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**ROP Safety Net: Risk Analysis**

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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.

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Screening and treating premature infants for ROP (retinopathy of prematurity) is an important aspect of ophthalmic care that provides a valuable service to not only the individual baby but also to society as a whole. Although claims for mismanagement of ROP are relatively infrequent, indemnity payments for these claims can be high due to the young age of the plaintiffs and the significant loss of vision that can result even with treatment. Concerned about their liability exposure, numerous screening and treating ophthalmologists have called OMIC to request sample protocols to help standardize care.

OMIC first developed and distributed the ROP Safety Net protocols in 2006. Our experience in helping ophthalmologists implement these patient safety measures has convinced us that liability for ROP care can only be decreased if ophthalmologists work closely with neonatologists, nurses in Neonatal Intensive Care Units (NICUs), hospitals, and parents. We accordingly developed sample protocols—our ROP Safety Net Toolkit—for both office- and hospital-based care. OMIC-insured ophthalmologists must implement certain aspects of the ROP Safety Net protocols as a condition of coverage for ROP care, including ROP-related CME, hospital and office tracking, parental education, documented hand-offs, etc.

This document, “ROP Safety Net: Risk Analysis,” will present the obstacles to safe ROP care, OMIC’s ROP claims experience, and our risk management recommendations. Toolkits that detail every step in the care process are available from our website at <http://www.omic.com/rop-safety-net/>.

# **Why is the ROP care process so problematic?**

**Difficulties in Providing Vision-Preserving Care to Premature Infants**

Some aspects of ROP care put premature infants and the entire healthcare team at risk. Premature infants face a host of severe medical problems. While some are life threatening, ROP is sight threatening. The neonatologist and nurses in the neonatal intensive care unit spend considerable amounts of time coordinating and orchestrating consultations and care. The ophthalmologist is just one of a number of physicians who care for these patients.

Generally, ophthalmologists come to the hospital at periodic intervals, usually one day each week, to evaluate those infants whom the neonatologist has identified as meeting the ROP screening criteria. The ophthalmologist notes the ROP status and indicates a follow-up interval in the hospital record. The hospital adds the baby’s name to the list of those to be screened on the next ROP exam day.

Problems arise when babies are discharged or transferred before the follow-up date or are unavailable at the time of the ophthalmologist’s visit (e.g., are undergoing surgical procedures, or are too ill). Many times, the ophthalmologists who comprise the ROP screening and treating panel are not notified of the location and status of the baby. Plaintiffs have successfully sued ophthalmologists who had no prior contact with the baby. Some defendants saw the baby once and properly screened him but were not asked to see the baby again in the hospital. Others were never contacted by the parents, even though the parents were advised by the baby’s neonatologist or pediatrician to schedule an outpatient ophthalmology appointment.

Parents of premature infants tend to feel overwhelmed. Some are young women with little prenatal care; others have minimal family support. At times, infants may end up being cared for by other family members or foster parents. Our claims experience has taught us that these beleaguered parents cannot be relied upon to schedule appointments, and may require significant follow-up efforts to ensure that screening and treatment occur at the appropriate intervals.

While many ophthalmic conditions need timely follow-up, the treatment window for ROP is exceedingly short: once the need for intervention has been identified by the ophthalmologist, treatment must be provided within 72 hours.The hospital needs time to arrange the laser surgery and anesthesia care. If the hospital does not have an ophthalmologist on staff to provide the treatment, it must transfer the baby to a hospital that can provide such care during the same 72-hour period. The entire team—ophthalmologists, neonatologists, pediatricians, nurses, and hospitals—become targets of litigation when ROP care protocols for screening and treatment break down. More importantly, a baby can lose sight.

# **What causes ROP lawsuits?**

**ROP Claims Experience**

Since its inception in 1987, OMIC-insured physicians and their practices have faced claims for medical malpractice on behalf of 21 infants with ROP. ROP claims are thus low frequency events (<1% of OMIC’s total claims). Plaintiffs often sue more than one defendant. If OMIC insures both defendants, or if the physician and his/her practice (with separate limits) are sued, more than one claim per infant may result. These 21 cases have thus resulted in 30 claims/suits.

While infrequent, ROP claims are the highest severity events in OMIC’s claims experience. They require the most money to settle, since ROP often leads to bilateral blindness or severe visual loss. ROP claims account for 6% of paid OMIC claims. They close with an indemnity payment about three times more often than overall claims (59% versus 21%). ROP claims have a higher mean ($675,962 vs. $177,700) and median ($500,000 vs. $90,000) payment than overall claims. Four of our top ten indemnity payments were for ROP, including our highest-ever payment of $3,375,000.

Non-OMIC ROP claims have had reported verdicts of $20,000,000 against an ophthalmologist, neonatologist, and hospital in Pennsylvania (the hospital and its insured neonatologist were responsible for 95% of the verdict, the ophthalmologist for 5%), and $38,000,000 against another non-OMIC insured ophthalmologist.

**ROP Causation Analysis**

It is not always possible to prevent poor outcomes; some infants end up blind despite appropriate screening and treatment. We examined our 30 claims to determine what led to the poor outcome in order to learn ways to prevent similar problems. Four types of factors impact care outcomes: clinical, systems, physician, and patient/parent. We identified the primary, secondary, and tertiary causes in each category and provide the results in **Table 1**. Explanations and examples of the categories follow.

**Table 1. Factors impacting outcomes of ROP care**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **CLINICAL** | **SYSTEMS** | **PHYSICIAN** | **PARENT/PATIENT** |
| Primary | 2 | 18 | 5 | 0 |
| Secondary | 3 | 3 | 2 | 6 |
| Tertiary | 2 | 0 | 1 | 4 |
| **Total** | **7** | **21** | **8** | **10** |

**CLINICAL FACTORS**

This category describes situations in which the knowledge and clinical guidelines needed to improve the outcome were nonexistent, evolving, or controversial (e.g., no treatment existed when the disease was known as “retrolental fibroplasia”). We feel that physicians should not be held liable for poor outcomes when treatment is not available or there is no established standard of care. We noted that in some lawsuits, plaintiff experts tried to apply a later standard of care. We based our analysis on what was accepted as the standard of care at the time treatment was rendered.

**Examples of claims impacted by the lack of treatment or guidelines**

* The care was provided prior to the publication of the results of the CRYO-ROP clinical trial, which showed cryotherapy as an effective treatment.
* No clinical guidelines at the time of care addressed the extent of laser needed to treat ROP.
* The clinical course was inconsistent with the usual natural history of ROP, raising questions about comorbidities that were difficult to identify or verify. For example, none of the treating physicians (or defense expert witnesses) could explain one baby’s eye condition; all agreed it was not caused by ROP.

**SYSTEMS**

This category generally refers to a breakdown in a process of care where the outcome is not due to the action of a single individual. The most common systems issue was follow-up (e.g., the physician noted in the medical record that the infant needed to be seen again in two weeks, consistent with the clinical guidelines, but the infant did not get the exam at the correct time for a variety of reasons).

**Examples of preventable breakdowns in the process of care**

* ROP exam scheduling
  + Lack of request for an ROP screening in the hospital.
  + Discharge before ROP screening or without scheduling a follow-up outpatient appointment, leading to a significant delay in diagnosis.
  + Transfer without arrangements for an ophthalmology consult at the new facility.
  + Outpatient appointment scheduled at an incorrect interval.
* Follow up on missed appointments
  + Hospital deleted infant from re-examination list.
* Referral to a specialist
  + The screening ophthalmologist told the parents to schedule an appointment with a treating physician rather than making it for them.

**Location of breakdown in the process of care**

* Hospital only: 6
* Hospital-office coordination: 4
* Office only: 1

**Prevention of systems errors**

* Create and maintain a tracking system.
  + Build in redundancy.
    - Two people track infants in the hospital: a staff member at the ophthalmologist’s office (office ROP coordinator or O-ROPC), and the hospital ROPC. The ROPCs compare the list of hospitalized infants receiving ROP care at least once a week. They notify the ophthalmologist and neonatologist of missed or delayed exams.
    - The O-ROPC tracks missed outpatient exams in two ways: by checking for ROP appointments daily, and by reviewing the Outpatient ROP Tracking List at least once a week. The O-ROPC notifies the ophthalmologist of all missed, cancelled, and rescheduled ROP appointments.
  + Track until infants meet end-of-screening/treatment criteria.
* Put screening and treatment clinical guidelines at the point of care so that physicians or staff who are less familiar with them can confirm current recommendations.
* Write the follow-up order as both an interval and an approximate date (e.g., “next ROP exam in 2 weeks on about 7/19/18”).
* Conduct an ROP exam prior to discharge or transfer from the hospital.
* Coordinate the discharge and initial outpatient appointment.
  + Notify the ophthalmologist before the baby is discharged or transferred to ensure that exams are up to date and needed treatment has been provided.
    - Contact both the inpatient and outpatient screening ophthalmologists if the baby will be screened for ROP after discharge by a different ophthalmologist.
  + Contact the office ROPC or Admitting Nurse at the 2nd hospital to schedule the next eye exam, and send necessary records and contact information.
  + Inform the parents in writing of the appointment date and the risks of not getting care when needed.

**PHYSICIAN FACTORS**

Lack of physician knowledge or competency was the primary problem in four claims, the secondary in two and the tertiary in one. These claims showed a lack of familiarity with established clinical guidelines.

**Examples of claims impacted by physician factors**

* Baby born at 27 weeks, seen at 31 weeks: 6 week follow-up ordered instead of 2 weeks.
* Baby born at 26 weeks, seen at 32 weeks: 6 month follow-up ordered instead of 2 weeks.
* Baby born at 24 weeks, seen at 33 weeks: 4 week follow-up ordered instead of 2 weeks.

**Prevention**

* Complete courses on ROP diagnosis and treatment at regular intervals.
* Provide regular training on ROP systems issues to ophthalmologists and staff.
* Put clinical guidelines in hospital and office protocols so they are available at the point of care.
* Instruct the hospital and office ROPCs to compare the follow-up interval ordered by the physician to those in the clinical guidelines. Ensure that exams for acute phase ROP take place at least every 2-3 weeks; they may need to be one week or less for certain infants.

**PARENT**

Parent noncompliance was never the primary cause, but was a secondary issue in six cases, and the tertiary in four.

**Examples of claims impacted by parent’s behavior**

* Did not make an outpatient appointment in the period required.
* Did not keep scheduled appointments.

**Prevention**

* Start ROP education at the time of the initial screening, and repeat it when the ROP status changes, the patient needs treatment, at the time of hospital discharge, and at the initial outpatient appointment.
  + Provide our “Dear Parent” letter and ROP brochures.
  + Discuss the disease, risk of blindness, current status, and next eye exam.
  + Document educational efforts and discussions.
* Schedule all appointments: do not ask parents to make them.
* Ask the office ROP coordinator to notify the ophthalmologist immediately if the appointment is missed or rescheduled.
* Ask the office ROP coordinator to call the parent about any missed or rescheduled appointments.
  + Document the conversation.
  + Send a missed appointment letter right away if the parents cannot be reached by phone or does not agree to bring the baby for the exam as requested. The office toolkit contains a sample letter.
* Contact Child Protective Services if needed in order to enforce compliance with appointments at appropriate intervals.

# **Implement the ROP Safety Net**

We believe that implementing our ROP Safety Net can help prevent blindness from ROP. In addition to promoting patient safety, we aim to increase the defensibility and minimize the liability of ROP care. We cannot stress enough that risk management recommendations do **not** establish a standard of care. Rather, they serve as suggestions on how the healthcare team—the ophthalmologist, neonatologist/pediatrician, NICU nurses, hospital, ROP coordinators, and parents—can create a safety net for these at-risk infants.

Clarification of roles and standardization of care are key components of the ROP Safety Net. The entire team needs to be involved at critical junctures in the ROP care process, including tracking, the ongoing education of the parents, treatment, and coordinating transfer of care to ophthalmologists at another hospital or in an outpatient setting. The ROP toolkits assign responsibility for each task in the ROP care process, both in the hospital (or other healthcare facility) and during outpatient care so that there is no confusion about who is responsible for decision-making and follow-up.

Conduct a risk analysis of your current process of care to evaluate weak spots in the “safety net.” Identify any steps in the toolkit protocols for which responsibility has not been assigned or where care is not being provided according to current clinical guidelines such as the ROP Screening Policy Statement.[[1]](#footnote-1)

We welcome questions about the ROP Safety Net as well as suggestions on how to improve it. We can help OMIC policyholders to customize the procedures to their practice and hospitals. Please contact our Risk Management Hotline at 800-562-6642, option 4, or at [riskmanagement@omic.com](mailto:riskmanagement@omic.com).

1. “Screening Examination of Premature Infants for Retinopathy of Prematurity.” Policy Statement issued by the American Academy of Pediatrics (AAP) Section on Ophthalmology, the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and the American Academy of Ophthalmology (AAO). Originally issued in 1997 and updated in 2001, 2005, and 2006; current version published in *Pediatrics* (Volume 131, Number 1, 2013, at <http://pediatrics.aappublications.org/content/131/1/189>. [↑](#footnote-ref-1)