Chapter 19
Pediatric Ophthalmology

Edward L. Raab

Introduction

Efforts that lower the physician’s risk also usually result in better patient care. Limiting risk exposure is to a considerable extent a common sense endeavor, the main thrust being to apply, as physicians typically do on a daily basis, the principles of best practice.

Pediatric ophthalmology is characterized by the necessity to make crucial decisions and take actions intended to serve the young patient for a lifetime. Liability for inappropriate practice can in some instances be imposed 20 or more years beyond the event, and the damages could be monumental.

This chapter details several situations in pediatric ophthalmology that if approached improperly could expose the physician to liability. Some aspects of the discussion extend to ophthalmologic practice beyond the care of children. While not to be taken as legal advice, appropriate avoidance measures will be suggested. Note: even though in any of these settings your status as an employee may shift the obligation of payment of a judgment elsewhere, you will nevertheless be cited in the National Practitioner Data Bank.

The Unaccompanied Minor

What should take place when confronted with an unaccompanied minor presenting for examination? This would be unpermitted “contact,” as minors are considered to be without capacity to consent. Of all the items to be discussed, this probably is the easiest to address. It is more a matter of patient convenience than quality of care.

In general, parents or a guardian (a reliable adult who may not always be formally appointed) are responsible for health care decisions for an underage child. There are legally defined exceptions for minors who are married, pregnant, parents, self-supporting, or a member of the military (so-called emancipated minors). Routine eye care is rarely permissible for a minor who does not qualify as one of these exceptions.
It is most unlikely that a child would on his or her own initiative report for an examination, especially one likely to include the dreaded “blurring drops,” against the express wishes of a parent. However, it would be hazardous to rely on this “real life” inference of parental consent. The safest course is to require written authorization or consent by telephone. The latter requires a reasonable good faith belief that the consenting person at the remote location is the appropriate individual.

For problems that are more urgent but not true emergencies, relatives or an adult sibling may stand in for an absent guardian. Here, too, the circumstances should be such that there is reason to accept what is represented as to the accompanying adult’s identity.

Duty to Third Parties

We have a duty of care to our child patients, exercised through their parents or guardian. The responsible adult legally is a stand in for the child. Can there somehow be an additional duty to third parties, one that usually does not exist toward those who may accompany or even assist a competent adult in a medical care setting? The following illustrations are derived from actual cases.

A young child received a poliomyelitis vaccination. Her principal care giver was a parent whose own resistance to infection was reduced by recent surgery. The child’s pediatrician did not inform the parent of the precautions to be taken in handling the child’s waste and secretions. The parent contracted the disease and successfully sued the physician for negligence in failing to provide the pertinent information.\(^1\)

A psychiatrist was informed by a disturbed patient of intent to kill another person, whom the patient named. The psychiatrist concluded that warning the intended victim would violate physician–patient confidentiality. The patient accomplished the killing. The victim’s family successfully sued the doctor for the victim’s wrongful death resulting from the negligent failure to warn.\(^2\)

The law distinguishes different degrees of closeness between third parties and patients, either child or adult. Those who are either responsible for the minor or for an incapacitated patient’s general welfare and have decisional power and regular interaction with such a patient, or those emotionally close to the patient but who may not be formally responsible, have been included within the duty to warn assumed by the physician, which arises when the third party is known to be at risk from a specific threat and when the harm is readily foreseeable.

Accordingly, as just one example, the discovery by the pediatric ophthalmologist of a retinoblastoma as the explanation for a white appearance to the pupil, especially when bilateral, calls for investigation of parents, siblings, and perhaps close relatives in order to establish, by the detection of spontaneously regressed lesions and by modern genetic analysis, the likelihood of very young children of the family and its extension and of as yet unborn children being similarly afflicted. Omission of such widely practiced counseling and analysis could be regarded as negligent care, because there is a specific, foreseeable threat of harm to ascertained individuals. Once again, protection for the physician enhances overall quality of care.
Promises

“This operation will cure the glaucoma.” “These glasses will straighten your child’s crossed eyes.”

Such absolute declarations should be avoided. We know from experience that such statements are not always true. They are promises of results and if relied on by the patient in accepting treatment can be viewed as making a contract. This is not the same as malpractice and has the strategic advantages of not requiring expert testimony, and a longer statute of limitations.

The physician should studiously avoid any discussion that could be construed as an express promise. Expressing confidence that falls short of a promise in an outcome based on reliable evidence or your own experience (“therapeutic assurance”) is consistent with good medical practice and a much safer course.

Abandonment

A physician–patient relationship can be terminated by the physician for any reason or for no reason provided it is done with adequate notice and an offer to furnish the patient’s record to a successor physician. However, bad consequences from abandonment of a patient during a course of treatment would be difficult to defend.

Suppose you have under your care a child with an established diagnosis of juvenile rheumatoid arthritis. On one or more prior occasions, your examination has shown no uveitis. The patient does not appear for the next scheduled visit.

Now suppose alternatively that in a similar situation, you have detected uveitis and prescribed treatment. As proposed above, this child too is a “no show.” In both instances, you have appropriately counseled the responsible adult of the necessity for periodic follow up. Is your risk different in the two situations?

Abandonment applies when the patient is under an active course of care, which does not include merely a series of checkup visits for a certain diagnosis. Regardless, although the first scenario is essentially a periodic screening, best medical practice calls for at least a reasonable attempt to reschedule the appointment. Especially if such an effort is documented in the patient’s record, the risk of liability for a subsequent poor outcome is rather low. For the second child, a more vigorous attempt (again with documentation) to reestablish care is called for, as the child is in the midst of treatment for a potentially destructive disease. In another context familiar to the pediatric ophthalmologist, a child on an occlusion program for amblyopia, whose vision is periodically checked and the regimen adjusted, probably is under active treatment that may include the danger of occlusion amblyopia of the previously preferred eye, whereas the same child, undergoing interval vision checks once occlusion is discontinued, probably is not.

There is no rigorous definition of what constitutes a “reasonable” or sufficiently “vigorous” attempt. These determinations are fact specific and will be decided by a jury, if matters go that far. Properly documented efforts are not only medically correct but the best defense against the necessity for a jury to consider the question at all.
The Consultant

Most pediatric ophthalmology patients are referred for care, not merely for guidance. The ophthalmologist may report to the referring physician, but this is largely informational. A referral for diagnosis and treatment by a physician who is not a member of our specialty clearly implies that the patient (through his or her guardian) and the ophthalmologist understand that they are in a mutual undertaking.

Consider the following: you attend grand rounds or you are with a colleague in the staff dining room or at the scrub sink. You comment on a case. Your advice is followed; harm to the patient results, and you are sued. What is your risk of liability in this setting? As shown in several courts,3 reasonable jurors probably would not find any implication of a physician–patient relationship in this type of encounter, the existence of which most likely is even unknown to the patient.

In another context involving an unaware patient, the outcome could be different. Suppose now that you are the ophthalmologist on call for your hospital’s pediatric emergency room, and you are informed of a patient with an eye problem. Must you see the patient, or is telephone advice sufficient?

Several cases have indicated that it would be a departure from the standard of care to not personally attend a patient in these circumstances when indicated by the communicated findings.4 In the end, it is a matter of judgment; the response involves a weighing of the likely consequence of the injury if not immediately attended by a knowledgeable specialist against the inconvenience of your personal participation. Although the patient has not consulted you or even necessarily knows your identity, he or she has presented for care by the hospital, of which you are the understood designee to carry out the hospital’s obligation. When in doubt, go.

There also are occasions when you as the treating ophthalmologist seek consultation for your patient. What if in this instance you do not accept the consulted ophthalmologist’s recommendations? Given that you found it necessary to go beyond your own capabilities in the first place, are you at risk for a malpractice verdict if you ignore the advice and the case has a poor result?

Ultimately, you are not bound to follow a consultant’s recommendation, but your reasons for rejecting it should be documented. What is important is that these reasons be sound and preferably based at least in part on your own experience and that it is clear that you considered the consultant’s suggestions.

Right Eye or Left Eye?

Imagine the disaster (it has happened) when a mistake as to side occurs in an enucleation, even though in most cases the eye indicated for that operation is readily apparent. The possibility of error for interventions of a less critical nature also cannot be ignored; should correction of strabismus involve the only good eye of an amblyopic patient or one with a structural defect in one eye, other than in limited special circumstances (e.g., null-point motor nystagmus)?
Surgical facilities have increasingly become aware of the necessity to guard against such errors. Marking the operative site on the patient and “time outs” for verbal review of the proposed procedure among all participants are now institutional policy at many facilities, reinforced in some instances by state law or regulation.

Errors of this type usually occasion much finger pointing, but the last clear chance for prevention lies with the surgeon. No source, including the patient’s impression, the hospital’s operation schedule, and the insurance company’s authorization, other than your own record establishes the ultimate facts.

It is my practice to have my entire record available at the procedure and affix the sheet stating my plan to the wall or an instrument stand for ready reference rather than to bring only a short summary prepared as a brief admission note, because other questions about examination details may arise during the operation, especially in repeat strabismus procedures. The risk avoidance value of observing this ritual exceeds by far any slight inconvenience.

**Novel Treatment**

There are occasions when the physician finds justification for treatment that is neither established nor experimental, such as disinsertion and reattachment of all four horizontal rectus muscles for motor nystagmus. In such situations, the actual surgical handling may be entirely conventional; it becomes “novel treatment” by application in a novel setting. What risk-limiting precautions are appropriate here?

Professional common sense should prevail. Most important, there should be no increase in the expected occurrence rate of dangerous complications. Second, the remedy should relate logically to what is known about the abnormal condition. Published experience with the treatment by other ophthalmologists is valuable for this purpose. If there is no such prior evidence and the treatment is essentially untried, this calls for adherence to a full investigational protocol. Again, whatever lessens risk has a positive effect on quality of care.

**Off-Label Prescribing**

The term *off label* refers to the use of drugs and devices not authorized by the U.S. Food and Drug Administration (FDA), usually because they have not been evaluated for safety and efficacy in certain populations or in certain dosages. The package inserts for such drugs typically contain the warning “not approved for children” or a similar message. This situation is changing somewhat. Since 1998, the FDA has had a “pediatric rule” that requires studies on children as part of a new drug application unless children do not contract the disease the drug treats or the outcome is already known.
Among the most serious conditions leading the pediatric ophthalmologist to prescribe off label are certain forms of childhood glaucoma, retinoblastoma, and severe uveitis from various causes. In such cases there are few effective alternatives, so it is even possible that failure to prescribe off label could be deemed malpractice.

What liability exposure attaches to off-label prescribing? The FDA provides a Practice of Medicine Exemption under which it is lawful to vary the conditions of use of a drug from those detailed in the package insert without FDA approval, provided that the unapproved use is based on reasonable medical evidence, without fraudulent intent and that it requires the same judgment and prudence as exercised in medical practice in general.

The items of prudence considered critical are a good faith effort to evaluate all that is known about the drug and informed consent from the child’s caregiver, many of whom will notice the “not approved for children” warning. I have found it best to anticipate their hesitation by pointing out the difference between disapproved and nonapproved and that what is known about the drug’s effects, as well as prior experience, reasonably indicates that its use is appropriate.

Retinopathy of Prematurity

Experience has shown retinopathy of prematurity (ROP) to be a leading risk setting for the pediatric ophthalmologist. Modern concepts of appropriate care for premature infants are based on the premise, firmly supported by recent technical advances and a body of sound clinical studies, that the disastrous consequences of ROP can be avoided in most cases. The key is timely detection. Legal action mostly involves a break in the screening sequence once the infant is discharged from the nursery.

Consider the following actual occurrence: A pediatric ophthalmologist provides ROP screening services to the neonatal intensive care unit (NICU) of a regional hospital. The NICU has sole responsibility for identifying the infants at risk requiring screening. Examination of one such infant results in a properly charted note stating a diagnosis of “immature retina” in zone 2 and recommending a repeated screening in 2 weeks. The attending neonatologist misinterprets the note as conclusively ruling out ROP and transmits this information in his discharge note to the infant’s succeeding pediatrician, who considers the follow up to be only routine and elective. The parents arrange the next appointment by a delayed effort and cannot secure an appointment until several weeks later. At this examination, advanced ROP is evident, with a poor visual outcome. The pediatric ophthalmologist is named as one of the defendants in the subsequent lawsuit.

This is a rather typical scenario for ROP incidents that result in malpractice lawsuits. Omitting discussion here of how liability might be apportioned between the hospital neonatologist and the successor pediatrician, what was the ophthalmologist’s exposure, and how might it be minimized?
The case points out the importance of a thoroughly understood practice pattern among these participants. While “immature retina” arguably should have been understood by the neonatologist as not eliminating the possibility of ROP, especially because a short interval repeated screening was recommended, there should be an established understanding among the involved physicians regarding what meaning such an ophthalmologic description conveys.

There should be further understanding of whether responsibility for follow up is shared by the ophthalmologist or remains with the nursery or the subsequent pediatrician during the stage of screening, however many sessions are required before terminating scrutiny. Because the latter two coordinate all care during and following discharge, logic suggests that the responsibility best remains with them, but this is entirely a local determination. However, at the point where any degree of ROP has been detected, the capacity to address the matter has gone beyond the primary care givers, and it would be difficult for the pediatric ophthalmologist to deny some share of responsibility while being in the better position to carry out the necessary treatment or to secure this service from a colleague.

In the case described above, no ROP was evident at the first screening, but through a misunderstanding of the result, follow up was not arranged appropriately through no fault of the ophthalmologist. What then constituted his risk? It was that there was no system in place within his office for spotting compliance failures and assisting in efforts at rectification.

Other opportunities for a break in the system can occur. It is important that when medical considerations prevent the ophthalmologist from accomplishing the screening, this should be documented in the chart and some type of reminder should exist for restoring the infant to the schedule. When the screening ophthalmologist is not the person responsible for treatment, this too increases the possibility of a communication failure and gives a further responsibility to ensure compliance when the referral for treatment arises.

It is best to memorialize this or any other variation of understanding in a document freely available and universally adopted, but consistent custom and practice will govern in the alternative. Be aware that these understandings fix the working relationships at a particular institution, but no agreement to assign responsibility for any aspect of care elsewhere from where the facts of the specific case indicate it should lie will immunize against liability for negligence. The patient is not bound by arrangements between the involved physicians.

Final Thoughts

Try to accomplish an entire examination in one visit; it limits what might otherwise “fall through the cracks” if the patient does not return. You might avoid missing a retinal lesion, causing what may otherwise appear to be a routine strabismus problem or one that explains why an infant with supposed amblyopia is not improving with adequate occlusion.
Although it may seem clear that a tearing infant has lacrimal obstruction, always harbor a suspicion of congenital glaucoma. No ophthalmologist, especially not a pediatric ophthalmologist, should overlook this possibility.

Surgical over- and undercorrection of strabismus occurs frequently enough. Avoid characterizing these as complications, because they are within the spectrum of foreseeable outcomes, even though disappointing. Your informed consent procedure should establish this view.

Your informed consent discussions should include risks, benefits, and alternatives respecting the proposed treatment, but full disclosure still leaves room for you to rank the alternatives. Remember also to present not only the alternatives but also their risks and benefits as well as those of your preference. As to risks, the discussion is not complete without giving some idea of the likelihood of any risk materializing. I have seen several instances of adults with strabismus unduly discouraged from improving their self-image and business/social acceptance through surgery by an exaggerated estimate of the risk of intractable postoperative diplopia. Surely this unusual complication should be revealed, but in proper perspective relative to the likelihood of achieving the anticipated benefits.

References
