# Trends in the Screening and Treatment of Retinopathy of Prematurity

Rebecca J. Vartanian, MD,[a] Cagri G. Besirli, MD, PhD,[b] John D. Barks, MD,[a]
Chris A. Andrews, PhD,[b] David C. Musch, PhD, MPH[b,c]

abstract

**OBJECTIVES:** To determine the current practice patterns of retinopathy of prematurity (ROP) screening and treatment and the attitudes toward new screening and treatment modalities in level III and level IV NICUs, as reported by medical directors.

**METHODS:** Surveys were mailed to the medical directors of 847 level III NICUs identified in the 2011 American Academy of Pediatrics directory in April 2015. In September 2015, responses were compared with American Academy of Pediatrics guidelines and previous reports. Within-sample comparisons were made by level, setting, size, and academic status.

**RESULTS:** Respondents indicated that ROP screening is most often performed in their NICUs by pediatric and/or retina specialists (90%); retinal imaging devices are infrequently used (21%). Treatment is performed by pediatric (39%) and/or retina (57%) specialists in the NICU, usually under conscious sedation (60%). The most common treatment modality was laser photocoagulation (85%), followed by anti–vascular endothelial growth factor injection (20%). Some NICUs do not provide treatment services (28%), often due to a lack of ophthalmologists (78%). Respondents showed slightly more agreement (35%) than disagreement (25%) that a retinal imaging device could replace indirect ophthalmoscopy (40% were neutral). More respondents agreed than disagreed (30% vs 15%) that telemedicine for ROP screening is safe, but most were neutral (55%).

**CONCLUSIONS:** Screening and treatment of ROP are not implemented uniformly in NICUs across the United States. Concerns regarding an insufficient ROP workforce are validated.

*Departments of [a]Pediatrics and Communicable Diseases, and [b]Ophthalmology and Visual Sciences, University of Michigan Health Systems, Ann Arbor, Michigan; and [c]Department of Epidemiology, University of Michigan School of Public Health, Ann Arbor, Michigan*

Dr Vartanian collaborated in the development of the survey and drafted the initial manuscript; Dr Andrews collaborated in the development of the survey, conducted the statistical analyses, and contributed to manuscript preparation; Dr Besirli collaborated in the development of the survey and contributed to manuscript preparation; Dr Musch collaborated in the development of the survey and directed its conduct and contributed to manuscript preparation; Dr Barks collaborated in the development of the survey; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Address correspondence to Rebecca J. Vartanian, MD, 1540 East Medical Center Dr, Ann Arbor, MI 48109. E-mail: rebeccav@med.umich.edu

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**WHAT'S KNOWN ON THIS SUBJECT:** Retinopathy of prematurity (ROP) is a sight-threatening disease with treatments available. National screening and treatment guidelines have been developed to aid clinicians in decision-making.

**WHAT THIS STUDY ADDS:** There is significant heterogeneity in ROP screening and treatment practices in NICUs throughout the United States, with continued concern regarding the experience and availability of care providers for ROP.

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The identification and care of infants with retinopathy of prematurity (ROP) are evolving as new technologies and treatments become available. Although serial binocular indirect ophthalmoscopy has been used for many years to detect signs of ROP, digital imaging strategies have come to play a role in screening for ROP. Current guidelines[1] continue to recommend serial examinations, but they allow for an alternative approach that includes digital imaging with at least 1 ROP examination before treatment or discharging infants from further ROP monitoring. A recent multicenter study[2] validated 1 such imaging strategy, which would precede and prompt an ROP examination upon detecting abnormal findings on digital image evaluation.

The Section on Ophthalmology, American Academy of Pediatrics (AAP); the American Academy of Ophthalmology (AAO); and the American Association for Pediatric Ophthalmology and Strabismus have released joint statements providing recommended gestational age and birth weight cutoffs for ROP screening, along with timing and treatment recommendations. Current recommendations are for all infants with a birth weight of ≤1500 g or a gestational age of ≤30 weeks to be screened for ROP and selected screening for infants with an unstable clinical course with a birth weight between 1500 and 2000 g or a gestational age of >30 weeks.[1] Previous recommendations advised the use of a lower gestational age cutoff of ≤28 weeks,[3,4] which was increased to ≤30 weeks in an erratum to the 2006 statement[5] (which corrected an erroneously recommended screening age cutoff of ≤32 weeks).[6] These recommendations are comparable but subtly different from those in other high-income countries.[7–9] In a 2006 survey of neonatologists,[10] only 19% used the recommended gestational age for screening, and the median age used was ≤32 weeks despite the published erratum to the 2006 statement.[6]

A survey by the AAO in 2006 showed that many ophthalmologists managing ROP planned to stop in the future.[11] Reasons for not managing ROP included insufficient reimbursement and concerns regarding liability.[12] Concordantly, neonatologists perceived that the lack of ophthalmologists willing and able to screen for ROP was at least a minor barrier.[10] Solutions to this workforce shift could include changes to reimbursement and malpractice coverage. The use of telemedicine for ROP screening has also emerged in the past 15 years as a method to identify referral-warranted ROP (RW-ROP) for further ophthalmologic care, although feasibility and logistics, including cost, may preclude easy adoption.[13] In a multicenter study, validation statistics were estimated for the practical use of telemedicine for ROP screening, including remote evaluation by nonphysician trained readers.[2] Parental perceptions toward having their premature infants evaluated by telemedicine have been reported.[14]

Given the concerns regarding a decreasing ROP management workforce in the setting of a potential increase in ROP if new oxygen targets are adopted,[15] we surveyed NICU medical directors to ascertain their units' current ROP care practices and to identify if any are experiencing difficulties in obtaining ROP services. We also explored attitudes and experience with telemedicine applications to ROP to gain insights in its use within nonresearch settings.

## METHODS

### Survey Development

Content areas for the survey were developed with guidance from previous surveys of neonatologists[10] and ophthalmologists[12] and input from content experts. Five content areas were identified, including current screening criteria, current ROP workforce, recent changes in institutional ROP screening programs, current use of digital imaging devices, and attitudes regarding the use of digital imaging devices and telemedicine for ROP screening. Questions and associated responses were composed to address the content areas and were shared with neonatology faculty colleagues and survey methodologists to obtain revisions to improve clarity of meaning and consistency of response options. The survey instrument is available as Supplemental Fig 1.

### Survey Population

With permission from the AAP we accessed the AAP's 2011 Section on Perinatal Pediatrics NICU and Neonatologist directory to identify 847 medical directors of level III NICUs (levels of neonatal care were redefined in 2012 to include level IV)[16] in the United States. Although both levels provide neonatal intensive care including a full range of respiratory support, level IV NICUs have additional capabilities, including onsite pediatric surgical and medical subspecialists. Both levels were included because they provide comprehensive care for premature infants at risk of ROP.

### Survey Administration

The first survey was sent in April 2015 via priority mail and included the survey, a cover letter signed by 2 of the authors (R.J.V. and D.C.M.), an incentive gift (a $2 bill), and a preaddressed business reply envelope. At 4 and 8 weeks after the initial mailing, nonrespondents were mailed a reminder to complete and return the survey. Double data entry was used on a randomly selected subset of 53 surveys to evaluate the accuracy of data entry.

**TABLE 1** Respondent and Unit Demographic Characteristics

| Demographic Characteristic | *n* (%) |
|---|---|
| Respondent is board-certified neonatologist | 368 (97) |
| Respondent is NICU medical director | 364 (96) |
| Respondent has primary academic appointment | 181 (48) |
| Respondent's number of years as medical director | |
| ≥10 | 231 (64) |
| 5–9 | 87 (24) |
| 0–4 | 44 (12) |
| NICU level | |
| Level IV | 81 (21) |
| Level III | 298 (79) |
| NICU size | |
| >60 beds | 31 (8) |
| 26–60 beds | 151 (41) |
| <26 beds | 188 (51) |
| NICU setting | |
| Urban | 225 (60) |
| Suburban | 114 (30) |
| Rural | 36 (10) |

Responses are from 379 NICUs. *n* (%) of nonmissing responses are shown.

### Data Management and Analysis

After completing the survey receipt period (September 2015), responses to the survey questions were entered into an Excel (Microsoft Corporation, Redmond, WA) file with fields corresponding to each question. Double entry of 53 surveys yielded an upper bound to the data entry error rate of 0.4%. Data were uploaded for analysis in R 3.2.2 (R Foundation for Statistical Consulting, Vienna, Austria). Categorical variables were summarized by counts, percentages, and bar graphs; continuous variables were analyzed by means, SDs, quartiles, and histograms. Responses were compared with AAP guidelines and previous reports. Within-sample comparisons were made by level, setting, size, and academic status. Missing data were excluded case-wise. This study was determined to be exempt from ongoing review by the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board.

## RESULTS

### Response Rate and Demographic Characteristics

Of the 405 surveys returned, 12 were duplicated and the survey completed by the NICU medical director was used. The overall response rate was 46% (393 of 847). Fourteen surveys from non–level III or IV NICUs were excluded from analyses (9 level II, 5 missing); the analytic sample therefore comprised 379 surveys. Responses were received from all 9 US Census divisions and from 47 states (see Table 1). Nearly all respondents were medical directors (96%), with a majority in their positions for ≥10 years (64%) and 48% had a primary appointment at an academic medical institution.

The estimated numbers of admissions, very low birth weight admissions, and beds were positively correlated (correlations ranging from 0.45 to 0.68). Level IV NICUs are generally larger than level III NICUs (median number of beds = 47 vs 23). NICUs in urban settings have a median number of beds (30) that are larger than those in suburban (22) or rural (21) settings. NICUs with an academic affiliation have a median number of beds (28) that are somewhat larger than those without (24).

### Trends in ROP Screening

Nearly all respondents (97%) use gestational age as a screening criterion. More than half (55%) screen infants with a gestational age ≤31 weeks or use an even more inclusive criterion (eg, ≤32 weeks). Birth weight was also commonly indicated (80%) as a screening criterion, with 91% using the recommendation of ≤1500 g. Fifty-four percent of respondents indicated that the infant's clinical course affects the screening decision. The median estimated number of ROP screenings performed in the NICU during 1 week is 3.5 (range: 0–25). Respondents indicated that infants eligible for ROP screening were rarely or never missed (99%).

ROP screening examinations are most often conducted by pediatric ophthalmologists and/or retina specialists (90%), with the remaining responses citing general ophthalmologists, ophthalmology trainees, neonatologists, and nurses. Of the 10 respondents who checked "nurse" and/or "neonatologist" without any ophthalmology representation, 9 use a retinal imaging device for primary screening. Overall, retinal imaging devices are used for primary screening in 26 centers (7%) and as an adjunct to examination in 51 centers (14%). NICUs that use a retinal imaging device as a primary tool for ROP screening (versus use as an adjunct) were more likely to be smaller (median number of beds = 16 vs 40; $P < .001$), level III (92% vs 51%; $P < .001$), and in a rural setting (24% vs 8%; $P = .04$) and less likely to have an academic affiliation (44% vs 65%; $P = .09$).

### ROP Treatment

Many NICUs are able to offer treatment of infants with ROP (72%). Of the centers that do not offer treatment ($n = 107$), many indicated that the reason is the lack of ophthalmologic services (78%). Respondents also indicated a lack

**TABLE 2** Treatment Locations and Modalities

| Treatment | *n* (%) |
|---|---|
| Location | |
| NICU, conscious sedation | 162 (60) |
| NICU, general anesthesia | 50 (18) |
| OR, conscious sedation | 12 (4) |
| OR, general anesthesia | 44 (16) |
| Other | 15 (6) |
| Modality | |
| Laser | 231 (85) |
| Anti-VEGF | 55 (20) |
| Cryotherapy | 3 (1) |
| Unknown or other | 4 (1) |

Responses are among NICUs that treat ROP ($N = 272$). *n* (%) of nonmissing responses are shown. Respondents were asked to select all that apply. VEGF, vascular endothelial growth factor.

**TABLE 3** Reasons for Difficulty Retaining or Maintaining ROP Services During the Past 2 Years

| Reason | *n* (%) |
|---|---|
| Contract issues | 54 (71) |
| Liability risk | 47 (62) |
| Insufficient reimbursement | 39 (51) |
| Cost of malpractice coverage | 34 (45) |
| Lack of trained and qualified ophthalmologists | 28 (37) |
| Other | 12 (16) |

Responses were among those that indicated any difficulty ($n = 76$). *n* (%) of nonmissing responses are shown. Respondents were asked to select all that apply.

**TABLE 4** Methods of Reimbursement for ROP Care

| Type of Reimbursement | *n* (%) |
|---|---|
| Direct billing | 223 (59) |
| Retainer | 144 (38) |
| Fee for service | 34 (9) |
| Unsure | 61 (16) |
| Other | 28 (7) |

Responses are from 379 NICUs. *n* (%) of nonmissing responses are shown. Respondents were asked to select all that apply.

or low volume of patients requiring treatment, lack of equipment, or lack of access to anesthesia as reasons for not offering treatment. Nearly all centers that do not routinely treat ROP would transfer eligible infants (97%), although 3% of respondents indicated they would provide treatment.

The median number of ROP treatments per year was 3 (range: 0–40). Treatment locations and modalities are presented in Table 2. Laser therapy for ROP treatment was the most common method used (85%). NICUs that use anti–vascular endothelial growth factor therapy as the primary treatment (versus those using laser) were often level IV (33% vs 29%; $P = .59$), urban (74% vs 66%; $P = .22$), and in academic settings (62% vs 53%; $P = .22$). The average number of treatments per year increased with the size of the NICU as measured by the number of admissions (Spearman's $\rho = 0.39$, $P < .001$) and the number of beds ($\rho = 0.47$, $P < .001$).

## ROP Workforce Problems

Seventy-six respondents (20%) reported difficulty retaining or maintaining ophthalmologic services for ROP in the past 2 years, and their reasons are provided in Table 3. Of the 303 not reporting problems, 41 (14%) indicated that they foresee problems securing ROP care in the near future and 20 of these 41 respondents (49%) mentioned retirement of their current provider as a contributor. Overall, only 56% of respondents at least agreed that there are enough ophthalmologists who screen and/or treat ROP in their local area. NICUs that have experienced difficulty obtaining screening services are slightly more likely to be level 3 (84% vs 77%; $P = .18$) and suburban (42% vs 27%; $P = .04$) and slightly less likely to have an academic affiliation (50% vs 60%; $P = .11$) than those not experiencing difficulty obtaining services.

Because financial reasons were frequently identified as problems in securing ROP services, method(s) of reimbursement for those that screen and/or treat infants for ROP were obtained (Table 4). Approximately one-third of respondents indicated that the availability of ROP services in other care facilities affected back transfers (32%) and family-centered care (35%). The availability of ROP services in the community was identified by some respondents as affecting the duration of hospitalization (23%) and family-centered care (30%), presumably due to the need for close and careful observation conflicting with discharge plans.

## Attitudes Toward Telemedicine

Only 35% of respondents agreed that a retinal imaging device could replace screening with indirect ophthalmoscopy, and only 30% agreed that telemedicine was a safe practice for ROP screening. Moreover, only 15% of respondents agreed that a well-trained reader who was not a physician could be relied upon to review telemedicine images to determine RW-ROP (Table 5).

# DISCUSSION

Our study adds the opinions and experiences of medical directors to

**TABLE 5** Attitudes of NICU Medical Directors Toward Telemedicine for ROP Screening

| Question | Responses, *n* | Agree/Strongly Agree, *n* (%) | Neutral, *n* (%) | Disagree/Strongly Disagree, *n* (%) |
|---|---|---|---|---|
| Retinal imaging device could replace screening by indirect ophthalmoscopy | 377 | 130 (35) | 152 (40) | 95 (25) |
| Telemedicine is a safe practice | 376 | 114 (30) | 206 (55) | 56 (15) |
| A well-trained reader (nonphysician) could review images for referral | 375 | 56 (15) | 137 (37) | 182 (49) |

*n* (%) of nonmissing responses are shown. Percentages may not equal 100% due to rounding.

previous reports about an evolving ROP workforce and highlights several areas for improvement and/or concern. The development and monitoring of unit-based screening guidelines represents 1 such area for improvement. Consistent with previous findings reported by Kemper and Wallace,[10] medical directors report more conservative guidelines for routine screening than current recommendations provided by professional societies. Possible reasons for this trend include clinical discretion, disparate international recommendations,[9] and publications regarding alternative screening solutions.[17] Our study shows that ongoing confusion regarding the appropriate gestational age and birth weight criteria[1,5] in the United States may still exist. It is also surprising that only approximately half of neonatologists surveyed consider the infant's clinical course as a factor for screening. Our survey was not designed to explore this further, but we speculate that the subjectivity of the recommendation to screen those with an "unstable clinical course" may contribute.

A particularly concerning finding of our study is that nearly 30% of responding medical directors opined that there are not enough ophthalmologists to screen or treat ROP, consistent with a previous survey of ophthalmologists.[18] Moreover, 20% of respondents have experienced difficulty retaining or maintaining ROP services. This finding is concordant with the projected decrease in the ROP workforce presented by the AAO in 2006.[11] This workforce transition may become more problematic if an increase in ROP disease as a result of changes in oxygen targeting practices does in fact occur, as some experts speculate.[15] The implications of a reduced ROP workforce extend beyond just the home institution, because NICU directors report that the lack of available services at other facilities or in the community may affect back transfers, length of stay, and family-centered care.

Reasons provided by respondents for difficulty with providing ROP services include the lack of trained and qualified providers and liability/financial concerns. Our results indicate that the ROP workforce is composed mainly of pediatric ophthalmologists and retina specialists. There are few reports on the level of training that pediatric ophthalmology and retinal fellowship programs provide for ROP care; yet, the importance of experience in ROP care as a key factor in reducing the number of ROP treatments and retreatments was recently highlighted in a single-center retrospective review.[19] In a survey of fellowship trainees, only 1 of 51 fellows reported formal evaluation of their ROP examinations, although 84% felt competent in ROP management at the time of their survey participation, which was an improvement from 6% at the start of their fellowship.[20] Most surveyed ophthalmologists who screen for ROP felt prepared to do so after training (91%).[12] On the basis of this self-assessed competency for ROP care, it may be that the number of specialists who are trained and/or willing to provide ROP care is inadequate to address this problem, but those who receive appropriate training feel competent to provide ROP screening and care.

The top reasons provided by ophthalmologists for no longer taking part in ROP care in the 2006 AAO survey included medical liability, reimbursement concerns, and lack of hospital support.[11] ROP detection and treatment remain one of the most publicized litigious areas in ophthalmology, with high jury awards in medical malpractice cases.[21,22] Physician malpractice insurance rates are higher for ophthalmologists who provide ROP screening and treatment. These factors, as well as the lack of training during residency and fellowship, form barriers to recruiting ophthalmologists willing to provide ROP care. In addition, reimbursement strategies vary among hospitals and ophthalmologists performing ROP screening, which likely leads to regional differences in the level of compensation offered for ROP screening.[23] Alternative reimbursement methods and hospital-provided malpractice insurance coverage as part of the contract for ROP-related services may be required to maintain and improve the current ROP workforce.

Although increasing the number of well-trained eye care providers willing to screen and care for ROP would be ideal, a recent study[2] showed that a telemedicine system, in which nonphysician NICU staff trained in the use of wide-field digital photography obtained images of infants' retinas and relayed the images electronically to a reading center, where they were read by nonphysician readers, produced sound validation statistics (90% sensitivity and 87% specificity) relative to an ROP specialist's examination that used indirect ophthalmoscopy. Our study showed that most NICU medical directors were unsure if or disagreed that telemedicine is a safe practice for ROP screening. However, the published data for retinal imaging performed in established ROP telemedicine programs show that telemedicine provides an accurate means to detect RW-ROP.[24,25] Telemedicine applications deserve serious consideration for the detection of RW-ROP at local hospitals, as do the associated legal ramifications of their use. We show that centers that currently use a retinal imaging device for primary ROP screening were more likely to be small, level III NICUs in rural areas. This finding may be secondary to the difficulty of

obtaining ophthalmology services in these communities, necessitating the use of retinal imaging as the only available method of ROP screening to maintain a level III NICU status and to improve family-centered care by limiting frequent transfers to distant NICUs for ROP screening. Further efforts are needed at the local, state, and national levels to address and improve these knowledge gaps.

Another area for improvement is the clinically relevant heterogeneity in perioperative care for infants requiring ROP treatment, as previously reported in the United States[26] and in the United Kingdom.[27] In previous studies, those in favor of intubation cited medical stability and decreased movement as benefits during ROP treatment, whereas difficulty extubating postoperatively was a common concern among those that routinely used intravenous sedation.[26] A comparative study has started the process of objectively evaluating this question in a Turkish cohort of 60 premature infants,[28] but further investigation is currently warranted to delineate perioperative outcomes.

There are several limitations to this study. Nonresponse could bias our results, and although our response rate (46%) was within reported averages for surveys,[29] we did obtain surveys from all states and regions and we targeted the medical director who we felt would be most familiar with ROP screening and treatment practices. Another limitation is the generalizability of the results outside the United States. Although variability in guideline adherence is not unique to the United States,[9,30] the burden of ROP disease is heavily weighted toward low- and middle-income countries[31] and often affects larger, more mature infants. Countries such as Mexico report difficulty with their ophthalmology coverage and access to equipment, leading to overall suboptimal compliance with their national guidelines.[30] The need for alternative solutions for ROP screening in developing countries was highlighted in 1 report investigating the use of a smart phone and a lens to provide remote screening.[32] A proposed "paradigm change" in the approach to ROP care has been made to address resource and personnel shortages, especially in low- and middle-income countries.[33] Each health system is likely to have its own unique reasons for difficulties with ROP care; however, it is clear from these combined results that global attention to optimizing ROP care is warranted, even in a relatively resource-rich country like the United States.

Despite these limitations, this study highlights the continued need for improved screening and treatment of ROP throughout the United States, with an emphasis on ensuring a stable, trained workforce. For those centers facing workforce reductions or in need of an alternative screening program, the AAP has issued a technical report regarding the evidence and practical considerations of a safe telemedicine program for ROP screening.[13]

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## ABBREVIATIONS

AAO: American Academy of Ophthalmology
AAP: American Academy of Pediatrics
ROP: retinopathy of prematurity
RW-ROP: referral-warranted retinopathy of prematurity

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