

# Informed Consent: A Socio-Legal Study

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## SUMMARY

**Introduction:** Informed consent [IC] is a recognized socio-legal obligation for the medical profession. The doctrine of IC involves the law, which aims to ensure the lawfulness of health assistance and tends to reflect the concept of autonomy of the person requiring and requesting medical and/or surgical treatment. Recent changes in the health care delivery system and the complex sociological settings, in which it is practiced, have resulted in an increase in judicial activity and medical negligence lawsuits for physicians. While IC is a well-established practice, it often fails to meet its stated purpose. In the common law, the standard of medical care to disclose risks has been laid down by the Bolam test- a familiar concept to most physicians, but it has been challenged recently in many jurisdictions. This paper aims to discuss some important judgments in cases of alleged medical negligence so as to familiarize doctors regarding their socio-legal obligations. We also propose to discuss some factors that influence the quality of IC in clinical practice.

**Methods:** Literature review.

**Results:** The law of medical consent has been undergoing changes in recent years. Case law appears to be evolving towards a more patient centered standard of disclosure. Patient's expectations are higher and they are aware of the power of exercising their rights. Failure to obtain IC is one of the common allegations in medical malpractice suits.

**Conclusion:** The medical professionals need to change their mindset and avoid claims of negligence by providing information that is "reasonable" in the eyes of the court.

## KEY WORDS:

*Informed consent, medical negligence, Medical ethics, Investigation, Bolam test*

## INTRODUCTION

Informed consent [IC] is a recognized socio-legal obligation for the medical profession<sup>1</sup>. It is described as "a voluntary and explicit agreement made by an individual who is sufficiently competent or autonomous, on the basis of adequate information in a comprehensible form and with adequate deliberation to make an intelligent choice about a proposed action"<sup>2</sup>. This requires effective communication and education between the physician and patient. Physicians are expected to possess technical skill, scientific knowledge,

problem-solving, and human understanding, which are considered to be doctor's prima facie duties to the patients and the society. Society expects them to serve as one of the guardians of society's moral values<sup>3</sup>. They are expected to demonstrate morality and integrity in their practice, as well as in their everyday life. They must be committed to the primacy of the patient in all health care endeavors. Medical law and medical ethics thus share the goal of creating and maintaining social good.

The basis of IC is the patients right to self-determination, perhaps best enunciated by an American judge, Justice Cardozo, in case of *Schloendorff v. Society of New York Hospital* (1914),<sup>4</sup> as: "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 concept was approved in the House of Lords<sup>5</sup>.

The law of medical consent has been undergoing changes in recent years. The hyper-specialism and increasing use of medical technology has tended to distance the physician from the patient as now they rely more on sophisticated tests rather than obtaining an adequate history and physical examination<sup>6,7</sup>. Further the recent trend toward commercialised medical practice and changing moral values of the community, have marred the image of medical profession. It finds itself under pressure to become more "business" like. In such circumstances, patients feel unsatisfied with the health care delivery system. They resort to complaints or lawsuits against physicians for the actions they had undertaken, due to absence of information and explanation, inappropriate conduct or when no proper diagnosis was made. This has brought the performance of medical profession under scrutiny of both the public and the courts. Physicians are now frequently caught in difficult dilemmas in their daily practice. Issues of medical negligence attract wide media coverage. The doctrine of IC has evolved largely through the medium of case law<sup>8</sup> but these legal aspects are addressed only superficially in the medical curriculum and many physicians misunderstand their legal obligations. Although standards and regulations for medical negligence vary by country and jurisdiction within countries, they are becoming increasingly important for medical personal in their every day practice. As such, there is an increasing need for them to know their socio-legal obligations to avoid litigation. This article explores the extent of the possible criminal and civil liability of medical professionals

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on the basis of some landmark legal judgments. Knowledge of these cases is essential to understand the patients' rights and why they have been supported by courts. We hope this information will help them to understand their roles and responsibilities better.

### PROFESSIONAL AND LEGAL OBLIGATIONS

Medical IC law developed from the intentional tort of battery. It requires a competent patient to have IC to medical treatment. This right of self determination is recognized and protected by law of IC<sup>9</sup>. It protects individuals from an unwanted physical touching of the body by others having neither express nor implied consent. Battery occurs in the medical setting when:

1. The physician performs a procedure without the consent of the patient. For example
  - a. **Schloendorff v. Society of New York Hospital**;<sup>4</sup> The plaintiff was admitted to New York Hospital and consented to examination under ether anaesthesia to determine if a diagnosed fibroid tumor was malignant or not. She did not consent for its removal. The surgeon examined the tumor, found it malignant, and removed it. The Court found that the operation to which the plaintiff did not consent constituted battery.
  - b. **Beck v. Lovell**, (unauthorized tubal ligation) 10 In this case the plaintiff complained against a physician who had done tubal ligation without her express or implied consent. Plaintiff was awarded for damages by the court.
  - c. In case of **Malette v. Shulman**,<sup>11</sup> the physician gave blood transfusion to an unconscious patient who was severely injured in an automobile accident. She carried a signed card indicating that she was a Jehovah's Witness with firm religious convictions and did not want to receive blood transfusions under any circumstances. Physician ignored these instructions and gave blood transfusion. Although the transfusions saved the patient's life, the court held the physician liable for battery. However, the court was of the view that if she had not carried a signed card indicating that she did not want to receive blood transfusions under any circumstances, physician would have been correct to administer blood transfusion as part of emergency treatment.

It is unlawful to treat an adult, who is conscious and of sound mind, without his consent<sup>12</sup>. "The principle of self determination requires that respect must be given to the wishes of the patient, so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his/her life would or might be prolonged, the physicians responsible for his/her care must give effect to his wishes, even though they do not consider it to be in his/her best interests to do so. ... To this extent the principle of the sanctity of human life must yield to the principle of self determination ..... and for present purposes perhaps more important, the physician's duty to act in the best interests of his patient must likewise be qualified." 17 (per Lord Goff in the case of **Airedale NHS Trust v Bland** [1993] AC 789 at p. 864) These lines suggest that the principle of autonomy overrides the principle of beneficence so far as a patient is concerned.

2. A patient is free to decline to undergo a treatment although his decision may result in his death. (per Lord Keith in the case of **Airedale NHS Trust v Bland** [1993] AC 789 at p. 857). Likewise, there is no law which bars a person from putting an end to his life support systems by refusing his consent to their continuation. (per Lord Browne-Wilkinson in the case of **Airedale NHS Trust v Bland** [1993] AC 789 at p. 882.) Thus, a physician is supposed not to proceed with the treatment in the face of objection, even if it is plain to all, including the patient that adverse consequences and even death will or may ensue." (per Lord Mustill in the case of **Airedale NHS Trust v Bland** [1993] AC 789 at p.891.)<sup>12</sup>
3. Exceeded consent: A physician can commit battery when a procedure is done or a treatment is given beyond that to which the patient has consented, even if he is acting in the best interests of his patient, as exemplified by:
  - a. **Devi v West Midlands**<sup>13</sup>. In this case plaintiff, a Sikh aged 29, whilst undergoing an abdominal operation to repair a perforation of her uterus, which had been punctured during an evacuation of retained products following the birth of her fourth child, was subjected to hysterectomy. She had given consent to repair her uterus only. The surgeon, believing it was in the patient's best interest to remove her uterus, did her hysterectomy. The Court found the surgeon liable for battery.
  - b. **Campbell v. Oliva**, consent was given to repair one condyle, not both<sup>14</sup>.
  - c. **Jackson v. Julian**, consent was given to remove one ovary, both were removed<sup>15</sup>.
  - d. **Wells v. Van Nort**, a woman consented to surgery to remove her appendix, but during the surgery her fallopian tubes were removed because they were found diseased<sup>16</sup>.
4. The physician performs a substantially different procedure than the one for which consent was given as exemplified in **Mohr v. Williams** (1905)<sup>17</sup>. In this case, the Williams, an ear specialist obtained the patient's consent to perform surgery on her right ear. After putting the plaintiff under anesthesia, the surgeon realised that the patient's left ear needed the surgical procedure rather than the right ear, which he successfully performed. Mohr sued Williams for battery. The court determined that the surgeon had violated the terms of the IC, stating that the patient "enters into a contract authorizing the physician to operate to the extent of the consent given, but no further". Similarly in case of **Maercklein v. Smith** consent was for circumcision, not for vasectomy<sup>18</sup> and in case of **Lane v. United States** -surgery was done on wrong knee<sup>19</sup>.
5. When a different physician carries out the procedure than the one to whom consent was given. This issue did arise in **Perna v. Pirozzi** case. 20 The plaintiff in this case gave consent for a surgical procedure to be performed by his personal surgeon. Two other surgeons, however, performed the procedure. Even though the plaintiff sustained no injuries attributable to the surgical procedure, he contended that he would have decided not to have the surgery if he knew that his personal surgeon was not going to perform the procedure. The Court concluded that switching surgeons amounted to deceit, and treated as battery. The court was of the view that the patients have the right to choose the physicians who perform procedures, operations or treatments on them.

Negligence on the other hand is applied when the physician has already got the consent of the patient but fails to execute his duty adequately or his willful negligence in the treatment causes harm to the patient<sup>21</sup>. The plaintiff is provided compensation only if he can provide convincing evidence to a judge that that the defendant owed him a duty of care and breach of the said duty caused his injury. Currently, the courts nearly unanimously characterize lack of IC as a matter of negligence of the physician to disclose necessary information to patients<sup>22, 23</sup>.

Every medical practitioner must possess a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. All those involved in the care of the patient, also owe such an obligation to the patient. In case of **Laxman v. Trimbak**, the Supreme Court of India held that a medical practitioner who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for that purpose and must exercise a reasonable degree of care<sup>24</sup>. A breach of any of those duties gives a right of action for negligence to the patient. The competence of the medical practitioner is to be judged in the light of an ordinary competent person exercising ordinary skill in that profession. In this case, Anand, the son of the respondent, died due to shock resulting from reduction of fracture attempted by the physician without taking the elementary caution of giving anesthesia to the patient. The court held that the physician was negligent in the performance of his medical duty.

Physicians are expected to act according to responsible medical opinion and current knowledge. In case of **Crawford v Charing Cross Hospital** the plaintiff developed brachial palsy his arm following blood transfusion while he was undergoing surgery<sup>25</sup>. He claimed that the anesthetist should have been aware of the risk because of an article on lancet six months previously. However, the judicial opinion was that it does not mean that physician has to keep himself informed with every new development or knowledge all the time.

**Independent Medical Examination:** When an employer, police or any third party want somebody to be examined medically or review his radiology films or other diagnostic tests and asks the physician for medical certificate to be issued, written consent of the concerned person must be obtained to avoid the risk of liability<sup>26</sup>. The physician must tell the person the purpose of the examination, and the obligation he owes towards the parties concerned. He must ensure that the person is aware what information will be disclosed and the likely consequences.

#### RECENT DEVELOPMENTS IN IC

Medical ethics and medical law are both dynamic and are in a constant state of change. For example new legislation or court decisions occur and medical ethics responds to challenges created by new laws by providing new ethical standards. In the **Bolam v Friern Hospital Management Committee (1957)**<sup>27</sup> case it was held that "a defendant will not be deemed to have breached his duty of care if he has "acted in accordance with a practice accepted as proper by a responsible body of ... men skilled in that particular art"...

Cases' involving negligence of a medical practitioner was determined with the help of "expert medical opinion." As long as the expert witness approves his action, he escapes liability. The test is the standard of the ordinary skilled man exercising and professing to have that special skill-he does not have to be the best physician. The standard of care has to be judged in the light of knowledge available at the time of the incident and not at the date of the trial. Consequently the 'Bolam test' set the standard of care required of the defendant into the hands of it's the peers and not into those of the court. Bolam principle was reinforced by the decision of the House of Lords in the case of **Sidaway v Bethlem Royal Hospital Governors [1985]**, where the court rejected a negligence claim against a neurosurgeon for failing to inform the patient of the risk of paraplegia from cervical cord decompression (which occurs in less than 1% of cases). As Lord Scarman commented: "...the law imposes the duty of care, but the standard of care is a matter of medical judgement"<sup>5</sup>. The Bolam test was however amended by a judgment in case of **Huck v Cole**, when the defendant, a general practitioner was held negligent in not treating a patient with penicillin<sup>28</sup>. Mrs. Huck a patient in a maternity hospital developed septic spots on her skin, after giving birth to her child. The physician put her on a five-day course of antibiotics – tetracycline and stopped it as the sores were improving. The next day, Mrs. Huck contracted septicaemia. She sued Dr Cole for negligence, alleging that he should have treated her with penicillin. The defendant contended that he had acted in accordance with the reasonable practice of other doctors with obstetric experience. Despite expert evidence by some physicians that they would have either not given penicillin to the patient, the court decided to select the opinion of the experts for the appellant and held the physician negligent. The decision in **Hucks** was followed by the House of Lords in the case of **Bolitho v City & Hackney Health Authority** wherein the plaintiff a two year old boy, admitted to hospital with croup died due to respiratory failure and cardiac arrest<sup>29</sup>. The mother sued the hospital for medical negligence. Lord Browne-Wilkinson delivering the judgment expressed that the court is not bound to accept the evidence from medical experts unless it withstand logical analysis.<sup>30</sup> In other words medical profession has not the final say in determining the standard of reasonable care. In the Singapore case of **Dr Khoo James & Anor v Gunapathy**, the Court of Appeal affirmed the Bolam principle but supplemented it by the Bolitho v City & Hackney Health Authority<sup>31</sup>. Thus even though the Bolam principle is relevant, the defendant can still be held negligent if the action taken cannot withstand logical analysis. Case law appears to be evolving towards a more patient centered standard of disclosure. In both **Chappel v. Hart**<sup>32</sup> and **Rogers v. Whitaker**<sup>33</sup> cases the Bolam principle was rejected. Both courts treated the Bolam principle as a useful guide, but in the end it was for the court to decide whether the patient was given sufficient information to enable him to make an informed decision regarding his treatment. In case of **Chappell v Hart**, an ear, nose and throat specialist, removed a pharyngeal pouch from the esophagus of the patient, who latter suffered vocal cord damage. The plaintiff claimed damages, alleging that the surgeon had not informed her of this risk. The court agreed with the plaintiff and held the surgeon liable. Likewise, in **Rogers v. Whitaker**, the plaintiff, Mrs. Whitaker, who was

almost totally blind in her right eye, consulted Rogers, an ophthalmic surgeon for its treatment. The surgeon advised her that an operation on her right eye would not only improve its appearance but would probably restore significant sight to it. She agreed to the surgery and the operation on her right eye was performed competently, but post-operatively she developed a rare complication (1: 14,000) called sympathetic ophthalmia in her left eye, leaving her almost completely blind. The High Court of Australia held surgeon liable as he had failed to warn the plaintiff of this risk. The court was of the view that patients must be given sufficient information about treatment and told about all material risks. According to the court, a risk is material, if in the circumstances of a particular case, a reasonable person in the patient's position, if warned of the risk, would likely attach significance to it.

In Malaysia the Bolam principle has been routinely applied by the courts to medical negligence cases in determining the physician's standard of care<sup>34</sup>. Such cases include: *Swamy v Matthews* [1967] 1 MLJ 142; *Swamy v Matthews* [1968] 1 MLJ 138; *Chin Keow v Government of Malaysia* [1967] 2 MLJ 45; *Elizabeth Choo v Government of Malaysia* [1970] 2 MLJ 171; *Kow Nam Seng v Nagamah* [1982] 1 MLJ 128. However in recent years a number of Malaysian decisions have followed the Australian approach. For example in case of **Kamalan v Eastern Plantation Agency** the defendant physician failed to diagnose the plaintiff's ailment, which turned out to be a stroke, causing his death<sup>35</sup>. The court found the physician had fallen below the standard of care required of him. In another case of **Hong Chuan Law v Dr Eddie Soo Fook Mun** (1998), the court held that it was for the court, and not medical men, to judge the adequacy of information disclosed<sup>36</sup>. In **Foo Fio Na v. Dr. Soo Fook Mun** case, the Federal Court, the final court of appeal in Malaysia, decided to disagree with medical opinion<sup>37</sup>. In this case, the plaintiff who was involved in an accident leading to closed dislocation of C4 and C5 vertebrae underwent a surgical operation on her cervical spine and three weeks later suffered total paralysis of the upper and lower limbs along incontinence. Plaintiff claimed that she was not informed of the risk of paralysis from the particular surgery. The then Chief judge of Malaya Tan Sri Siti Norma binti Yaakob, who wrote the judgment, said, "We are of the opinion that the Bolam test has no relevance to the duty and standard of care of a medical practitioner in providing advice to a patient on the inherent and material risks of the proposed treatment." The Federal Court in its conclusions stated that "we are of the view that the Rogers v Whitaker test would be more appropriate and a viable test of this millennium than the Bolam test".

These legal judgments and recent developments signal the need for physicians to encourage IC in clinical practice. They are obliged to understand the medical IC process and foster patient participation in decision-making, considering the autonomy of their patients. They must discuss with them about the likely diagnosis, the nature and reason for the proposed treatment or procedure, its potential risks and benefits as well as any feasible alternatives. They must concern for the emotional and social problems caused by the disease and answer any questions and issues, patient wants to know. Patient must be informed about all material risks, including unusual risks of treatment depending on the nature

of the procedure. Material risks (death, paralysis, loss of cognition, loss of a limb) should always be disclosed, even if the chances of occurrence are negligible<sup>38</sup>. This exchange of information will promote patient-physician relationship and thus yield informed decisions and best outcome. At the same time it will limit the potential for negligence. The only exceptions to these basic principles are emergencies or mentally incompetent patients and therapeutic privilege<sup>39</sup>. When immediate medical treatment is needed to save the life of a patient who is temporarily incapacitated by reason of his illness, physician is duty-bound to treat him without waiting for any formalities like consent, considering the sanctity of life and when attempting to secure consent would detrimentally delay treatment<sup>12</sup>. The courts have accepted the physician's action in such emergencies<sup>40</sup>. Similarly when an urgent operation is needed to save the life of a patient and the surgeon fails to perform it for want of consent, he will be held liable for negligence<sup>41</sup>. In **Clark v. Maclennan** case, the surgeon did not perform an emergency operation on a patient with acute abdomen (perforated appendix with peritonitis) for want of consent leading to death of the patient<sup>42</sup>. The court delivered a verdict in favor of the plaintiffs, stating that consent under such an emergent situation is not mandatory. However, this doctrine does not apply to elective procedures, no matter how badly needed. The courts have to balance both these fundamental principles, the right to decide as opposed to the sanctity of life.

#### MEDICAL PROFESSION AND SOCIETY

Historically members of a medical profession have had a number of important prerogatives and societal responsibilities based on long established moral principles of self-evident value. Medical Profession is not like other professions and services in a community or nation. For physicians, it demands commitment to the primacy of the patient in all health care endeavors. They deal with patients when they are vulnerable, with the immediate issues of life and death. Society expects them to be honorable, competent, and vigilant for the welfare of the community. They are expected to deliver their complex services with care and compassion, respecting dignity and maintaining confidentiality of their patients or family and society on matters of health. Society in turn grants them status, respect, autonomy in practice and financial rewards, thereby creating a social contract<sup>43</sup>. They are empowered to ask intrusive questions and carry out invasive procedures. In recent decades due to commercialization of health care and changing market forces, the social contract between medicine and society has greatly diverged and a gap has grown between them. Medicine is being looked upon as a business; with the patient being regarded as a consumer. As a result, physicians find it increasingly difficult to meet their responsibilities towards patients and society. In these circumstances, they must reaffirm the fundamental and universal principles and values of medical professionalism, which remain ideals to be pursued by all physicians.

#### IC IN CLINICAL PRACTICE

IC is now accepted as the cornerstone of medical practice<sup>3,8,44</sup> however it is still challenged in many third world countries. Many regard it as unwelcome, but necessary paperwork to

avoid litigation. Despite the name IC, it is not always totally informed. A significant gap persists between the spirit of IC and what it actually means. Too often it is a one-way and one-time communication and patient's choices are more of compliance rather than a reasonable man's decision<sup>45</sup>. A number of studies have revealed that current IC practices fall short of their goal, especially in providing sufficient information about the patient's diagnosis, available treatment options, risks and uncertainties<sup>46-49</sup>. Similar discrepancies have been observed among patients undergoing surgery or other procedures<sup>50, 51</sup>. Other studies among research subjects undergoing clinical trials have revealed that the participants were not told the aim of the trial, its methodology, potential hazards or anticipated benefits of treatment<sup>52-54</sup>.

Further IC is not uniformly accepted by some clinicians who argue that some patients want little or no information about therapeutic risks<sup>55</sup>. Many elderly and acutely ill patients want to share authority with their physician or explicitly want him to make the final decision about their care<sup>56-59</sup>. Even patients who actively seek information regarding their ailment may not make the final decision about their treatment<sup>60, 61</sup>. In certain parts of the world, like Asia, social and family norms may influence the process of IC<sup>62-64</sup>. A study in rural north India for research participation, revealed that majority of the community interviewed could decide only after discussing with other community members<sup>65</sup>.

Despite exercising great skill and care, things can go wrong in medical practice. According to Lord Nathan, the standard of care that the law requires is not an insurance against accidental slips but a degree of care as a normally skillful member of the profession is expected to exercise in the actual circumstances of the case<sup>66</sup>. Sometimes problems arise outside the control of the physician. For example there may be lack of sufficient time spent with the patient because of excessive workload, too many admissions (on many occasions two patients on a bed and many more on the floor) as is seen in third world countries, examining in a hurry, dearth of staff etc. Lack of continuity of care may be a problem in both the inpatient and outpatient settings as a result of shift work and multiple responsibilities. Thus many factors influence the quality of IC in clinical practice. Physicians' interaction with patients—apart from the technical knowledge, is thus a critical aspect of patient care. In the event of an adverse medical outcome written records of such discussions can be physician's best defense as the court can demand relevant documents/ X-ray films of the patient<sup>67</sup>.

## CONCLUSION

Recent developments in IC are helping to evolve a law which insists on a more patient centered standard of disclosure in the best interest of the patients. Patients nowadays no longer want to be treated as passive recipients of medical care. Medical litigation and demands for medical accountability is the trend of the day. This article highlights some important judgments in cases of alleged medical negligence. It is imperative that medical personal are knowledgeable about the legal issues affecting them in their daily practice beyond their professional role. Because laws and ethical standards have been created to protect both the consumer and society

at large, decisions in this regard must be taken seriously. It can therefore be concluded that IC should be taken seriously by all clinicians and medical researchers in the broader interest of patient-physician relationship and there should be no compromise in providing information that is not "reasonable" in the eyes of the court.

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