MALPRACTICE AND THE QUALITY OF CARE IN RETINOPATHY OF PREMATURITY (AN AMERICAN OPHTHALMOLOGICAL SOCIETY THESIS)

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ABSTRACT

Purpose: A review of retinopathy of prematurity (ROP) malpractice cases will identify specific, repetitive problems in the provision of care and the reasons underlying these problems. Opportunities to improve the quality of care provided to premature infants with ROP will result.

Methods: A retrospective review of a series of 13 ROP malpractice cases in which the author served as a paid consultant, as well as a review of the literature for additional cases, was conducted. The series of 13 involved a review of the entire medical record as well as testimony and depositions. The characteristics of each case are tabulated, including state, date, allegations, defendants, disposition, award, the medical facts and care issues involved, and the judgment of medical error. In addition, a merit review was performed on the care in each case, and an error assessment was performed.

Results: The quality of care issues included neonatology failure to refer or follow up in 8 of 13, failure to adequately supervise resident care in 2 of 13, ophthalmologic failure to follow up in 6 of 13, and failure to properly diagnose and manage in 9 of 13. The latter included 4 of 13 that hinged on zone III issues and the presence or absence of full nasal vascularization with or without previous zone II disease. Merit review found negligent error by at least one party in 12 of 13. Ophthalmology error was found in 6 of 13. Malpractice, ie, negligent error causing negligent harm, was judged to be present in 9 of 13.

Conclusions: Negligent errors are common in malpractice cases that proceed to disposition. There are a limited number of repetitive errors that produce malpractice. An explanation of how these errors occur, coupled with the pertinent pathophysiology, afford an excellent opportunity to improve patient care

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INTRODUCTION

Retinopathy of prematurity (ROP) continues to be a medical and a socioeconomic problem.[1-3] First described by Terry in 1942, the paper coined the term *retrolental fibroplasia*.[4,5] Terry concluded his 1942 paper by calling for more study in the disease's "frequency, cause and full nature" and the hope for "prophylactic treatment and effective therapy." For over 60 years ophthalmologists and neonatologists have been trying to answer Terry's call. For most of those years neonatology care issues, such as supplemental oxygen and blood oxygen saturation levels, were the only clinical concerns for ROP.

Ophthalmologists' involvement in ROP was limited to research and clinical observation. We could examine and document but were without an effective treatment. In 1988 the Cryotherapy for Retinopathy of Prematurity (CRYO-ROP) study changed all that.[6] Ophthalmologists could now both assess and treat the condition, and therefore screening took on a much greater significance. There was now a duty to refer, examine, diagnose, and, if need be, treat in a timely manner. With that knowledge and ability came responsibility.

However, at our current level of knowledge, we cannot totally eliminate the blindness that can result from ROP. We are able to dramatically improve anatomic and functional results, yet optimal care can still result in very poor outcomes. Unfortunately, suboptimal care, although rare, can also occur. Such care and its improvement are the subject of this thesis.

The purpose of this thesis is to explore specific medical and legal issues relating to ROP, to analyze a retrospective, case series of ROP malpractice cases over the last 8 years that are public record, to review additional malpractice cases culled from the literature, to identify specific areas of current medical practice that have been the focus of malpractice actions, and to suggest specific responses that will improve clinical outcomes as well as lessen the likelihood of suits. Such an analysis can use the lessons learned from malpractice to improve the quality of care provided to premature infants. Thus the primary hypothesis of this thesis is that an analysis of the care concerns identified in these malpractice cases will detect specific problems, the explanation of which will provide specific opportunities to improve care.

It is important to recognize that best practices are shaped not only by critically assessing the literature and judging conflicting evidence. They are also shaped by evolving case law that can highlight problem areas and the remedial measures that need to be taken to address those problems. Conducting a disease-specific review of ROP malpractice issues and promulgating suggested corrective actions can directly influence the quality of care. In this sense malpractice disputes may have a positive influence on quality. In fact, what we refer to as the standard of care is a legal concept that is clearly shaped by case law

However, malpractice can have deleterious effects also. The threat of lawsuits and the fear of liability can push physicians to limit their practices and negatively impact access to care. There is little question that ROP care is provided by a very small number of qualified physicians and that hospitals and nurseries could be drastically impacted if even a small number of examiners chose to withdraw from an unprofitable, time-consuming, relatively thankless, and now high-liability ROP screening program. It is possible that such a crisis could develop in ROP care. Reducing liability exposure by improving physician awareness and the quality of care provided could help retain full access to care.

The goal of this thesis is therefore to educate health care providers in areas critical to the quality of care of ROP and to reduce liability as a result of improved practices and hence help maintain patient access and quality care. In order to proceed, it is essential to be aware of the areas of medical knowledge in ROP that specifically pertain to liability issues. It is also important to have at least a rudimentary legal knowledge of the general principles involved in malpractice litigation. One caveat is very important. This entire analysis is conducted in order to improve the quality of care. It does not purport to give specific legal advice nor to affect or alter the legal standard of care.

MEDICAL BACKGROUND

Several critical areas in ROP represent the medical foundations of ROP litigation. These include portions of classification, natural history, incidence, screening, and, to a lesser degree, treatment. Although the pathogenesis of ROP may be the most exciting part of ROP research, it is not typically an element of litigation. It is essential that our care reflect a full appreciation of the evidence-based medical knowledge in these critical areas. It is especially important when dealing with alleged malpractice to be sensitive to the way scientific knowledge evolves and to the fact that errors of interpretation do occur.

The history of miscues and missteps in ROP investigation can be briefly illustrated. Jacobson and Feinstein[7] document all the failures in ROP research leading up to Kinsey's National Collaborative Trial.[8,9] Bolton and Cross[10] document the unfortunate ramification of Kinsey, ie, a beneficial reduction in ROP but an unfortunate increase in systemic mortality and morbidity. Silverman[11] effectively summarizes the lack of evidence-based supplemental oxygen guidelines. Wallace[12] updates that controversy by highlighting the deficiencies of observational data vs an adequately powered, prospective, randomized trial.

Classification

A descriptive disease classification comprises a shared language among all interested parties. It is the essence of consistent communication. A classification should also be meaningful and utilitarian, that is, it should represent an accurate description of the disease with recognizable components that have interobserver reliability. The lack of an agreed upon classification prior to 1984 made it difficult to analyze data and the natural history of ROP. This was eliminated by the International Classification in 1984 and 1987.[13,14] The CRYO-ROP and Early Treatment for Retinopathy of Prematurity (ET-ROP) trials continued the useful evolution of this critical parameter.[6,15,16] Further publications will continue to refine the usefulness of the system.

The current classification of acute ROP describes the level of disease severity (stages), the location of the disease within the retina (zones), the extent of disease (clock hours and plus disease), and clinical modifiers (prethreshold ROP, threshold ROP, and rush disease). Each one of these is quantitative except plus disease and rush disease. Plus disease is probably the single most important retinal finding in the prognosis of this disease and is now the essential finding influencing treatment decisions.[16] It is defined by a single representative photograph that has been widely promulgated. Hence the single most critical determining factor in ROP is an examiner judgment call, with all the inherent problems associated with that.[17]

Natural History

The best resource for natural history arises from pooled data from randomized, rigorously designed and controlled, multicenter trials, such as CRYO-ROP, Light Reduction in Retinopathy of Prematurity (LIGHT-ROP), and ET-ROP. They define large patient populations with statistically calculable means, medians, ranges, and standard deviations. This is often misunderstood by practitioners and expert witnesses. Individual variation can be dramatic, and the standard deviation and the exception are as important as the mean.

The LIGHT-ROP trial produced data on the normal progress of disease-free retinal vascularization.[18] CRYO-ROP produced an enormous amount of published data. Perhaps the single most important information was that the timing of onset of the various stages of ROP was related to gestational age and not chronologic age.[19] This demonstrated that ROP was not an exclusively environmentally determined disease. Disease onset correlated better with the internal time clock of retinal development than it did with how long the retina had been exposed to the extrauterine environment. This yielded a population curve of ROP onset tied to postgestational or postmenstrual age. CRYO-ROP also helped define retinal risk factors, disease progression, prognosis, and others. A critical element of natural history was recognized and reported in 2000.[20] This helped explain the controversy of highly unusual unfavorable outcomes in zone III disease. These cases may very well represent temporal zone II disease classified as zone III due to nasal development. It is a flaw in the classification of ROP that this risk could be overlooked.[17]

Incidence

This is an area in which wide disagreement occurs. Individual, single-center, retrospective series with relatively small sample sizes can find dramatically different incidence figures.[21-23] That is an inherent problem in this type of literature comparison.[24,25] But large randomized, prospective, multicenter trials can more reliably demonstrate incidence figures. CRYO-ROP, LIGHT-ROP, and ET-ROP are such trials. The enrollment periods for these three trials were separated by over 15 years. Neonatal intensive care nursery practices changed considerably over this time.[17] Yet the incidence figures are remarkably similar (Table 1).

All three trials had similar screening protocols and similar demographics for infants < 1251g. The CRYO-ROP trial and LIGHT-ROP trial reported raw incidence data. However, ET-ROP did not. The investigators used a method to calculate an imputed value. The ET-ROP trial also was by definition an early intervention trial. Therefore, no comparable incidence exists for threshold disease, and they provided no pure prethreshold group. They therefore again statistically manipulated data to come up with recomputed figures for both studies for a prethreshold incidence of 36.9% for ET-ROP and 27.1% for CRYO-ROP. While the lack of raw data is disappointing, clearly the incidence of ROP is not decreasing and is very probably stable.

The important point is twofold. The incidence of ROP is not decreasing, and it will continue to be a major health issue for the

foreseeable future. Secondarily it is important to recognize that local experiences with small, nonrepresentative samples are subject to significant deviations from the mean. Comparing one neonatal intensive care unit's experience to the summed experiences of units in a multicenter trial is much like comparing an individual patient to the entire population. Disease patterns and patient behavior are represented by distribution curves subject to standard deviations.

TABLE 1. INCIDENCE AND SEVERITY OF ROP REPORTED IN THREE TRIALS

CATEGORY	CRYO-ROP	LIGHT-ROP	ET-ROP
Enrollment years	1986-1987	1995-1997	2000-2002
Patients	4099	361	6998
Any ROP	2699 (65.6%)	251 (69.5%)	68%
Prethreshold ROP	731 (17.8%)	52 (14.4%)	*
Threshold ROP	245 (6.0%)	18 (4.9%)	*

CRYO-ROP, Cryotherapy for Retinopathy of Prematurity; ET-ROP, Early Treatment for Retinopathy of Prematurity; LIGHT-ROP, Light Reduction in Retinopathy of Prematurity.
*Comparative raw data not available.

Finally, a note should be made regarding the dramatic differences in incidence that are possible worldwide. International conditions are not homogenous as they are in the United States. The pattern of ROP incidence throughout the world is closely tied to the wealth of the country being studied.[5,26-28]

Screening

Probably nothing is more critical to the ROP legal debate than screening. The most current state of ROP screening is the consensus statement published in 2006.[29,30] But the issue is more complex. First, these published statements are guidelines. Deviating from them does not constitute a deviation from the standard of care if it is medically reasonable. Second, these recommendations are consensus statements.[29,31,32] That is, they are the product of compromise by several experts. And third, there has been a dearth of reliable evidence from which to draw valid conclusions. An analysis of CRYO-ROP and LIGHT-ROP data published in 2002 provided the first multicenter trial evidence-based screening protocol.[33] The most recent consensus statement promulgated by the American Academy of Ophthalmology, American Association of Pediatric Ophthalmology and Strabismus, and American Academy of Pediatrics is largely based on this analysis.[29,30]

The goal of screening is to detect serious ROP that is within the window of opportunity for the optimal application of proven therapy. Ideally, it should be consistent, reliable, and cost-effective. For ROP, recommendations should guide us on when to initiate examinations, when to reexamine, and when to conclude acute screening examinations. A modified summary of the 2006 recommendations is listed in Tables 2 through 4.[29,30]

TABLE 2. TIMING OF INITIATION OF ACUTE ROP SCREENING

GESTATIONAL AGE AT BIRTH, WK	AGE AT INITIAL EXAMINATION, WK	
	POSTMENSTRUAL	CHRONOLOGIC
22	31	9
23	31	8
24	31	7
25	31	6
26	31	5
27	31	4
28	32	4
29	33	4
30	34	4
31*	35	4
32*	36	4

ROP, retinopathy of prematurity.
*If necessary.

TABLE 3. RECOMMENDED TIME INTERVALS FOR FOLLOW-UP EXAMINATIONS IN RETINOPATHY OF PREMATURITY (ROP)

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 I ROP: zone II

TABLE 4. INDICATIONS FOR CONCLUSION OF ACUTE RETINOPATHY OF PREMATURITY (ROP) SCREENING

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 (if the postmenstrual age is less than 36 weeks, confirmatory examinations may be warranted);

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

Treatment

CRYO-ROP has already been given credit for its groundbreaking discovery. But refinements continue. ET-ROP is the most recent.[16] Refinements in treatment regimens can also impact the need for change in screening protocols. The 2006 screening guidelines reflect the ET-ROP study findings. Treatment of cicatricial disease with scleral buckling, lensectomy, vitrectomy, etc, is highly debated and evolving.[34-44] Like disease pathogenesis, this has not developed into a legal issue of debate. The probable reason that treatment for cicatricial disease is not yet a medicolegal issue is that the results are accepted to be poor. Expected poor outcomes do not lead to unreasonable expectations. If and when this form of treatment improves, then individual outcomes could become more debatable and therefore actionable.

Pathogenesis

This is the most rapidly evolving area of ROP research. Investigators are actively engaged in attempting to understand normal fetal retinal development as well as the abnormal. How does retinal vascularization occur? What cytokines are involved, and how do they interact within a microenvironment? What are the nutritional requirements of the fetal retina? How does exposure to an ambient environment change these complex interactions? There are many more unanswered questions. However, the only conclusion in this area of research that is pertinent to the medicolegal world of ROP is this: no one knows the cause of ROP. No one knows how oxygen specifically interacts with this disease process. No one knows what level or levels of oxygenation are best regarding ROP.[11,12] Until this is known, there should be no real actionable issues regarding oxygenation levels and ROP outcomes.

This brief assay of our current state of ROP knowledge is by no means all-inclusive or definitive. It has focused on areas that specifically generate areas of contention in ROP litigation. It is presented as a general prelude to the more meaningful goal of analyzing ROP liability and improving ROP care.

LEGAL BACKGROUND

Just as it is necessary to understand ROP disease processes in order to appreciate the medicolegal issues of the disease, a rudimentary appreciation for the general legal principles is a prerequisite to case analysis. Although not essential to our primary goal of improving the quality of care, it is valuable to understand the legal foundation upon which these cases stand.

Liability is a combination of legislation and case law, ie, precedent. Legislation can expressly promote or prohibit liability, but it usually defines a fairly vague realm within which the general legal concepts apply. Case law, on the other hand, constitutes "the application of common law principles, statutes, and state or federal constitutions to a particular set of facts, which establishes or clarifies how the law should be applied to the case at hand and similar cases in the future"[45] It is critical to appreciate that past decisions shape future liability. It does not hinge on medical issues alone.

In order for liability to be assigned, two essential elements must be met: negligence and harm. *Negligence* is "the failure to

exercise the standard of care that a reasonably prudent person would have exercised in a similar situation; any conduct that falls below the legal standard established to protect others against unreasonable risk of harm, except for conduct that is intentionally, wantonly, or willfully disregardful of other's rights. The term denotes culpable carelessness."[45] Wanton disregard is excepted above because this may lead to more serious consequences than civil liability. The two critical words or phrases are *standard of care* and *reasonable*.

Harm is even more subtle. "In the context of medical malpractice, harm is physical injury, or serious emotional suffering that results from the breach of a legally imposed duty."[45] Harm is not simply a bad outcome, it is a bad outcome that resulted from some breach of care.

In the subsequent case analysis, the complex interplay of these two principles will be critical in assigning liability. A party can be negligent and cause no injury. An injury, or in our terms an unfavorable outcome, can occur and not be the result of a breach, ie, no harm. So in ROP, assignment of liability requires an unfavorable outcome, and that outcome must have as its proximate cause a negligent breach of care.

The above discussion raises two additional elements in assigning liability: causation and standard of care. Causation involves several terms. *Proximate cause* is "a cause that is legally sufficient to result in liability; an act or omission that is considered in law to result in a consequence, so that liability can be imposed on the actor."[45] A *cause in fact* is "the cause without which the event could not have occurred. Also termed actual cause or factual cause."[45] Specifically in relation to ROP the phrase *act or omission* is huge, since many cases hinge on omissions, as we will see.

The standard of care is more subtle. There is more than one, and it can be applied with different rules. The standard for general practitioners is always local, but the standard for specialists can be national. The standard of care in ROP is almost always applied on a national level, regardless of the geographic location.[46] However, jurisdictions will have different rules as to how the standard of care can be interpreted or derived. Many observe the 50% rule: Would more than 50% hold a similar opinion or is there a greater than 50% chance (more likely than not) that this does or does not constitute a deviation from the standard of care? This is not an easy concept to apply. It must acknowledge that the occurrence of rare events, ie, events that might occur naturally without negligent cause less than 5% or 1% of the time, is not necessarily more likely than not a result of a breach of the standard. This is a critical factor in case analysis. Another way to view this is as a preponderance of the evidence, ie, again "more likely than not."[47]

Other terms are less central but still important to understand. Those include competence or reliability of expert witnesses, definitive source, physician judgment, and remedial measures.

The requirements placed on the expert witness are several. They must educate the finder of fact (jury or judge), they must hold special knowledge and experience, their methodology must be accepted, and they may testify as to their opinion, which is very different than plaintiff and defendant and other witnesses of fact. Pretrial conversations with any party other than the attorneys may be discoverable and hence should not occur.

A definitive source is held to establish conclusions or facts that are unimpeachable and not subject to the debate of opinion. Within science, such sources rarely exist. In ROP, probably none exist. The expert witness and physicians involved in cases must understand this.

Remedial measures represent a fascinating concept. They are actions taken by a party, often a defendant, to rectify problems, acts, or omissions, and improve future care. As such they are a tacit admission of an issue that can be improved. They are not an explicit acknowledgment of negligence. Nonetheless, they could be prejudicial at trial. Most states recognize one of the values of case law, ie, it can result in remedial measures that can improve care. So as to promote this, most states will not allow testimony regarding defendants' actions to institute remedial measures.

The exercise of clinical judgment, when reasonable, can be wrong yet not negligent even when harm occurs in relation to that judgment. It is a very subtle concept and varies by state. But a judgment is not an act or an omission in and of itself. If it leads to one that is unreasonable, then negligence has occurred. But if it leads to a reasonable one, then no negligence has occurred. The *error of judgment* doctrine holds that "the rule requiring a doctor to use one's best judgment does not hold him liable for a mere error of judgment, providing one does what one thinks is best after careful examination."[48] An excellent example of this is making a choice among two or more medically acceptable alternatives. In such cases it is always reasonable to document the role of judgment in the exercise of the chosen diagnostic or treatment path.

How do these elements interact? An example of medical knowledge with legal applications is highlighted by the large National Institutes of Health–funded multicenter trials. These trials are critical in providing statistically proven, evidence-based data. However, the interpretation of that data can be both used and abused in court.

CRYO-ROP parameters were designed as a consensus protocol based on contradictory or inconsistent data. In essence it tested the hypothesis of an empirically derived protocol. The study proved the efficacy of its specific treatment protocol. It did not prove or disprove other potentially more or less valid treatment protocols. CRYO-ROP defined not only a treatment method, ie, peripheral retinal ablation via cryotherapy, it also defined a stage of disease for intervention, ie, threshold ROP. This has often been thought of as defining a window of opportunity. Again, the concept of threshold ROP was an empirical, consensus-based construct. Its intended purpose was to ensure adequate separation between treatment group and control group. If intervention was set at an earlier disease point, the control group could do too well and the patient numbers necessary to demonstrate a difference between treated and control would have been excessive. If the intervention was set at a later date, the treatment group could do too poorly, again limiting the two groups' separation and requiring a much larger study patient volume. As it worked out, the designers of CRYO-ROP hit the "LD 50" of ROP by using threshold. It allowed excellent separation between control and treatment groups. But it was a design construct nonetheless and should always be viewed as such. One should be very careful in elevating an arbitrary study protocol, designed to test

a specific experiment, to a position in which it defines the standard of care.

A study cannot prove or disprove the efficacy of other intervention protocols. This is often misunderstood, and consequently study design protocols become accepted as gospel when in fact they only represent one method of testing the central hypothesis. Several different protocols may have yielded similar or even better results. Indeed, the ET-ROP trial was exactly that.[16] It rigorously tested the major hypothesis of earlier intervention, and this was proven efficacious.

The point is that CRYO-ROP, as all studies, can be given more legal weight than it deserves. When ET-ROP challenged the empirical consensus of treating at threshold, it essentially redefined a new intervention timing paradigm. Likewise, ET-ROP protocols may not represent ideal best practice. A similar perspective may pertain to the ET-ROP protocol for examination frequency. Study protocols are designed to prove a hypothesis. Study designers therefore want to maximize the separation between treatment group and control. This can often mean artificially excessive examinations that are not necessary in standard care. Thus the frequency of examinations in ET-ROP has generated debate precisely because the frequency of examinations was a design parameter, not a tested hypothesis.

This is not meant to detract from the dramatic contributions of these studies. It is meant to illustrate the subtlety between accepting a proven hypothesis and assigning too much meaning to a study design protocol. The former is a data-driven conclusion. The latter is an empirical and statistical construct meant in part to enhance the ability to expediently test the hypothesis.

Thus the data from these trials are priceless. The proven conclusions are valuable and have altered how we practice, but are still subject to evolving refinements, eg, CRYO-ROP to ET-ROP. But the specific protocols do not necessarily reflect ideal practices and should not be assumed to define the standard of care.

METHODS

The author reviewed a series of 13 malpractice cases within the last 10 years in which ROP was the central issue. Each case has completed disposition and is public record. No pending cases were included in the review. The author was involved as a paid expert in each case and was able to review the complaints, the defendants and plaintiffs, the entire medical record, and pretrial depositions when taken. The author was retained as an expert in both plaintiff and defendant roles. The author never examined any infant, and no physician-patient relationship existed in any of the cited cases. Several cases did not come to trial, but when they did, the author participated in testimony except when engaged specifically as a nontestifying expert. Confidentiality agreements can preclude disposition details such as acknowledgment of liability and dollar amounts. All infants involved were born well after the main CRYO-ROP results were published. The issues for debate in each case are relevant to current practices. Epidemiologic data were tabulated for each case and included the infant birth weight and gestational ages at birth, the location by state, the defendants in each case, the allegations of negligence, the disposition and awards when available, and the date of disposition.

The author also searched legal databases and previous publications in an attempt to identify and review ROP malpractice cases in which the author was not personally involved. The location, allegations, dispositions, awards, and dates were tabulated. It should be noted that no database contained every case, although there was clearly overlap. References could be brief yet provide leads to more detailed information elsewhere. In each case the review confirmed ROP as a central issue in the case, the plaintiffs and defendants, and the disposition. The full merits of each case were not available to review, since this would require a review of the medical record plus testimony. Such an outside review is not possible. The goal was to identify as many core ROP cases as possible in order to provide a reasonable estimate of the denominator of national cases. This could then be used as an indication of the percentage of national cases which this series of 13 represented.

Finally, the merits of each case were analyzed based on the author's extensive experience in ROP epidemiologic research, clinical care, and ROP expert witness analysis. An objective judgment was made regarding the presence or absence of medical error causing injury, ie, negligent practice. The definition of error as defined by the Institute of Medicine was modified specifically for ROP.[49]

RESULTS

The baseline characteristics of the 13 cases are presented in Table 5. The case number, gestational age and birth weight of the baby, state in which the case occurred, disposition, and date of disposition are listed. The date of disposition is the year in which the court action actually occurred and may not coincide with the date it was officially recorded.

The monetary award is listed when available. A jury or judicial award is always public record. However, settlement amounts are not always available. Often the court will approve a settlement, publish it, and therefore make it public. The court can also seal some details of a settlement as a consequence of the negotiations for that particular settlement. Monetary amounts as well as assignment of responsibility can be ruled confidential. In light of that, the award column is incomplete. Where available it contains both a monetary amount and a party responsible for that award. It also may contain the responsible party, but not the monetary amount. Lastly, the column may contain a reference to the relative size of the settlement if not the actual amount. Settlements arise from negotiations. As such, they reflect the relative strength of the adversarial positions. Small settlements reflect a strong defense position, whereas large settlements reflect the relative strength of the plaintiff claims.

There are notable issues evident here in the disposition and award data. In only one case was there a complete defense victory. Twelve of the 13 cases resulted in a monetary award for the plaintiffs. Yet few actually went to full verdict and court-determined award. Most involved a settlement. Appeals therefore are rare, since settlements preclude appeals. This does not necessarily imply that every potential ROP malpractice case has merit. On the contrary, cases are initiated that do not move forward owing to lack of merit.

But of the cases that do move forward, most are settled and almost all involve some form of plaintiff award.

TABLE 5. BASELINE CHARACTERISTICS OF 13 RETINOPATHY OF PREMATURITY (ROP) MALPRACTICE CASES

CASE	STATE	DISPOSITION	AWARD		DATE
			PARTY	AMOUNT	
1 GA 26 wk BW 890 g	Arizona	Settlement/Arbitration following verdict	Obstetrician Pediatrician Hospital/Resident	$150,000 $1.2 million	1999 2000
2 GA 23 wk BW 535 g	Florida	Settlement	Hospital	$1 million	1999
3 GA 27 wk BW 848 g	Connecticut	Settlement		Plaintiff favor	1999
4 GA 25 wk BW 640 g	North Carolina	Settlement after trial	Pediatrician Hospital	$1.1 million $2.4 million	2000
5 GA 29 wk BW 1170 & 1406 g	Texas	Verdict Appeal	All Ophthalmologist	$15 million Reversed	2001 2004
6 GA 27 wk BW 950 g One of triplets	Illinois	Settlement	Neonatologist	Defendant favor	2001
7 GW 30 wk BW 1530 g	North Carolina	Settlement	Ophthalmologist	Defendant favor	2001
8 GA 27 wk BW 540 g	Virginia	Settlement after trial	Ophthalmologist Hospital/Neonatologist	Nonsuited Plaintiff favor	2002
9 GA 25 wk BW 790 g	British Columbia	Settlement	Ophthalmologist	Defendant favor	2002
10 GA 26 wk BW 921 g	New Jersey	Dismissed		None	2002
11 GA 25 wk BW 553 g	Missouri	Settlement		Confidential	2004
12 GA 29 wk BW 1530 g	New Jersey	Verdict	Pediatrician/Neonatologist Ophthalmologist	$6.0 million $0	2004
13 GA 24 wk BW 787 g	Hawaii	Settlement		Confidential	2006

BW, birth weight; GA, gestational age.

In this series 10 of 13 cases were settled. Of those, 7 were settled prior to trial or verdict, and 3 were settled after the verdict was rendered, but before the award amount was determined. Only 3 of the 13 never involved a settlement. One was dismissed. One went to verdict and a large court determined plaintiff award that was subsequently partially vacated on appeal by one defendant. And one went to verdict and a large court determined plaintiff award that is still subject to appeal.

It should also be pointed out that not every defendant is assigned equal responsibility. Even a large award may represent a relative plaintiff victory, but individual defendants may be found to have zero or very little responsibility. That is a victory for that particular defendant. Hence the defense is capable of mounting a plausible argument that can be convincing in these cases.

Each of the 13 cases involves a complex series of events, in medically complicated patients, dealing with an extremely complex disease. However, the actual medical facts in the cases are relatively straightforward. The interpretation of those facts and the nondocumented testamentary facts are what lead to the typical convolutions of malpractice cases.

The documented facts of each case are therefore easy to present in brief. These facts are derived from the actual contemporaneous

medical records. Quotations from the chart notes are included when particularly pertinent. The author's opinions are kept to a minimum except when pointing out inconsistencies. The brevity of each summary cannot hope to capture all the issues and ramifications of various interpretations. Yet these basic factual events will enable the reader to understand the issues at dispute.

INDIVIDUAL CASE SUMMARY

Case 1: A 26-week, 890-g premature infant was born. Nursery personnel requested ophthalmologic consultation in a timely manner. The eye examinations were done by a resident physician. The initial examination occurred at 32 weeks postmenstrual age (PMA) and 6 weeks chronologic age (CA), and incomplete vascularization in zone II was noted. The second eye examination, performed at PMA 35 weeks, noted "immature retina" "few clock hours of ridge" "(Stage I)" and "Plus" and recommended 2-week follow-up. These findings include incompatible results. Subsequent transfer to another hospital occurred the next day, and no eye examination was ordered or performed. A nurse practitioner's progress note on admission noted "will need ROP F/U" and 8 days later "ROP exam as OP." The infant was discharged 13 days after admission and 14 days after the last eye examination. The relevant issues here are negligent resident examinations and poor follow-up.

Case 2: A 23-week, 535-g premature infant was born. Neonatologists did not obtain ophthalmologic consultation in a timely manner. The initial eye examination occurred late and noted disease beyond threshold. No formal hospital protocol existed for determining ROP screening eligibility. No ophthalmology issues were subject to suit. The relevant issue here is timely initial referral.

Case 3: A 27-week, 848-g premature infant was born. Nursery personnel requested ophthalmologic consultation in a timely manner. The only screening examination was the initial eye examination, which occurred at 33 weeks PMA and 6 weeks chronologic age. The findings were "normal discs, vessels, no ROP." Six-month follow-up was recommended. Six months later bilateral stage 5 ROP was diagnosed. The relevant issues here are a negligent eye examination and lack of appropriate follow-up recommendations.

Case 4: A 25-week, 640-g premature infant was born. The infant was transported to another hospital. Eye examinations were performed at PMA of 29, 31, and 33 weeks. Immature zone III vascularization was noted. The next eye examination was not performed until 38 weeks PMA. Serious ROP was diagnosed, immediate referral was made, and disease beyond threshold (4A+ and 3+) was diagnosed and treated. An unfavorable outcome resulted. The relevant issues here are negligent eye examinations and lack of appropriate follow-up. Zone III pathophysiology is relevant. The ophthalmologist was not a party to the suit.

Case 5: Twins of 29 weeks and 1170 and 1406 g, respectively, were born prematurely. Nursery personnel requested ophthalmologic consultation in a timely manner. The initial eye examination on twin 1 occurred at 35 weeks PMA and 7 weeks CA. Twin 2 was discharged prior to the initial examination. The examining ophthalmologist diagnosis and follow-up recommendation of 2 weeks was appropriate. Twin 1 was discharged before the second examination. Both twins followed up multiple times with the pediatrician as outpatients. Ophthalmology outpatient examinations were scheduled but not kept by the family. The second eye examination did not occur until 4 months after discharge. Cicatricial ROP was diagnosed. A change in the infants' last name occurred some time after discharge, further confusing the issue. The relevant issues here are lack of appropriate initial and follow-up examinations.

Case 6: One of triplets was born prematurely at 27 weeks and 950 g. The neonatologists requested ophthalmologic consultation at 34 weeks PMA and 7 weeks CA. The initial eye examination occurred days later at 35 weeks PMA and 8 weeks CA. Despite being late, this first eye examination diagnosed threshold ROP but no detachment. Treatment occurred in a timely manner. Eye examination notes were not well documented in a manner fully consistent with the international classification. All 3 of the triplets had cicatricial disease, but only triplet 1 had bilateral unfavorable vision as defined by CRYO-ROP. The relevant issues here are lack of appropriate initial examination and negligent eye examinations. The issue of poor outcome vs negligent harm is also relevant.

Case 7: A premature infant was born at 30 weeks and 1530 g. Nursery personnel requested ophthalmologic consultation in a timely manner. The initial eye examination occurred at 34 weeks PMA and 4 weeks CA and documented full nasal vascularization yet assessed this to be zone II. The second examination occurred 20 days later. ROP stage 1-2 in zone III with "mild vessel tortuosity" was diagnosed. A ridge was described, yet stage 1 was diagnosed. The third examination followed guidelines appropriate for zone III disease. Serious ROP was diagnosed, appropriate referral was made, and ROP was found to be beyond threshold and a poor outcome resulted. The relevant issues here are negligent eye examinations and lack of appropriate follow-up. Again, zone III pathophysiology is involved as well as the birth weight and gestational age.

Case 8: A premature infant was born at 27 weeks and 540 g. Nursery personnel requested ophthalmologic consultation in a timely manner. Eye examinations occurred at 32 weeks PMA and 6 weeks CA and subsequently at 34 weeks PMA/8 weeks CA, 35 weeks PMA/9 weeks CA, 37 weeks PMA/11 weeks CA, and 40 weeks PMA/14 weeks CA. Examinations 1, 2, and 4 were done by residents only. Examinations 3 and 5 were done by the attending ophthalmologist. The third examination noted incomplete vascularization. The fourth examination noted ROP stage 0 and 1 in zone II. The fifth examination at 40 weeks PMA/14 weeks CA occurred 25 days after examination 4. During the interval between examinations 4 and 5, the patient was discharged and readmitted. Examination 5 diagnosed serious ROP beyond threshold (4+ and 4+). An unfavorable outcome resulted. The relevant issues here are lack of appropriate follow-up examination intervals, negligent resident eye examinations, and negligent supervision.

Case 9: A premature infant was born at 25 weeks and 730 g. Nursery personnel requested ophthalmologic consultation in a timely manner. The initial eye examination occurred at 33 weeks PMA and 7 weeks CA. ROP was diagnosed as stage 1, zone III bilaterally. The follow-up recommendation is not clear. The next eye examination occurred over 7 weeks later. Bilateral stage 5 ROP was

diagnosed, and an unfavorable outcome resulted. The relevant issues here are negligent eye examinations and lack of appropriate follow-up recommendations. Zone III pathophysiology is involved.

Case 10: A premature infant was born at 26 weeks and 921 g. Nursery personnel requested ophthalmologic consultation later than the typical initial window. The initial eye examination occurred at 36 weeks PMA and 11 weeks CA. ROP stage 2, zone III bilaterally was diagnosed. The next eye examination occurred 1 week later at 37 weeks PMA. Threshold ROP but no detachment was diagnosed. Laser treatment occurred that day. An unfavorable outcome resulted. The relevant issues here are lack of appropriately timed initial examination and negligent eye examinations. Zone III pathophysiology is involved as well as the issue of bad outcome vs negligent harm.

Case 11: A premature infant was born at 25 weeks and 553 g. Nursery personnel requested ophthalmologic consultation in a timely manner. The initial eye examination occurred at 32 weeks PMA and 7 weeks CA. Subsequent examinations occurred at 34 weeks PMA/9 weeks CA and 36 weeks PMA/11 weeks CA. The initial examination found "very dilated and tortuous vessels." It was not put in terms of plus disease. Recommended follow-up was 2 weeks. The second examination again noted posterior pole vessel changes and now also noted findings "suggestive of neovascularization." Follow-up was recommended for "1 week" but did not occur until 13 days later. This third examination diagnosed threshold ROP. Treatment occurred 4 days later. An eventual unfavorable outcome resulted. Eye examination documentation did not follow international classification guidelines for staging or plus disease. The relevant issues here are negligent eye examinations and lack of appropriate follow-up recommendations and time to treatment. The issue of bad outcome vs negligent harm is involved.

Case 12: A premature infant was born at 28 weeks and 1530 g. Nursery personnel requested ophthalmologic consultation in a timely manner. The initial eye examination occurred at 32 weeks PMA and 4 weeks CA. No ROP was noted, but "scattered hemorrhages" were noted. The patient was discharged 8 days later. The second eye examination did not occur until 44 weeks PMA. ROP stage 4-5 was found and 4 days later was noted to be stage 5 bilaterally. An unfavorable outcome resulted. At the time of discharge, the neonatologists did document attempts to ensure follow-up. The relevant issues here are lack of appropriate follow-up and negligent eye examination. Birth weight is notable.

Case 13: A premature infant was born at 24 weeks and 787 g. Nursery personnel requested ophthalmologic consultation in a timely manner. The initial eye examination occurs at 30 weeks PMA and 6 weeks CA. Immature retinas were noted. Less than 2 weeks later, ROP of 0-1 was noted. The third examination did not occur until more than 4 weeks later at 36 weeks PMA. The examination note was misplaced. All subsequent eye examinations were misplaced, although the pediatric progress notes summarize them. At 37 weeks PMA ROP stage 2 and 3 were noted. At 39 weeks bilateral stage 3 was noted. One day later laser surgery was performed and ROP stage 3+ and 4A was noted at the time in an actual eye note. The patient was transferred 8 days later. No follow-up occurred until 23 days after laser, when bilateral stage 5 was diagnosed. The relevant issues here are lack of appropriate follow-up and negligent eye examinations and recommendations.

Table 6 summarizes the 13 cases by the defendants and plaintiff allegations. There are essentially 3 groups of defendants: pediatricians and neonatologists, including both inpatient intensivists and outpatient generalists; examining ophthalmologists, both inpatient and outpatient; and hospitals as general agents for nursery practices or oversight/supervisory agents for personnel including residents.

The allegations also fall into 3 natural subdivisions. These include (1) a failure to obtain ophthalmologic consultation in a timely manner that allows treatment intervention during the recommended window of disease opportunity; this can be an initial consultation or a necessary follow-up consultation; (2) a failure to have mechanisms or protocols in place to assure proper care, ie, screening protocols of some nature; a failure to supervise personnel, especially residents or nonphysician care givers; and (3) a failure of the examining ophthalmologist to adequately diagnose and/or appropriately follow these patients in such a manner that allows recognition of a degree of serious retinal disease that is within but not beyond the accepted window of opportunity for intervention. No allegations of negligent treatment were made in any of these 13 cases.

Table 7 is a quantification of the involvement of certain medical issues in these 13 cases. Issues 1 through 7 are based on care issues that readily are linked to plaintiff allegations. Issues 8 through 10 are more specific factors that are areas of particular debate and therefore deserve highlighting. Each issue is important and will be explained in the "Discussion" section, but the two most frequent issues involve the pediatric/neonatology follow-up arrangements and the ophthalmologic examinations and/or diagnoses in which the examination and/or diagnosis is inconsistent with, or not adequately predictive of, unfavorable outcome.

A review of the medical and legal literature for the comparable years of 1999-2006 yielded only 5 other ROP malpractice cases, and even in one of those (Illinois case), ROP was a peripheral issue in an obstetrician-centered case. An additional case (Texas, 2006) is known to the author via personal communication but is not yet in the legal literature. The information available on these cases is rudimentary, but what is available demonstrates that these cases closely mimic the 13 cases in this review. All but one resulted in an award, and the allegations were all typical, except in Texas, 2006. The summary characteristics of these 6 cases are provided in Table 8.

As an example, the Massachusetts case information was as follows: A 28-week, 1265-g infant was born prematurely. Nursery personnel requested ophthalmologic consultation in a timely manner. The initial eye examination was conducted at 32 weeks gestational age. Full retinal vascularization was noted. No follow-up was recommended. Several months later the infant was found to have cicatricial stage 5 ROP in each eye.

TABLE 6. DEFENDANTS AND ALLEGED ACTS OR OMISSIONS IN RETINOPATHY OF PREMATURITY (ROP) MALPRACTICE

CASE	AUTHOR COMPENSATION	DEFENDANTS	ALLEGATIONS
1	Defense	Obstetrician	Failure to prevent/manage premature birth.
GA 26 wk		Pediatrician/Neonatologist	Failure to refer after hospital transfer/discharge
BW 890 g		Hospital (Resident ophthalmologist)	Failure to supervise/diagnose/manage
2	Plaintiff	Board of Regents/Hospital	Failure to refer/follow
GA 23 wk		(Pediatrician/Neonatologist were	Failure to have referral system
B.A. 535 g.		indemnified as agents of the state)	
3	Plaintiff	Ophthalmologist	Failure to diagnose
GA 27 wk			
BW 848 g.			
4	Plaintiff	Neonatologist	Failure to refer
GA 25 wks		Hospital	Failure to supervise, implement protocol
BW 640 g			
5	Defense	Neonatologist	Failure to refer/follow up/educate
GA 29 wk		Pediatrician	Failure to refer
BW 1170 & 1406 g.		Ophthalmologist	Failure to follow up
		Hospital	Failure to supervise
6	Defense	Neonatologist	Failure to refer
GA 27 wks			
BW 950 g.			
One of triplets			
7	Defense	Ophthalmologist	Failure to diagnose/manage/follow
GA 30 wk			
BW 1530 g.			
8	Defense	Neonatologist	Failure to refer/follow/educate
GA 27 wk		Pediatrician	Failure to refer
BW 540 g.		Hospital	Failure to oversee/supervise
		Resident ophthalmologist	Failure to diagnose
		Ophthalmologist	Failure to follow/supervise
9	Defense	Ophthalmologist	Failure to diagnose/manage/follow
GA 25 wk			
BW 750			
10	Defense	Neonatologist	Failure to refer
GA 26 wk		Ophthalmologist	Failure to diagnose/manage
BW 921 g			
11	Plaintiff	Ophthalmologist	Failure to diagnose/manage
GA 25 wk			
BW 553 g			
12	Defense	Neonatologist	Failure to refer/follow/educate
GA 29 wk		Pediatrician	Failure to refer
BW 1530 g		Ophthalmologist	Failure to diagnose/follow
		Hospital	Failure to oversee
13	Plaintiff	Ophthalmologist	Failure to diagnose/manage/follow
GA 24 wk		Hospital	Failure to oversee
BW 787 g			

BW, birth weight; GA, gestational age.

Finally, Table 9 represents the results of the merit review of the 13 cases. Each defendant's acts or omissions were reviewed, and a judgment on the presence or absence of negligent error was made and whether this negligent error directly led to a negligent injury, ie, harm. A positive decision on both error and causative harm led to a conclusion of malpractice.

TABLE 7. SUMMARY OF MEDICAL CARE ISSUES IN RETINOPATHY OF PREMATURITY IN 13 CASES

ISSUE	NO. OF CASES
1. Failure to refer/missed window of opportunity Inpatient vs outpatient vs transfer (neonatologist/pediatrician)	8
2. Failure to educate parents (neonatologist/pediatrician)	3
3. Failure to oversee (hospital)	7
4. Failure to follow up (ophthalmologist)	6
5. Failure to supervise (ophthalmologist/resident ophthalmologist)	2
6. Negligent examination/diagnosis (ophthalmologist)	9
7. Negligent treatment (ophthalmologist)	0
8. Rare but expected occurrence (ophthalmologist)	2
9. Zone III (ophthalmologist)	4
10. Issue of harm (all)	3

TABLE 8. CHARACTERISTICS OF RETINOPATHY OF PREMATURITY MALPRACTICE CASES FROM LITERATURE REVIEW

STATE	DISPOSITION	AWARD		DATE	ALLEGATIONS
		PARTY	AMOUNT		
Illinois*	Verdict	Obstetrician	$8.35 million	1999	Failure to prevent premature birth
California	Verdict Settlement after trial	Ophthalmologist	$6.9 million $850,000	1999	Failure to refer
California	Settlement	Ophthalmologist	$1.2 million	1999	Failure to follow
Texas	Settlement	?	$400,000	2001	?
Massachusetts	Settlement	Ophthalmologist	$1.75 million	2004	Failure to diagnose/manage
Texas†	Verdict	Ophthalmologist	None	2006	Failure to manage

*Case listed in Westlaw and in Weber (2002),[68] but ROP not a central issue.
†Case not found in literature review but known by author via personal communication.

TABLE 9. RESULTS OF MERIT REVIEW OF 13 CASES OF ROP MALPRACTICE*

CASE	NEGLIGENCE		HARM	MALPRACTICE
1	Pediatrician/Neonatologist	Yes	Yes	Yes
	Resident ophthalmologist	Yes	Yes	Yes
2	Hospital	Yes	Yes	Yes
3	Ophthalmologist	Yes	Yes	Yes
4	Neonatologist	Yes	Yes	Yes
	Hospital	Yes	Yes	Yes
	(Ophthalmologist)	(Yes)	(Yes)	(Yes)
5	Pediatrician/Neonatologist	Yes	Yes	Yes
	Hospital	Yes	Yes	Yes
	Ophthalmologist	No	No	No
6	Neonatologist	Yes	No Treated at T	No
7	Ophthalmologist	No	No	No Zone III rare event in very large baby
8	Pediatrician/Neonatologist	Yes	Yes	Yes
	Hospital	Yes	Yes	Yes
	Resident Ophthalmologist	Yes	Yes	Yes
	Ophthalmologist	No	No	No

TABLE 9 (continued). RESULTS OF MERIT REVIEW OF 13 CASES OF ROP MALPRACTICE*

CASE	NEGLIGENCE		HARM	MALPRACTICE
9	Ophthalmologist	Yes	Yes	Yes Zone III rare event – unlikely
10	Neonatologist	Yes	No	No
	Ophthalmologist	No	No Treated at T	No Zone III rare event
11	Ophthalmologist	Yes	No Treated at T	No
12	Pediatrician/Neonatologist	Yes	Yes	Yes
	Ophthalmologist	No	No	No
13	Hospital	Yes	Yes	Yes
	Ophthalmologist	Yes	Yes	Yes

T, threshold.
*Parentheses indicate author's opinion on a non-defendant in the suit.

DISCUSSION

The 13 ROP malpractice cases reviewed here represent the largest series in the literature. It is the only series not based on the files of malpractice insurance companies, and where the author personally reviewed the entire medical record in each case, and in which the review was conducted by a physician experienced in the clinical care and research of ROP.

These 13 cases likely represent a large majority of the ROP-related cases over the 8-year span from 1999-2006. Only 6 additional cases were identified in a literature and legal database search in this time period. Due to the vagaries of court reporting procedures, there may be undiscovered cases that completed disposition. However, it is unlikely that such potentially unidentified cases would be numerous. Therefore this sample is highly representative if not exhaustively inclusive.

The characteristics of these 13 cases are described in Tables 5 and 6. It is notable that the cases arise from a wide geographic distribution. If one includes the cases from the literature review (Table 8), the geographic distribution remains diverse, but there are coincidences. Three of 19 are from Texas, 2 of 19 are from California, 2 of 19 from New Jersey, 2 of 19 from North Carolina, and 2 of 19 from Illinois. Eleven of 19 are from just 5 states. This could be simple coincidence, or it might relate to the general litigiousness of the location.

Tables 5 and 8 list the dispositions and awards in each case. In evaluating the dispositions and awards, it is important to remember that our court system is an adversarial one. Conflicting evidence is presented, and fallible people must weigh that evidence. They do so not only based on merit, but on how well that evidence was presented and interpreted by attorney and expert witness. It is not just the presentation of fact, but how the facts are presented. Since evidence is conflicting and presenting talent is variable, the jury has a difficult and unpredictable task. It is a big gamble for each side to depend on the jury verdict. In addition, it is a big gamble to depend on the size of the jury award. Each side dislikes accepting these risks, and they minimize these risks by negotiating a settlement. So, court settlements are at least as much about containing risk as they are about merit. And a settlement can occur at any point: pretrial, during or after testimony, and some even past verdict but preaward, as in 3 of these cases.

The dispositions of ROP malpractice reflect these tendencies. Of the 13 cases, 10 concluded with settlements. One was dismissed, and two went to jury verdict and resulted in dramatically large awards, one of which was partially vacated on appeal. So the 10 settlements provided each side with contained and predictable results, hopefully somewhat based on merit.

It is useful to examine the birth weight and gestational age of each of these infants with serious ROP and determine if various screening protocols would have captured these infants who obviously needed acute screening. The 14 infants involved in this series cannot be used to determine appropriate screening eligibility criteria. However, they do represent infants with serious ROP and can serve to test inclusion criteria. The 2006 consensus screening guidelines are very much based on the 2002 evidence-based criteria derived from CRYO-ROP and LIGHT-ROP and the design parameters from ET-ROP. Since screening protocols have changed over the years, it is reasonable to continue to test their applicability. Table 5 includes each infant's birth weight and gestational age at birth. Ten of the 14 infants were under 1000 g at birth. The twins in case 5 were 1170 and 1406 g at birth. But two of the infants (cases 7 and 12) were over 1500 g at birth. One of these two had a gestational age at birth of 28 weeks, and one was 30 weeks.

Applying the joint statement screening guidelines published in 2006, all of these infants would be eligible for acute ROP screening.[29,30] These guidelines recommended screening infants with birth weights less than 1500 g or gestational ages of 30 weeks or less. So the two infants over 1500 g would be included based on gestational age.

However, these two infants would not have met the systematic inclusion criteria of all other screening protocols. The 2001 consensus guidelines suggested 1500 g and/or 28 weeks.[50] Case seven would therefore be missed. Although the screening guidelines published by the American Academy of Ophthalmology, American Academy of Pediatrics, and American Association for Pediatric

Ophthalmology and Strabismus represent the most frequently quoted standard in court, many other published works may offer differing guidelines. Again, case 7 and even case 12 would not meet the suggested eligibility criteria in several recent publications.[51-55] However, the criteria of others would have captured them in a systematic way.[56-58]

This series represents infants with serious ROP and proves that serious ROP can occur in older, bigger babies in the United States. It is comforting to know that each of these infants would fit under the evidence-based screening protocols that were based on CRYO-ROP and LIGHT-ROP and the 2006 consensus guidelines, which were predominantly based on that study. On the other hand, it is very disquieting to know that authors suggesting screening protocols based on cost-effectiveness, such as Lee and coworkers, would indeed fail to screen 3 of these 14 infants.[55] If the primary goal of screening is to recognize infants with potentially blinding, serious ROP, then the 2002 evidence-based guidelines and the 2006 consensus guidelines do just that.

We can now turn to the specific issues of care that arise from an analysis of the medical records in these 13 cases. Table 7 is a summary of all the relevant medical care issues and their frequency of occurrence in this series of 13. Table 9 is the author's educated judgment of negligent error and negligent harm for each case and each defendant, which is a necessary part of any medical issue assessment.

NEONATOLOGY/PEDIATRIC CARE ISSUES

The first and perhaps most dramatic issue in its implications at trial is a failure of the neonatology/pediatric team to refer an infant for appropriate ophthalmologic consultation. This can most egregiously involve an infant who simply "falls through the cracks" and never receives a timely examination. An example of this is case 2. The initial consultation request was clearly late, the initial eye examination noted disease beyond threshold, ie, disease outside the optimal intervention point, and a poor outcome resulted. The relevant issues involved only the neonatology team. No ophthalmologic issues were present. And there is no reasonable defense. This child was negligently denied a timely examination, and directly related harm was the result.

This type of egregious negligence is unusual. Typically this failure to refer allegation occurs in more disputable ways. An initial referral can fail to be made in a timely manner, ie, well beyond the recommended age for the conduct of the initial examination. But the later-than-recommended eye examination finds serious ROP that is not outside the acceptable intervention window, ie, still at threshold or better. Case 6 is an excellent example. The initial eye examination occurred at PMA 35 weeks and CA 8 weeks, clearly later than recommended. However, the ROP detected was not beyond threshold, and appropriate treatment was provided. Negligent referral may have been present and a poor outcome occurred, but that harm was not negligent, since treatment occurred at threshold and this infant could reasonably be placed in the group of eyes that can have an expected poor outcome despite adequate treatment. The court settlement reflected the strength of the defense here. How this case came to litigation and why a settlement was acceptable to the defense relates to other issues, ie, zone III centered disputes, which will be covered subsequently.

Another failure to refer issue can relate to hospital transfers. Eye examinations may occur if indicated at the initial admitting hospital nursery, but subsequent eye examinations do not occur after transport to another geographic hospital location. Case 1 is an example of this. Although there are applicable ophthalmologic issues in this case, it is apparent that no eye examination occurred or was ordered by the second receiving hospital. On merit review, this was a negligent error of omission.

Probably the most frequent situation relating to the failure to refer issue is the failure to obtain ophthalmologic consultation as an outpatient following discharge from the hospital. This occurred in cases 1, 5, 8, and 12. Four of the 13 cases involve a lack of outpatient eye examinations. These 4 have other contributory elements, but clearly this is a critical time for at-risk infants and their caregivers. Case 12 is particularly illuminating, since no real ophthalmology issues are involved. Although the ophthalmologist was a defendant, no error was made. In this case the infant had an appropriate eye examination at 32 weeks PMA and 4 weeks CA, but was discharged 8 days later. The second eye examination did not occur until 44 weeks PMA. The neonatologists vigorously defended their attempts to schedule an appropriate outpatient examination, and some of those efforts were documented. The pediatrician, however, never addressed the issue despite several office visits with the child. The result was predictable. Negligence occurred, negligent harm resulted, and a large award was made. Even if the parents share the blame, as they did in this case and in case 5, every responsible party shares in the obligation to ensure timely eye examinations.

There are several lessons from this care issue of appropriate referral.

1. No infant can be allowed to "fall through the cracks." Eligible infants must be referred.
2. Appropriate referral is the responsibility of the admitting nursery, the transferring nursery, the receiving nursery, the discharging staff, and the receiving pediatricians, as well as the parents themselves.
3. No caregiver should provide care for these infants or accept such infants into their practice unless they are familiar with the ROP screening eligibility requirements. Ignorance of these by ordinary pediatricians who accept such at-risk infants is no excuse or defense, as seen in case 12.
4. Assuming appropriate knowledge is present and appropriate actions are taken, proper documentation of that knowledge and effort is critical. Knowing a baby needs an examination and informing a parent of this is little defense without solid documentation.
5. Parents must be appropriately informed of the necessary actions and potential consequences.
6. Recognize that human error can occur. Develop a system that includes all parties and various checks and balances to ensure proper tracking and referral. Eliminate sources of human error when possible by the use of such a systems approach. Several publications have detailed suggestions for successful referral.[59-61] All involved parties should periodically assess and reassess their particular success in this area.

The additional neonatology issues involving allegations of failure to educate or failure to properly oversee involve the same elements as above. The parents must be involved and educated appropriately, this activity should be documented in some way, handouts can be useful, and the need should be reinforced if noncompliance is occurring. And institutions do have an obligation to ensure that their staff members are providing appropriate care, especially when a cross-departmental protocol such as screening is involved.

Before leaving the area of greatest concern to neonatology and turning to the ophthalmologist, it is appropriate to comment on the oxygenation controversy. None of the 13 cases subject to this thesis had supplemental oxygen utilization as a critical factor. However, given a poor treatment result when all other care is clearly appropriate, this could become an element of dispute.

A 2006 publication in this area[62] quotes Silverman[11] in stating that the optimal level of oxygenation for infants after premature birth is yet unknown. However, observational studies are suggesting that reduced oxygenation may reduce ROP in some way.[62-66] The bottom line is we still do not know.[12] More and better data are needed. Malpractice based on allegations of negligent oxygenation is not supportable unless some outlandish events took place. There is no reliable evidence-based data upon which to base such an allegation.

OPHTHALMOLOGIC CARE ISSUES

These are more complex, since they are more disease-based and hence more involved with physician judgment. Table 7 again lists the medical care issues and a large number of them do relate to the examining ophthalmologist. Although failure to refer or request initial consultation is an exclusively neonatal/nursery issue, the ophthalmologist can become involved in follow-up appointment disputes relating solely to administrative or clerical functions as opposed to recommendations based on a disputed medical exam.

Issue 1: Follow-up

Six of 13 cases involved an allegation about failure to properly follow an infant by the ophthalmologist. However, these usually involve disputes between the ophthalmology recommended follow-up interval and the acceptable standard of care. Hence, they relate to potential errors of examination and diagnosis. Only one case of alleged failure to follow was purely administrative, and that is case 5. The initial eye examination was requested and performed appropriately on twin 1. Twin 2 was discharged prior to the examination. Despite the 2-week follow-up recommended by the ophthalmologist, no examination was performed until 4 months later. Several factors involved negligence here, including parental behavior. But was the examining ophthalmologist liable for ensuring that the family keeps an initial outpatient appointment? The trial court said yes, but this was reversed on appeal. On merit analysis, there was no ophthalmologic error in this case.

The ophthalmologist is exclusively a consultant in the hospital nursery. As such, the ophthalmologist is unaware of the hospital course of these infants following their examinations. These infants may remain in the hospital and have further consultations, they may be transferred, they may develop medical conditions that preclude safe examination and thus be discretionarily delayed by the neonatal team, or they may be discharged. Frequently the ophthalmologist never has an opportunity to meet the parents and relies on the neonatal team to communicate examination findings. In addition, name changes often occur after discharge. Baby Smith may become Mary Jones and the ophthalmologist has no way of tracking these events.

For these reasons and more, it is not in the best interest of the infant to have the ophthalmologist play a role in initial outpatient follow-up compliance. The ophthalmologist has no reasonable opportunity to do this effectively. Assigning such a role, even a shared role, is a recipe for noncompliance. This responsibility must be assumed by the primary care givers if it is to be at its most reliable. This does not apply to outpatient visits subsequent to the initial visit, when a more traditional physician-patient relationship exists.

Issue 2: Resident Care

An area of concern that is very pertinent occurred in 2 of the 13 cases. Unsupervised resident ophthalmologic examinations represent a major risk. Cases 1 and 8 involve just such unsupervised examinations. In case 1 a resident examination noted the incompatible findings of a “ridge” and a diagnosis of stage 1. “Plus” disease was also noted, yet a 2-week follow-up was recommended. Such incompatible results strongly support negligent examinations. If harm results, malpractice is clear.

Residents are by nature students and not work substitutes. Attending physician educators and hospitals must recognize this. However, they are capable of performing examinations and procedures consistent with their level of training under the direct or indirect supervision of licensed physicians. The resident performance in these two cases does not live up to these criteria. They clearly did not have an acceptable knowledge of ROP, their examinations under these documented conditions were not adequately supervised (eg, paired examinations did not occur), and they were incapable of deciding on their own when they needed help. Resident involvement in ROP screening must be rigorously defined and supervised.

Issue 3: Diagnosis and Recommendation

The dominant medical care issue for the ophthalmologist is proper diagnosis and follow-up recommendation. Nine of 13 cases alleged negligence in this area. Those not involving residents are cases 3, 7, 9, 10, 11, 12, and 13. Some of these also involve zone III issues and potentially rare events. These are the cases that are the most complex, most affected by examination findings, most involved with physician judgment, and most likely to be averted by sound, reliable, evidence-based medical knowledge.

The natural history of normal retinal vascularization is critical to know when examining infants. Reynolds and coworkers[33] examined CRYO-ROP and LIGHT-ROP data to determine the time course of normal vascularization in prematurely born infants. Vascularization reached to within 1 disc diameter of the nasal ora in at least 1 clock hour at a median of approximately 35 weeks PMA. Only 5% of infants achieved zone III vascularization by age 32 weeks PMA. Full vascularization was achieved by 50% at 36

weeks PMA, by 95% at 42 weeks PMA, and by 99% at 43 weeks. Examiners must keep this natural history in mind when assessing the need for follow-up.

Case 3 is an excellent example of the dilemma. An initial, timely examination was performed at 33 weeks PMA and 6 weeks chronologic age. The findings were "normal discs, vessels, without ROP." A follow-up interval of 6 months was recommended, and bilateral stage 5 ROP was diagnosed at that time. The defense claimed that the examination notes meant that full retinal vascularization was present and that the tractional retinal detachments were not produced by ROP but rather an unknown disorder. Despite defense claims to the contrary, ROP was extremely likely to be the cause. No other diagnosis, such as familial exudative vitreoretinopathy, could be plausibly made. Could ROP retinal detachment occur following full retinal vascularization? No such case exists in the literature. Therefore the conclusion is that the retinas were not fully vascularized and negligence occurred.

What knowledge or experience was necessary to prevent such an occurrence? We know even experienced examiners can fail to agree on retinal findings 100% of the time. This potential examiner error has been described.[33] Therefore, experience alone could not be expected to avoid this misdiagnosis. However, we know the natural history of normal retinal vascularization. At 33 weeks PMA, as in case 3, only about 15% of infants would have achieved even full nasal vascularization, with an even smaller percentage reaching the temporal ora.

Was patient 3 one of those very, very few babies with full retinal vascularization at 33 weeks PMA? It is possible, but extremely improbable considering the stage 5 detachments that later occurred. Clearly the examination was in error. This error was not negligent. It is a recognized and understandable event. What was negligent was the 6-month follow-up recommendation, which resulted from a lack of knowledge about the natural history of ROP. It was critical to know at that time, and not just in hindsight, that examination error was more likely than full retinal vascularization in such an immature retina. Repeat examination in 2 to 3 weeks was indicated.

Issue 4: Zone III

The issue of zone III disease merits special attention. Does serious zone III ROP exist? Can zone III disease lead to an unfavorable outcome? What is the relevant pathophysiology? Are there specific sources of misunderstanding about zone III disease?

It is essential to consider the classification of zone III when assessing retinal signs. Zone III is arbitrarily classified according to findings of the nasal retina only. The temporal retina is assumed to mirror the nasal retina. No independent temporal retinal landmarks are used in the international classification. The intent of this classification system is to use readily recognized retinal landmarks to determine the location of normal vascularization or disease. Unfortunately, there are no such landmarks in the midtemporal periphery, and this led to the reliance on nasal only signs. This represents an understandable flaw in the classification system that has directly led to malpractice conflict. How has this happened?

Normal retinal vascularization has been recognized to occur in a radial fashion beginning at the optic nerve. As long as no process interrupts this, the vascularization proceeds symmetrically. However, ROP can interfere with this process. ROP may develop in mid zone II in the temporal retina and yet normal nasal vascularization proceeds. If normal vessels reach within 1 disc diameter of the nasal ora, this temporal zone II disease is now correctly classified as zone III, even though it is still mid zone II on the temporal side and subject to the natural history of zone II ROP. Hence, in the desire of the designers of the international classification for ease of recognition and repeatability, this flaw was introduced.

The critical question to be determined in assigning retinal activity in zone III, then, is whether there was preexisting ROP on the temporal side. And take note that only 1 clock hour of nasal vascularization to the ora is required to denote zone III. Eleven hours may not yet have completed vascularization fully.

A review of CRYO-ROP data with this in mind answers all of our zone III questions. No patient without preexisting ROP in whom retinal vascularization reached zone III ever developed serious disease. One patient (0.2%) in whom ROP was first observed in zone III developed serious ROP.[67] But an important exception was noted by Repka and coworkers[20] and is explained by the classification flaw. Zone II ROP that later became zone III, ie, temporal only disease, had an unfavorable anatomic outcome in 2 of 200 eyes (1%). Therefore zone III ROP can be serious; it can lead to unfavorable outcomes; and it has led to unrecognized risk that resulted in patient harm, as the following cases will demonstrate.

Cases 7, 9, and 10 are similar but subtly and importantly different. Each involves a dispute surrounding zone III. In case 7, zone III vascularization was noted at 34 weeks PMA, an expected occurrence about 30% of the time.[33] Case 9 had ROP of stage 1 in zone III, which could have followed the normal vascularization into zone III in about 15% of infants at 33 weeks PMA. And case 10 noted ROP stage 2, zone III at 36 weeks PMA. If the ROP onset was very recent, then a majority of infants could reach zone III vascularization prior to the onset of stage 2. The mean PMA at which zone III normal vascularization occurs is 34.3 weeks for LIGHT-ROP data and 35.6 weeks for CRYO-ROP data.[33] So in each of these cases the percentages of expected zone III findings noted are not beyond possibility.

In case 7, zone III activity was documented twice, first as immature vascularization and then with ROP stage 1 or 2. Examination findings that are found consistently rather than just once are more believable and less error-prone. The screening guidelines recommend just such a reasonable repeat examination.[29,30,33] However, infant 7 did go on to serious ROP with a poor outcome. Is this negligent diagnosis or a rare, unpredictable event?

Case 9 similarly noted ROP stage 1, zone III, but did so only once before stage 5 ROP was noted over 7 weeks later. Is this a negligent diagnosis or rare event? The lack of documented follow-up recommendations was a significant factor in this case, as well as an unrepeated examination finding coupled with the high risk of the infant's birth weight and gestational age.

Finally, case 10 is quite different even though zone III ROP is an issue. Despite a diagnosis of ROP stage 2, zone III, repeated examination occurs 1 week later and threshold ROP is diagnosed and treated. An unfavorable, but potentially expected outcome

occurs. Is this negligent or not?

What is the answer in these 3 zone III cases? Case 7 is clearly debatable, but the repeated examinations within acceptable windows coupled with the extremely low risk of such a larger, older infant at birth suggest that a series of rare events is as likely as negligence. Case 9 is less debatable. Although a rare zone III event is possible, there are no mitigating circumstances. Repka and colleagues' work[20] may be relevant here in explaining an outcome consistent with the examination, but the examination may also be negligent. Case 10, on the other hand, diagnosed ROP stage 2, zone III, but repeated an examination in only 1 week. Although surprisingly now at threshold, this sequence of events is highly defensible. The zone III diagnosis may have been in error, but repeated examination in 1 week is the proper response to that possibility. Then the appropriate diagnosis of threshold occurs in time, and unfortunately a poor but potentially expected result occurs. Hence case 7 is probably not malpractice but rather a rare event. Repeated examinations were prudently performed despite an initial finding of zone III. Case 9 is likely malpractice, since the unlikely zone III finding did not stimulate prudent confirmatory examination. And case 10 is not malpractice. Despite a zone III finding, appropriate reexamination was performed, the possible error was caught in a timely fashion, and appropriate treatment occurred.

Issue 5: Documentation

Cases 11 through 13 involve several issues besides just diagnosis. Case 11 demonstrates two issues. The foremost issue is the need for consistency of documentation and the need to act on one's own recommendations. In case 11 an examination noted "very dilated and tortuous vessels." No mention was made as to whether this represented plus disease. Accepted nomenclature demands that such a finding be described as plus or pre-plus. Descriptive elements are useful, but proper nomenclature cannot be ignored. Follow-up examination noted findings that were "suggestive of neovascularization," Again, is this stage 3 ROP or not? One week follow-up is recommended but does not occur for 13 days, at which time threshold ROP is noted. The absence of adequate use of the international classification, coupled with poor documentation in general and failure to take appropriate management actions, is apparent.

Case 11 is highly suggestive of negligent diagnosis, negligent documentation, and negligent follow-up. However, since the patient was diagnosed at a timely point, ie, threshold, no harm resulted from that negligence. The unfavorable outcome was the poor outcome that can expectedly result from proper and timely treatment. This element of negligence without causative harm is also evident in cases 6 and 10. Negligent error occurs in all 3 cases, but ultimately treatment is applied at threshold, nonnegligent harm occurs, and hence no malpractice occurs.

Case 12 alleged ophthalmologist negligence, but the case was essentially all about poor pediatrician/neonatologist referral issues.

Case 13 could be viewed as the ultimate documentation problem. The eye examination notes were lost, and no defense is possible without them. The pediatric notes suggest negligent timing. The issue of diagnosis at threshold or beyond is present, but such woeful record keeping is unlikely to mitigate the plaintiff allegations.

The lessons for the ophthalmologist are clear. They are as follows:

1. The examining ophthalmologist should not be responsible for ensuring initial outpatient appointments. It is wise to participate in ROP screenings only when a written protocol or clear oral unwritten understanding exists among all parties that spells this out. Such a protocol or understanding must include a delineation of to whom this responsibility is assigned. An ophthalmologist should make every attempt to ensure that there is no misunderstanding in regards to this. Such clear delineations do not insulate the ophthalmologist from suit, but they should help dramatically in winning such a suit. Clearly a by-product of such action will be improved follow-up compliance and improved care.
2. The examining ophthalmologist is unavoidably responsible for outpatient visits subsequent to the initial visit. The initial visit establishes a patient-physician relationship that is no longer purely consultative and is relatively independent of other health care providers. Proper administrative/clerical protocols should exist for tracking and recalling noncompliant families.
3. An acute ROP screening eligibility protocol should be adopted in each nursery. The 2006 consensus guidelines would have functioned well in systematically identifying all 14 infants in this case series. However, other protocols have been suggested, and each nursery should actively select criteria for systematic screening eligibility.
4. Residents can participate in ROP examination, diagnosis, and management, in a hands-on fashion as part of an appropriate educational experience. They cannot assume sole responsibility for the ROP care of these infants. They cannot be depended on to use their own discretion in determining when paired examinations are necessary. Resident examinations do not require attending repetition of every element. They do require appropriate supervision. ROP screening programs should be extremely cautious of entrusting these examinations to inappropriately supervised residents.
5. Examiner error occurs.[33] Examining ophthalmologists should keep their own fallibility in mind and prudently reexamine if elements of the case warrant such confirmation.
6. Zone III ROP cannot be considered "safe." The work of Repka and coworkers[20] must be considered. Unless one is fully confident that no preexisting temporal zone II disease was present, reexamination is prudent.[33]
7. Normal retinal vascularization proceeds in a predictable way within a fairly tight time frame.[19,33] Confirmatory examinations are prudent when there is any doubt about the zone or if the infant is unexpectedly young when zone III or full vascularization is thought to have been reached.
8. It should be self-evident, but ophthalmologists should be very familiar with normal and abnormal retinal development and the classification and nomenclature of ROP. The documentation of their findings must be consistent. One cannot mention or draw a ridge and entertain a diagnosis of stage 1 ROP. One cannot mention plus without taking appropriate action.

These lessons have applicability for ophthalmologists caring for any disease in any patient. They broadly relate to a physician's

responsibility in patient education; patient compliance; physician/consultant/patient relationships; appropriate protocols for supervising both clerical staff and medical staff, eg, clerical staff involved in timely patient access; resident supervision; awareness of the potential for physician error and the need for procedures to minimize the impact of that error; finally, a thorough knowledge of the literature and best practices on diseases within one's scope of practice.

ROP malpractice cases are infrequent but are dramatic, since they involve serious harm with a lifetime effect. Both the settlements and the jury awards are up to 10 times larger than most ophthalmologic cases, respectively. This analysis has identified specific areas of care that constitute the main areas of concern in these cases. Issues of referral and follow-up, issues of supervision, and issues of diagnosis and management constitute the basis of malpractice allegations in ROP.

Issues of referral and follow-up are primarily procedural in nature. All the providers should be active in overseeing what is essentially a clerical function. A medically acceptable screening eligibility protocol must be in place, and it then must be administered appropriately. The ophthalmologist should participate in the selection of the screening eligibility protocol, but it is the responsibility of neonatology to administer it and ensure timely initial consultation request.

As we have documented, follow-up consultations/appointments are more difficult to assure. Several of the 13 cases demonstrate this. Participants should strive for a foolproof procedure. Whenever patient/parent compliance is involved, no system in any area of medicine will achieve 100% success. However, the participants must make all reasonable efforts to ensure compliance. Parental compliance failure will still occur, but if a procedure is effective, such noncompliance will be minimized and will be the result of demonstrably unreasonable parental actions.

Achieving such a system is difficult and fraught with potential error points. Every participant will likely bear responsibility here. It serves the interests of patient and provider alike to view this process in a nondefensive way. The parties most able to effectively and reasonably secure follow-up compliance need to accept this responsibility. As noted before, this is not the ophthalmologist. Clearly, the nursery personnel and the outpatient pediatrician are afforded a much greater opportunity to interact with the family and establish compliance.

But there is a difference between what is practical or even ideal and what is found legally binding. These two at times contradictory elements must be fused by negotiation and planning. Ophthalmologists must not put themselves in legally compromising positions by assuming responsibility that they cannot deliver upon. Conversely, they cannot negotiate the avoidance of a legally unavoidable duty. Begin a dialogue, develop a system-wide protocol, negotiate the ophthalmology role, and get legal advice to ensure success.

The importance of appropriate supervision is much more straightforward than compliance. The involved physicians and the hospital are ultimately responsible for patient care. Nurses, practitioners, residents, and clerical workers are all subject to supervision in some fashion. The examining ophthalmologist can teach residents and fellows and supervise care. ROP examinations are no different than teaching surgery. But the key in any resident learning experience is proper supervision.

Finally, this report has documented recurring difficulties in the ophthalmology role of diagnosis and management. Areas requiring special emphasis are as follows:

- Knowledge of the natural history of normal retinal vascularization
- Knowledge of the natural history of ROP development
- Facility with the international classification
- The subtleties and pitfalls of zone III recognition and disease
- An appreciation of the potential for human error and the ability to act in such a way as to not only minimize such errors, but to minimize the impact of such errors, eg, timely confirmation of unusual findings
- Experience and facility with indirect ophthalmoscopy and scleral depression in tiny infants

Knowledge and experience alone cannot insulate an examiner from malpractice claims. But being forewarned of the critical problem areas as well as the tools necessary to be forearmed can go a long way in helping to provide the highest quality of care. Additionally, an understanding of the pathophysiology involved in diagnostic problem areas; eg, zone III issues, will lead to fewer errors and a lessening of the impact of these errors.

CONCLUSION

The interests of the patient are paramount. These infants must be screened and followed. The participating ophthalmologist must have the requisite knowledge and skill and be responsible for appropriate retinal diagnosis and management. An appropriate eligibility protocol must be selected. An attending ophthalmologist should agree to monitor and appropriately supervise any resident involved in care. And the ophthalmologist should accept only those administrative duties that he or she can provide and that are in the best interests of the infants. These latter procedural issues are negotiable. The ophthalmologist can and should negotiate with other team members in developing optimal procedures to ensure compliance.

The pediatrician and neonatologist are mandatory participants in ROP screening. It is part of their job. However, the ophthalmologist is an essential, yet voluntary participant. The ophthalmologist can thus be a demanding patient advocate. The ophthalmologist's participation can be predicated upon the assurance that responsibilities are reasonably and properly assigned. The ophthalmologist retains sole responsibility in retinal diagnosis and management. The ophthalmologist also accepts a patient-physician duty once that infant is seen in the outpatient office and therefore must have procedures in place to provide continued care or referral.

But other responsibilities are negotiable. Neonatology convenience, hospital resources, past practices, defensive medicine, and avoiding controversy are all subservient to the interests of the patient. And the ophthalmologist can help assure that by appropriate knowledge and skill, supervision of residents, and negotiating a reasonable role in an effective follow-up compliance protocol.

The primary goal of this thesis has been to improve the quality of care provided to premature infants. A review of malpractice cases has yielded a consistent pattern of a limited number of problem issues in the provision of ROP care. An in-depth analysis of these problem areas, including the applicable retinal pathophysiology involved, has highlighted the knowledge necessary to stimulate improved care. Specific suggestions have been made in how to take action that will, if followed, ultimately improve the quality of care. The secondary goal has been to help retain patient access to care by diminishing physician liability exposure. It remains to be seen whether this will be accomplished.

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