Consents: A Legal Perspective

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The number of procedures performed in 2022 is 1.5 billion.[4] Each one of those procedures required the patient to give consent. But what exactly is consent and why is it so important? In the general sense consent is easy to define: a voluntary agreement to a proposition or an act of another. A concurrence of wills.[8] But the concept of consent, as it applies in a medical setting, is much more complex. It includes topics such as general consent, special consent, express consent, implied consent, informed consent, and even informed refusal. These concepts are rooted and evolved from the United States' court systems through what is known as case law. Consent in its modern usage spring in large part from a series of early 20th century lawsuits involving overreach by physicians. *Pratt v. Davis* (1905) and *Mohr v. Williams* (1905) are two such cases which saw their manifestation in the 1914 case of *Schloendorff v Society of New York Hospital;* this being the final "landmark case that legally established the principle of patient autonomy."[1]

In *Pratt v. Davis*, plaintiff Pamela Davis sued Dr. Edwin Pratt for battery after he performed a hysterectomy without her permission. Dr. Pratt had obtained consent for a different surgery, but did not disclose to Mrs. Davis that he intended to remove her uterus to "treat Mrs. Davis's epileptic seizures … Dr Edwin H. Pratt, acknowledged intentionally misleading the plaintiff as to the purpose of the operation, claiming that because Mrs. Davis suffered from epilepsy, she was not competent to give her consent or to deliberate intelligently about her situation."[1] The appellate court succinctly formed the right of consent in its opinion when it reiterated that a citizens' first and greatest right is to himself and this right forbids a physician or surgeon to violate the bodily integrity of his patient.[7] This opinion was further developed in the Minnesota Supreme Court Case *Mohr v. Williams*.

LEARNING OBJECTIVES

- Define medical consent
- Review the history of patient consent practices
- List the cases that changed medical consent in the US
- Discuss explicit permission

Anna Mohr consented for Dr. Cornelius Williams to perform an operation on her right ear. When Mrs. Mohr was anesthetized, Dr. Williams examined and concluded that the disease in her left ear was more advanced, so he performed the surgical procedure on her left ear. Although the procedure further impaired Anna Mohr's hearing, it was "in every way successful and skillfully performed" according to the prevailing medical practice at the time.[7] Instead of ordinary negligence, Mrs. Mohr sued Dr. Williams for assault and battery citing the lack of consent for operating on the left ear. Minnesota Supreme Court Judge Brown not only cited the opinion of the *Pratt v. Davis* case but integrated it firmly within the tort of battery by citing a torts treatise to show that the consent requirement must authorize a touching only after an informed decision is made. The decision to proceed or to refuse is a legal right. "Consent, therefore, of an individual, must be either expressly or impliedly given before a surgeon may have the right to operate."[7] Dr. Williams defended himself by arguing that "there is a total lack of evidence showing … that the operation was negligently performed." The Court blatantly rejected this defense stating that "It was a violent assault, not a mere pleasantry; and, even though no negligence is shown, it was wrongful and unlawful."[7]

The concept of consent as central to upholding patient autonomy was given much of its modern form in the landmark case of *Schloendorff v Society of New York Hospital*, written by the influential jurist Justice Cardozo. Plaintiff Mary Schloendorff consented to an examination under ether to determine the character of a fibroid tumor. Prior to the examination, Mrs. Schloendorff repeatedly confirmed that she wanted no operation to be performed, however once asleep, the tumor was removed.[12] In his opinion, Justice Cardozo "affirmed a patient's right of self-determination when he wrote: In the case at hand, the wrong complained of is not merely negligence. It is trespass. Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained."[12] Justice Cardozo gave force to an early-modern conception of patient autonomy, the principle that adults of sound mind may determine what happens to their own body, by embodying it in a legal principle that a surgeon who performs without consent is negligent. Explicit permission, better known as express consent, must be given or else a physician who commits an unauthorized touching of a patient may be liable for assault and or battery; although as Justic Cardozo foresaw, it may be necessary in an emergency to operate without express consent.

> Each one of these court cases shows the fundamental right of the patient to determine what happens to their body. This determination is led by a legal duty of every physician to give their patients as much information as needed to aid the patient in making an informed decision.

Express consent must be given prior to a procedure, but if a patient is not informed of the risks inherent in a proposed surgery, the courts must decide if implied consent is a defense for negligence. This was the case in 1960 with the hearing for *Rogers v. Lumbermens Mutual Casualty Company.* Dolly Rogers sought out the services of Dr. L. Keith Mason and his partner, Dr. Fleater Palmer, Jr. to perform an appendectomy. Mrs. Rogers signed a consent form that from the perspective of Judge Hardy was "so ambiguous as to be almost completely worthless, and, certainly, since it fails to designate the nature of the operation authorized, and for which consent was given, it can have no possible weight under the factual circumstances of the instant case."[9] Mrs. Rogers testified that she understood the surgery was to remove her appendix, but at the conclusion of the procedure she had undergone a total hysterectomy, a bilateral salpingo-oopherectomy, and an appendectomy. During his testimony, Dr. Mason claimed to have a poor memory and could not give exact details on what he discussed with Mrs. Rogers prior to her surgery. His defense failed even further when the court observed "that the alleged defenses of emergency, or of the necessity for the operations performed in the interest of the health of the patient, are completely demolished by the testimony of Dr. Mason that no emergency existed and that he removed the female organs as a

precautionary measure and because he felt it was good surgical procedure."[9] The judgment of the court was in favor of Mrs. Rogers. Although Mrs. Rogers signed a general consent, the additional procedures were battery because the consent form was ambiguous, and no emergency existed to justify the removal of her healthy organs.

However, in the event of a medical emergency, courts do support physicians in making life-saving medical decisions. In effect, there is an implied consent to preserve life and limb of a patient. *Davidson v. Shirley* is one of the early precedents for implied consent during an emergency and was a 1980 Fifth Circuit Court of Appeals case. Annelle Davidson was advised by Dr. William Shirley to have a caesarean section due to the size and position of the fetus. Upon admission, Mrs. Davidson signed a consent form authorizing the caesarean section. The consent form included authorization for "such additional operations or procedures as are considered therapeutically necessary on the basis of finding during the course of said operation." (3) Mrs. Davidson, a registered nurse, testified that she read and understood the language of the consent form. During the procedure, the surgical team struggled to control bleeding after delivery of the newborn and discovered a "grapefruit-sized" tumor covering the right ovary and adhered to the uterus. The tumor was removed. During both the C-Section and the excision of the ovarian tumor, Mrs. Davidson suffered more than 1,000cc of blood loss stemming from the uterus. When medication and suture ligation failed, Dr. Shirleys' team performed a hysterectomy. Annelle Davidson sued Dr. William Shirley for negligence, assault, and battery. The district court denied the charge of negligence and treated the claim as one for battery. Consent is a legal defense against a battery claim and the district court found the consent valid, due to the emergency circumstances, so judgement was rendered in favor of Dr. Shirley.[3]

Absent a medical emergency, implied consent was not always included in the general or surgical consent form. The traditional practice was that unless a true emergency existed, the original surgery would be completed, and the newly discovered condition would be addressed at a later time. However, this practice subjected patients to additional surgeries and the risks thereof.[11] As the surgical consent form evolved over time it fully incorporated a clause like the one in *Davidson v. Shirley*, and is based upon the ideology to protect and preserve life. Surgical technologists recognize it as "and any other indicated procedures." However, more recent cases have begun to limit the scope of what emergency procedures can be justified in consent forms, as we see in the 1992 case of *Fox v. Smith* and the 2017 case of *Dodd v. Hines*.

When Lana Fox experienced severe abdominal pain she consulted Dr. Perrin Smith, an obstetrician-gynecologist. After a pelvic exam, it was suspected that Mrs. Fox either had endometriosis or a cyst and recommended an exploratory laparoscopy for a diagnosis. Upon admission for surgery, Lana Fox read and confirmed her consent for a laparoscopy but questioned the wording for additional indicated procedures. In her testimony, Mrs. Fox felt that she had communicated her desire to retain her IUD. When Dr. Smith testified before the court, he explained that during instrument placement for the laparoscopic procedure, he found the IUD extruding from the cervix. the plastic was calcified, and the copper wiring was not intact. In addition to the laparoscopic procedure, Dr. Smith performed a D&C to remove the foreign material that had broken loose from the IUD and had removed the IUD itself. Lana Fox sued Dr. Perrin Smith for battery. While the trial court in *Fox v. Smith* granted a directed verdict in favor of Dr. Smith, the Mississippi Supreme Court reversed the decision and sent the case back to Lowndes County Circuit Court for a new trial.[6] In his opinion, Justice Lee wrote: "If we were to accept Dr. Smith's argument, then we must first ignore Mrs. Fox's testimony that she specifically forbade Dr. Smith to remove the IUD. Second, the consent form authorizes necessary and unforeseen procedures 'during the course of the operation.' It is unclear from this record whether or not an IUD removal is necessary and unforeseen when a laparoscopy is the authorized procedure."[6] This case was heavily cited in the more recent *Dodd v. Hines*.

Lacy Dodd sought out the services of Dr. Randall Hine for removal of an ovarian cyst and possibly a fallopian tube in the hopes of increasing her chances of conception. During the laparoscopic surgery, Dr. Hines found both of Lacy Dodd's ovaries to be abnormal and consulted with Dr. Paul Seago, a physician in the field of gynecology and obstetrics with a subspeciality in gynecological oncology. No biopsy was taken for confirmation of cancer and Dr. Hines, with the recommendation and agreement of Dr. Seago, removed both of Lacy Dodd's ovaries. Upon removal, both ovaries were sent to pathology and were found to have "'serous cystadenofibroma,' a condition where a benign tumor appears

cancerous."[5] Lacy Dodd filed a complaint against Dr. Hine and Dr. Seago. In his defense, Dr. Hine supported his decision by stating the removal was not only medically necessary for Mrs. Dodd's continued good health, but that the "consent form did not require him to conclude the surgery and awaken Lacy to obtain specific consent prior to performing the oophorectomy when he and Dr. Seago discovered what appeared to be ovarian cancer … Lacy Dodd's ovaries was consented to and authorized by Mrs. Dodd in the consent form which she signed which specifically granted to the operating physicians the authority to perform 'such additional surgeries and procedures (whether or not arising from presently unforeseen conditions) considered necessary or emergent in the judgment of my doctor.'"[5] And while the trial court granted summary judgement in favor of Dr. Hines and Dr. Seago, the Supreme Court of Mississippi reversed the decision and sent the case back to the lower court for a new judgement.

In his opinion, Justice Coleman succinctly framed the issue as one of "whether Lacy provided appropriate consent for the removal of her ovaries, eliminating her ability to conceive."[5] Increasing her chances of conception was the sole reason Mrs. Dodd sought out the services of Dr. Hines and agreed to the original laparoscopic procedure. The Supreme Court of Mississippi further noted that the removal of Mrs. Dodd's ovaries was "not only substantially different from the authorized procedure, but it was 'antithetical to the purpose of the surgery'… [W]e find that, under the battery-based analysis of consent, Lacy did not give express consent for the removal of her ovaries and that the consent form signed by Lacy did not summarily provide consent to remove her ovaries. As the circuit court's decision did not reach whether or not the removal of her ovaries became necessary or emergent during the medical procedure that was consented to by Lacy, nor did the judgment address any other analysis of consent pertinent to theories of medical liability, we reverse and remand."[5]

These two court cases, *Fox v. Smith* and *Dodd v. Hines*, show that courts are beginning to narrowly apply the idea of implied consent in the surgical theater to one of emergency versus non-emergency. Is the evolution of implied consent going to be defined as acceptable only in cases in which hemorrhage is uncontrollable or only where cancer is confirmed? Will this narrow interpretation by the courts soon require all patients to give durable power of attorney to a person prior to any surgery to make medical decisions; and how will this increase anesthesia time while the team attempts to contact the proxy for a decision? Or is it even possible that implied consent will be completely removed from the surgical process and the surgical theater will revert to the fundament idea of completing only the consented surgery and thus exposing the patient to additional surgeries in the future? The principle of implied consent during surgery will change as these cases, and hundreds of others, move through the court systems; the impact of these decisions will also change the way hospitals manage the informed consent process.

This process was intertwined with the duty to obtain consent and the self-determination principle, but the term "informed consent" was not introduced until the 1957 court case *Salgo v. Leland Stanford Jr. University Board of Trustees*.[7] Martin Salgo suffered from peripheral vascular disease with his chief complaint being intermittent claudication. Dr. Frank Gerbode examined Mr. Salgo and determined that there was a "serious circulatory disturbance, that the examination indicated that plaintiff might have a block in his abdominal aorta."[10] Dr. Gerbode explained his desire to complete a number of diagnostic tests, including an aortogram, before performing surgery to remove and replace a segment of the aorta. According to court records," Dr. Gerbode did not explain all of the various possibilities to plaintiff of the proposed procedures but did say that his circulatory situation was quite serious."[10] The aortogram was completed with the use of a 6-inch, 18-gauge needle and 50 mL of 70% sodium urokon. The procedure was deemed routine, but upon waking, Mr. Salgo's lower extremities were permanently paralyzed. Mr. Salgo testified that paralysis was not presented to him as a possible outcome of the aortogram. Expert testimony during the trial could not pinpoint the exact cause of the paraplegia but offered up three possibilities[1]: "constriction of the blood vessels in the spinal cord, due to the urokon;[2] direct damage to the spinal cord from urokon in the spinal cord circulation;[3] the plaintiff's condition, a partially blocked aorta, arteriosclerosis and high blood pressure of several years standing, obliteration of blood vessels and blood supply to legs, was such that sudden and total paralysis could occur at any moment."[10]

In his opinion for *Salgo v. Leland Stanford Jr. University Board of Trustees*, Judge Edward Molkenbuhr set no less than three precedents when he wrote: "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed

treatment. Likewise, the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. At the same time, the physician must place the welfare of his patient above all else and this very fact places him in a position in which he sometimes must choose between two alternative courses of action. One is to explain to the patient every risk attendant upon any surgical procedure or operation, no matter how remote; this may well result in alarming a patient who is already unduly apprehensive and who may as a result refuse to undertake surgery in which there is in fact minimal risk; it may also result in actually increasing the risks by reason of the physiological results of the apprehension itself. The other is to recognize that each patient presents a separate problem, that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent."[10] The first precedent set in this opinion was that physicians may now face liability for battery if they do not properly give the patient the knowledge needed to make an informed decision. The second precedent is that a physician now has a duty to disclose every risk that might affect a patient's treatment decision as well as alternative options for treatment. The third precedent coined the term informed consent.

Informed consent is not a guaranteed waiver of liability for a physician. A physician can fulfill their duty to disclose every common risk and alternative options for treatment and yet still be negligent if the patient does not understand how they will be affected; also, a physician can be liable if they perform within their duty, or standard of care, but it is found that inherent risks were not disclosed in a manner to allow a patient to make an informed decision. "The standard is based on what the reasonable patient would want to know. And while there are a few states that still cling to the customary "reasonable physician" standard, most jurisdictions have shifted focus and now adhere to the "reasonable patient" standard. The 'reasonable patient' concept was well summarized in the landmark 1972 California Supreme Court case of *Cobbs v. Grant*, in which the judge instructed the jury as follows: A physician's duty to disclose is not governed by the standard practice in the community; rather it is a duty imposed by law. A physician violates his duty to his patient and subjects himself to liability if he withholds any facts [that] are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[11]

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Ralph Cobbs went to his family physician, Dr. Jerome Sands after experiencing lower abdominal pain, nausea, and dizziness. Dr. Sands diagnosed Mr. Cobbs with a duodenal ulcer and sent him home on medication. Mr. Cobbs' condition worsened, and he was ultimately admitted to Laurel Grove Hospital for surgery. Dr. Sands "discussed the prospective surgery with plaintiff, and advised him of the possible hazards: the chances of ulcer recurrence, 'dumping' (distension of the intestinal tract which can cause diarrhea and vomiting), and the risk of general anesthesia."[2] Dr. Dudley P. Grant was called in to perform a vagotomy and pyloroplasty; and while he explained the surgical plan to Mr. Cobb, Dr. Grant did not discuss any risks inherent in the procedures. Both the vagotomy and pyloroplasty were performed by Dr. Grant with Dr Sands assisting, Mr. Cobb recovered well in the hospital and was discharged. Mr. Cobb returned to the hospital the day after discharge suffering from pain and respiratory distress; when he arrived, he went into shock. An exploratory laparotomy was performed. During surgery: "Massive bleeding was observed, and a bleeding vessel was located at the hilum of the spleen. It was determined that the 'treatment of choice' was the removal of the spleen, and this was done. No other bleeding having been observed, the abdomen was closed after the spleen was removed. Plaintiff recovered satisfactorily from this operation, and was discharged."[2]

During the trial, expert witnesses testified that "The incidence of spleen injury 'during or following a vagotomy' is only one to five percent … spleen injury is a possible result of vagotomy, due to the pressure of retractors on the spleen during the operation. In this instance, he [expert witness]

testified that it was not 'standard practice in this community' to discuss the possibility of spleen injury with a patient who was to undergo gastric surgery, because such injury infrequently occurs and because the spleen 'is easily removed …, and causes no harm to the patient when it is removed."[2] Mr. Cobbs did not directly testify that his consent would have been withheld if Dr. Grant had discussed the possibility of injury to his spleen, but given the circumstances of intense pain and repeated surgery, the court felt there was sufficient evidence to "support the inference that he would not have agreed to the original operation if he had been fully informed of the attendant risks."[2] Not only did Associate Justice Rattigan develop the reasonable patient standard, in his opinion he brought forth the concept of informed refusal. While Associate Justice Rattigan opined a patient has a right to refuse a procedure if properly informed of the risks and benefits of having the surgery, it was Chief Justice Bird who declared a patient must be aware of the consequences of refusal in the 1980 case of *Truman v. Thomas*.

Dr. Claude R. Thomas was the family physician for Rena Truman. After an unsuccessful resolution of a UTI treated by Dr. Thomas, Mrs. Truman consulted a urologist. Under examination, the urologist found heavy vaginal discharge and an unusually rough cervix so he made an appointment with Dr. Ritter a gynecologist. Dr. Ritter confirmed that Mrs. Truman's cervix "had been largely replaced by a cancerous tumor. Too far advance to be removed by surgery, the tumor was unsuccessfully treated by other methods." Mrs. Truman died in July of 1970 at the age of 30. Her two children sued Dr. Thomas for wrongful death on the basis of "his failure to perform a pap smear test on their mother."[13] The Superior Court of Butte County found that Dr. Thomas was free of any negligence that directly caused the death of Mrs. Truman, her family appealed the judgment to the Supreme Court of California. The central issue in this appeals case was if Dr. Thomas breached his duty of care by failing to inform Rena Truman of the consequences of not receiving a pap smear.[13] In essence, was Rena Truman given the right of informed refusal.

In his opinion, Chief Justice Bird stated: "The scope of a physician's duty to disclose is measured by the amount of knowledge a patient needs in order to make an informed choice. All information material to the patient's decision should be given. Material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure."[13] In his defense, Dr. Thomas testified that "on at least two occasions when he performed pelvic examinations of Mrs. Truman, she refused him permission to perform the [pap smear] test, stating she could not afford the cost. Dr. Thomas offered to defer payment, but Mrs. Truman wanted to pay cash." Dr. Thomas never did perform a pap smear on Rena Truman. "Dr. Thomas testified that he did not "specifically" inform Mrs. Truman of the risk involved in any failure to undergo the pap smear test. Rather, "I said, 'You should have a pap smear.' We don't say by now it can be Stage Two [in the development of cervical cancer] or go through all of the different lectures about cancer. I think it is a widely known and generally accepted manner of treatment and I think the patient has a high degree of responsibility. We are not enforcers, we are advisors."[13] The Supreme Court of California reversed the Superior Court's verdict in favor of Dr. Thomas.

Each one of these court cases shows the fundamental right of the patient to determine what happens to their body. This determination is led by a legal duty of every physician to give their patients as much information as needed to aid the patient in making an informed decision. This duty also entails information to allow a patient to refuse or to limit the type of treatment they will accept. Hospitals and physicians must balance what are known outcomes in any treatment process against what is unknown to create policies that allow patients to exercise their fundamental right to life. This process of consent must be transparent, collaborative, truthful and accurate. As the principle of consent continues to be a basis of protection from harm, a legal precedent to empower patient choice, and a measure for lifesaving actions in the face of an emergency, the United States' judiciary system will continue to face challenges between patient autonomy and sound medical judgement.

This article has been peer reviewed by Dr. William Biggs, J.D.

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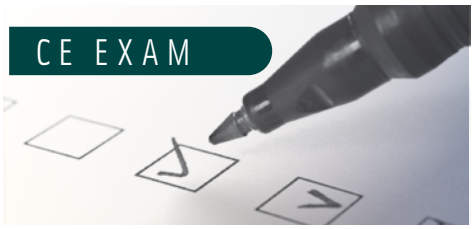

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Consents: A Legal Perspective

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1. **The "reasonable patient" concept was summarized in which landmark case?**
   a. Cobbs v Grant
   b. Salgo v. Leland Stanford Jr. University Board of Trustees
   c. Fox v. Smith
   d. Dodd v. Hines

2. **The reasonable patient concept says that a physician's duty is imposed by:**
   a. Standard practice in the community
   b. Law
   c. Code of ethics
   d. All of the above

3. **In Pratt v. Davis, the plaintiff sued for battery after a ____ was performed without her permission.**
   a. Thyroidectomy
   b. Removal of tumor
   c. Hysterectomy
   d. None of the above

4. **The concept of central to upholding patient autonomy was given much of its modern form in the landmark case of:**
   a. Schloendorff v Society of New York Hospital
   b. Rogers v. Lumbermens Mutual Casualty Company
   c. Davidson v Shirley
   d. Dodd v Hines

5. **Davidson v. Shirley is one of the early precedents for:**
   a. Implied consent
   b. Reasonable patient consent
   c. Upholding patient autonomy
   d. All of the above

6. **In which case was the patient deemed paralyzed below the waist?**
   a. Davidson v Lumbermens Mutual Casualty Company
   b. Dodd v Hines
   c. Salgo v. Leland Stanford Jr. University Board of Trustees
   d. Scholendorff v Society of New York Hospital

7. **The number of procedures performed in 2022 was:**
   a. 1 million
   b. 1.5 billion
   c. 2 million
   d. 2.5 billion

8. **Which case was the final landmark case that legally established the principle of patient autonomy?**
   a. Fox v. Smith
   b. Truman v. Thomas
   c. Cobbs v. Grant
   d. Scholendorff v Society of New York Hospital

9. **True or false: In the Mohr case, an operation for the patient's right ear turned into removing both ears.**
   a. True
   b. False

10. **In which case was an operation performed after the patient specifically said they did not want a procedure performed?**
    a. Truman v. Thomas
    b. Fox v. Smith
    c. Dodd v. Hines
    d. Schloendorff v Society of New York Hospital

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