Malpractice and the Clinical Laboratory

Laboratories should become more aware of the medicolegal problems they may have to face.

Don Harper Mills

A stranger enters your office. He hands you an unfamiliar document. As you read it your curiosity changes to surprise, then to indignation, anger, and finally to frustration. You are accused of performing badly something you have spent your professional life trying to perfect. You have been sued for malpractice.

In the medical field, the probability of this happening depends on (i) the extent of a physician's personal contact with patients and (ii) the degree of risk of injury from procedures he performs. Active practitioners lead the list on both counts; consequently, they are sued quite regularly nowadays. Last year one claim was filed for every 12 physicians in Southern California—twice the rate of 1957! Clinical laboratories, on the other hand, are seldom named as primary defendants. They have less personal contact with patients and the procedures performed are generally less hazardous. It is interesting to note that clinical investigators are virtually free from suits, even though they have considerable direct patient contact and perform in arenas of unknown hazards. Their secret should be better known; but perhaps in the light of current publicity, conditions may soon change.

While some fields have sustained greater impact than others, law is increasing its penetration in every branch of medical and paramedical practice. Clinical laboratories may yet be in a favorable position, but future involvement is assured. In anticipation, they should become more aware of their potential medicolegal exposure. That is the purpose of this article, and it is best initiated by a discussion of the general status of professional liability litigation.

The author is assistant clinical professor of forensic medicine and pathology, University of Southern California School of Medicine, and is a consultant in forensic medicine.

Cause for Concern

Why has the incidence of malpractice claims taken a startling jump in the past two decades? The right to sue professional men is not new, though it is clear that many were not aware of this right until recently. The average patient now knows that not all untoward results and complications stem directly from the natural history of whatever disease he may have had. He knows that professional errors do occur. It is now the general opinion that modern medicine has such wonderful drugs and devices that anything less than a perfect result casts doubt upon the doctor's proficiency. According to Ellis, ". . . every individual becomes more conscious of medicine, and more demanding of it, tending to overrate its power and to underrate its dangers. In consequence, the profession tends to be more respected by the people, who at the same time have become more critical of it" (*1*).

While malpractice charges have been accentuated by their novelty, by no means do they yet occupy a disproportionate place in the administration of justice. There is more of everything today, including lawsuits. Indeed, a law explosion has occurred, described by Jones as a "proliferation of controversies and legal problems of range and number quite beyond anything with which an earlier legal order has ever had to deal" (*2*).

The progress of malpractice litigation has not been without recriminations. Courts have been accused of liberalizing rules to facilitate adverse judgments against physicians. For instance, there have been more frequent applications of the legal doctrine, *res ipsa loquitur* (the thing speaks for itself). Labeled a "rule of sympathy" (*3*), it states, in part, that if the injury suffered by the patient is one which does not ordinarily happen in the exercise of proper care, a presumption (or inference) of negligence is created against the doctor. It then becomes the task of the doctor to rebut this presumption if he hopes to be vindicated. Imagine the average juror's reaction to this: before him sits a permanently injured patient and he is instructed by the judge that the doctor may be presumed to have been negligent. While the medical profession claims that this is unfair, some courts have openly stated the responsibility for this trend rests with doctors themselves. They have openly accused doctors of a "conspiracy of silence" to prevent successful prosecution of justifiable malpractice claims.

Courts have long recognized the inability of a lay jury to determine if a particular medical or surgical act constituted negligence. Therefore, a doctor could be found liable only if he admitted liability or if another physician testified that the doctor-defendant's conduct was negligent. It is easy to see that liability could be circumvented if doctors refused to testify against each other. Whether an actual agreement or conspiracy to this effect was ever consummated is open to question. However, the courts apparently felt too many "bad" cases were resulting in verdicts for the defense. They became convinced that the lack of proper medical testimony was the reason, so they began taking counter measures. One of these was the doctrine of *res ipsa loquitur*, which could create liability even though a doctor did not testify on behalf of the patient. It is only necessary that the jury have the ability to conclude that the injury would not ordinarily have happened had the doctor exercised proper care. The California Supreme Court put it this way: "without the aid of the doctrine a patient who received permanent injuries of a serious character, *obviously* the result of someone's negligence, would be entirely unable to recover [win the lawsuit] unless the doctors and nurses in attendance voluntarily chose to disclose the identity of the negligent person and the facts establishing liability" (*4*)

(italics mine). This was in a case which came up in 1944. There has since been a definite tendency to apply the doctrine in *less obvious* cases, and even in cases where doctors do testify for the patient. Fortunately, there has been indication, in California, of a trend to curtail these inroads against the medical profession. In two recent cases it has been stated: "to permit an inference of negligence under the doctrine of *res ipsa loquitur* solely because an uncommon complication develops would place too great a burden upon the medical profession and might result in an undesirable limitation on the use of operations or new procedures involving an inherent risk of injury even when due care is used. Where risks are inherent in an operation and an injury of a type which is rare does occur, the doctrine should not be applicable unless it can be stated that, in light of past experience, such an occurrence is more likely the result of negligence than some other cause for which the defendant is not responsible" (*5*).

Where this trend will end remains to be seen, but it should be quite clear that an assessment of responsibility for malpractice conditions at present is no simple matter. A solution, if one is to be found, will require much more reasonable cooperation than now exists among the various interested parties.

Your Case

Once you have been sued for malpractice it is usually of little importance *why* you were sued. A determination of these reasons may help to calm your outrage, but it seldom contributes directly to your defense. The real issues facing you at this time are: (i) Was the patient injured (did he suffer some complication or lack of cure)? (ii) If so, did you or your employee cause it? and (iii) Was your conduct negligent (did your conduct fail to meet the professional standards of other similarly trained persons)? If each of these is answered in the affirmative, you should consider disposing of the case out of court. If any one or more of the answers is negative, the case should be defensible. It is important to realize, however, the resolution of each issue depends on facts, and there may be several ways to interpret them. What does the patient say about what happened? What do witnesses, if any, have to say? How do these versions compare with yours? If inconsistencies are present, can they be resolved satisfactorily by recourse to your records? Or, are your records so inadequate that the jury has little more than conflicting oral testimony upon which to reach a conclusion of what actually occurred? Never underestimate the necessity for good records. While many practicing physicians lament the need to compile records of the quality recommended for their defense, little can be done except to lend a sympathetic ear. If a reconstruction of events is to be carried out for defense purposes, the routine documentation must be adequate. This adequacy requires objectivity; that is, while you may claim your charts provide an adequate reconstruction of facts, your notes must be sufficient to allow another qualified person to do the same thing. If this cannot be accomplished, it sometimes becomes difficult to prevent the accusation that your own interpretation from the records is based upon unfounded extrapolations (*6*).

If you successfully hurdle these collateral matters in establishing the facts, you still face critical issues on the medical merits. Why did the error or complication occur? Was it the result of negligence, or was it one which occasionally happens despite skillful attention? Were you or your employee competent to perform the procedure from which the error or complication arose? Should you have anticipated it? What did you do to try to prevent it? Was there an untimely delay in recognizing its occurrence? Once discovered, did you handle it properly? When relevant, these searching questions must be answered to the jury's satisfaction. No one in court is expected to be better versed on these than yourself. This is your field. Nevertheless, enough suits are lost on medical issues to warrant periodic examination of them, even those which may seem quite unimportant. Increased awareness and anticipation of potential pitfalls could have prevented a number of adverse verdicts; therefore, I propose to discuss some of those which have come to my attention while assisting in the defense of physicians and laboratories. The scope here will encompass all possible functions of a clinical laboratory, including the applicable practice of pathology. For emphasis I will occasionally assume the role of an advocate; however, since I am not an expert in clinical laboratory medicine, nothing I say here should be construed as establishing standards of laboratory conduct.

Obtaining the Specimen

When a laboratory is accused of producing a false result, I look first to see if an error in specimen identification has occurred. Was it properly labeled when received? Was it properly entered in the log book? Do the records provide sufficient evidence to trace the course of this specimen through various procedures? Finally, is there any inconsistency in identification between receipt and result? I have never found an identification error in laboratories with good bookkeeping systems. Unfortunately, inadequate recording procedures are numerous enough to make this issue a recurring defense problem. Sometimes the error can be localized to a particular act; but occasionally the available evidence is so poor that one can only presume an identification error must have occurred somewhere along the line. Laboratories in this category try to exculpate themselves by offering evidence showing procedural routines. However, a lawsuit is concerned with a specific instance. Evidence of a custom or habit, therefore, is not frequently convincing.

When the laboratory is responsible for acquiring specimens directly from patients, as in hospitals, patient identification becomes a source of error. Mistakes here are practically indefensible for the laboratory even though hospitals themselves may contribute through inadequate patient-tagging methods. Generally, however, identification markings attached to patients (such as wrist bands) are becoming commonplace, and these should be used by laboratory personnel seeking specimens. Oral statements of patients should not be relied upon whenever objective identification evidence is available. Ultimately, the frequency of similarity in names may also demand checking of hospital numbers as well.

To assure the accuracy of some tests, a determination of the method of collecting the specimen may be required of the laboratory. Pregnancy tests constitute frequent offenders. Such tests are often required to rule out pregnancy in preparation for pelvic surgery. My own files contain 12 cases wherein false negative reports led to the performance of unnecessary abdominal operations on pregnant women. In at least four of these, unsuitable urine specimens may have been the cause. The attending physicians had given no instructions and the laboratories had asked no questions. In any situation

where the method of acquisition is of importance, laboratories should be more alert than present practices indicate.

Some litigated cases against laboratories arise from injuries suffered by patients during the course of acquisition of specimens by laboratory personnel. Cases involving local infection and thrombophlebitis following venipuncture demand careful attention on the part of laboratories concerning sterilization techniques and injection practices. Each time an infection problem goes to court, sterilization routines become a central issue of potential liability. Some laboratories cannot afford such close scrutiny.

Difficult cases to evaluate are those in which numerous attempts were made to obtain blood or spinal fluid specimens from an individual patient. How many times should the attempt be made? Should needling of all four extremities be permitted before deciding that the risks involved in obtaining the specimen outweigh the potential benefits from the test itself? Is it good practice for the laboratory physician to spend 45 minutes performing a dozen lumbar punctures before finally giving up? One case resulted in severe transient meningismus requiring hospitalization. Even though the attending physician ordered the test, laboratory personnel must exercise some discretion if difficulty is encountered. There should be less hesitancy about contacting the personal physician to determine the future course.

Of the laboratory tests requiring administration of intravenous substances, bromsulfophthalein (BSP) has produced the most complications. It has caused several local reactions and extensive sloughs in the area of injection, even when given by competent personnel in an appropriate manner. Dangers such as these require that patients be questioned about receiving previous similar tests and their reactions, if any. Additionally, the answers must be recorded. Should a patient suffer a reaction and decide to file a lawsuit, he will probably deny such questions were ever asked. The only reliable proof in defense will be the records.

Many "acquisition" cases result from injuries received by falling from tables, chairs, and stools. They usually occur after venipuncture. They can often be defended successfully if the evidence reveals the patient was observed and protected for a reasonable time after the procedure. The price of defending them, however, warrants *more* effort to prevent these injuries. Should stools or chairs without arms be used for blood letting? Should patients be allowed to get on and off tables without direct assistance? Finally, should laboratory personnel fail to inquire about fainting tendencies before any procedure which might precipitate such a condition is started? A hospital radiologist was held liable for injuries incurred by a patient who fainted while undergoing x-ray examination. The doctor could have determined, by examining the medical history, that this patient had a tendency to faint. Had he known this history, he could have undertaken specific measures to protect the patient. Similar liability conceivably could arise in laboratory practice.

To complete this section, three cases must be mentioned in which specimens were lost prior to analysis. All the specimens were tissue sections from biopsies. A second biopsy could be obtained in only one case. In the other two the initial biopsies included entire lesions (both were moles) and the loss precluded determination of whether or not malignant changes were present. Such cases are nearly indefensible.

Performance of Tests

A patient may be seriously injured if his doctor relies on erroneous laboratory results. However, a lawsuit against the laboratory may encounter difficult problems of proof. Clinical and biological tests on specimens rarely leave evidentiary traces. When nothing is left for retesting, it is almost impossible to prove that an error occurred except by arguing that the false result speaks for itself (*res ipsa loquitur*). This approach has been tried by some attorneys. In most instances they have failed because they could not establish the major premise—that the result was indeed false. Merely because a test result does not agree with others on the same patient does not prove error, unless the time lapse between tests is sufficiently short to exclude a possible real change in the composition of the specimen. For instance, test results which show, in a suspected erythroblastotic infant, a rise of bilirubin from 11 mg/100 ml to 42 mg/100 ml in 1 hour raise a strong suspicion of error somewhere. If the infant soon displays evidence of the central nervous system being damaged from kernicterus (bile staining of the brain), the finger is pointed toward the earlier test.

In tests requiring computations, errors can be detected if adequate records are maintained. Knowing this, the first inclination may be to keep no records. One should realize, however, that more cases are defended successfully than are lost by laboratories with good records. It is more often important to show the absence of errors in computation than to have to admit that one did occur. Records are needed for both.

Many laboratory malpractice cases alleging improper performance arise from blood typing and from the interpretation of tissue slides. These tests usually leave evidentiary traces. In the former, the patient's blood can be rechecked even though from a different specimen. In the latter, tissue slides or blocks are usually retained and can be re-examined at a later date.

Approximately one-half of the cases concerning blood typing involve alleged errors in prenatal testing, leading to a failure to anticipate potential mother-fetus incompatibility and possible erythroblastosis fetalis. Such an error may cause a disastrous delay in the exchange transfusion of the infant. The other half are directly associated with transfusion reactions. If an error can be traced to the initial typing, defense is almost impossible; however, most incompatible transfusion cases are frustratingly difficult to solve and it is beyond my scope here to discuss the multitude of problems encountered.

Misreading tissue slides is a hazard encountered by many pathologists. Someone else has the opportunity to examine the identical material. It must be emphasized, however, that something more than an honest difference of opinion is necessary to constitute evidence of negligence. Actually, pathologists prove to be more dangerous to others than to themselves. That is, in the final evaluation of tissue removed during surgery, misinterpretations reflect upon the surgeon, not the pathologist, by suggesting that the surgeon unnecessarily removed normal tissue or that he had removed the wrong tissue. Such errors, by pathologists, usually cause no actual harm to the patient since the operation has already been performed, but in several instances they have precipitated lawsuits against the surgeons, and in others they have increased the tasks of defense. Either the pathologist had to admit the error or it had to be proved through other pathologists that he had erred.

These statements are as applicable to conclusions drawn at autopsy as they are to surgical tissue analyses. The pathologist is relied upon to establish the cause of death and the attending physician usually accepts his conclusions when completing the death certificate. If the pathologist's conclusions are incorrect, the attending physician unwittingly adopts the error when he signs the death certificate. This doubles the difficulty in defending the case.

There are two major pitfalls associated with determining the cause of death. The first is the failure by the pathologist to correlate the clinical course of the patient with his findings at autopsy. The second is the failure to spell out the complete cause of death, not only with the immediate cause, but also with underlying conditions which led to the final demise. A classical example occurred some time ago when an autopsy was performed on an individual who had died in the hospital after several days of being subjected to diagnostic procedures and treatment for a comatose condition. The autopsy revealed no significant anatomical findings other than severe bronchopneumonia. This was the sole entry in the "cause of death" section on the death certificate. Seeing this, the spouse sued the attending physicians on the theory that the patient contracted and died of pneumonia while under treatment for something totally unrelated. Of course, physicians realize that a comatose patient is markedly predisposed to the development of pulmonary congestion and infection, even under the best of care. Therefore, this case actually did not represent an unrelated terminal event. However, this relationship did not appear on the death certificate and there was no attempt to clarify the problem to the spouse. The case was defended, but an unnecessary suit had been precipitated.

Reporting and Supplying

Transcription errors on final reporting forms are not rare. Common offenders are transpositions of numbers and decimals, though fortunately, they seldom cause harm. More annoying than dangerous are sloppy reports, sometimes completely illegible. It seems incredible that doctors would rely on such reports; however, some cases are devoid of evidence to indicate the attending physician sought clarification of the results.

Some laboratory reports find their way into the wrong charts. One would think the dissimilarity in names would alert any observer, but not so. Once inserted in the medical record these reports are rarely examined by anyone other than the attending physicians, and these doctors are interested more in the results than in the labels on the reports. Imagine the difficulty when the names are the same. One case involved prenatal blood typing performed while the patient was hospitalized. Another patient's blood-typing report got into her chart by mistake. The names were identical. It showed her to be Rh positive. Her baby was delivered without incident; but when she became pregnant again her physician relied on that report and did not have her retyped. Unfortunately, she was actually Rh negative and her next child developed severe erythroblastosis and secondary brain injury before her physician became sufficiently aware of what was going on. It was not until after he was sued that someone discovered the hospital number on the report was not hers. The procedure was done properly, but the result was inserted into the wrong patient's chart.

Misdirection of properly labeled blood for transfusion has led to disastrous complications medically and legally. Responsibility for administering blood to the wrong patient rests more often with hospital personnel than with the laboratory. In either case, however, the cause is a lack of diligence in identifying the blood or the recipient, or both. It is disheartening that these tragedies should arise solely from ministerial acts.

As noted previously, laboratories may have a duty to determine the suitability and adequacy of specimens to assure reliable results. If any deficiency is discovered, it should be reported along with the test results. Several cases involving biopsy specimens indicated that the laboratory should have known the specimens were inadequate for reliable examination; yet, in each case the attending physician was not notified in time to seek further specimens for review before dismissing the lesions as nonmalignant.

Consent

Every procedure performed directly on patients requires consent. For simple procedures it need not be in writing. Often it is not even expressed verbally. Fortunately, the law implies consent by the conduct of the patient if he submits to the procedure without objection. Of course, a written consent should be demanded from the parent or guardian if a minor arrives unaccompanied (unless he is a patient in the hospital).

Obtaining proper consent may be more complicated when test substances are being administered, particularly those which are capable of producing complications. With the "informed consent" rule now applied by some states, *someone* may be required to inform patients of these risks before the consents are considered valid. If a state does create this duty despite existing standards of practice (most physicians and laboratories do not inform patients of such risks), upon whom would this responsibility fall, the requesting physician or the laboratory? While physicians do decide which tests are to be performed, they themselves are often not sufficiently aware of the risks to inform the patients. This places the burden, if any, upon the laboratories. Few laboratories will relish this role and few physicians will appreciate learning that their patients are too frightened to have the tests done.

The informed consent rule has created considerable confusion. For those states whose courts have not yet pronounced a decision, I can offer no dependable advice. Even in some states where rules have been formulated, physicians are still in the dark. Must patients be informed of risks even though most physicians and laboratories do not do so? If so, how extensive must this information be? In each state the answer depends on the theory and precise language of the rule and on the particular procedure in question. No one doubts the right of patients to ask and expect truthful answers about potential risks.

The informed consent rule, however, requires physicians to offer *unsolicited* information concerning risks. For this, resentment and resistance must be expected. Indeed many mature physicians feel strongly that this rule is an unnecessary and frivolous legal interference in the practice of medicine. Who is better equipped than well trained doctors to decide whether indicated procedures should be performed? Is the patient really emotionally and intellectually capable of weighing the risks and benefits? Why has it been necessary to create this fictitious right when it clearly opposes sound medical

thinking? The informed consent rule is not a way to protect patients from unnecessary procedures. If followed liberally it will produce more health havoc than legal protection.

Conclusion

Those familiar with malpractice problems realize there is no panacea in sight, nor is one expected in the immediate future, at least of the type which would satisfy most parties. There are just too many variables in the present situation. Therefore, physicians must seek practical methods to reduce malpractice threats. This is no less true for clinical laboratories. Recognition of potential pitfalls, particularly those which have plagued less fortunate colleagues, is a start in that direction (*7*). To assist in this I have subdivided usual laboratory conduct into four phases: obtaining the specimen, performance of tests, reporting and supplying, and consent. For each phase I have briefly presented the more serious and common issues which have developed in malpractice cases. Awareness of these may prevent some from occurring. If an injury does occur, however, proof that it happened despite diligent preventive measures and adequate management certainly increases the probability of a successful defense.

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Curriculum Reform

Courses and teaching methods are changing at all levels, not just in high school, where it all began.

John Walsh

This year for the first time, textbooks and supplementary materials in the "new" biology and chemistry for high schools are generally available and are selling well. Courses in the new physics and mathematics preceded biology and chemistry, and it appears that the curriculum reform movement has reached its first major way station.

What has been heralded as a revolution in the teaching of science and mathematics in secondary schools is also having an agitating effect on elementary school and college curricula, on teacher education, and on commercial textbook publishing. And like other reform movements, curriculum reform has produced some interesting secondary aspects. It can be argued, for instance, that the effort to improve course content has had a vitalizing effect on educational research and, judged on a cost-effectiveness basis, is the most important program of federal aid to schools extant.

The operative principle in the current curriculum reform effort is the collaboration of research scholars and school teachers, financed by the National Science Foundation.

Like a good many NSF programs, the course content improvement projects, as NSF calls them, are not mentioned in the statute establishing NSF, but were created out of a general feeling of necessity and are based on the agency's responsibility for strengthening science education.

While most proposals for federal aid to schools become tangled in congressional barbed wire, the course content projects have remained remarkably uncontroversial. In part this may be because the program required no separate legislation and was handled administratively. But the explanation for the peaceful progress lies probably in its lack of ingredients to ignite religious or racial issues, which make legislative powder kegs of most school aid proposals. NSF has also leaned over backward to avoid any suggestion of federal control.

Furthermore, the cost of the program has been relatively modest, although the annual bill is rising steadily. Something over $50 million has been spent since 1954. The annual budget has reached about $14 million, but this represents a small part of the $350-million NSF budget and is an inconspicuous amount compared with billions spent on public education by state and local governments.

A pattern for the present round of curriculum reform seems to have been set before NSF took the plunge with support of a major project in 1956. Many people date the beginning of the present surge back to the establishment of the University of Illinois Committee on School Mathematics (UICSM) in 1951. With Max Beberman as chairman and the Carnegie Corporation as patron, UICSM proved a prototype both in aims and organization.

In the early 1950's the chorus of lament from university scientists about the widening gap between science as practiced by the researcher and science as taught in the high schools had kindled NSF concern over high school teaching. But a catalyst was needed to get the agency committeed, and the function seems to have been performed by Jerrold R. Zacharias, physics professor at M.I.T.

Zacharias had made some public statements about the responsibility of university researchers for helping in the modernization of high school science and math curricula, and after a series of conversations which culminated in a meeting between Zacharias and NSF director Alan Waterman, there emerged the idea for the Physical Sciences Study Committee (PSSC), which was to produce the pioneering course in the new physics.

Zacharias, a persuasive man and a driver, remains an active and influential figure in the curriculum reform

The author is a member of the staff of *Science*; he writes for the "News and Comments" section.