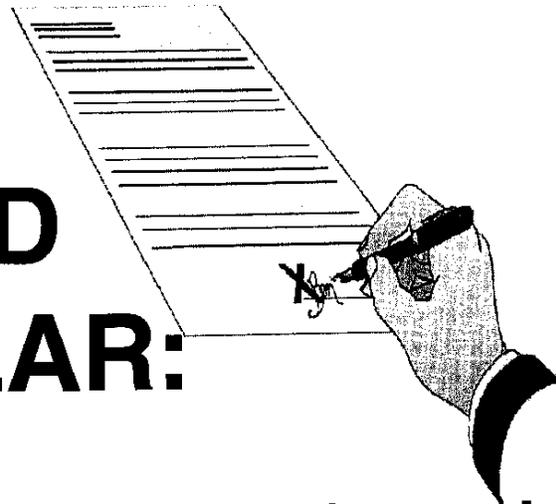


INFORMED CONSENT AND THE PAP SMEAR:



Avoiding Malpractice Through Information

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Primary care providers, cytotechnologists, and pathologists are being subjected to claims of professional negligence in the collection and interpretation of cervical cytology specimens at an alarming and ever increasing rate. This process continues to jeopardize the availability of the Pap smear because the increasingly large damage awards, low reimbursement, increasing government regulation, and the possibility that laboratories may be required to make large capital expenditures for new automated technologies are forcing many laboratories to discontinue the service. In an effort to reduce liability, many authors have suggested obtaining a patient's informed consent prior to obtaining a Pap smear. This paper examines the history and development of the doctrine of informed consent and explores the legal effects of obtaining a patient's informed consent prior to obtaining a Pap smear.

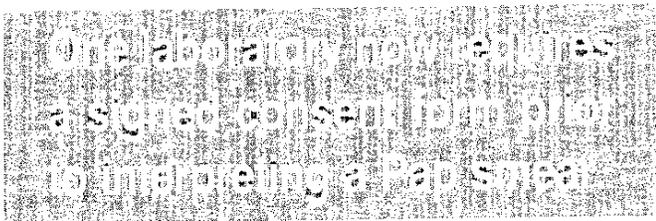
Historically, pathologists have enjoyed a relatively protected position in the arena of medical malpractice litigation. Many reasons have been offered to explain this liability protection, but most notably pathologists generally have no direct patient contact and generally are not involved in high-risk procedures. Another factor leading liability away from the laboratory is the delay or extended time period between the diagnosis and the discovery

of any error. Additionally, a pathology malpractice case can be relatively costly to litigate. The interpretation of cytologic or histologic specimens and their explanation to a lay jury can require an expensive "battle of the experts," and the often conflicting expert opinions can create confusion about the applicable medical standard of care. These factors combined to create a deterrent to legal actions against pathologists.

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Today, however, pathologists, insurance companies, and their attorneys have come to realize that any perceived protections were illusory. Pap smears and cytology practices in general have become rapidly growing areas of potential liability for pathologists. A recent article, citing the experience of the Doctors' Company, noted that cervical cytology claims are more costly than the average pathology claim and the number of claims has at least doubled since 1988. Cervical cytology claims represented almost 30% of the total claims against pathologists in 1995, with the total indemnity paid for cervical cytology claims nearly 40% of the total paid for all claims against pathologists in 1995.¹

An increase in liability is naturally followed by the efforts of risk managers and quality assurance managers to reduce that liability. The College of American Pathologists recently devoted an entire conference to define and emphasize the trends in liability.² Also, the International Academy of Cytology published a summary of recommendations from their task force on medicolegal affairs with respect to Pap smears and liability.³ One idea that has been receiving attention is the doctrine of informed consent and its application to cervical cytology.⁴ One laboratory now requires a signed informed consent form prior to interpreting a Pap smear.⁵ This article explores the history and development of the doctrine of informed consent and provides a brief analysis of its use with Pap smears.



History and Development

The current doctrine of informed consent imposes a legal duty upon physicians to provide adequate disclosure of the medically recognized risks, benefits, and alternatives to any proposed diagnostic or therapeutic medical procedure so their patients can make informed decisions and give informed consents to

those procedures. This doctrine is entrenched in all fifty states as well as the District of Columbia. It rests on several specific legal premises including the idea that touching without consent is battery, that treatment without consent is a violation of the provider's fiduciary duty to the patient, and that the patient has a right to self-determination or autonomy.⁶

Historically, physicians maintained the position of patriarchal authority and courts provided them great deference. Patients did not question their doctor's treatments or methods. This deference began to erode as medical science grew. Hospitalization, aseptic technique, and improvements in anesthesia made it possible for larger, more extensive surgeries that naturally carried increased morbidity and mortality. Courts were forced to recognize the flaw in patriarchal deference when highlighted by the helplessness associated with anesthesia. Furthermore, they realized some patients would not want to take the increased risks associated with these new and developing procedures. The early cases, decided around the turn of the century, focused mainly on simple consent. In *Pratt v. Davis*,⁷ the patient's husband had consented to only one operation and the court determined a battery had been committed when the surgeon extended the procedure to include a "second" operation without consent. *Schloendorff v. Society of New York Hospital*⁸ memorialized the notion that tort law, specifically battery, can apply to physician-patient relationships.

The doctrine remained unchanged until 1960 when the courts finally took note that the requirement for simple consent only disguised the patriarchal deference used in the eighteenth century. Courts had empowered patients by requiring their consent for diagnosis and treatment; however, the rule did not provide or require any basis or knowledge to help make that choice. Many patients, then and now, simply relied upon and trusted the expertise of their doctor. The first case to expand the simple consent theory was *Natanson v. Kline*,⁹ which held that a

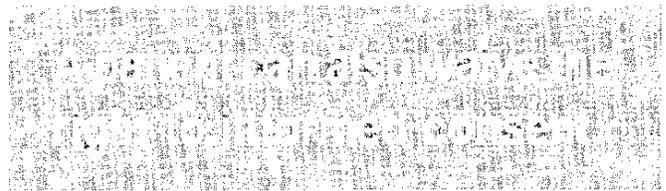
physician had to disclose enough information to allow the patient to understand the recommended treatment before obtaining a patient's consent. The duty to disclose arose out of a physician's fiduciary duty to the patient created by the disproportionate level of knowledge and experience.

This subtle change created a massive switch in legal direction. The applicable body or theory of law changed from an intentional tort, namely a battery, to a cause of action based more closely on the tort law of negligence. The court now focused on the specific information the physician passed on to the patient, and compared the information required for disclosure to that which would be expected from the average reasonable medical professional similarly trained and in similar circumstances.¹⁰ The standard is the same one used in medical malpractice or other professional negligence claims to determine if the standard of care has been breached. This is known as the "professional" standard and is currently the rule followed in just over half the jurisdictions.¹¹

This standard, however, did not gain universal acceptance and controversy developed over its application. Many argued that patients could only be protected by a standard which focused on the needs of the patient and not on what the medical establishment believed to be important. The next leading case to refine the standard of disclosure, *Canterbury v. Spence*,¹² suggested the "prudent patient" standard which remains the minority approach.¹³ It requires the disclosure of all information that would be "material" to a reasonable person in the patient's position when faced with a similar decision. The debate over how to protect patients grew even larger when the courts of Oklahoma and West Virginia removed the "reasonable person" requirement from the standard.¹⁴ To fulfill their duty under this third standard, providers must tailor their disclosure to the individual patient's needs based on that particular patient's values, knowledge base, and concerns.

During the 1970s many state legislatures took the debate away from the courts and enacted statutes to

codify the common law. These laws further modified the requirements for the use of informed consent by specifying in which cases it was required, what documentation was required, and how much information should be exchanged. Three states (Hawaii, Louisiana and Texas) completely changed the process by creating "Medical Disclosure Panels."¹⁵ Since state legislatures have created great diversity in the requirements and methods by which the doctrine of informed consent is satisfied, each physician is encouraged to become familiar with the relevant statutes in his or her jurisdiction.



Elements, Defenses, and Analysis

An allegation of malpractice based on the lack of informed consent rests on the idea that an injury occurred without consent. The patient did not "accept the risk." A patient so injured must establish the standard four elements of a negligence claim as modified for informed consent cases. These elements include the following: 1) a provider's specific duty to disclose particular information; 2) a breach of that duty because the information was not disclosed; 3) the occurrence of an injury; and 4) the failure to disclose the information caused the injury. The last element, causation, can be further divided into two necessary components. First, the patient must show that if the required information had been provided he or she would have forgone treatment or elected to proceed with an alternative method. The second component requires that the injury was the direct result of the medical care provided and the particular risk was known or reasonably should have been known to be associated with the patient's medical care.¹⁶

The establishment of these elements does not always signal liability. The courts recognize specific instances where limited or no disclosure is necessary

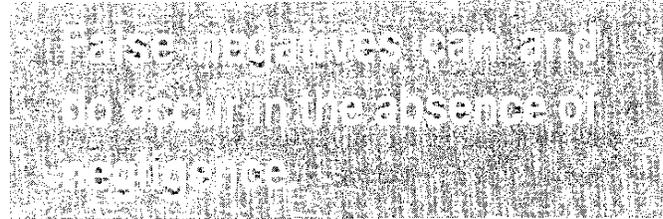
and desirable. One obvious instance is where a particular patient already knew or should have known the risks or alternatives. In some jurisdictions, a patient can also waive the right to informed consent; however, the physician must clearly document the waiver including the patient's desire to undergo treatment regardless of the risks. The patient must understand she has a right to the information and decline it without pressure. Thus, the waiver must also be an "informed waiver."

Emergencies, by definition, require prompt decisive action precluding the discussions necessary to obtain an informed consent. Also, courts recognize that most "reasonable patients" would not forgo the emergency treatment and therefore the element of causation is not met. There are times when courts may mandate treatment, which removes the need for informed consent, such as the drawing of blood alcohol or the removal of trace evidence. Finally, the need for disclosure is removed when the mere act of revealing the material information alone will cause harm to the patient's recovery or cause undue stress that derails therapy. This exception is known as the "therapeutic privilege." Again, the use of this defense requires clear documentation in the medical record including the reasons for withholding relevant information. The decision should be supported with opinions from professional peers if possible.

Relevance to Pap Smears

The doctrine of informed consent and its use as a defense to professional negligence in cervical cytology lawsuits has appeared in recent articles, and some authors have regarded it as being of limited value.¹⁷ This opinion seems to discount several factors. First, as illustrated by one author,¹⁸ the majority of suits tend to follow a "script" which includes many claims of negligence, only one of which is the lack of informed consent. Second, patient education can take place by helping to remove the public notion that cervical cytology is 100% accurate. Finally, the process helps strengthen the physician-patient relationship through cooperation, which may reduce the likelihood of later legal action.

A false negative diagnosis will be better understood by the patient and thus remove some of the motivation to consult an attorney.



The entire process serves to shift the burden of risk of potential or expected complications from the physician to the patient, once she has agreed to proceed despite the possibility of disclosed dangers. In the case of Pap smears, the patient has formally accepted the fact that there is a recognized error rate and false negatives can and do occur in the absence of negligence. The physician, of course, will remain liable for care provided in a manner that falls below the appropriate and reasonable standard of care with respect to the actual cytologic slide interpretation, its processing, and reporting. However, well documented informed consent allows the defense to show the jury that, while unfortunate, mistakes do happen without fault, and therefore there should be no liability. Arguments that emphasize the patient's responsibility for follow-up care and repeat testing become much stronger.

Documentation of informed consent is invaluable at the time of trial. In a case involving a claim of negligence and lack of informed consent, a court noted that in the state of Washington a signed consent form is prima facie evidence of informed consent.¹⁹ This means that once the form is introduced by the defendant physician at trial, the plaintiff must produce evidence to rebut the idea that she consented to the testing. In the case of Pap smear litigation, the jury would hear from the defense that the patient consented, knowing that false negatives could occur even in the best laboratories. Plaintiff would then have to demonstrate to the jury how the alleged diagnostic error fell outside those errors which could be expected and predictable.

The doctrine of informed consent can provide physicians needed protection from liability associated with cervical cytology and Pap smears. Physician liability cannot result from harm caused by expected or predicted dangers once the patient has agreed to proceed after knowing those risks. Many observers have discounted the legal protections afforded by informed consent because most malpractice cases will also center on allegations of substandard care resulting in unexpected injuries. However, it is clear that proper informed consent can limit liability by providing needed education regarding the limitations associated with screening, as well as shift the burden of known risks to the patient. Also, it can assist in the development of trust and encourage patient participation in decision-making. These factors often combine to make the patient less likely to initiate a lawsuit. If a lawsuit is ultimately brought, well documented informed consent forces the patient to differentiate between those errors that were the result of true screening failures and those caused by negligence.

For these reasons, the doctrine of informed consent should encourage physicians to discuss openly and honestly the limitations of cervical cytology. Many laboratory tests, including screening tests like the Pap smear, are not capable of a "yes/no" answer. In the profession's rush to extort the virtues of mass screening, it chose not to emphasize that the Pap smear is a test incapable of 100% sensitivity for fear some women would forgo this valuable test altogether.²⁰ Taking the time to educate patients will help emphasize the value of repeat testing and will place some responsibility on the patients once they are involved with the decision-making process. Proper repeat testing can greatly reduce the possibility of missing treatable disease, which again lowers the chance of a lawsuit.

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