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**ROP Safety Net Toolkit**

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**OMIC policyholders who provide care must comply with the ROP Safety Net.**

OMIC’s ROP Safety Net is based on our claims experience. It is designed to address the causes of ROP lawsuits in order to protect the infant and the ophthalmologist. The ROP Safety Net Toolkit contains sample protocols, which may need to be customized, and refers to ROP clinical care guidelines. These protocols and guidelines are recommendations and do not constitute the standard of care. Ophthalmologists should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation.

The Toolkit does not provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

**Version 2/14/19**

# **Procedure 4. Discharge**

**Discharge principles**

1. The hospital either allows infants discharged from the NICU to be readmitted for ROP treatment or has a transfer agreement in place with a hospital that does allow discharged infants to be admitted for ROP treatment within 72 hours of notice that it is needed.
2. No hospital may discharge an infant who needs ROP care unless it first:
   1. Obtains the agreement of the hospital-based ophthalmologist **AND**
   2. Schedules ophthalmic care in the outpatient setting with an ophthalmologist who agrees to screen the ROP patient **AND**
   3. Sends the ophthalmologist appropriate records and current contact information for the parent.
3. The hospital has a written discharge agreement with outpatient ophthalmologists who do not provide ROP care at the hospital. The agreement addresses ROP tracking, follow-up, and treatment.

**Discharge process**

**Use the hyperlinks to see tables and forms. To go back to where you were in the document, press Alt+left arrow if using a PC.**

1. The neonatologist notifies the ophthalmologist and hospital ROP coordinator (H-ROPC) that a discharge is planned.
2. The ophthalmologist determines if the infant needs another ROP exam or additional treatment prior to discharge and writes a final ophthalmic consult note that summarizes the infant’s current ROP status and screening/treatment recommendations (a new note may not be needed if the ophthalmologist has evaluated or treated the infant very recently).
3. The ophthalmologist tells the H-ROPC (hospital ROPC) and O-ROPC (office ROPC):
   1. The interval and approximate date of the next ROP exam if screening is not complete (e.g., follow-up exam in 2 weeks around 9/25/19) [[Table 3. Follow-up exams](#_Table_3._)].
   2. If ROP screening is complete [[Table 5. When to stop](#_Table_5._)].
4. The ophthalmologist instructs the ROPCs to update the Hospital [ROP Tracking List](#_Tracking_list) to show that the infant was discharged.
5. The ophthalmologist completes and signs the [Discharge letter](#_Consent_for_laser) or [Spanish Discharge letter](#_ICROP._Synopsis_of_1), and writes an order for the hospital ROPC or NICU nurse to:
   1. Review the letter with the parent, and obtain the parent’s signature.
   2. Give a copy of the signed document to the parent.
   3. Place a copy of the signed document in the infant’s medical record.
6. The neonatologist explicitly addresses eye care in the discharge summary based upon the most recent ophthalmology note:
   1. States the interval and approximate date of the next exam (e.g., ROP exam needed in two weeks around 9/25/19) if ROP screening is not complete **OR**
   2. Directs the pediatrician to refer the infant to an ophthalmologist to screen for conditions common in premature infants, such as amblyopia, strabismus, etc.
7. The H-ROPC coordinates the discharge:
   1. Confirms that the ophthalmologist has been notified of the discharge and has agreed to it.
   2. Contacts the O-ROPC of the ophthalmologist who will provide outpatient ROP care and:
      1. Confirms that an ophthalmologist has agreed to take over the ROP care,
      2. Indicates the interval and approximate date of the first outpatient exam,
      3. Schedules the initial ROP exam with the ophthalmologist, and
      4. Sends all pertinent medical records and current contact information for the parent.
   3. Informs the parent:
      1. Of the name of the outpatient ophthalmologist,
      2. The date and location of the next ROP exam, and
      3. That Child Protective Services may be contacted if the parent does not keep outpatient appointments exactly as scheduled.

# **[Table 1. Which infants need an ROP screening examination](#Table_1)[[1]](#footnote-1)**

Infants meeting any of the following criteria need an exam:

* Birth weight of ≤ 1500 g (3 lbs., 4 oz.)
* Gestational age of 30 weeks or less (as defined by the attending neonatologist)
* Selected infants with a birth weight between 1500 and 2000 g (from 3 lbs., 4 oz. to 4lbs, 6 oz.) or gestational age of more than 30 weeks who are believed by their attending pediatrician or neonatologist to be at risk for ROP (such as infants with hypotension requiring inotropic support, infants who received oxygen supplementation for more than a few days, or infants who received oxygen without saturation monitoring).

**REFERENCE: ROP Screening Policy Statement # 1**. Based on Recchia, Franco and Capone, Antonio, Contemporary Understanding and Management of Retinopathy of Prematurity, *Retina* 2004; 24:283-92.

# [**Table 2. When to start ROP screening**](#Table_2)

The onset of serious ROP correlates better with postmenstrual age (gestational age at birth plus chronological age) than with postnatal age. This protocol bases the initial eye examination on postmenstrual age and chronological age. The initial eye examination should be conducted:

* By 31 weeks postmenstrual age if gestational age < 27 weeks
* At 4 weeks chronological age if gestational age ≥ 27 weeks

**Age in weeks at initial exam**

|  |  |  |
| --- | --- | --- |
| **Gestational age at birth** | **Postmenstrual age** | **Chronologic age** |
| 22a\* | 31 | 9 |
| 23a\* | 31 | 8 |
| 24\* | 31 | 7 |
| 25\* | 31 | 6 |
| 26 | 31 | 5 |
| 27 | 31 | 4 |
| 28 | 32 | 4 |
| 29 | 33 | 4 |
| 30 or more | 34 | 4 |
|  |  |  |

a This guideline should be considered tentative rather than evidence-based for 22-to-23-week infants owing to the small number of survivors in these gestational age categories.

**\***Some practitioners have advocated for earlier screening on the basis of speculation that treatable aggressive posterior ROP (AP-ROP) could occur before 31 weeks postmenstrual age. AP-ROP is a severe form of ROP that is characterized by rapid progression to advanced states in posterior ROP.

**REFERENCE:ROP Screening Policy Statement #2.** Based upon Reynolds JD, Dobson V, Quinn GE, et al. 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.* 2002; 120 (11): 1470-1476.

# **[Table 3. Follow-up schedule for ROP exams](#Table_3)**

The examining ophthalmologist should use retinal findings as classified by ICROP[[2]](#footnote-2) to determine the timing of the follow-up examinations.

* 1 week or less
  + Zone I: Immature vascularization, no ROP
  + Zone I: Stage 1 or 2 ROP
    - **NOTE IN PS:** Zone I, Stage 3 requires treatment, not observation
  + Immature retina extends into posterior zone I, near the boundary of zone –zone II.
  + Suspected presence of AP-ROP (aggressive posterior ROP)
  + After laser photocoagulation or anti-VEGF injection to ensure that there is no need for additional laser treatment in areas where ablative treatment was not complete or additional anti-VEGF injection.
* 1 to 2 weeks
  + Posterior zone II: Immature vascularization
  + Zone II, Stage 2 ROP
  + Zone I: Unequivocally regressing ROP
* 2 weeks
  + Zone II: Stage 1 ROP
  + Zone II: no ROP, immature vascularization
  + Zone II: Unequivocally regressing ROP
* 2 to 3 weeks
  + Zone III: Stage 1 or 2 ROP
  + Zone III: Regressing ROP

**REFERENCE**:**ROP Screening Policy Statement #4**. Based on Reynolds JD, Dobson V, Quinn GE, et al. 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.* 2002; 120 (11): 1470-1476.

# **Table 4. When to treat ROP**

* The presence of plus disease in zones I or II suggests that peripheral ablation, rather than observation, is appropriate.\*
  + Plus disease is defined as abnormal dilatation and tortuosity of the posterior retinal blood vessels in 2 or more quadrants of the retina meeting or exceeding the degree of abnormality represented in reference photographs
  + The presence of plus disease rather than the number of clock hours of disease, is the better determining factor in recommending ablative treatment.
* Treatment should be initiated for the following retinal findings that characterize Type 1 ROP:
  + Zone I ROP: any stage with plus disease
  + Zone I ROP: stage 3, no plus disease
  + Zone II ROP: stage 2 or 3 with plus disease
* Treatment should generally be accomplished, when possible, within 72 hours of determination of treatable disease to minimize the risk of retinal detachment.
* Consideration may be given to treatment of infants with zone I stage 3+ ROP with intravitreal injection of bevacizumab.#
  + Bevacizumab and other anti-VEGF substances are not approved by the US Food and Drug Administration for the treatment of ROP.
  + Treatment should only be administered after obtaining detailed informed consent, because there remain unanswered questions involving dosage, timing, safety, and visual and systemic outcomes. Studies have yielded contrary findings on the increased incidence of neurodevelopmental problems, including severe cerebral palsy, hearing loss, and bilateral blindness.
  + Infants treated with bevacizumab should be monitored closelyuntil at least 65 weeks postmenstrual age
  + Longer follow-up is required because recurrence occurs considerably later (16 ± 4.6 weeks vs 6.2 ± 5.7 weeks) than after laser therapy. There are reports of recurrence requiring retreatment as late as 65 to 70 weeks postmenstrual age.
  + The timeframe of highest disease reactivation is between 45 and 55 weeks.
* Follow up is recommended in 3 to 7 days after laser photocoagulation or anti-VEGF injection to ensure that there is no need for additional laser treatment in areas where ablative treatment was not complete or for additional anti-VEGF injection.

**REFERENCE:ROP Screening Policy Statement #4 based upon:**

\* 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.* 2003; 121:1684-1694.

* # Mintz-Hittner HA, Kennedy KA, Chuang AZ; BEAT-ROP Cooperative Group. Efficacy of intravitreal bevacizumab for stage 3+ retinopathy of prematurity. *N Engl J Med*. 2011; 364(7):603–615.

# **Table 5. When to stop ROP screening**

**Per the Policy Statement, one exam is sufficient only if it unequivocally shows the retina to be fully vascularized in both eyes.**

The conclusion of acute-retinal-screening examinations should be based on age and retinal ophthalmoscopic findings. Findings that suggest that examinations can be terminated include:

* Full retinal vascularization in close proximity to the ora serrata for 360°--that is, the normal distance found in mature retina between the end of vascularization and the ora serrata.
* 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.
* Postmenstrual age of 45 weeks: No type 1 ROP or worse is present, and no anti-VEGF treatment
  + Type 1 ROP disease (previously called “pretheshold”) defined as:
    - Stage 3 ROP in zone II
    - Any ROP in zone I
* Postmenstrual age of 65 weeks: Infants treated with anti-VEGF
  + Follow closely until at least 65 weeks postmenstrual age
  + Particularly close follow-up is needed during the time of highest risk for disease reactivation (45 to 55 weeks PMA)
  + Care must be taken to be sure that there is no abnormal vascular tissue present that is capable of reactivation and progression in Zone II or III
  + Full retinal vascularization should be the criterion for all infants treated solely with anti-VEGF medication.
  + Full retinal vascularization is not always achieved in infants treated with anti-VEGF alone.
  + If there is not full retinal vascularization at 65 weeks PMA, rely upon prolonged observation, clinical judgment, and evolving criteria for termination of exams or a need for further treatment.
* Regression of ROP (see ICROP)
  + Care must be taken to be sure that there is no abnormal vascular tissue present that is capable of reactivation and progression in zone II or III.

**REFERENCE:ROP Screening Policy Statement # 4.** Based upon Reynolds JD, Dobson V, Quinn GE, et al. 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.*Arch Ophthalmol.* 2002; 120 (11): 1470-1476.

# **ROP Tracking List**

NOTE: To use as an Excel document, click on the list, choose “Worksheet Object” and then “Open.”



# **Discharge letter**

Ophthalmologist: Place on your letterhead

Dear \_\_\_\_\_\_\_\_\_

I am an ophthalmologist (eye physician and surgeon). Your baby’s doctor asked me to examine the baby’s eyes. This letter will explain why I did the exam. It will also explain when an ophthalmologist needs to examine the baby’s eyes again.

**Your baby may have a condition of the retina (the back of the eye) called ROP (retinopathy of prematurity).** After a premature birth, the blood vessels at the back of the eye may stop growing. The baby’s body responds by making a chemical called VEGF (vascular endothelial growth factor). This chemical makes new blood vessels start growing.

But these are not normal blood vessels. These abnormal blood vessels can bleed. They can also pull (detach) the retina away from its normal position. This is called an RD (retinal detachment), and it can cause blindness. ROP needs to be treated with 72 hours if it reaches a certain stage. Your baby could go blind without treatment.

**The next few months are very important.** We need your help to keep your baby from going blind. An ophthalmologist will need to examine the baby’s eyes many times. The ophthalmologist is checking for abnormal blood vessels. The exams must continue until the blood vessels heal.

You must bring the baby in to the office or clinic for every appointment. The ophthalmologist will contact you if you missan appointment. If the ophthalmologist cannot reach you, the ophthalmologist may need to contact Child Protective Services to help bring the baby in for an eye exam.

**Here is what I found today when I examined your baby**

* \_\_\_\_Your baby’s blood vessels are abnormal. The baby may need treatment soon. An ophthalmologist will examine the baby each week to see if treatment is needed. The next ROP exam will take place around \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) in \_\_\_\_\_ weeks.
* \_\_\_\_Your baby’s blood vessels are abnormal. But the baby does not need treatment right now. An ophthalmologist will examine the baby again to see if treatment is needed. The next ROP exam is on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) in \_\_\_\_\_ weeks.
* \_\_\_\_\_Your baby’s blood vessels are almost normal. The baby will not need treatment for ROP. But the baby needs a different type of eye exam. This exam will include a check for crossed eyes, lazy eye, or nearsightedness. Your baby needs to be checked on about \_\_\_\_\_\_\_\_\_\_\_ (date). Ask the baby’s doctor (pediatrician) for a referral to an ophthalmologist. Then call the ophthalmologist and make the appointment.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name of ophthalmologist \_\_\_\_\_ Date

# **Carta de referencia**

Nota para el Oftalmólogo: Copie esto en su papel membretado

Ophthalmologist: Place on your letterhead

Apreciado(a) \_\_\_\_\_\_\_\_\_

Soy oftalmólogo(a) (médico y cirujano de los ojos). El médico que atiende a su bebé me pidió que le examinara los ojos. En esta carta le explicaré porqué hice el examen. Le explicaré también cuándo es necesario que un(a) oftalmólogo(a) examine de nuevo los ojos de su bebé.

**Es posible que su bebé tenga una afección de la retina (la parte de atrás del ojo) que se conoce como ROP (retinopatía de la prematurez).** Después de un nacimiento prematuro, los vasos sanguíneos de la parte posterior del ojo pueden dejar de crecer. El organismo del bebé responde produciendo una sustancia química conocida como VEGF (factor de crecimiento de la vasculatura endotelial). Esta sustancia química hace que comiencen a desarrollarse nuevos vasos sanguíneos.

Pero estos vasos sanguíneos no son normales. Son vasos sanguíneos anormales que pueden sangrar. También halan (desprenden) la retina separándola de su posición normal. Es lo que se conoce como DR (desprendimiento de retina), y puede causar ceguera. Si esta afección avanza a una cierta etapa, será necesario tratar la ROP en el trascurso de 72 horas. Su bebé podría quedar ciego(a) si no se le trata oportunamente.

**Los meses inmediatamente siguientes son muy importantes.** Necesitamos su ayuda para evitar que su bebé pierda la visión. Será necesario que un(a) oftalmólogo(a) examine los ojos de su bebé muchas veces. El (la) oftalmólogo(a) verifica que no haya vasos sanguíneos anormales. Los exámenes deben continuar hasta que los vasos sanguíneos sanen.

Deberá llevar a su bebé al consultorio o a la clínica a cada una de las citas de control. El oftalmólogo se comunicará con usted en caso de que falte a alguna cita. Si el oftalmólogo no se puede comunicar con usted, tal vez tenga que contactar a los Servicios de Protección de Menores para ayudar a que su bebé vuelva a recibir los exámenes oculares necesarios.

**Al examinar hoy a su bebé encontré lo siguiente:**

* \_\_\_\_Los vasos sanguíneos de su bebé son anormales. Es posible que el bebé requiera tratamiento a la mayor brevedad. Un(a) oftalmólogo(a) lo examinará todas las semanas para ver si se necesita tratamiento. El próximo examen de la ROP será aproximadamente el \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (fecha) en \_\_\_\_\_ semanas.

* \_\_\_\_ Los vasos sanguíneos de su bebé son anormales. Pero el bebé no requiere tratamiento de inmediato. Un(a) oftalmólogo(a) lo examinará de nuevo para ver si se requiere tratamiento. El siguiente examen de ROP será el \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (fecha) en \_\_\_\_\_ semanas.

* \_\_\_\_\_Los vasos sanguíneos de su bebé están casi normales. el bebé no requerirá tratamiento para la ROP. Sin embargo, requiere un tipo diferente de examen ocular. Este examen incluirá un estudio para determinar si es bizco, si tiene un ojo perezoso o si es miope. Su bebé deberá ser examinado(a) en una cita de control aproximadamente el \_\_\_\_\_\_\_\_\_\_\_ (fecha). Pídale a la médico (pediatra) de su bebé que lo (la) remita a un oftalmólogo. Después llame al consultorio del oftalmólogo a pedir una cita.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Nombre del oftalmólogo \_\_\_\_\_ Fecha

1. Clinical tables based upon Fierson WM. “Screening Examination of Premature Infants for Retinopathy of Prematurity.” Policy Statement (PS) issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Association of Certified Orthoptists. Originally issued in 1997 and updated in 2001, 2005, 2006, and 2018; current version published in *Pediatrics* (Volume 142, Number 6, 2018, at <http://pediatrics.aappublications.org/content/early/2018/11/21/peds.20183061>. This document refers to recommendations based upon the numbers assigned to them in the PS. [↑](#footnote-ref-1)
2. The International Classification of Retinopathy of Prematurity Revisited. International Committee for the Classification of Retinopathy of Prematurity. *Arch Ophthalmol* 2005. 123: 991-999. Available at <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/417157>. [↑](#footnote-ref-2)