NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0483 **NQF Project:** Perinatal and Reproductive Health Project
(for Endorsement Maintenance Review) **Original Endorsement Date:** Oct 24, 2008 **Most Recent Endorsement Date:** Oct 24, 2008
BRIEF MEASURE INFORMATION
De.1 Measure Title: Proportion of infants 22 to 29 weeks gestation screened for retinopathy of prematurity.
Co.1.1 Measure Steward: Vermont Oxford Network
De.2 Brief Description of Measure: Proportion of infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for retinopathy of prematurity (ROP) screening by the American Academy of Pediatrics (AAP) and who received a retinal examination for ROP prior to discharge.
2a1.1 Numerator Statement: Number of infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP and who received a retinal exam for ROP prior to discharge.
2a1.4 Denominator Statement: All eligible infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP.

2a1.8 Denominator Exclusions: 1. Infants outside the gestational age range of 22 to 29 weeks.
2. Outborn infants admitted to the reporting hospital more than 28 days after
   birth.
3. Outborn infants who have been home prior to admission.
4. Infants who die in the delivery room or initial resuscitation area prior to
   admission to the neonatal intensive care unit.
5. Infants not in the reporting hospital at the postnatal age recommended for
   ROP screening by the AAP.

1.1 Measure Type: Process **2a1. 25-26 Data Source:** Administrative claims, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records **2a1.33 Level of Analysis:** Facility **1.2-1.4 Is this measure paired with another measure?** No **De.3 If included in a composite, please identify the composite measure** (*title and NQF number if endorsed*): N/A

STAFF NOTES (*issues or questions regarding any criteria*)
Comments on Conditions for Consideration:
Is the measure untested? Yes☐ No☐ If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*): 5. Similar/related endorsed or submitted measures (*check 5.1*): Other Criteria:

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable   1

Staff Reviewer Name(s):

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.
(evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas (*Check all the areas that apply*):   Perinatal
De.5 Cross Cutting Areas (*Check all the areas that apply*):   Safety : Complications

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, Patient/societal consequences of poor quality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (*Provide epidemiologic or resource use data*):
"Retinopathy of prematurity (ROP) is a disorder of the developing retina of low birth weight preterm infants that potentially leads to blindness in a small but significant percentage of those infants. ...Because of the sequential nature of ROP progression and the proven benefits of timely treatment in reducing the risk of visual loss, effective care now requires that at-risk infants receive carefully timed retinal examinations by an ophthalmologist who is experienced in the examination of preterm infants for ROP and that all pediatricians who care for these at-risk preterm infants be aware of this timing (Section on Opthalmology AAP 2006)." However, due to shortages of trained specialists to perform screening and difficulties in coordinating and scheduling retinal exams, screening may be delayed or in some cases missed.

1a.4 Citations for Evidence of High Impact cited in 1a.3: . American Academy of Pediatrics, Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus. Screening examination of premature infants for retinopathy of prematurity. Pediatrics. 2006;117 :572 –576.

1b. Opportunity for Improvement: H☐ M☐ L☐ I☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
Increased proportion of high risk infants who receive retinal screening on the recommended schedule.

1b.2 Summary of Data Demonstrating Performance Gap (*Variation or overall less than optimal performance across providers*):
[*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
In a survey of neonatologists, 29% of the respondents agreed that some children in their state develop ROP-related visual impairment that could have been prevented with timely screening (Kemper 2007). Unfortunately, no studies on visual outcomes are available to confirm or refute this dismal assessment. In unpublished data from the Vermont Oxford Network, of 31,401 infants with gestational ages of 22 to 29 weeks, 81% were still hospitalized at the postnatal age at which retinal screening is recommended, yet 7% of these infants did not receive screening prior to discharge. At the 25% of hospitals with the lowest rates of screening over 12% of all infants 22 to 29 weeks gestation and over 23% of infants at 29 weeks gestation were not screened prior to discharge. These data suggest that there are significant opportunities to improve performance of retinal screening exams for infants at risk of developing ROP and subsequent visual sequelae.

1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
1. American Academy of Pediatrics, Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus. Screening examination of premature infants for retinopathy of prematurity. Pediatrics.

2006;117 :572 –576.

2. American Academy of Pediatrics, Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus. Errata: screening examination of premature infants for retinopathy of prematurity. Pediatrics. 2006;118 :132.

3. Kemper AR, Wallace DK. Neonatologists´ Practices and Experiences in Arranging Retinopathy of Prematurity Screening Services. Pediatrics 2007;120:527-531.

4. Vermont Oxford Network unbublished data, 2007.

1b.4 **Summary of Data on Disparities by Population Group:** [*For* <u>*Maintenance*</u> *–Descriptive statistics for performance results for this measure by population group*]
N/A

1b.5 **Citations for Data on Disparities Cited in 1b.4:** [*For* <u>*Maintenance*</u> *– Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
N/A

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes☐ No☐   <u>If not a health outcome</u>, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐   Quality: H☐ M☐ L☐ I☐   Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No**☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise **No**☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 **Structure-Process-Outcome Relationship** (*Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome*):
Health outcome: visual acuity, blindness
Intermediate clinical outcome: timely retinal ablation surgery
Process: processes for identifying eligible infants and scheduling and performing retinal exams
Structure: staffing with pediatric retinal specialists or other ophthalmology personnel

1c.2-3 **Type of Evidence** (*Check all that apply*):
Clinical Practice Guideline, Selected individual studies (rather than entire body of evidence), Systematic review of body of evidence (other than within guideline development)

1c.4 **Directness of Evidence to the Specified Measure** (*State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population*):
As far as we are aware the guidelines for timing of retinal examination have not been tested in a randomized trial. However, given the clear evidence from the Cryo-ROP study of the effectiveness of surgical intervention for infants with threshold ROP there is little doubt that appropriately timed retinal exams are required to identify infants who will benefit from surgery.

The Cryotherapy for Retinopathy of Prematurity Cooperative Group reported preliminary results in 1988. This study registered 9,751 infants with birth weights less than 1,251 grams at 23 study centers. Of these infants, 4,099 were systematically examined. The defined threshold severity of ROP developed in 291 infants.

Cryotherapy was performed in half the eligible eyes of the 291 infants. Twelve months after randomization, the results of masked grading of fundus photographs of the posterior pole indicated an unfavorable outcome in 25.7 percent of the eyes that had received cryotherapy and in 47.4 percent of the control eyes. Masked Teller Acuity Card assessment of grating acuity indicated an unfavorable functional outcome in 35 percent of the treated eyes, compared with 56.3 percent of the control eyes. These results indicate that cryotherapy reduces the risk of unfavorable retinal and functional outcome from threshold ROP.

Although the surgery was stressful, no major complications occurred during or following treatment. Physicians´ diagnoses and the unbiased photograph gradings were statistically similar. These data support the efficacy of cryotherapy in reducing by approximately one-half the risk of unfavorable retinal outcome from threshold ROP.

At 3½ years following randomization, functional outcome was evaluated by masked assessment of visual acuity (using only the letters H, O, T, and V) and of grating acuity (using the Teller Acuity Card procedure). Structural outcome was evaluated by the physician´s assessment of ROP residua in the posterior pole. All three outcome measures showed a reduction of unfavorable outcomes in treated versus control eyes: 46.6 percent versus 57.5 percent (p < 0.01) for letter acuity, 52.4 percent versus 65.6 percent (p < 0.001) for grating acuity, and 26.1 percent versus 45.4 percent (p < 0.001) for posterior pole status.

At 5½ years following randomization, Snellen visual acuity was measured by masked testers. Again, structural outcome was evaluated by the physician´s assessment of ROP residua in the posterior pole. Both visual acuity and fundus structure continued to show fewer unfavorable outcomes in treated versus control eyes: 47.1 percent versus 61.7 percent (p < 0.005) for visual acuity, and 26.9 percent versus 45.4 percent (p < 0.001) for fundus status. detailed analysis of visual acuity outcomes for all eyes revealed that while fewer treated eyes (31.5 percent) than control eyes (47.7 percent) were blind (p < 0.001), there was a slight trend toward fewer eyes with a visual acuity of 20/40 or better in the treated (12.6 percent) versus control (16.7 percent) groups (p = 0.19).

Results at 3½ years and 5½ years following randomization continue to support the long-term efficacy and safety of cryotherapy in the treatment of severe ROP. Although the 5½-year data suggested that cryotherapy could reduce the chance of normal vision in some cases, nevertheless findings from the 10-year examination showed fewer unfavorable outcomes for both visual acuity and structure in treated vs untreated eyes. For distance visual acuity, 44.4 percent of treated eyes had unfavorable outcomes versus 62.1 percent of control eyes (p < 0.001). similarly, for near visual acuity, 42.5 percent of treated eyes versus 61.6 percent of control eyes had unfavorable outcomes (p < 0.001). the fundus status results showed that 27.2 percent of treated eyes versus 47.9 percent of control eyes had unfavorable outcomes (p < 0.001). eyes that received cryotherapy were at least as likely as control eyes to have 20/40 or better visual acuity.

The examination at age 10 included measurement of contrast sensitivity and visual fields. Results of contrast sensitivity testing demonstrated no evidence of adverse treatment effects in eyes that received cryotherapy: 39.7 percent of treated eyes had unfavorable outcomes versus 59.3 percent of control eyes (p < 0.001). the findings for visual field testing with goldmann perimetry showed a visual field area that was 24 percent to 26 percent larger in treated eyes versus untreated eyes, when blind eyes were included and assigned a score of 0. when blind eyes were excluded, visual field area was 5 percent smaller for treated eyes than for untreated eyes, indicating that cryotherapy slightly reduces the visual field area in eyes with severe rop. this small reduction in visual field area in treated eyes is minor when compared with the much greater risk that an eye will be blind without treatment. however, this and any other possible adverse side effects are important considerations in determining whether to treat milder cases of rop that have a relatively good prognosis for vision without treatment.

Cryotherapy is now recommended for both eyes whenever stage 3+ retinopathy of prematurity involves approximately half the circumference in either zone I or zone II. There are, as yet, insufficient data to mandate cryotherapy in any method different from the one used in this trial, or to apply it to patients with less severe disease. Following the publication of the positive results of this study in 1988, the U.S. pattern of care changed rapidly to embrace these guidelines as standard practice.

The Early Treatment for Retinopathy of Prematurity Study (ETROP) is to test the hypothesis that earlier treatment in carefully selected cases will result in an overall better visual outcome than treatment at the conventional CRYO-ROP threshold point in the disease.

Earlier treatment is defined as retinal ablation administered to the avascular retina when an eye reaches high risk prethreshold retinopathy of prematurity (ROP). Prethreshold indicates any Zone I ROP; or Zone II stage 2 with plus disease, or stage 3; or Zone II with less than 5 contiguous or 8 cumulative clock hours of stage 3 ROP with plus disease. Recognizing that a substantial number of eyes undergo spontaneous resolution of ROP, eyes will be randomized to early treatment only when high risk for an unfavorable visual acuity outcome is identified. High risk will be determined using a risk model analysis program based on longitudinal natural history data obtained from the CRYO-ROP study. This model integrates risk factors to assign a risk of progression to blindness without treatment. These factors include birth weight, gestational age, ethnicity, singleton/multiple status, outborn status, Zone on first exam, severity of ROP and rate of progression of ROP. When an infant develops prethreshold ROP and greater than or equal to 15 percent risk of unfavorable outcome, randomization to early treatment of one eye will occur. Visual acuity outcome will be measured by masked observers after wearing best correction using the Teller Acuity Card Procedure at 9 months corrected age.

Grating acuity results showed a reduction in unfavorable visual acuity outcomes with earlier treat-ment, from 19.5% to 14.5% (P = .01). Unfavorable structural outcomes were reduced from 15.6% to 9.1% (P<.001) at 9 months. further analysis supported retinal ablative therapy for eyes with type 1 rop, defined as zone i, any stage rop with plus disease (a degree of dilation and tortuosity of the posterior retinal blood vessels meeting or exceeding that of a standard photograph); zone i, stage 3 rop without plus disease; or zone ii, stage 2 or 3 rop with plus disease. the analysis supported a wait-and-watch approach to type 2 rop, defined as zone i, stage 1 or 2 rop without plus disease or zone ii, stage 3 rop without plus disease. these eyes should be considered for treatment only if they progress to type 1 or threshold rop.

Early treatment of high-risk prethreshold ROP significantly reduced unfavorable outcomes to a clinically important degree. Additional analyses led to modified recommendations for the use of peripheral retinal ablation in eyes with ROP. Long-term follow-up is being conducted to learn whether the benefits noted in the first year after birth will persist into childhood.

Sources:

http://www.nei.nih.gov/neitrials/static/study32.asp
http://www.nei.nih.gov/neitrials/static/study83.asp

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: Multiple studies cited below

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): Strong evidence for the benefit of surgical intervention for infants with threshold ROP.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect)*: Consistent

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
See summary of evidence above for improved visual outcomes

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: N/A

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: Not graded

1c.13 Grade Assigned to the Body of Evidence: N/A

1c.14 Summary of Controversy/Contradictory Evidence: None cited

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)***:**

Reynolds JD, Dobson V, Quinn GE, Fielder AR, Palmer EA, Saunders RA, Hardy RJ, Phelps DL, Baker JD, Trese MT, Schaffer DB, Tung B, for the CRYO-ROP and LIGHT-ROP Cooperative Groups: Evidence-based screening criteria for retinopathy of prematurity: natural history data from the CRYO-ROP and LIGHT-ROP studies. Arch Ophthalmol 120: 1470-1476, 2002.

Editorial Committee, for the Cryotherapy for Retinopathy of Prematurity Cooperative Group: Multicenter trial of cryotherapy for retinopathy of prematurity: Natural history ROP: Ocular outcome at 5 1/2 years in premature infants with birth weights less than 12. Arch Ophthalmol 120: 595-599, 2002.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: Contrast sensitivity at age 10 years in children who had threshold retinopathy of prematurity. Arch Ophthalmol 119: 1129-1133, 2001.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: Effect of retinal ablative therapy for threshold retinopathy of prematurity. Arch Ophthalmol 119: 1120-1125, 2001.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: Multicenter trial of cryotherapy for retinopathy of prematurity: Ophthalmological outcomes at 10 years. Arch Ophthalmol 119: 1110-1118, 2001.

Quinn GE, Dobson V, Siatkowski RM, Hardy RJ, Kivlin J, Palmer EA, Phelps DL, Repka MX, Summers CG, Tung B, Chan W, for the Cryotherapy for Retinopathy of Prematurity Cooperative Group: Does cryotherapy affect refractive error? Results from treated versus control eyes in the cryotherapy for retinopathy of prematurity trial. Ophthalmology 108: 343-347, 2001.

Repka MX, Palmer EA, Tung B, on Behalf of the Cryotherapy for Retinopathy of Prematurity Cooperative Group: Involution of retinopathy of prematurity. Arch Ophthalmol 118: 645-649, 2000.

Msall ME, Phelps DL, DiGaudio KM, Dobson V, Tung B, McClead RE, Quinn GE, Reynolds JD, Hardy RJ, Palmer EA: Severity of neonatal retinopathy of prematurity (ROP) is predictive of neurodevelopmental functional outcome at age 5.5 years. Pediatrics 106: 998-1005, 2000.

Dobson V, Quinn GE, Siatkowski RM, Baker JD, Hardy RJ, Reynolds JD, Trese MT, Tung B, for the Cryotherapy for Retinopathy of Prematurity Cooperative Group: Agreement between grating acuity at age 1 year and Snellen acuity at age 5.5 years in the preterm child. Invest Ophthalmol Vis Sci 40: 496-503, 1999.

Harvey ME, Dobson V, Quinn GE, Tung B, Hardy RJ: Interobserver agreement for grating acuity and letter acuity assessment in 1- to 5.5-year-olds with severe retinopathy of prematurity. Invest Ophthalmol Vis Sci 40: 1565-1576, 1999.

Quinn GE, Dobson V, Kivlin J, Kaufman LM, Repka MX, Reynolds JD, Gordon RA, Hardy RJ, Tung B, Stone RA, for the Cryotherapy for Retinopathy of Prematurity Cooperative Group: Prevalence of myopia between 3 months and 5½ years in preterm infants with and without retinopathy of prematurity. Ophthalmology 105: 1292-1300, 1998.

Bremer DL, Palmer EA, Fellows RR, Baker JD, Hardy RJ, Tung B, Rogers GL: Strabismus in premature infants in the first year of life. Arch Ophthalmol 116: 329-333, 1998.

Repka MX, Summers CG, Palmer EA, Dobson V, Tung B, Davis B, on behalf of the Cryotherapy for Retinopathy of Prematurity Cooperative Group: The incidence of ophthalmological interventions in children with birth weights less than 1251 grams: Results through 5½ years. Ophthalmology 105: 1621-1627, 1998.

Hardy RJ, Palmer EA, Schaffer DB, Phelps DL, Davis BR, Cooper CJ, CRYO-ROP Cooperative Group: Outcome-based management of retinopathy of prematurity. JAAPOS 1: 46-54, 1997.

Saunders RA, Christmann LM, Donohue M, Pakalnis VA, Phelps DL, Tung B: Racial variation in retinopathy of prematurity. Arch

Ophthalmol 115: 604-608, 1997.

Bartholomew PA, Chao J, Evans JL, Hammel AM, Trueb AL, Verness JL, Dobson V, Quinn GE: Acceptance/Use of the Teller acuity card procedure in the clinic. Am Orthoptic J 46: 100-106, 1996.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: Multicenter Trial of Cryotherapy for Retinopathy of Prematurity: Snellen acuity and structural outcome at 5½ years. Arch Ophthalmol 114(4): 417-424, 1996.

Dobson V, Quinn GE, Abramov I, Hardy RJ, Tung B, Siakowski RM, Phelps DL, Cryotherapy for Retinopathy of Prematurity Group: Color vision measured with standard pseudoisochromatic plates at 5½ years in eyes of children from the CRYO-ROP study. Inv Ophthalmol Vis Sci 37: 2467-2474, 1996.

Gilbert WS, Quinn GE, Dobson V, Reynolds J, Hardy RJ, Palmer EA, CRYO-ROP Cooperative Group: Partial retinal detachment at 3 months after threshold retinopathy of prematurity: Long term structural and functional outcome. Arch Ophthalmol 114: 1085-1091, 1996.

Kivlin JD, Biglan AW, Gordon RA, Dobson V, Hardy RA, Palmer EA, Tung B, Gilbert W, Spencer R, Cheng KP, Buckley E: Cryotherapy for Retinopathy of Prematurity (CRYO-ROP) Cooperative Group: Early retinal vessel development and iris vessel dilatation as factors in retinopathy of prematurity. Arch Ophthalmol 114: 150-154, 1996.

Quinn GE, Dobson V, Barr CC, Davis BR, Palmer EA, Robertson J, Summers CG, Trese MT, Tung B, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Visual acuity of eyes after vitrectomy for ROP: Follow-up at 5½ years. Ophthalmology 103(4): 595-600, 1996.

Quinn GE, Dobson V, Hardy RJ, Phelps DL, Tung B, Palmer EA, CRYO-ROP Cooperative Group: Visual fields measured with double-arc perimetry in eyes with threshold retinopathy of prematurity (ROP) from the CRYO-ROP trial. Ophthalmology 103(9): 1432-1437, 1996.

Dobson V, Quinn GE, Saunders RA, Spencer R, Davis BR, Risser J, Palmer EA, Cryotherapy for Retinopathy of Prematurity Group: Grating acuity in eyes with retinal residua of retinopathy of prematurity (ROP). Arch Ophthalmol 113: 1172-1177, 1995.

Dobson V, Quinn GE, Tung B, Palmer EA, Reynolds JD, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Comparison of recognition and grating acuities in very low birth weight children with and without retinal residua of retinopathy of prematurity (ROP). Invest Ophthalmol Vis Sci 36: 692-702, 1995.

Kivlin JD, Biglan AW, Gordon RA, Dobson V, Hardy RA, Palmer EA, Tung B, Gilbert W, Spencer R, Cheng KP, Buckley E, Cryotherapy for Retinopathy of Prematurity Group: Early retinal vessel development as a factor in retinopathy of prematurity and its functional sequelae. Arch Ophthalmol 114: 150-154, 1995.

Quinn GE, Dobson V, Biglan A, Evans J, Plotsky D, Hardy RJ, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Correlation of retinopathy of prematurity in fellow eyes in the CRYO-ROP study. Arch Ophthalmol 113: 469-473, 1995.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: The natural ocular outcome of premature birth and retinopathy: Status at one year. Arch Ophthalmol 112: 903-912, 1994.

Dobson V, Quinn GE, Summers CG, Saunders RA, Phelps DL, Tung B, Palmer EA, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Effect of acute-phase retinopathy of prematurity on grating acuity development in the very low birth weight infant. Invest Ophthalmol Vis Sc 35: 4236-4244, 1994.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: Multicenter Trial of Cryotherapy for Retinopathy of Prematurity: 3½ year outcome—structure and function. Arch Ophthalmol 111: 339-344, 1993.

Evans MS, Wallace PR, Palmer EA: Fundus photography in small infants. J Ophthal Photography 15(1): 38-39, 1993.

Reynolds J, Dobson V, Flynn JT, Gilbert WS, Quinn GE, Tung B, Robertson J, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Prediction of visual function in eyes with mild to moderate posterior pole residua of retinopathy of prematurity. Arch Ophthalmol 111(8): 1050-1056, 1993.

Schaffer DB, Palmer EA, Plotsky DF, Metz HS, Flynn JT, Tung B, Hardy RJ, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Prognostic factors in the natural course of retinopathy of prematurity (ROP). Ophthalmology 100(2): 230-236, 1993.

Gilbert WS, Dobson V, Quinn GE, Reynolds J, Tun B, Flynn JT, Cryotherapy for Retinopathy of Prematurity Cooperative Group: The correlation of visual function with posterior retinal structure in severe retinopathy of prematurity. Arch Ophthalmol 110: 625-631, 1992.

Quinn GE, Dobson V, Repka MX, Reynolds J, Kivlin J, Davis B, Buckley E, Flynn JT, Palmer EA, Quinn GE, Dobson V, Repka MX, Reynolds J, kivlin J, Davis B, Buckley E, Flynn JT, Palmer EA, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Development of myopia in infants with birth weights less than 1251 grams. Ophthalmology 99: 329-340, 1992.

Summers GC, Phelps DL, Tung B, Palmer EA, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Ocular cosmesis in retinopathy of prematurity. Arch Ophthalmol 110: 1092-1097, 1992.

Trueb L, Evans J, Hammel A, Bartholomew P, Dobson D: Assessing visual acuity of visually impaired children using the Teller acuity cards. Am Orthoptic J 42: 149-154, 1992.

Hardy RJ, Davis BR, Palmer EA, Tung B, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Statistical considerations in the early termination of the multicenter trial of cryotherapy for retinopathy of prematurity. Controlled Clin Trials 12: 293-303, 1991.

Palmer EA, Flynn JT, Hardy RJ, Phelps DL, Phillips CL, Schaffer DB, Tung B, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Incidence and early course of retinopathy of prematurity. Ophthalmology 98: 1628-1640, 1991.

Palmer EA, Hardy RJ, Mowery R, Davis BR, Tung B, Phelps DL, Schaffer DB, Flynn JT, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Operational aspects of early termination of the multicenter trial of cryotherapy for retinopathy of prematurity. Controlled Clin Trials 12: 277-292, 1991.

Phelps DL, Brown DR, Tung B, Cassady G, McClead RE, Purohit DM, Palmer EA, Cryotherapy for Retinopathy of Prematurity Cooperative Group: 28-day survival rates of 6676 neonates with birth weights of 1250 grams or less. Pediatrics 87: 7-17, 1991.

Quinn GE, Dobson V, Barr CC, Davis BR, Flynn JT, Palmer EA, Robertson J, Trese MT: Visual acuity in infants after vitrectomy for severe retinopathy of prematurity. Ophthalmology 98: 5-13, 1991.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: Multicenter Trial of Cryotherapy for Retinopathy of Prematurity. Three-month outcome. Arch Ophthalmol 108: 195-204, 1990.

Dobson V, Quinn GE, Biglan AW, Tung B, Flynn JT, Palmer EA, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Acuity card assessment of visual function in the Cryotherapy for Retinopathy of Prematurity trial. Invest Ophthalmol Vis Sci 31: 1702-1708, 1990.

Watzke RC, Robertson JE, Palmer EA, Wallace PR, Evans MS, Soldevilla JED, Cryotherapy for Retinopathy of Prematurity Cooperative Group: Photographic grading in the retinopathy of prematurity trial. Arch Ophthalmol 108: 950-955, 1990.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: Multicenter Trial of Cryotherapy for Retinopathy of Prematurity. Preliminary results. Arch Ophthalmol 106: 471-479, 1988.

Cryotherapy for Retinopathy of Prematurity Cooperative Group: Multicenter Trial of Cryotherapy for Retinopathy of Prematurity. Preliminary results. Pediatrics 81: 697-706, 1988.

Early Treatment for Retinopathy of Prematurity Cooperative Group: Revised Indications for the Treatment of Retinopathy of Prematurity: Results of the Early Treatment for Retinopathy of Prematurity Randomized Trial . Arch Ophthalmol 121: 1684-1694, 2003.

Good WV, Hardy RJ, on behalf of the ETROP Multicenter Study Group: The Multicenter Study of Early Treatment for Retinopathy of Prematurity. Ophthalmology Volume 108, Number 6: 1013-1014, 2001.

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> *(Including guideline # and/or page #)*:

This statement revises a previous statement on screening of preterm infants for retinopathy of prematurity (ROP) that was published in 2001. ROP is a pathologic process that occurs only in immature retinal tissue and can progress to a tractional retinal detachment, which can result in functional or complete blindness. Recent development of peripheral retinal ablative therapy using laser photocoagulation has resulted in the possibility of markedly decreasing the incidence of this poor visual outcome, but the sequential nature of ROP creates a requirement that at-risk preterm infants be examined at proper times to detect the changes of ROP before they become permanently destructive. This statement presents the attributes on which an effective program for detecting and treating ROP could be based, including the timing of initial examination and subsequent reexamination intervals.

1.Infants with a birth weight of less than 1500 g or gestational age of 32 weeks or less (as defined by the attending neonatologist) and selected infants with a birth weight between 1500 and 2000 g or gestational age of more than 32 weeks with an unstable clinical course, including those requiring cardiorespiratory support and who are believed by their attending pediatrician or neonatologist to be at high risk, should have retinal screening examinations performed after pupillary dilation using binocular indirect ophthalmoscopy to detect ROP. One examination is sufficient only if it unequivocally shows the retina to be fully vascularized in each eye. Effort should be made to minimize the discomfort and systemic effect of this examination by pretreatment of the eyes with a topical anesthetic agent such as proparacaine; consideration also may be given to the use of pacifiers, oral sucrose, etc.

2.Retinal examinations in preterm infants should be performed by an ophthalmologist who has sufficient knowledge and experience to enable accurate identification of the location and sequential retinal changes of ROP. "The International Classification of Retinopathy of Prematurity Revisited"9 should be used to classify, diagram, and record these retinal findings at the time of examination.

3.The initiation of acute-phase ROP screening should be based on the infant´s age. The onset of serious ROP correlates better with postmenstrual age (gestational age at birth plus chronologic age) than with postnatal age.10 That is, the youngest infants at birth take the longest time to develop serious ROP. This knowledge has been used previously in conducting a screening schedule.11,12 Table 1 was developed from an evidence-based analysis of the Multicenter Trial of Cryotherapy for Retinopathy of Prematurity natural history data and confirmed by the Light Reduction in ROP Study, which was conducted a decade later.13 It represents a suggested schedule for the timing of the initial eye examinations based on postmenstrual age and chronologic (postnatal) age to detect ROP before it becomes severe enough to result in retinal detachment while minimizing the number of potentially traumatic examinations.14 Table 1 provides a schedule for detecting ROP potentially damaging to the retina with 99% confidence.

4.Follow-up examinations should be recommended by the examining ophthalmologist on the basis of retinal findings classified according to the international classification.9 The following schedule is suggested (see Fig 1):

1-week or less follow-up

?stage 1 or 2 ROP: zone I

?stage 3 ROP: zone II

1- to 2-week follow-up

?immature vascularization: zone I—no ROP

?stage 2 ROP: zone II

?regressing ROP: zone I

2-week follow-up

?stage 1 ROP: zone II

?regressing ROP: zone II

2- to 3-week follow-up

?immature vascularization: zone II—no ROP

?stage 1 or 2 ROP: zone III

?regressing ROP: zone III

The presence of plus disease (defined as dilation and tortuosity of the posterior retinal blood vessels, see below) in zones I or II suggests that peripheral ablation, rather than observation, is appropriate.14

5.Practitioners involved in the ophthalmologic care of preterm infants should be aware that the retinal findings that require strong consideration of ablative treatment were revised recently according to the Early Treatment for Retinopathy of Prematurity Randomized Trial study.7 The finding of threshold ROP, as defined in the Multicenter Trial of Cryotherapy for Retinopathy of Prematurity, may no longer be the preferred time of intervention.

Treatment may also be initiated for the following retinal findings:

?zone I ROP: any stage with plus disease

?zone I ROP: stage 3—no plus disease

?zone II: stage 2 or 3 with plus disease

Plus disease is defined as a degree of dilation and tortuosity of the posterior retinal blood vessels as defined by a standard photograph.1,9 Special care must be used in determining the zone of disease. The number of clock hours of disease may no longer be the determining factor in recommending ablative treatment. Treatment should generally be accomplished, when possible, within 72 hours of determination of treatable disease to minimize the risk of retinal detachment.

6.The conclusion of acute retinal screening examinations should be based on age and retinal ophthalmoscopic findings.14 Findings that suggest that examinations can be curtailed include the following:

?zone III retinal vascularization attained without previous zone I or II ROP (if there is examiner doubt about the zone or if the postmenstrual age is less than 35 weeks, confirmatory examinations may be warranted);

?full retinal vascularization;

?postmenstrual age of 45 weeks and no prethreshold disease (defined as stage 3 ROP in zone II, any ROP in zone I) or worse ROP is present; or

?regression of ROP15 (care must be taken to be sure that there is no abnormal vascular tissue present that is capable of reactivation and progression).

7.Communication with the parents by members of the staff is very important. Parents should be aware of ROP examinations and should be informed if their child has ROP, with subsequent updates on ROP progression. The possible consequences of serious ROP should be discussed at the time that a significant risk of poor visual outcome develops. Documentation of such conversations

with parents in the nurse or physician notes is highly recommended.

8.Responsibility for examination and follow-up of infants at risk of ROP must be carefully defined by each NICU. Unit-specific criteria with respect to birth weight and gestational age for examination for ROP should be established for each NICU by consultation and agreement between neonatology and ophthalmology services. These criteria should be recorded and should automatically trigger ophthalmologic examinations. If hospital discharge or transfer to another neonatal unit or hospital is contemplated before retinal maturation into zone III has taken place or if the infant has been treated by ablation for ROP and is not yet fully healed, the availability of appropriate follow-up ophthalmologic examination must be ensured, and specific arrangement for that examination must be made before such discharge or transfer occurs. The transferring primary physician, after communication with the examining ophthalmologist, should have the responsibility for communicating what eye examinations are needed and their required timing to the infant´s new primary physician. The new primary physician should ascertain the current ocular examination status of the infant from the record and through communication with the transferring physician so that any necessary examinations by an ophthalmologist with ongoing experience and expertise in examination of preterm infants for ROP can be arranged promptly at the receiving facility or on an outpatient basis if discharge is contemplated before the need for continued examination has ceased, as outlined in recommendation 6. If responsibility for arranging follow-up ophthalmologic care after discharge is delegated to the parents, they should be made to understand the potential for severe visual loss, including blindness; that there is a critical time window to be met if treatment is to be successful; and that timely follow-up examination is essential to successful treatment. This information preferably should be communicated both verbally and in writing. If such arrangements for communication and follow-up after transfer or discharge cannot be made, the infant should not be transferred or discharged until appropriate follow-up examination can be arranged by the unit that is discharging the infant.

1c.17 Clinical Practice Guideline Citation: American Academy of Pediatrics, Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus. Screening examination of premature infants for retinopathy of prematurity. Pediatrics. 2006;117 :572 –576.

American Academy of Pediatrics, Section on Ophthalmology, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus. Errata: screening examination of premature infants for retinopathy of prematurity. Pediatrics. 2006;118 :132.

1c.18 National Guideline Clearinghouse or other URL:
http://www.guideline.gov/content.aspx?id=8713&search=retinopathy+of+prematurity

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: Not graded

1c.23 Grade Assigned to the Recommendation: Not graded

1c.24 Rationale for Using this Guideline Over Others: AAP is the authoritative source.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High   **1c.26** Quality: High**1c.27** Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*)   Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for

improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (<u>evaluation criteria</u>)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See <u>guidance on measure testing</u>.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained)*. Do you have a web page where current detailed specifications for <u>this</u> measure can be obtained? Yes

S.2 If yes, provide web page URL: http://www.vtoxford.org/about/NQF%20Measure%200483.pdf

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Number of infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP and who received a retinal exam for ROP prior to discharge.

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
From birth until retinal exam for ROP.

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
All eligible infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP)and who had an retinal examination for Retinopathy of Prematurity prior to discharge.

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All eligible infants 22 to 29 weeks gestation who were in the reporting hospital at the postnatal age recommended for ROP screening by the AAP.

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Children's Health

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
From birth until discharge home from the reporting hospital, death or transfer to another hospital. Monitoring continues for transfered infants who are subsequently readmitted to the reporting hospital after initial transfer.

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
Any infant who is born at the reporting hospital and whose gestational age is
between 22 weeks, 0 days and 29 weeks, 6 days should be included if they are in the reporting hospital at the postnatal age recommended for ROP screening by the AAP.
Any outborn infant who is admitted to any location in the reporting hospital within 28 days of birth, without first having gone home, and whose gestational age is between 22 weeks, 0 days and 29 weeks, 6 days should be included if they are in the reporting hospital at the postnatal age recommended for ROP screening by the AAP.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
1. Infants outside the gestational age range of 22 to 29 weeks.
2. Outborn infants admitted to the reporting hospital more than 28 days after

birth.
3. Outborn infants who have been home prior to admission.
4. Infants who die in the delivery room or initial resuscitation area prior to
   admission to the neonatal intensive care unit.
5. Infants not in the reporting hospital at the postnatal age recommended for
   ROP screening by the AAP.

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
See 2a1.8 above.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
Reports are stratified by gestational age, birth location and birth weight category.

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: Stratification by risk category/subgroup   **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
N/A

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*: Better quality = Higher score

2a1.20 Calculation Algorithm/Measure Logic *(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
1. Identify the population of eligible infants: all infants whose gestational
   age is between 22 weeks, 0 days, and 29 weeks, 6 days, who are born at or
   admitted to the hospital within 28 days of birth without having been
   discharged home and who are still hospitalized at the postnatal age at which
   the first retinal screening exam is recommended by the AAP guidelines.
   a. Determine the infant's postnatal age at discharge. This is calculated in
      days as date of discharge minus date of admission +1. Divide by 7 to
      determine the postnatal age at discharge in weeks.
   b. Compare each infant's postnatal age at discharge to the appropriate row
      in the following table adapted from: American Academy of Pediatrics,
      Section on Ophthalmology, American Academy of Ophthalmology, American
      Association for Pediatric Ophthalmology and Strabismus. Screening
      examination of premature infants for retinopathy of prematurity.
      Pediatrics. 2006;117 :572 –576.

   Timing of First Eye Examination Based on Gestational Age at Birth

```
-----------------------------------------------------------------
Gestational age at birth              Postnatal Age (weeks)
(completed weeks)              at initial ROP screening exam
----------------------         ----------------------------
    22                               9
    23                                8
    24                                7
    25                                6
    26                                5
    27                                4
    28                                4
    29                                4
```

   c. If the infant's postnatal age at discharge is greater than or equal to
     the postnatal age for initial ROP screening from the table, the infant is
     classified as "still hospitalized at the time of recommended initial ROP
     screening".
2. Among the population of eligible infants:
   a. Count the number of infants in the population of eligible infants. This
     number is the denominator for the measure: DENOM.
   b. Count the number of infants who had a retinal examination prior to
     discharge. This number is the numerator for the measure: NUM.
   c. The measure is calculated as:
     NUM / DENOM
     This measure represents the proportion of infants 22 to 29 weeks
     gestation who were hospitalized at the age when ROP screening is
     recommended who were screened prior to discharge.
   d. To stratify by gestational age, limit the counts and calculation to
     infants in the gestational age for the range 22-29 weeks.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
URL
http://www.vtoxford.org/about/NQF%20Measure%200483.pdf

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
Data for all eligible infants born during the reporting period are collected.

2a1.25 Data Source (*Check all the sources for which the measure is specified and tested*). If other, please describe:
 Administrative claims, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Vermont Oxford Network Database

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
http://www.vtoxford.org/about/network_db.aspx

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
http://www.vtoxford.org/tools/ManualofOperationsPart2.pdf

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested*): Facility

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Hospital/Acute Care Facility

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Data for infants 22-29 weeks gestation born between 2006 and 2010 by gestational age are shown below.

```
ROP Screening,        ----------------Gestational Age-------------------
AAP Recommended Age    22    23    24    25    26    27    28    29
------------------     --    --    --    --    --    --    --    --
Yes                    12   136   394   571  1025  1631  2382  3747
No                    338  3990 11128 15776 20114 24485 28933 30397
```

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
The number and percent of eligible infants who were in the reporting hospital at the postnata age recommended for ROP screening by the AAP and who received a retinal examination for ROP prior to discharge are reported, along with
Network mean values and the 25th and 75th percentile values for all hospitals in the Network. Statistics are reported for all eligible infants and by gestational age, birth weight category and birth location.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
N/A

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H☐ M☐ L☐ I☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* **are consistent with the evidence cited in support of the measure focus (***criterion 1c***) and identify any differences from the evidence:**
Guidelines are provided by the American Academy of Pediatrics ("Screening Examination of Premature Infants for Retinopathy of Prematurity," Pediatrics, Vol. 117, No. 2, Feb 2006, 572-576, and Erratum, Pediatrics, Vol. 117, No. 4, Apr 2006, 1468).

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.*)

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Data for member hospitals from 2006 to 2010 are summarized below.

Birth Year	Hospitals	Minimum Infants	Maximum Infants
2006	629	1	184
2007	675	1	201
2008	740	1	234
2009	801	1	206
2010	827	1	202

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Comprehensive business rules have been implemented in software applications so that each record submitted is tested for consistency, completeness and accuracy. Submitted records with errors must be corrected before data are finalized and reports of the measures are provided to hospitals.

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
There is an annual assessment of item definitions by the Network Database Advisory Committee. The annual assessment results in modifications to the definitions for measures. Expert advisors to the registry directors provide recommendations for measure improvement and clarification of item criteria.

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results*

demonstrating the need to specify them.)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Infants outside the gestational age range and infants discharged before the recommended postnatal age for ROP screening are excluded, as are infants who die in the delivery room or initial resuscitation area prior to NICU admission.

2b3.2 Analytic Method *(Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
Exclusions are enforced by business rules that assure database integrity.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses)*:
The following table shows the number of infants, number of records excluded and percent excluded for birth years 2006-2010.

Birth Year	Number of Infants	Number Excluded	Percent Excluded
2006	33,917	7947	23.4%
2007	36,420	8145	22.4%
2008	38,533	8493	22.0%
2009	39,357	8706	22.1%
2010	38,222	8099	21.2%

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Reported data are stratified by gestational age, birth weight category and birth location (inborn, outborn). Data are not risk adjusted.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
Guidelines for ROP screening are provided by the AAP by postnatal age. Reports by gestational age, birth weight category and birth location are helpful to identify potential improvement opportunities.

2b4.3 Testing Results *(Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)*:
The number of infants and percent where ROP screening was done for eligible infants are shown below by gestational age for infants born between 2006 and 2010.

Gestational Age (completed weeks)	Number of Infants	Percent Screened Prior to Discharge
22	350	96.6
23	4126	96.7
24	11522	96.6
25	16347	96.5
26	21139	95.2
27	26116	93.8
28	31315	92.4
29	34144	89.0

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: ROP screening at the AAP recommended age is an important quality measure and is a matter of hospital protocol and leadership.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed*)

and discriminated meaningful differences in quality.)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
In 2010 reports were sent to 850 hospitals, and the measure was applicable for 29,145 infants.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
Results for hospitals are stratified by gestational age, birth weight category and birth location. The distribution of 2010 overall results among hospitals for key percentiles was analyzed univariately.

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
The hospital distribution of 2010 results among 850 hospitals for specific percentiles is shown below.

```
          Percent in Hospital at Recommended
Percentile   Given Retinal and Given Eye Exam
----------   --------------------------------
10th               79.2
25th               90.0
50th               96.2
75th              100.0
90th              100.0
```

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
N/A

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
N/A

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
N/A

2c. Disparities in Care: H☐ M☐ L☐ I ☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: N/A

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
N/A

2.1-2.3 Supplemental Testing Methodology Information:
URL
http://www.vtoxford.org/about/NQF%20Measure%200483.pdf

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 **Intended Purpose/ Use** *(Check all the purposes and/or uses for which the measure is intended)*:   Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 **Current Use** *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*:   Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For* <u>Maintenance</u> – *If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
Performance results are made available to the members of the Vermont Oxford Network at: https://nightingale.vtoxford.org Participants in the Vermont Oxford Network may access a fully featured Internet reporting system (Nightingale), as well as printed reports, which document patient characteristics, treatment practices, morbidity, mortality, and length of stay for the institution. The reports also track performance over time, comparing the institution's performance to that of the Network as a whole and with subgroups of similar institutions.

Vermont Oxford Network members may make their performance available to the public at their discretion.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results:
Retinopathy of prematurity (ROP) is a disorder that leads to blindness in neonates. Timely treatment of ROP is shown to reduce the risk of visual loss. Measuring and reporting the rate of the timely screening of infants for ROP allows care providers to evaluate performance and identify opportunities for improved practices.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): N/A

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For* <u>Maintenance</u> – *If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
Performance results are used for quality improvement by the members of the Vermont Oxford Network: http://www.vtoxford.org/about/membership.aspx. Participants in the Vermont Oxford Network may access a fully featured Internet reporting system (Nightingale), as well as printed reports, which document patient characteristics, treatment practices, morbidity, mortality, and length of stay for the institution. The reports also track performance over time, comparing the institution's performance to that of the Network as a whole and with subgroups of similar institutions.

Performance results are also used by participants in the Vermont Oxford Network's Quality Improvement Collaboratives: http://www.vtoxford.org/quality/nicq/nicq.aspx

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated *(e.g., QI initiative)*, describe the data, method and results:

Timely treatment of ROP is shown to reduce the risk of visual loss. Measuring and reporting the rate of the timely screening of infants for ROP allows care providers to evaluate performance and identify opportunities for improved practices. Measuring the performance of timely screenings allows care providers to identify opportunities to improve practices and to improve processes for identifying eligible infants and scheduling and performing retinal exams.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (**evaluation criteria**)

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H☐ M☐ L☐ I☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements are in a combination of electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
A manual of operations for the registry is published annually, with definitions and criterial clearly operationalized for the measure. Comprehensive business rules are implemented in software to verify records for consistency, completeness and accuracy. A definitive process is in effect to assure that the measure is not reported until data are complete and correct. Hospital contacts must verify that data for all eligible infants are submitted prior to finalization.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I☐

A.2 Please check if either of the following apply (*regarding proprietary measures*)**:**
4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (*e.g., fees for use of proprietary measures*)**:**
Patient identifiers are not collected in the registry. Confidentiality for each hospital member is strictly maintained. Procedures in place assure reasonable confidence that data are complete and accurate. There are no specific fees for this measure, although members of the Vermont Oxford Network pay an annual membership fee.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population)*, list the NQF # and title of all related and/or competing measures:

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Vermont Oxford Network, 33 Kilburn St, Burlington, Vermont, 05401

Co.2 Point of Contact: Beth, Anderson, banderson@vtoxford.org, 802-865-4814-237

Co.3 Measure Developer if different from Measure Steward: Vermont Oxford Network, 33 Kilburn St, Burlington, Vermont, 05401

Co.4 Point of Contact: Beth, Anderson, banderson@vtoxford.org, 802-865-4814-237

Co.5 Submitter: Beth, Anderson, banderson@vtoxford.org, 802-865-4814-237, Vermont Oxford Network

Co.6 Additional organizations that sponsored/participated in measure development:

Co.7 Public Contact: Beth, Anderson, banderson@vtoxford.org, 802-865-4814-237, Vermont Oxford Network

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
N/A

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: N/A

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.3 Year the measure was first released: 2008
Ad.4 Month and Year of most recent revision: 10, 2011
Ad.5 What is your frequency for review/update of this measure? Annual

Ad.6 When is the next scheduled review/update for this measure? 09, 2012	
Ad.7 Copyright statement: Copyright © 2011 Vermont Oxford Network, Inc.	
Ad.8 Disclaimers:	
Ad.9 Additional Information/Comments:	
Date of Submission (*MM/DD/YY*): 10/17/2011	