large-scale, National Eye Institute-sponsored, multicenter study in the US to train and assess the ability of nonphysicians to successfully obtain retinal images using a wide-angle 130° retinal camera (RetCam Shuttle, Clarity Inc, Pleasanton, CA) in obtaining digital images of preterm infants with birth weight of <1251 g. These images were evaluated by nonphysician trained readers to identify eyes with RW-ROP.[9] From May 2011 to October 2013, 1,257 infants were enrolled and underwent imaging in each eye. Trained nonphysician readers (vs trained nonphysician imagers) were able to detect the presence of RW-ROP in one or both eyes of an infant with a sensitivity of 90% and specificity of 87%.[10] The purpose of this study was to describe the retinal *imagers*' training and certification process and examine the factors that affected image acquisition and image quality in the e-ROP study.

Methods

A standardized protocol for image submission and certification was developed for the e-ROP Study. The protocol and informed consent processes were approved by the Institutional Review Boards of the participating study centers, and informed consent was obtained. Monitoring, reporting of patient volume, image acquisition, and quality by clinical center was performed throughout the study in order to maintain proficiency of the certified retinal imagers (CRIs). Monthly conference calls were held among imagers to share technical tips for successful imaging.

Image acquisition requires a team of at least two persons: a CRI proficient in imaging and another person to monitor and support the infant. The imaging team selection was an essential component in e-ROP. The CRIs were registered nurses, nurse practitioners, ophthalmic technicians, or photographers. The support person was either another CRI or an experienced neonatal intensive care unit (NICU) nurse. The study visits were planned and timed around clinically indicated ROP examinations.

Imager Training and Certification

Imagers underwent an extensive training process. At the initial meeting of the entire e-ROP Cooperative Group, imagers learned about ROP, VLBW infants, and image acquisition, selection, and grading criteria. In addition to addressing the challenges of imaging VLBW infants, optimal positioning and comfort measures were emphasized. Additional training included further onsite instruction by representatives from Clarity Medical Systems. Also, hands-on technical training with the RetCam and use of a model eye allowed imagers familiarity with the camera and imaging techniques before imaging an infant in the NICU. Further education requirements included review of the e-ROP manual of procedures, the RetCam and the e-ROP imaging manuals, data entry, export, image selection, as well as import and transfer of images through a secure server to the Image Data Center. After completion of these tasks, imagers embarked on the certification process described below.

As per the e-ROP protocol, an imaging session included 2 sets of 6 images, one set from each eye for a total of 12 still images at each session selected from a video stream and uploaded to the server for grading at the e-ROP Reading Center. An image *set* included an external image to assess pupillary dilation, and 5 retinal views: disk center and 4 disk off-centered, giving views of the inferior, superior, temporal, and nasal retina. Off-center disk placement was emphasized at 12, 3, 6, and 9 o'clock positions, with the disk visible but as close to the edge of the image as possible (Figure 1).

After training on a model eye, the imager underwent general and role-specific e-ROP knowledge assessments along with a practical examination including submission of image sets with required fields from infants. To be certified, imagers were required to submit to the e-ROP Reading Center[11] image sets of good quality for 3 right and 3 left eyes; images were judged according to placement, clarity, and focus. Feedback was provided to the imager and additional sets submitted if necessary until sufficient image quality was achieved. During the study, an image set was scored for both quality and the presence of RW-ROP (see Table 2 and Table 1 in Daniel and colleauges[11]).

Once imagers were certified, the clinical centers could initiate the acquisition and submission of images for the e-ROP study. During this early period, site visits were undertaken by the teams from Office of the Study Chair and the Data Coordinating Center to evaluate imaging onsite and establish readiness for enrolling patients. Image acquisition and quality for each retinal view was assessed and general feedback provided throughout the study and reported at monthly CRI calls and yearly technical group meetings.

Imaging Procedure

When approaching an infant for imaging, CRIs were instructed to concentrate on safety while obtaining highest image quality, with clarity and focus (especially of the periphery) and disk placement that optimized the view of the peripheral retina. Imagers acquired the techniques to overcome the physical barriers around the eye, such as the obstructive modes of ventilatory support, poor dilation, and low-contrast fundi, all of which may affect image acquisition and quality. CRIs were instructed to record findings if images were difficult to obtain, such as hazy vitreous or tunica vasculosa lentis, if present.

The numerous modes of ventilatory support that premature infants require often obstruct access to the infant's eye. In such difficult circumstances, imagers may devise new techniques to acquire quality images. The imaging team was trained in optimum positioning of the infant and the ventilator apparatus so that the