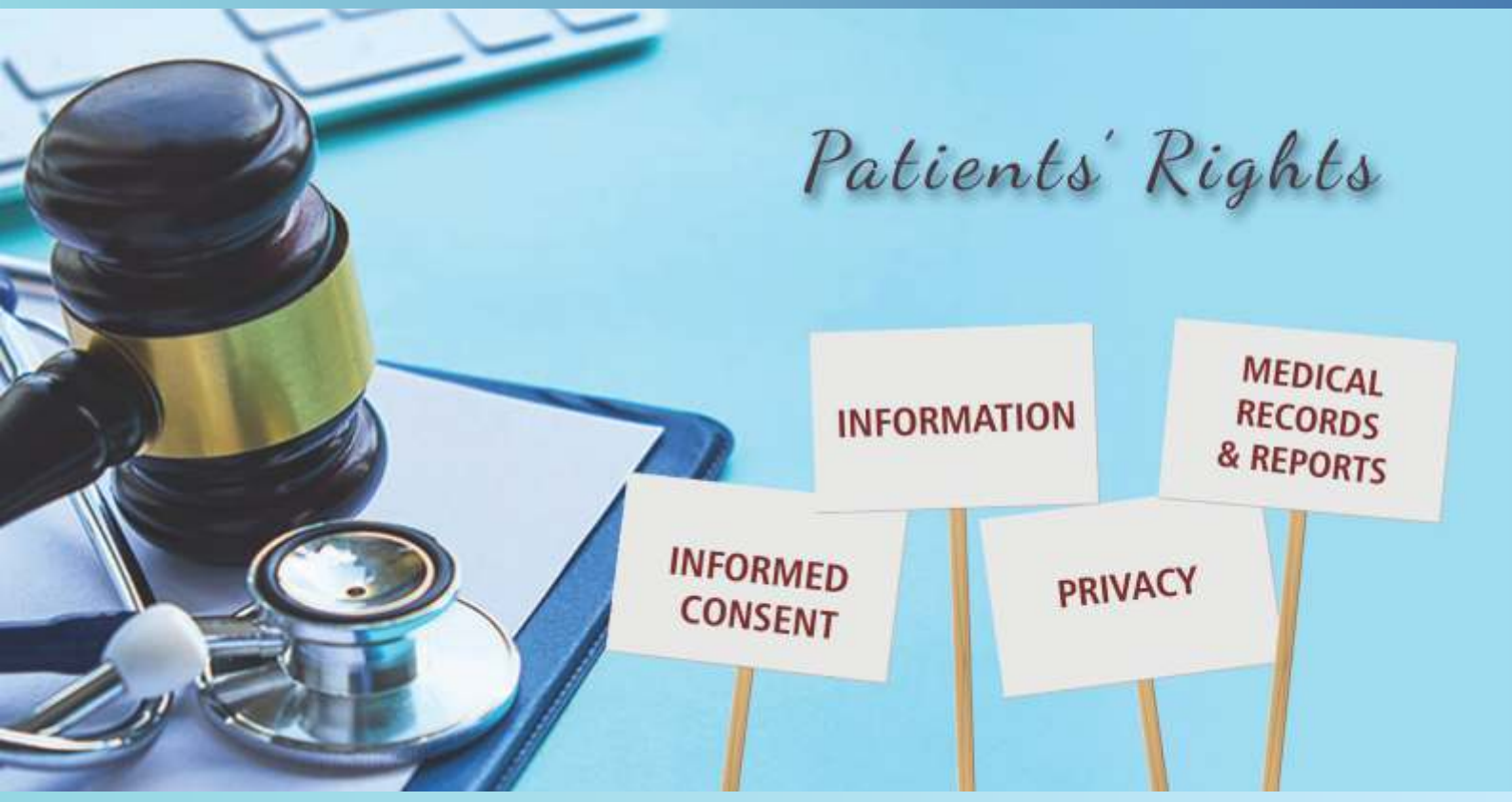
CHARTER OF PATIENTS' RIGHTS: GLOBAL TREND



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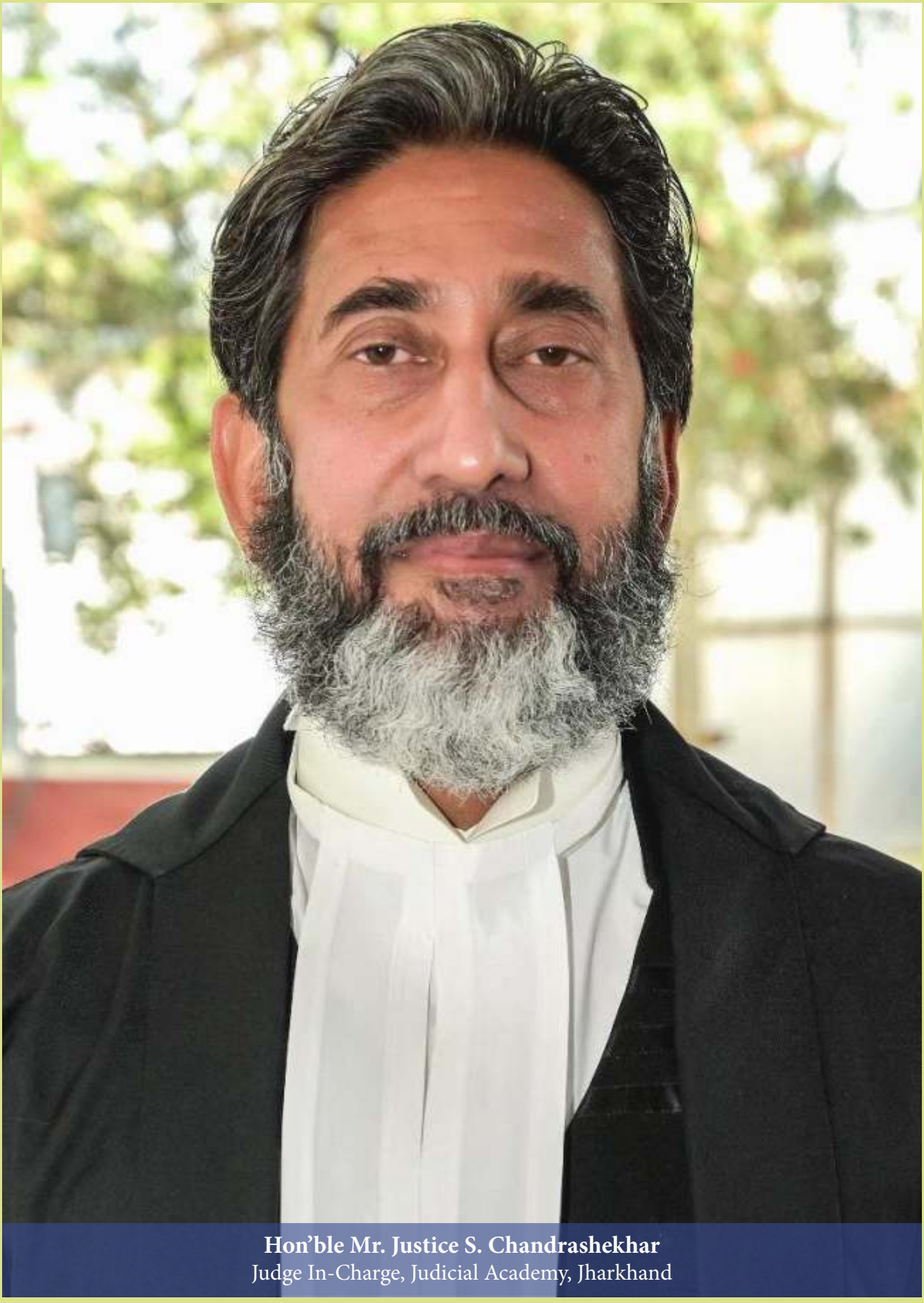

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FOREWORD

The current pandemic has tested the inherent vulnerabilities of India's healthcare system. It has, in fact, overwhelmed the capacities of the medical system and put tremendous pressure on doctors and other healthcare workers. Under such demanding situation, the only fabric which remained intact was of trust of the patients in doctors. More than anything, the trust that exists in doctor-patient relation builds the foundation of the healthcare system. In this context, therefore, the right of a patient to access his medical records and to be informed about his treatment transcends beyond the characteristics of being merely a right and has far-reaching consequences on patients and doctors in particular and the healthcare system in general.

The right to access one's medical records is an extension of the right to privacy and autonomy and the right to know. Existence of an effective patients' rights charter in any system would have a positive effect on a Patients' trust in the doctor-patient relationship. The importance of maintaining medical records of any patient is multi-faceted. The patient is well informed about the details of his diagnosis and treatment which ultimately helps him in making an informed decision. On the other hand, the doctors can easily refer to the medical records of a patient and decide the future course of treatment. Properly maintained medical records absolve the doctors of any unwarranted accusations which at times may be made by the patient or his relatives when a treatment does not yield expected results. A properly designed, legally enforceable patients' charter is a win-win proposition for the patients and the healthcare professionals.

The Judicial Academy, Jharkhand has prepared this research paper on 'Charter of Patients' Rights: Changing Global Trend' with an object to reach out to stakeholders including legal and healthcare experts. Consolidating the patients' rights existing across the globe, after studying the prevailing norms related to its effective implementation by the concerned state machineries, in a single document is not an easy task. I find that all the relevant aspects concerning patients' rights have been compiled, which, I hope will generate widespread awareness about what is expected from the healthcare providers regarding the quality of care and information.

'Charter of Patient Rights' prepared by the National Human Rights Commission (NHRC) and released by the Ministry of Health and Family Welfare, Government of India in 2018 contains 17 basic rights of a patient. There is an imminent need to supplement the Charter with a legally enforceable framework that is accountable to the people. A proper groundwork for harmonization of Patients' interest is required for the effective implementation of the charter rights. I hope this research work would be a step towards preparing such groundwork.

I appreciate the concerted efforts of the dedicated team involved in preparation of this research paper. It is my firm conviction that this paper on patients' rights will go a long way in paving the path for authorities to improve the efficacy of the existing healthcare system. It will be a reference material for framing norms relating to enforcement of the Charter of Patients' Rights in our country. I hope and believe that this research work will be taken in the right spirit for strengthening and streamlining our healthcare system.

Dr. Ravi Ranjan
Chief Justice-cum-Patron In-Chief
Judicial Academy, Jharkhand

PREFACE

The research paper on "Charter of Patients' Rights: Global Trend" prepared by Judicial Academy, Jharkhand highlights the important facets of patients' rights recognized by different countries and its effective implementation by the concerned state machineries. The purpose behind preparing this research paper is to study the historical background and existing legislations/ charters/ regulations dealing with patients' rights across the world.

Every patient has the right to receive treatment without any discrimination based on his or her illnesses or conditions, including HIV status or other health conditions, religion, caste, ethnicity, gender, age, sexual orientation, linguistic or geographical/ social origins. The Constitution of India does not expressly guarantee a fundamental right to health. However, there are multiple references in the Constitution to public health and on the role of the State in the provision of healthcare to citizens. In September 2019, a High-Level Group on the health sector constituted under the 15th Finance Commission had recommended that right to Health be declared a fundamental right. It also put forward a recommendation to shift the subject of health from the State List to the Concurrent List. At present, the subject of "public health and sanitation; hospitals and dispensaries" falls under the State List in the 7th Schedule of the Constitution of India, which means that state governments are under constitutional directives to adopt, enact and enforce public health regulations.The recommendation to declare the right to health a fundamental right, if implemented, will strengthen people's access to healthcare.

The right to access one's medical records is an extension of the right to privacy and autonomy and the right to know. Existence of an effective patients' rights charter in any system has a positive effect on a Patients' trust in the doctor-patient relationship. The importance of maintaining medical records of any patient is multi-faceted. The patient is well-informed about the details of his diagnosis and treatment which ultimately helps him in making an informed decision. On the other hand, the doctors can easily refer to the medical records of a patient and decide the future course of treatment.

Various aspects related to the research topic have been elaborately discussed with the help of leading case laws.The good practices adopted by renowned hospitals have been studied and incorporated in the research paper. Through this paper the Academy endeavors to reach out to all the stakeholders including people in need of healthcare facilities, doctors, hospital administration, NGOs, government agencies and judicial officers.

On behalf of the Judicial Academy, Jharkhand, I express my sincerest gratitude to Hon'ble the Chief Justice-cum-Patron in Chief, Judical Academy, Jharkhand for His Lordship's continuous encouragement in evolving the Academy as a centre for judicial research and I also express my gratitude to Hon'ble Mr. Justice Shree Chandrashekar, Judge, High Court of Jharkhand-cum-Judge In-Charge, Judicial Academy, Jharkhand for proposing the idea and motivating the Academy to come up with this research work. While preparing this research paper, the Academy contacted several renowned hospitals for collecting relevant data pertaining to the research topic. The response received from Tata Main Hospital and the presentation given by its team on "Vishwas" App is worth mentioning. Assistance rendered by Air Marshal (Dr) Rajan Chaudhry, Advisor, Medical Services, Tata Steel, Dr. Deb Sanjay Nag, Senior Consultant, Dept. of Anaesthesiology, Tata Main Hospital, Jamshedpur, Mr. Gyanendra Karn (Head, Legal) in this regard is commendable. The Academy received valuable suggestions from Sri Rajiv Ranjan, Advocate General, Government of Jharkhand, Sri Arun Kumar Singh, Additional Chief Secretary, Government of Jharkhand and Mr. A.K.Das Advocate, High Court of Jharkhand, in preparing this paper.

This compilation is a result of hard work put in by the research team of Judicial Academy which includes the Administrative Officer and the Research Scholars.

Deepak Nath Tiwari
Director

Patients' Right to Medical Records : An Introduction

Justice S. Chandrashekhar

Every human life is precious in God's sight, and no effort should be spared in the attempt to promote throughout the world a genuine respect for the inalienable rights and dignity of individuals and people everywhere.

Pope Benedict XVI

The fundamental principle of the sanctity of human life is recognized in all civilized societies. Significantly, Article 1 of the Universal Declaration of Human Rights, 1948 declares that all human beings are born free and equal in dignity and rights. Article 2 of the European Convention for Protection of Human Rights and Fundamental Freedoms, 1950 and Article 6 of the International Covenant on Civil and Political Rights, 1966 also lay stress on sanctity of the right to life. Article 38(1) of the Constitution of India builds the foundation for human life, and Article 21 ensures that life is much more beyond mere animal existence; rather, anything necessary to make life meaningful becomes an integral facet of the right to life. Therefore, all persons can rightfully claim the right to health as their fundamental right which the State has the responsibility to ensure. It is the obligation of the State to provide medical attention to every citizen [1]. In *"Paschim Banga Khet Mazdoor Samity"* [2] the Hon'ble Supreme Court has held that the Government is duty-bound to provide timely medical assistance to the persons in serious/moribund condition and the government hospitals cannot deny medical facilities to such patients on the ground of non-availability of bed.

2. This brings into focus the role of doctors and hospitals in fulfilling the right to health of a person. For it is one of the oldest and noblest professions of the world, the medical profession is revered by one and all. The Hippocratic Oath which contains a code of standards and ideals is still administered to the doctors, though in a modified version, when they join the profession. Written about two millennia ago, the Hippocratic Oath in its original form is considered obsolete by many but in whatever form it exists today - one of the most widely used version is the Declaration of Geneva adopted in 1948 - the soul remains the same, that he (the doctor) will prescribe regimens for the good of the patients according to his ability and judgment and never

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1. *"Rakesh Chandra Narayan vs. State of Bihar" : 1989 Supp (1) SCC 644*
2. *"Paschim Banga Khet Mazdoor Samity and others vs. State of West Bengal and another" : (1996) 4 SCC 37*

do harm to anyone. The medical profession was never considered a device to earn money and the obligation to provide medical aid to a person has been held to be absolute. A doctor has professional obligations to utilize his expertise in protecting life. Any laws of procedure that may interfere with the discharge of this obligation must give way, for the doctor is under an obligation to treat the injured victim on his appearance before him either by himself or carried by others. *In "Pt. Parmanand Katara"*[3] the Hon'ble Supreme Court has held that it is the State's obligation to preserve life and the professional obligations of all doctors, of the government hospitals or private,to immediately extend medical aid to the injured persons.

3. The ancient Indian texts such as *Brihat Trayee, Narada Smriti and Kautilya Arthashastra* narrate the responsibilities of a doctor. In these scriptures, we get a glimpse of a Patients' rights which spring from the duties of a doctor. In Ayurveda, we get a reference about informed consent of a patient or his relatives or the king before starting the treatment. The patients were informed about the illness and the treatment modalities, and in critical cases, before proceeding with the treatment the doctor was required to inform the relatives of the patient or the king about the Patients' serious condition. Sage *Sushruta* has cautioned that the doctors should enter the profession only after practicing their skills on the dummies to safeguard the patients from iatrogenic artifacts.

4. The obligations cast upon a doctor to treat a person have dragged him to the Courts in actions of professional misconduct and negligence. Sometimes the bonafide decision of a doctor is stigmatized by the family and friends of the victim. The Courts in India and across other jurisdictions have dwelt upon this issue. The doctrine of informed consent, originally articulated in the 1947 Nuremberg Code, is today applied to medical treatment. This doctrine requires the physicians to share certain information with the patient before asking for his consent to treatment. In *"Bolam vs. Friern Hospital Management Committee"*[4] it was observed that a man need not possess the highest expert skills at the risk of being found negligent. Bolam who was suffering from mental illness was advised to undergo electro-convulsive therapy. When the treatment was given to him Bolam sustained fractures but no relaxant drug or manual control was used throughout the treatment. It is significant to note that the Jury was instructed not to judge the defendant's action by the conduct of the man on the top of a

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[3]. *"Pt. Parmanand Katara vs. Union of India and others" : (1989) 4 SCC 286*

[4]. *"Bolam vs. Friern Hospital Management Committee" : (1957) 1 WLR 582 : (1957) 2 All ER 118*

Clapham Omnibus[5]. Rather, the test applied was of the ordinary skilled man exercising and professing to have that special skill. It was held that a doctor is not negligent, if he was acting in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art, merely because there is a body of such opinion that takes a contrary view.

5. McNair, LJ. has rendered the opinion thus: (WLR p. 587):

> *"… I myself would prefer to put it this way: A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art."*

6. *"Bolam"*[4] invited criticism and there is a large body of authors who consider the Bolam test merely a rule of practice and not the rule of law. In England, the Courts have now reformulated the standards of care: *"Maynard*[6]*"* ; *"Hucks*[7]*"* and; *"Bolitho*[8]*"* . In several cases, the Hon'ble Supreme Court has referred to the judgment in "Bolam"[4] and finally the *Bolam* test was approved in *"Jacob Mathew*[9]*"* . In *"Samira Kohli*[10]*"* the Hon'ble Supreme Court has held that to nurture the doctor and patient relationship based on trust, the extent and nature of information required to be given by the doctors should continue to be governed by the Bolam test rather than the "reasonably prudent patient" test evolved in *"Canterbury vs. Spence*[11]*"* .

7. Canterbury, a minor, approached Dr. Spence with complaints of pain in his upper back. Dr. Spence told Canterbury that he would have to undergo a laminectomy to correct what he suspected was a ruptured disc. The procedure to repair the disk was successfully performed. But while in the hospital, Canterbury fell out of bed and was paralyzed. Dr. Spence was sought to be held negligent because Canterbury was not advised of the risk of paralysis. Robinson, J. has held that the standard should rather be one of reasonableness: would a reasonable patient consider a particular risk significant in evaluating whether or not to go forward with a procedure?

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5. The phrase "The Man on the Clapham Omnibus" represents a hypothetical ordinary person introduced into English law during the Victorian era. Sir Richard Henn Collins, MR who put the phrase to legal use in "McQuire vs. Western Morning News" [1903] 2 K.B. 100, a libel case, traced the origin of the phrase to Lord Bowen, who said to have coined it as a junior counsel in the Tichborne Claimant case in 1871.

6. *"Maynard vs. West Midlands Regional Health Authority" : (1984) 1 WLR 634*

7. *"Hucks vs. Cole" : (1968) 118 New LJ 469*

8. *"Bolitho vs. City and Hackney Health Authority" : (1998) A.C. 232*

9. *"Jacob Mathew vs. State of Punjab" : (2005) 6 SCC 1*

10. *"Samira Kohli vs. Dr. Prabha Manchanda and another" : (2008) 2 SCC 1*

11. *"Canterbury vs. Spence" :464 F.2d 772*

8. As we see in the 20th century, more particularly since 1960's, the medical practice which was hitherto untouched by law changed drastically. The American philosopher Lon L. Fuller has distinguished between "morality of aspiration" which we can say symbolizes ethics, and "morality of duty" which refers to the law. Today doctors and hospitals worry about law as well as ethics both. The unfortunate consequence of lawsuits against doctors is that the doctors and hospitals are subjecting the patients to undergo various costly diagnostic procedures and tests to avoid any allegation of negligence. A more recent phenomenon is that more and more doctors, particularly the surgeons in private practice, are forced to cover themselves by taking insurance policies. But there are silver linings too. In *"State of Punjab vs. Shiv Ram and others"*[12] the uncertainty involved in medical procedures and emergent situations which may require a doctor to take a critical decision prompted the Court to observe that: "if the medical profession, as a whole, is hemmed in by threat of action, criminal and civil, the consequence will be loss to the patients". In *"Roe vs. Minister of Health*[13]*"* Denning, LJ. has observed that if the decision on medical negligence of a doctor is affected by a feeling that the patient should be compensated because he has suffered terrible consequences the Court would be doing a disservice to the community at large, if liability is imposed on hospitals and doctors for everything that happens to go wrong.

9. Denning, LJ. said : (QB pp. 83, 86 & 87)

> *"… It is so easy to be wise after the event and to condemn as negligence that which was only a misadventure. We ought always to be on our guard against it, especially in cases against hospitals and doctors. Medical science has conferred great benefits on mankind, but these benefits are attended by unavoidable risks. Every surgical operation is attended by risks. We cannot take the benefits without taking the risks. Every advance in technique is also attended by risks. Doctors, like the rest of us, have to learn by experience; and experience often teaches in a hard way.*
>
> ……
>
> *But we should be doing a disservice to the community at large if we were to impose liability on hospitals and doctors for everything that happens to go wrong. Doctors would be led to think more of their own safety than of the*

[12]. *"State of Punjab vs. Shiv Ram and others": (2005) 7 SCC 1*

[13]. *"Roe vs. Minister of Health" :(1954) 2 QB 66*

good of their patients. Initiative would be stifled and confidence shaken. A proper sense of proportion requires us to have regard to the conditions in which hospitals and doctors have to work. We must insist on due care for the patient at every point, but we must not condemn as negligence that which is only a misadventure."

10. Notwithstanding the intricacies of law and realities of life, it is trite that the core of the controversy revolving around negligence or otherwise of a doctor is resolved by the case history/notes and other medical records of the patient. The records of ancient civilizations such as those in Egypt, Greek and Rome reveal that a Patients' medical record was preserved as far back as 1600 BC. The Egyptians were meticulously preparing the medical history records on papyrus scrolls. Greek and Roman medical records, more than 2000 years ago, were transcribed on parchment. Medical records of a patient contain valuable information about the ailment and the line of treatment given to him. However, in the 1970's, a perception amongst the doctors that providing direct access to the medical records to the patient would harm the patient guided the United States Healthcare System to maintain a restrictive position. The next decade, however, saw emergence of a new trend towards accessibility. Finally, in 1984, the American Medical Association changed its restrictive stand and formed a view that the doctors should provide a copy or summary of the medical records to the patient upon the Patients' request. There is a growing trend of recognizing a Patients' accessibility to his medical records, and sometimes the Courts have relied upon common law rights to develop the Patients' right to access medical records. In *"Wallace vs. University Hospitals of Cleveland"*[14] the Court of Common Pleas of Cuyahoga County, Ohio held that the patient has a property right to the information contained in the records and is, therefore, entitled to a copy of the medical records. In *"Pyramid Life Ins. Company"*[15] the keeper of the records was considered just a custodian rather than the owner of the information in the Patients' medical records. It was held that the patient has the right to records and/or copy of the records without resorting to litigation. Other countries have also recognized the Patients' right to medical records, such as; the Australian Charter of Health Care Rights, 2019; in Germany the Patients' rights such as documentation of the treatment and inspection of the patient file are inserted in the Civil Code, and; in Switzerland a Patients' right includes access to the case file. The Singapore Medical Council's Ethical Code and Ethical Guidelines provide that the patient must be informed about the tests, diagnosis, prescription and treatments so as to ensure the

[14] . *"Wallace vs. University Hospitals of Cleveland" :164 N.E. 2d 917, (Ohio Common Pleas) (1959)*

[15] . *"Pyramid Life Ins. Company vs. Masonic Hosp. Ass'n of Payne Country" :191 F. Supp. 51 (1961)*

Patients' right to information and self-determination.

11. In India, regulations were framed by the Medical Council of India in exercise of the powers under section 33 of the Indian Medical Council Act, 1956 to regulate the medical profession. Regulation 1.3.1 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 required every physician to maintain medical records of the indoor patients for three years in a standard proforma. Under Regulation 1.3.2, every patient and his attendant/representative had a right to obtain medical records, and if any request was made the documents were to be provided to them within 72 hours. The Courts in India have also recognized that a patient and his family have an undeniable right to access medical records freely. In *"Rajappan"*[16] a patient or the victim's relative was held entitled to know whether proper medical care was rendered to the patient entrusted with the hospital, as that can be revealed only from the case history-sheet and medical records. The Kerala High Court further held that there should be absolute transparency with regard to the treatment of the patients, and a patient or the victim's relative is entitled to get copies of medical records. In *"Raghunath G. Raheja"*[17] the Bombay High Court has held that hospitals and doctors cannot claim any secrecy or any confidentiality in the matter of case papers and relevant documents relating to the patient.

12. The pandemic of Covid-19 has brought to the fore the right of the patients and their family to the medical records and the right to be informed by the doctors and hospitals. While some hospitals have devised a system to provide online the medical history and medical records of an outdoor patient, there is no satisfactory mechanism evolved by the hospitals, barring a few, to provide an indoor Patients' real-time health status and medical records. Due to the very contagious nature of coronavirus, entry of the visitors is restricted in the hospitals and the only source of information for the family and friends of a patient admitted in the hospital is telephonic talk with the patient and briefings by the doctor to a family member, which do not happen quite often. The situation is worse where the patient is seriously or critically ill. Most of the time the patient is unable to communicate with his family and the updated case history and medical records of the patient are not provided by the hospital. The recent Covid-19 second-wave experiences show that many lives were lost because the family could not decide on treatment of the patient or shift the patient to another place, on account of a deficient Hospital Management System that failed to provide real-time patient status, and/or secrecy maintained by the hospitals on the pretext of confidentiality.

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[16]. *"Rajappan vs. Sree Chitra Tirunal Institute for Medical Science & Technology" : (2004) SCC Online Kerala 410*

[17] . *"Raghunath G. Raheja vs. Maharashtra Medical Council and others" :1996 SCC Online Bom 5*

13. In *"Shiv Ram"*[12] the Hon'ble Supreme Court has observed that the medical practice has always had a place of honor in the society but currently the balance between service and business is shifting disturbingly towards business and this calls for improved and effective regulation, whether internal or external. More recently, the Hon'ble Supreme Court has made scathing remarks against the hospitals which seem to flourish on human distress[18]. The Clinical Establishment (Registration and Regulation) Act, 2010 was enacted to ensure that clinical establishments are run in accordance with the best industry practices but, till date, all States have yet not adopted this legislation. In view of large number of complaints about malpractices by clinical establishments, gross deficiency in services provided to the patients and for helping the patients identify their rights through a single, more accessible document, Draft Charter was prepared by the National Human Rights Commission (NHRC). Based on this, on 30th August, 2018, the Ministry of Health and Family Welfare released the first "Charter of Patient Rights" laying down 17 basic rights of a patient. It outlines the right to quality products, consent on clinical trials, and redress mechanisms too. The Draft Charter explains the responsibilities of patients and caretakers so that hospitals and doctors can perform their work satisfactorily. Regulation 1.3.4 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 envisaged a robust Hospital Management System which would keep medical records in digital form. The properly maintained medical records would absolve the doctors of unwarranted accusations which at times may be made by the patient or his relative when a treatment does not yield expected results. Similarly, supply of full information about a patient by the doctors and hospitals would go a long way in shielding them from the Court cases as also any other action for misconduct and negligence. In the present scenario, there appears lack of discussion among the stakeholders on the subject. Prima-facie, an indifferent political regime in several states and bureaucratic empathy have contributed to and compounded the problem of the people. But in a technology-driven world that now sees application of Artificial Intelligence in Science & Technology and Medicines, it is unacceptable that we keep losing lives due to lack of information about the patient. As Pope Francis would say: "life is a precious gift but we realize this only when we give it to others"; many feel that this is the time for judicial intervention.

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[18] . *"In Re : The proper treatment of Covid-19 Patients and Dignified Handling of Dead Bodies in the Hospitals."*

CHAPTER - I

PATIENTS' RIGHTS ACROSS THE WORLD

UNITED STATES OF AMERICA

UNITED STATES OF AMERICA

Patients' rights movement began in United States in the early 1970s and was part of the larger "right to know" movement. Many hospitals and healthcare organizations adopted their own bill of rights for patients by modifying the right to suit the needs of the healthcare services and needs of patients. Basic rights of a patient included right to clear communication, accurate information concerning possible medical care and procedures, informed participation in all decisions about the Patients' healthcare program, a clear and concise explanation of all proposed procedures including possible risks, side effects, and problems related to recuperation. Patients had had basic human rights including the right to privacy of both person and information, the right of access to people outside the healthcare facility and the right to leave the healthcare facility regardless of his or her condition.

The Freedom of Information Act, 1966 and the Privacy Act 1974 are the two federal statutes of United States that give patients a right to access their medical records. These two Acts allow access to medical records held by Federal Agencies only. In other cases, US Courts have relied upon the common law rights of a patient to access his medical records.

Patient Bill of Rights 1973

In 1969, the Joint Commission on Accreditation of Hospitals (JCAH) which is a private voluntary accreditation organization composed of members from the American Hospital Association (AHA) and the American Medical College of Surgeons (AMCS) issued its proposals for revisions in its standards. The National Welfare Rights Organization (NWRO), a consumer organization responded in June 1970 by drafting a document containing twenty-six demands. This happened to be the first comprehensive statement of "patients' rights" from the consumers' perspective. Several provisions included therein related to grievance resolution, community representation on hospital governing boards, non-discrimination on the basis of source of payment, restrictions on transfers, provisions on privacy and confidentiality and prompt attention to patients' requests for nursing assistance. After months of negotiation, a number of these items were specifically written into the revised standards of the JCAH. By the late 1980s, issues of access to care, of respect and dignity, privacy and confidentiality, consent, refusal of treatment, and transfer of a patient to another facility were specifically addressed in a new section of their accreditation manual called "Rights

and Responsibilities of Patients".

In around 1972, the AHA adopted Patient Bill of Rights based on the premise that "the traditional physician-patient relationship takes on a new dimension when care is rendered within an organizational structure; the institution itself also has a responsibility to the patient". The text of Patient Bill of Rights called for acknowledgment of the rights to (1) respectful care; (2) current medical information; (3) information requisite for informed consent; (4) refusal of treatment; (5) privacy; (6) confidentiality; (7) response to requests for service; (8) information on other institutions touching on the Patients' care; (9) refusal of participation in research projects; (10) continuity of care; (11) examination and explanation of financial charges; and (12) knowledge of hospital regulations. In 1992, items on access to medical records and use of advance directives were added. Although the list remains vague and incomplete and there is no enforcement mechanism, however, it moves in the direction of more adequately informing patients of their rights.

The Patient Bill of Rights was first adopted by the AHA in 1973 and revised in October 1992. Patient rights were developed with the expectation that hospitals and healthcare institutions would support these rights in the interest of delivering effective patient care. The AHA encourages institutions to translate and/or simplify the Bill of Rights to meet the needs of their specific patient population and to make patients' rights and responsibilities understandable to patients and their families. According to the AHA, a Patients' rights can be exercised on his or her behalf by a designated surrogate or proxy decision-maker if the patient lacks decision-making capacity is legally incompetent or is a minor.

Between 1974 and 1988, many states, including Arizona, California, Illinois, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, New Hampshire, New York, Pennsylvania, Rhode Island, and Vermont, adopted the Patient Bill of Rights by regulation or statute. All fifty-one states have adopted some form of advance healthcare directive document, such as a living will or durable power of attorney, in which people can express their wishes regarding medical care should they become incompetent. Former Presidents Richard Nixon and Jacqueline Kennedy Onassis used such documents in 1994.

The National Conference of Commissioners on United State Laws created a model uniform statute in 1985 titled as Uniform Healthcare Information Act. The American Bar Association approved this Act in 1986. This Act requires disclosure of a medical record for examination and copying upon request from a patient and provides

exceptions for denial of access. It provides for confidentiality of a Patients' healthcare records held by providers of healthcare unless otherwise agreed by the patient or ordered by a court or in other narrowly defined circumstances. Willful disclosure of healthcare information in violation of this Act is classified as a misdemeanour criminal offense.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that requires creation of national standards for protection of sensitive patient health information from being disclosed without the Patients' consent or knowledge. The US Department of Health and Human Services (HHS) issued the HIPAA Privacy Rule to implement the requirements of HIPAA. The Privacy Rule contains standards for individuals' rights to understand and control how their health information is used. A major goal of the Privacy Rule is to ensure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality healthcare and to protect the public's health and well-being.

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USA NEW YORK STATE HOSPITAL PATIENTS' BILL OF RIGHTS[1]

As a patient in a hospital in New York State, you have the right, consistent with law, to:

1. Understand and use these rights. If for any reason you do not understand or you need help, the hospital MUST provide assistance, including an interpreter.
2. Receive treatment without discrimination as to race, color, religion, sex, gender identity, national origin, disability, sexual orientation, age or source of payment.
3. Receive considerate and respectful care in a clean and safe environment free of unnecessary restraints.
4. Receive emergency care if you need it.
5. Be informed of the name and position of the doctor who will be in charge of your care in the hospital.
6. Know the names, positions and functions of any hospital staff involved in your care and refuse their treatment, examination or observation.
7. Identify a caregiver who will be included in your discharge planning and sharing of post discharge care information or instruction.
8. Receive complete information about your diagnosis, treatment and prognosis.
9. Receive all the information that you need to give informed consent for any proposed procedure or treatment. This information shall include the possible risks and benefits of the procedure or treatment.
10. Receive all the information you need to give informed consent for an order not to resuscitate. You also have the right to designate an individual to give this consent for you if you are too ill to do so. If you would like additional information, please ask for a copy of the pamphlet "Deciding About Health Care - A Guide for Patients and Families."
11. Refuse treatment and be told what effect this may have on your health.
12. Refuse to take part in research. In deciding whether or not to participate, you have the right to a full explanation.

[1] *Department of Health, New York State, available at https://www.health.ny.gov/publications/1500/.*

13. Privacy while in the hospital and confidentiality of all information and records regarding your care.

14. Participate in all decisions about your treatment and discharge from the hospital. The hospital must provide you with a written discharge plan and written description of how you can appeal your discharge.

15. Review your medical record without charge and, obtain a copy of your medical record for which the hospital can charge a reasonable fee. You cannot be denied a copy solely because you cannot afford to pay.

16. Receive an itemized bill and explanation of all charges.

17. View a list of the hospital's standard charges for items and services and the health plans the hospital participates with.

18. Challenge an unexpected bill through the Independent Dispute Resolution process.

19. Complain without fear of reprisals about the care and services you are receiving and to have the hospital respond to you and if you request it, a written response. If you are not satisfied with the hospital's response, you can complain to the New York State Health Department. The hospital must provide you with the State Health Department telephone number. 20. Authorize those family members and other adults who will be given priority to visit consistent with your ability to receive visitors.

21. Make known your wishes in regard to anatomical gifts. Persons sixteen years of age or older may document their consent to donate their organs, eyes and/or tissues, upon their death, by enrolling in the NYS Donate Life Registry or by documenting their authorization for organ and/or tissue donation in writing in a number of ways (such as a health care proxy, will, donor card, or other signed paper). The health care proxy is available from the hospital.

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PATIENTS' BILL OF RIGHTS[2]

(Adopted in 1995 by the Association of American Physicians and Surgeons)

All patients should be guaranteed the following freedoms :

- To seek consultation with the physician(s) of their choice;
- To contract with their physician(s) on mutually agreeable terms;
- To be treated confidentially, with access to their records limited to those involved in their care or designated by the patient;
- To use their own resources to purchase the care of their choice;
- To refuse medical treatment even if it is recommended by their physician(s);
- To be informed about their medical condition, the risks and benefits of treatment and appropriate alternatives;
- To refuse third-party interference in their medical care, and to be confident that their actions in seeking or declining medical care will not result in third-party-imposed penalties for patients or physicians;
- To receive full disclosure of their insurance plan in plain language, including:

1. **CONTRACTS :** A copy of the contract between the physician and health care plan, and between the patient or employer and the plan;
2. **INCENTIVES :** Whether participating physicians are offered financial incentives to reduce treatment or ration care;
3. **COST :** The full cost of the plan, including copayments, coinsurance, and deductibles;
4. **COVERAGE :** Benefits covered and excluded, including availability and location of 24-hour emergency care;
5. **QUALIFICATIONS :** A roster and qualifications of participating physicians;
6. **APPROVAL PROCEDURES :** Authorization procedures for services, whether doctors need approval of a committee or any other individual, and who decides what is medically necessary;
7. **REFERRALS :** Procedures for consulting a specialist, and who must authorize the referral;
8. **APPEALS :** Grievance procedures for claim or treatment denials;
9. **GAG RULE:** Whether physicians are subject to a gag rule, preventing criticism of the plan.

[2] *Patients' Bill of Rights, Association of American Physicians and Surgeons, available at https://www.aapsonline.org/patients/billrts.htm*

A PATIENTS' BILL OF RIGHTS[3]

(Adopted in 1972 by the American Hospitals Association)

Introduction

Effective health care requires collaboration between patients and physicians and other health care professionals. Open and honest communication, respect for personal and professional values, and sensitivity to differences are integral to optimal patient care. As the setting for the provision of health services, hospitals must provide a foundation for understanding and respecting the rights and responsibilities of patients, their families, physicians, and other caregivers. Hospitals must ensure a health care ethic that respects the role of patients in decision making about treatment choices and other aspects of their care. Hospitals must be sensitive to cultural, racial, linguistic, religious, age, gender, and other differences as well as the needs of persons with disabilities. The American Hospital Association presents A Patient's Bill of Rights with the expectation that it will contribute to more effective patient care and be supported by the hospital on behalf of the institution, its medical staff, employees, and patients. The American Hospital Association encourages health care institutions to tailor this bill of rights to their patient community by translating and/or simplifying the language of this bill of rights as may be necessary to ensure that patients and their families understand their rights and responsibilities.

Bill of Rights

These rights can be exercised on the patient's behalf by a designated surrogate or proxy decision maker if the patient lacks decision-making capacity, is legally incompetent, or is a minor.

1. The patient has the right to considerate and respectful care.
2. The patient has the right to and is encouraged to obtain from physicians and other direct caregivers relevant, current, and understandable information concerning diagnosis, treatment, and prognosis. Except in emergencies when the patient lacks decision-making capacity and the need for treatment is urgent, the patient is entitled to the opportunity to discuss and request information related to the specific procedures and/or treatments, the risks involved, the possible length of

[3] *A Patients' Bill of Rights (adopted by the trustees of the American Hospital Association in 1972), available at http://ethics.iit.edu/codes/AHA%201972.pdf*

recuperation, and the medically reasonable alternatives and their accompanying risks and benefits. Patients have the right to know the identity of physicians, nurses, and others involved in their care, as well as when those involved are students, residents, or other trainees. The patient also has the right to know the immediate and long-term financial implications of treatment choices, insofar as they are known.

3. The patient has the right to make decisions about the plan of care prior to and during the course of treatment and to refuse a recommended treatment or plan of care to the extent permitted by law and hospital policy and to be informed of the medical consequences of this action. In case of such refusal, the patient is entitled to other appropriate care and services that the hospital provides or transfer to another hospital. The hospital should notify patients of any policy that might affect patient choice within the institution.

4. The patient has the right to have an advance directive (such as a living will, health care proxy, or durable power of attorney for health care) concerning treatment or designating a surrogate decision maker with the expectation that the hospital will honor the intent of that directive to the extent permitted by law and hospital policy. Health care institutions must advise patients of their rights under state law and hospital policy to make informed medical choices, ask if the patient has an advance directive, and include that information in patient records. The patient has the right to timely information about hospital policy that may limit its ability to implement fully a legally valid advance directive.

5. The patient has the right to every consideration of privacy. Case discussion, consultation, examination, and treatment should be conducted so as to protect each patient's privacy.

6. The patient has the right to expect that all communications and records pertaining to his/ her care will be treated as confidential by the hospital, except in cases such as suspected abuse and public health hazards when reporting is permitted or required by law. The patient has the right to expect that the hospital will emphasize the confidentiality of this information when it releases it to any other parties entitled to review information in these records.

7. The patient has the right to review the records pertaining to his/her medical care and to have the information explained or interpreted as necessary, except when restricted by law.

8. The patient has the right to expect that, within its capacity and policies, a hospital will make reasonable response to the request of a patient for appropriate and medically indicated care and services. The hospital must provide evaluation, service, and/or referral as indicated by the urgency of the case. When medically appropriate and legally permissible, or when a patient has so requested, a patient may be transferred to another facility. The institution to which the patient is to be transferred must first have accepted the patient for transfer. The patient must also have the benefit of complete information and explanation concerning the need for, risks, benefits, and alternatives to such a transfer.

9. The patient has the right to ask and be informed of the existence of business relationships among the hospital, educational institutions, other health care providers, or payers that may influence the patient's treatment and care.

10. The patient has the right to consent to or decline to participate in proposed research studies or human experimentation affecting care and treatment or requiring direct patient involvement, and to have those studies fully explained prior to consent. A atient who declines to participate in research or experimentation is entitled to the most effective care that the hospital can otherwise provide.

11. The patient has the right to expect reasonable continuity of care when appropriate and to be informed by physicians and other caregivers of available and realistic patient care options when hospital care is no longer appropriate.

12. The patient has the right to be informed of hospital policies and practices that relate to patient care, treatment, and responsibilities. The patient has the right to be informed of available resources for resolving disputes, grievances, and conflicts, such as ethics committees, patient representatives, or other mechanisms available in the institution. The patient has the right to be informed of the hospital's charges for services and available payment methods.

The collaborative nature of health care requires that patients, or their families/ surrogates, participate in their care. The effectiveness of care and patient satisfaction with the course of treatment depend, in part, on the patient fulfilling certain responsibilities. Patients are responsible for providing information about past illnesses, hospitalizations, medications, and other matters related to health status. To participate effectively in decision making, patients must be encouraged to take responsibility for requesting additional information or clarification about their health status or

treatment when they do not fully understand information and instructions. Patients are also responsible for ensuring that the health care institution has a copy of their written advance directive if they have one. Patients are responsible for informing their physicians and other caregivers if they anticipate problems in following prescribed treatment.

Patients should also be aware of the hospital's obligation to be reasonably efficient and equitable in providing care to other patients and the community. The hospital's rules and regulations are designed to help the hospital meet this obligation. Patients and their families are responsible for making reasonable accommodations to the needs of the hospital, other patients, medical staff, and hospital employees. Patients are responsible for providing necessary information for insurance claims and for working with the hospital to make payment arrangements, when necessary.

A person's health depends on much more than health care services. Patients are responsible for recognizing the impact of their life-style on their personal health.

Conclusion

Hospitals have many functions to perform, including the enhancement of health status, health promotion, and the prevention and treatment of injury and disease; the immediate and ongoing care and rehabilitation of patients; the education of health professionals, patients, and the community; and research. All these activities must be conducted with an overriding concern for the values and dignity of patients.

"A Patient's Bill of Rights" was adopted by the American Hospital Association in 1972 which has now been replaced by the brochure on the following pages with respect to a patient's rights and responsibility.

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PATIENT CARE PARTNERSHIP[4]

Understanding Expectations, Rights and Responsibilities

- High quality hospital care.
- A clean and safe environment.
- Involvement in your care.
- Protection of your privacy.
- Help when leaving the hospital.
- Help with your billing claims.

What to expect during your hospital stay :

When you need hospital care, your doctor and the nurses and other professionals at our hospital are committed to working with you and your family to meet your health care needs. Our dedicated doctors and staff serve the community in all its ethnic, religious and economic diversity. Our goal is for you and your family to have the same care and attention we would want for our families and ourselves.

The sections explain some of the basics about how you can expect to be treated during your hospital stay. They also cover what we will need from you to care for you better. If you have questions at any time, please ask them. Unasked or unanswered questions can add to the stress of being in the hospital. Your comfort and confidence in your care are very important to us.

High quality hospital care.

Our first priority is to provide you the care you need, when you need it, with skill, compassion and respect. Tell your caregivers if you have concerns about your care or if you have pain. You have the right to know the identity of doctors, nurses and others involved in your care, and you have the right to know when they are students, residents or other trainees.

A clean and safe environment.

Our hospital works hard to keep you safe. We use special policies and procedures to avoid mistakes in your care and keep you free from abuse or neglect. If anything

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4. *Patient Care Partnership, American Hospital Association , available at https://www.aha.org/other-resourcess/patient/care/partnership*

unexpected and significant happens during your hospital stay, you will be told what happened, and any resulting changes in your care will be discussed with you.

Involvement in your care.

You and your doctor often make decisions about your care before you go to the hospital. Other times, especially in emergencies, those decisions are made during your hospital stay. When decision-making takes place, it should include :

Discussing your medical condition and information

To make informed decisions with your doctor, you need to understand :

- The benefits and risks of each treatment.
- Whether your treatment is experimental or part of a research study.
- What you can reasonably expect from your treatment and any long-term effects it might have on your quality of life.
- What you and your family will need to do after you leave the hospital.
- The financial consequences of using uncovered services or out-of-network providers.

Please tell your caregivers if you need more information about treatment choices.

Discussing your treatment plan.

When you enter the hospital, you sign a general consent to treatment. In some cases, such as surgery or experimental treatment, you may be asked to confirm in writing that you understand what is planned and agree to it. This process protects your right to consent to or refuse a treatment. Your doctor will explain the medical consequences of refusing recommended treatment. It also protects your right to decide if you want to participate in a research study.

Getting information from you.

Your caregivers need complete and correct information about your health and coverage so that they can make good decisions about your care. That includes :

- Past illnesses, surgeries or hospital stays.
- Past allergic reactions.
- Any medicines or dietary supplements (such as vitamins and herbs) that you are taking.

- Any network or admission requirements under your health plan.

Understanding your health care goals and values.

You may have health care goals and values or spiritual beliefs that are important to your well-being. They will be taken into account as much as possible throughout your hospital stay. Make sure your doctor, your family and your care team know your wishes.

Understanding who should make decisions when you cannot.

If you have signed a health care power of attorney stating who should speak for you if you become unable to make health care decisions for yourself, or a "living will" or "advance directive" that states your wishes about end-of-life care; give copies to your doctor, your family and your care team. If you or your family need help making difficult decisions, counselors, chaplains and others are available to help.

Protection of your privacy.

We respect the confidentiality of your relationship with your doctor and other caregivers, and the sensitive information about your health and health care that are part of that relationship. State and federal laws and hospital operating policies protect the privacy of your medical information. You will receive a Notice of Privacy Practices that describes the ways that we use, disclose and safeguard patient information and that explains how you can obtain a copy of information from our records about your care.

Your doctor works with hospital staff and professionals in your community. You and your family also play an important role in your care. The success of your treatment often depends on your efforts to follow medication, diet and therapy plans. Your family may need to help care for you at home.

Preparing you and your family for when you leave the hospital.

You can expect us to help you identify sources of follow-up care and to let you know if our hospital has a financial interest in any referrals. As long as you agree that we can share information about your care with them, we will coordinate our activities with your caregivers outside the hospital. You can also expect to receive information and, where possible, training about the self-care you will need when you go home.

Help with your bill and filing insurance claims.

Our staff will file claims for you with health care insurers or other programs such as Medicare and Medicaid. They also will help your doctor with needed

documentation. Hospital bills and insurance coverage are often confusing. If you have questions about your bill, contact our business office. If you need help understanding your insurance coverage or health plan, start with your insurance company or health benefits manager. If you do not have health coverage, we will try to help you and your family find financial help or make other arrangements. We need your help with collecting needed information and other requirements to obtain coverage or assistance.

While you are here, you will receive more detailed notices about some of the rights you have as a hospital patient and how to exercise them. We are always interested in improving. If you have questions, comments or concerns, please contact :

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UNITED KINGDOM

UNITED KINGDOM

During the second half of the 20th century, three distinct but overlapping visions of health rights were articulated in Britain - health as a human right, as a citizen's right and as a consumer's right. It was not until the United Nations Universal Declaration of Human Rights in 1948 that the right to health was contemplated on a global level. The right "to the enjoyment of the highest attainable standard of physical and mental health" was also central to the establishment of the World Health Organization in 1946 and was enshrined in international law through the International Covenant on Economic, Social and Cultural Rights which came into effect for member countries in 1976. Around 1970, the idea that health was a fundamental human right received added impetus from the Alma Ata Declaration on Primary Care in 1978 and through the international public health movement. Health as a human right became linked to development goals in around 1980 and since 1990, to combating HIV/AIDS.

In the medical marketplace that predated the NHS (National Health Services), patients had contractual and common-law rights relating to healthcare as with other goods and services. Entitlement also lay at the heart of the gradual development of state-sponsored healthcare in Britain up to and including the establishment of the NHS. The National Health Insurance Act of 1911 introduced compulsory health insurance for manual workers. In return for their financial contribution, members received benefits when sick and access to medical care without additional payment. Such a collective system (at the time unique to the United Kingdom) implied a more collective view of rights with respect to health. Although the National Health Service Act (1946) was framed around the duty of the minister of health to provide a comprehensive service and not around the right of a patient to receive this, the message that reached the public emphasized universal entitlement. Underpinning such promises was the notion of social rights. The NHS and the other achievements of the "classic" era of the British welfare state (1945- 1975) appeared to offer a kind of social citizenship based on collective rights.

Interwoven with ideas about the health rights of citizens was another set of expectations - the rights individuals could demand as consumers. By the middle of the 20th century however citizen and consumer identities were becoming welded together more tightly. The establishment of the Consumers' Association in 1956 was a significant point in the development of the organized consumer movement in Britain introducing comparative testing and consumer activism based on rational principles. The activities

of the Consumers' Association and other consumer groups helped to shift consumerism beyond "things" encompassing public goods and services as well as private ones. Few major alterations to the health service were attempted during the 1950s but the period from the 1960s to the mid-1970s witnessed an era of technocratic change. A series of measures were introduced to improve the efficiency and effectiveness of the NHS culminating in a complete structural reorganization in 1973. Consumer representation within the health service was in line with the general trend toward the improvement of citizen-consumer representation but could also be seen in the light of a number of high-profile failings of the NHS. The Patients Association was keen to establish the right of the patient to consent to all treatment whether experimental or not. Rights claims were essential to the work of a number of groups that attempted to represent the patient as a consumer in the latter half of the 20th century. During the period between 1970 and 1990, health consumer groups produced a range of guides to patients' rights.

The large number of charters produced by patient organizations hinted at the fragility and dubious legality of many of the rights proposed. Despite claiming to be comprehensive guides to the rights that patients held, many of these publications confessed to confusion and uncertainty about the nature and legitimacy of patients' rights. Most of the rights listed in the various guides and charters had no or little legal basis. A legal conception of rights was not the only way of viewing patients' rights and legalistic notions of rights have often been criticized for being too narrow in their focus. Nonetheless the legal development of patients' rights was significant as this indicates the extent to which these rights were being taken up by other actors most importantly by the state. During the early 1970s the Patients Association attempted to get a formal Patients' Rights Bill established. The association was particularly concerned about the practice of using patients in teaching hospitals for the purposes of medical education without their consent. In April 1974 the Patients Association succeeded in sponsoring a bill in the House of Commons. The Patients' Rights Bill however did not pass partly because health ministers thought that the issue was an unsuitable subject for legislation and officials believed that the bill was poorly drafted. But there were also more fundamental reasons why the bill failed. The failure of the Patients' Rights Bill did not stop patient groups in their attempts to establish formal rights for patients. Two areas where patient organizations had more success were in establishing a right to access medical records and in creating a right to complain. The right to access to medical records was introduced through two pieces of legislation - the Data Protection Act

(1984) and the Access to Health Records Act (1990) - that gave patients the right to see their own computerized and paper-based medical records. The Right to complain was ensured through the enactment of the Hospital Complaints Procedure Act, 1985. The introduction of these legislations was driven partly by the activities of patient organizations and also by European Union directives that required member countries to open up data to individuals. Patient-consumer groups helped produce a language of patients' rights that was then taken up by politicians, as can be seen in the later establishment of the Patients' Charter by the Department of Health in 1991. The Charter has been revised several times thereafter and according to the official website of the NHS, lastly in 2014.

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PATIENT CHARTER 2014

(Original Text as available in the official website of the NHS)

Commitments from the Practice	**Rights & Responsibilities of Patients**
You will be treated with courtesy & respect	You will treat practice staff with a courtesy and respect
You will have the choice to be seen by a male or female doctor for routine appointments (if available)	You will be a 'patient' patient
You will have appropriate treatment prescribed and clearly explained	You will respect that we are working very hard to provide the best service we can for all our patients, and any violent, aggressive or abusive behaviour may lead to being removed from the practice list, and/or police involvement
You will be seen the same day if you have a medically urgent complaint, though you may not be able to see your usual doctor	You will notify us as soon as possible if they are unable to keep an appointment as this allows other patients to be seen and keeps waiting times down.
You can email a clinician direct, for non-urgent clinical advice, and we will endeavour to respond within one working day; your email may be forwarded to another clinician, or a manager, if the clinician you email is out of the practice	You will ring the practice after 10.30am if you have a non-urgent enquiry
You will be referred to a consultant when your GP feels it necessary and be referred for a second opinion if both you and the GP agree this is desirable; this may be to another doctor/nurse within the practice	You will only request a home visit if you, or the genuinely are unable to come to the practice e.g. housebound, physically incapacitated. If a visit is required please ring before 10am
All referrals will usually be sent within 1 working day unless an internal second opinion is sought first.	You will be on time for your appointments and notify us as soon as possible if you need to cancel an appointment; persistent missed appointments may lead to being removed from the practice list

Commitments from the Practice	Rights & Responsibilities of Patients
You will have access your Health Records, including online access (subject to this facility being available through our clinical supplier)	You will allow 2 full working days when requesting a repeat prescription; repeat prescriptions will not be taken over the telephone (requests can be made by letter, email, via online request service, by visiting the practice and via the pharmacy; this avoids the unnecessary blocking of telephone lines.)
You will be offered appropriate advice by the Practice Team regarding keeping healthy	You will ring the practice after 10.30am if you have a non-urgent enquiry
You will be able to make suggestions to improve the practice and services we provide through feedback to the management team and/or the Practice Forum	You will only request a home visit if you, or the genuinely are unable to come to the practice e.g. housebound, physically incapacitated. If a visit is required please ring before 10am
Your complaints will be investigated thoroughly and promptly as per NHS complaints procedure. We endeavour to resolve complaints verbally but where a complaint requires investigation we will write to you with the outcome.	You will be on time for your appointments and notify us as soon as possible if you need to cancel an appointment; persistent missed appointments may lead to being removed from the practice list
All children will be offered immunisation.	You will allow 2 full working days when requesting a repeat prescription; repeat prescriptions will not be taken over the telephone (requests can be made by letter, email, via online request service, by visiting the practice and via the pharmacy; this avoids the unnecessary blocking of telephone lines.)
We recognise your need to discuss your concerns in private and will ensure privacy for consultations and confidentiality at all times.	You will request your repeat prescriptions in good time - this will avoid delays

Commitments from the Practice	Rights & Responsibilities of Patients
If you have any special needs or difficulties please discuss them with the doctor or other member of staff and we will do our best to appropriate arrangements	You will avoid ringing the practice for test results; most results are normal and, therefore, we will contact you if a doctor has identified an abnormality. Alternatively you can access all your test results via the online medical records service; just ask reception for a consent form
In the same way as patients can choose their doctor, the doctors reserve the right to accept or remove a patient from their list. This may happen if a patient is unable to work cooperatively with the Practice	You will not expect a prescription every time you visit your GP - good advice is often the best medicine
Your records, both written and computerised, will be kept secure and confidential at all times, in line with data protection guidelines, and NHS confidentiality policy	You will inform us if you change address or telephone number – we may need to contact you urgently
We endeavour to answer all telephone calls to the surgery within six rings.	Although we aim to offer you a choice of clinicians, and aim to offer continuity of care, you will accept that this is not always possible (eg holidays) and you will therefore be willing to see any clinician at the practice
Waiting times at the surgery are usually kept to a minimum, but delays are sometime unavoidable and you will be advised if there is a of more than 10-15 minutes, and you will be offered the choice of waiting or making an alternative appointment.	You will make allowances when waiting in the surgery for the fact that emergency cases will have to be given priority.
Non-NHS work e.g. insurance forms, will not be treated as a priority over NHS medical care	You will understand that there is a charge fro non-NHS work e.g. holiday cancellation forms, insurance forms, and they will take up to two weeks to process as NHS work will always take priority

Commitments from the Practice	Rights & Responsibilities of Patients
	You will take care of your own health by appropriate action, for example by not smoking, avoiding excessive alcohol or weight gain, eating sensibly and keeping active.
	If you are coming to see a clinician regarding a recent hospital appointment please ensure you bring a copy of your discharge / outpatient letter (the hospital should provide this to you) in case the hospital has not sent this to the practice

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AUSTRALIA

AUSTRALIA

For a long time, the Australian Courts did not recognize a Patients' right to access his medical records privately held by the doctors and hospitals, as is evident from the decision rendered by the High Court of Australia in the case of Breen v. Williams in 1996. Some legislative enactments however afforded the patients a right of access to records held in public hospitals. These statutes existed at both the federal and state levels. The Freedom of Information Act of 1982 as well as the Privacy Act of 1988 empowered individuals to access their health records directly from the public hospitals. The Freedom of Information Act enables individuals to have access to government-held information about them. Likewise, principle six of the Privacy Act entitles individuals to have access to records containing their personal information. Everyone who is seeking or receiving care in the Australian Health system has certain rights regarding the nature of that care. These are described in the Australian Charter of Healthcare Rights. The rights included in the Charter relates to access, safety, respect, communication, participation, privacy and comment. The Charter was developed after wide consultation by the Australian Commission on Safety and Quality in Healthcare and specifies key rights of the patients and consumers when seeking or receiving healthcare services. The Council of Australian Governments established a Commission to lead and coordinate national improvements in the safety and quality of healthcare. The Commission is a Commonwealth corporate entity and a part of the health portfolio of the Australian Government. As such, it is accountable to the Australian Parliament and the Minister for Health. The first edition of the Australia Charter of Healthcare Rights was endorsed by the Minister for Health in 2008. In 2018, the Commission commenced a review of the Charter. Over 1600 survey responses were received and eight workshops were held with consumers, health service staff and policymakers. The second edition was finally launched in August 2019.

The Commission's purpose in developing the Australia Charter of Healthcare Rights of national character was to have a document that specified the key rights for everyone receiving healthcare services in Australia. Because of the potential for confusion and duplication with multiple charters at national, jurisdictional and health service level, the Commission's view was that the Charter becomes the single statement of healthcare rights for Australia replacing all other existing charters.

The Australian Charter of Healthcare Rights is available to everyone in the healthcare system. It allows patients, consumers, families, carers and providers to share an understanding of the rights of people receiving healthcare. Though the Charter is not legally enforceable yet it reflects common law standards.

AUSTRALIAN CHARTER OF HEALTHCARE RIGHTS

(Original Text as available in the official website of the Australian Commission on Safety and Quality in Healthcare)

My healthcare rights

This is the second edition of the Australian Charter of Healthcare Rights. These rights apply to all people in all places where health care is provided in Australia. The Charter describes what you, or someone you care for, can expect when receiving health care.

I have a right to :

(a) Access

- Healthcare services and treatment that meets my needs

(b) Safety

- Receive safe and high quality health care that meets national standards
- Be cared for in an environment that is safe and makes me feel safe

(c) Respect

- Be treated as an individual, and with dignity and respect
- Have my culture, identity, beliefs and choices recognised and respected

(d) Partnership

- Ask questions and be involved in open and honest communication
- Make decisions with my healthcare provider, to the extent that I choose and am able to
- Include the people that I want in planning and decision-making

(e) Information

- Clear information about my condition, the possible benefits and risks of different tests and treatments, so I can give my informed consent
- Receive information about services, waiting times and costs

- Be given assistance, when I need it, to help me to understand and use health information
- Access my health information
- Be told if something has gone wrong during my health care, how it happened, how it may affect me and what is being done to make care safe

(f) Privacy

- Have my personal privacy respected
- Have information about me and my health kept secure and confidential

(g) Give feedback

- Provide feedback or make a complaint without it affecting the way that I am treated
- Have my concerns addressed in a transparent and timely way
- Share my experience and participate to improve the quality of care and health services

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GERMANY

GERMANY

In Germany, a Patients' right to access the medical records is derived from the right to self-determination and dignity, which presupposes that a patient may not be regarded as a mere object of treatment with no actual rights. This right includes access to diverse types of medical records such as those describing a Patients' current state of health and prognosis related thereto for the future. The patient has no actual obligation to demonstrate a legal interest in obtaining health records in conventional cases. The right of access to medical records is a contractual right and consequently derives its authority from the contract between a patient and a physician.

A meeting of the WHO European Consultation on the Rights of Patients in Amsterdam from 28th to 30th March 1994 endorsed the rights of patients in Europe as a set of principles for the promotion and implementation of patients' rights in WHO's European Member States. Declaration on the Promotion of Patients' Rights in Europe defined self-determination of a patient as a fundamental right. In addition, the Charter of Fundamental Rights of the EU was officially proclaimed in 2000 and made legally binding by the Treaty of Lisbon which came into force on 1st December, 2009. Article 35 of the Charter is titled "Healthcare" and it stipulates that "everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices".

A Patients' charter was introduced in the year 2002 by the representatives for patients, physicians, hospitals, sickness funds, private insurance companies, charity organizations, self-help groups and the Citizens Advice Bureaux in addition to the State Ministries dealing with the areas of health and justice. The charter aimed at making the existing legislation pertaining to health and healthcare more transparent for patients, describing patients' rights with regard to counseling, medical care and informed consent and rights and duties of patients and physicians. There is also a Charter of Rights for People in need of long-term care and assistance, which is based on the work of the Round Table on Long-term Care (Runder Tisch Pflege) initiated in the autumn of 2003 by the Federal Ministry of Family Affairs, Senior Citizens, Women and Youth and the Federal Ministry of Health.

The German Patients' Rights Act came into force on 26th February 2013. This Act bundled the patients' rights scattered across various laws and improved the protection of patients' rights thereby making it much easier to understand. The rules

enshrined therein create the conditions for legal relations between doctors and patients. All the rights and obligations related to medical treatment are anchored and codified in a new section of the German Civil Code (§§ 630 a to h). These rules include the duty to provide all kinds of clarification and the right of access to patient records. It enables the patients under the German Civil Law system to enforce their claims in a much better manner. Medical practitioners and hospitals are required to document all failures that occur or nearly occur during treatment. In cases of treatment failure, the health insurance companies are obliged to support their insured. The medical liability and the instruments to the burden of proof have been inserted in the German Civil Code.

The German Civil Code enumerates the following important patients' rights: -

- 630a - Typical contractual obligations in the treatment contract
- 630c - Participation of the contracting parties; Information requirements
- 630d - Consent
- 630e - Disclosure obligations - the treating person is obliged to inform the patient about all circumstances essential for the consent
- 630f - Proper documentation of the treatment given to patients
- 630g - Inspection of the patient file

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PROVISION OF THE CIVIL CODE OF GERMANY INCORPORATING TREATMENT CONTRACT

1. § 630a Typical contractual obligations in the treatment contract

(1) The treatment contract obliges the person who promises the medical treatment of a patient (treating person) to perform the promised treatment, the other part (patient) to grant the agreed remuneration, unless a third party is obliged to pay.

(2) The treatment must be carried out according to the generally recognized professional standards existing at the time of the treatment, unless otherwise agreed.

2. § 630b Applicable regulations

The provisions on the employment relationship, which is not an employment relationship within the meaning of Section 622, apply to the treatment relationship, unless otherwise stipulated in this sub-title.

3. § 630c Participation of the contracting parties; Information requirements

(1) The treating person and patient should work together to carry out the treatment.

(2) The treating person is obliged to explain to the patient in a comprehensible manner at the beginning of the treatment and, if necessary, in the course of it, all of the essential circumstances for the treatment, in particular the diagnosis, the probable health development, the therapy and the subsequent and subsequent steps measures to be taken of therapy. If the treating person recognizes circumstances that justify the assumption of a treatment error, he must inform the patient about these on request or in order to avert health risks. If the treating person or one of his relatives designated in Section 52 (1) of the Code of Criminal Procedure has made a treatment error,

(3) If the treating person knows that a third party cannot guarantee that the

treatment costs will be fully covered, or if the circumstances give rise to sufficient indications for this, he must inform the patient in writing of the likely costs of treatment before the start of treatment. Further formal requirements from other regulations remain unaffected.

(4) There is no need to inform the patient if, in exceptional circumstances, this is unnecessary, in particular if the treatment cannot be postponed or the patient has expressly waived the information.

4. § 630d Consent

(1) Before carrying out a medical measure, in particular an intervention in the body or health, the treating person is obliged to obtain the patient's consent. If the patient is unable to consent, the consent of an authorized person must be obtained, unless an advance directive pursuant to Section 1901a Paragraph 1 Clause 1 permits or prohibits the measure. Further requirements for consent from other regulations remain unaffected. If consent for a measure that cannot be postponed cannot be obtained in good time, it may be carried out without consent if it corresponds to the presumed wishes of the patient.

(2) The validity of the consent presupposes that the patient or, in the case of paragraph 1 sentence 2, the person entitled to consent has been informed prior to consent in accordance with Section 630e paragraphs 1 to 4.

(3) The consent can be revoked informally at any time and without giving reasons.

5. § 630e disclosure obligations

(1) The treating person is obliged to inform the patient about all circumstances essential for the consent. This includes in particular the type, scope, implementation, expected consequences and risks of the measure as well as its necessity, urgency, suitability and prospects of success with regard to the diagnosis or therapy. When providing information, it is also necessary to point out alternatives to the measure if several medically equally indicated and common methods can lead to significantly different burdens, risks or chances of recovery.

(2) The education must

1. orally by the treating person or by a person who has the necessary training to carry out the measure; In addition, reference can also be made to documents that the patient receives in text form,
2. take place in good time so that the patient can make a well-considered decision about consent,
3. be understandable to the patient. Copies of documents that they have signed in connection with the information or consent are given to the patient.

(3) The patient does not need to be informed if, in exceptional circumstances, this is unnecessary due to special circumstances, in particular if the measure cannot be postponed or the patient has expressly waived the need to provide information.

(4) If the consent of a person entitled to do so is to be obtained in accordance with Section 630d (1) sentence 2, this must be informed in accordance with paragraphs 1 to 3.

(5) In the case of Section 630d Paragraph 1 Clause 2, the essential circumstances according to Paragraph 1 are also to be explained to the patient in accordance with his understanding, provided that he is able to take up the explanation based on his level of development and his ability to understand, and insofar as this is for his own good does not run counter to. Paragraph 3 applies accordingly.

6. § 630f Documentation of the treatment

(1) The treating person is obliged to keep a patient file in paper form or electronically for the purpose of documentation in direct temporal connection with the treatment. Corrections and changes to entries in the patient file are only permitted if, in addition to the original content, it remains clear when they were made. This must also be ensured for electronically managed patient files.

(2) The treating person is obliged to record in the patient file all measures and their results that are essential from a professional point of view for the current and future treatment, in particular the anamnesis, diagnoses, examinations, examination results, findings, therapies and their effects,

interventions and their effects, Consents and explanations. Doctor's letters are to be included in the patient file.

(3) The treating person must keep the patient file for a period of ten years after the end of the treatment, unless other retention periods exist in accordance with other regulations.

7. § 630g Inspection of the patient file

(1) Upon request, the patient is to be given immediate access to the complete patient file concerning him, provided that the inspection does not conflict with significant therapeutic reasons or other significant rights of third parties. The refusal of inspection must be justified. § 811 is to be applied accordingly.

(2) The patient can also request electronic copies of the patient file. He must reimburse the treating person for the costs incurred.

(3) In the event of the patient's death, his heirs are entitled to the rights under Paragraphs 1 and 2 to protect property interests. The same applies to the patient's next of kin, insofar as they assert immaterial interests. The rights are excluded insofar as the patient's express or presumed will contradicts viewing.

8. § 630h Burden of proof in the case of liability for treatment and clarification errors

(1) A mistake on the part of the treating person is presumed if a general treatment risk has materialized which was fully controllable for the treating person and which led to injury to the patient's life, body or health.

(2) The treating person must prove that he has obtained consent in accordance with Section 630d and has provided information in accordance with the requirements of Section 630e. If the information does not meet the requirements of Section 630e, the treating person can plead that the patient would have consented to the measure even if the information had been properly provided.

(3) If the treating person has not recorded a medically required essential measure and its result in the patient file contrary to Section 630f (1) or Section 2 or if, contrary to Section 630f (3), he has not kept the patient file, it is assumed that he did not take this measure.

(4) If a practitioner was not qualified for the treatment he carried out, it is assumed that the insufficient qualification was the cause of the occurrence of the injury to life, body or health.

(5) If there is a gross treatment error and if it is fundamentally suitable to cause injury to life, body or health of the type that actually occurred, it is assumed that the treatment error was the cause of this injury. This also applies if the treating person has failed to collect or secure a medically required finding in good time, provided that the finding would have produced a result with sufficient probability that would have given rise to further measures, and if the failure to take such measures was grossly incorrect would have been.

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NEW ZEALAND

NEW ZEALAND

In New Zealand, the rights of the consumers of health and disability services were incorporated in the Code of Health and Disability Services Consumers' Rights created in 1996 as a regulation under the Health and Disability Commissioner Act 1994. The impetus for the passage of the Act came from two factors - the widespread view at the time that the law was inadequate to protect consumers of health and disability services and secondly, public concern about the imbalance in power and knowledge between healthcare professionals and healthcare consumers. This was documented by a commission of inquiry established by the New Zealand Government to investigate allegations relating to inadequate treatment of cervical cancer in a hospital in Auckland.

The Cartwright Inquiry and Report

In 1987, two members of a feminist women's health advocacy group in New Zealand publicly revealed in an article titled 'An Unfortunate Experiment' in the 'Metro Magazine', a long-running unethical experiment into the natural history of cervical cancer at the country's major women's teaching hospital, National Women's Hospital. It was alleged that Dr. Herbert Green of the hospital's cervical cancer clinic had become convinced that abnormal cells in the cervix did not necessarily progressed to invasive cancer. He began monitoring patients without treating them or informing them that they were taking part in an experiment. A number of women developed cervical cancer and some of them died.

The article caused public outrage and the Government established a Committee of Inquiry, headed by Judge Silvia Cartwright, to investigate the allegations of patient mistreatment. The Cartwright Inquiry Committee, commissioned by the Minister of Health, Michael Bassett, was set up to investigate whether, as alleged in an article in 'Metro' magazine, there had been a failure to treat patients adequately with cervical carcinoma in situ (CIS) at National Women's Hospital (NWH) by Herbert Green, a specialist obstetrician and gynecologist and associate professor at the Postgraduate School of Obstetrics and Gynecology, University of Auckland. The Report of the Committee was released on 5 August 1988.

Recommendations in the Report contributed to sweeping changes in law and practice around health and disability services consumers' rights in the 1990s and beyond. An independent advocate for patients was appointed at National Women's

Hospital, Auckland whose duty was to protect the patient and to ensure that she received full information and opportunity to consent to all procedures in which she might participate. On the recommendation of the Cartwright Report, the Human Rights Commission Act 1977 was amended to provide for a statement of patients' rights and also for the appointment of a Health Commissioner. The Code of Health and Disability Services Consumers' Rights, stating ten rights of health and disability services consumers and correlative duties owed to them by providers, was ultimately passed as regulations in 1996.

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NEW ZEALAND HEALTH AND DISABILITY COMMISSIONER (CODE OF HEALTH AND DISABILITY SERVICES CONSUMERS' RIGHTS) REGULATIONS 1996

1. Consumers have rights and providers have duties:

(1) Every consumer has the rights in this Code.

(2) Every provider is subject to the duties in this Code.

(3) Every provider must take action to -

(a) Inform consumers of their rights; and

(b) Enable consumers to exercise their rights.

2. Rights of consumers and duties of providers:

The rights of consumers and the duties of providers under this Code are as follows:

Right 1 : Right to be treated with respect

(1) Every consumer has the right to be treated with respect.

(2) Every consumer has the right to have his or her privacy respected.

(3) Every consumer has the right to be provided with services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Maori.

Right 2 : Right to freedom from discrimination, coercion, harassment, and exploitation

Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation.

Right 3 : Right to dignity and independence

Every consumer has the right to have services provided in a manner that respects the dignity and independence of the individual. Right 4 Right to services of an appropriate standard

(1) Every consumer has the right to have services provided with reasonable care and skill.

(2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

(3) Every consumer has the right to have services provided in a manner consistent with his or her needs.

(4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.

(5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

Right 5 : Right to effective communication

(1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.

(2) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

Right 6: Right to be fully informed

(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including—

(a) an explanation of his or her condition; and

(b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and

(c) advice of the estimated time within which the services will be provided; and

(d) notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and

(e) any other information required by legal, professional, ethical, and other relevant standards; and

(f) the results of tests; and

(g) the results of procedures.

(2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

(3) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about—

(a) the identity and qualifications of the provider; and

(b) the recommendation of the provider; and

(c) how to obtain an opinion from another provider; and

(d) the results of research.

(4) Every consumer has the right to receive, on request, a written summary of information provided.

Right 7 : Right to make an informed choice and give informed consent

(1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

(2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.

(3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

(4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where -

(a) it is in the best interests of the consumer; and

(b) reasonable steps have been taken to ascertain the views of the consumer; and

(c) either,

(i) if the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the

provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or

(ii) if the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

(5) Every consumer may use an advance directive in accordance with the common law.

(6) Where informed consent to a health care procedure is required, it must be in writing if :-

(a) the consumer is to participate in any research; or

(b) the procedure is experimental; or

(c) the consumer will be under general anaesthetic; or

(d) there is a significant risk of adverse effects on the consumer.

(7) Every consumer has the right to refuse services and to withdraw consent to services.

(8) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.

(9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

(10) No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than

(a) with the informed consent of the consumer; or

(b) for the purposes of research that has received the approval of an ethics committee; or

(c) for the purposes of 1 or more of the following activities, being activities that are each undertaken to assure or improve the quality of services:

(i) a professionally recognised quality assurance programme:

(ii) an external audit of services:

(iii) an external evaluation of services.

Right 8 : Right to support

Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed.

Right 9 : Rights in respect of teaching or research

The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

Right 10 : Right to complain

(1) Every consumer has the right to complain about a provider in any form appropriate to the consumer.

(2) Every consumer may make a complaint to -

- (a) the individual or individuals who provided the services complained of; and
- (b) any person authorised to receive complaints about that provider; and
- (c) any other appropriate person, including—
  - (i) an independent advocate provided under the Health and Disability Commissioner Act 1994; and
  - (ii) the Health and Disability Commissioner.

(3) Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.

(4) Every provider must inform a consumer about progress on the consumer's complaint at intervals of not more than 1 month.

(5) Every provider must comply with all the other relevant rights in this Code when dealing with complaints.

(6) Every provider, unless an employee of a provider, must have a complaints procedure that ensures that :-

- (a) the complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and
- (b) the consumer is informed of any relevant internal and external complaints procedures, including the availability of :-

(i) independent advocates provided under the Health and Disability Commissioner Act 1994; and

(ii) the Health and Disability Commissioner; and

(c) the consumer's complaint and the actions of the provider regarding that complaint are documented; and

(d) the consumer receives all information held by the provider that is or may be relevant to the complaint.

(7) Within 10 working days of giving written acknowledgement of a complaint, the provider must :-

(a) decide whether the provider—

(i) accepts that the complaint is justified; or

(ii) does not accept that the complaint is justified; or

(b) if it decides that more time is needed to investigate the complaint,—

(i) determine how much additional time is needed; and

(ii) if that additional time is more than 20 working days, inform the consumer of that determination and of the reasons for it.

(8) As soon as practicable after a provider decides whether or not it accepts that a complaint is justified, the provider must inform the consumer of :-

(a) the reasons for the decision; and

(b) any actions the provider proposes to take; and

(c) any appeal procedure the provider has in place.

3. Provider compliance

(1) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.

(2) The onus is on the provider to prove it took reasonable actions.

(3) For the purposes of this clause, the circumstances means all the relevant circumstances, including the consumer's clinical circumstances and the provider's resource constraints.

4. Definitions

In this Code, unless the context otherwise requires,—

Advance directive means a written or oral directive—

(a) by which a consumer makes a choice about a possible future health care procedure; and

(b) that is intended to be effective only when he or she is not competent:

Choice means a decision—

(a) to receive services:

(b) to refuse services:

(c) to withdraw consent to services:

Consumer means a health consumer or a disability services consumer; and, for the purposes of rights 5, 6, 7(1), 7(7) to 7(10), and 10, includes a person entitled to give consent on behalf of that consumer.

Discrimination means discrimination that is unlawful by virtue of Part II of the Human Rights Act 1993.

Duties includes duties and obligations corresponding to the rights in this Code.
Ethics committee means an ethics committee—

(a) established by, or appointed under, an enactment; or

(b) approved by the Director-General of Health.

Exploitation includes any abuse of a position of trust, breach of a fiduciary duty, or exercise of undue influence.

Optimise the quality of life means to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances.

Privacy means all matters of privacy in respect of a consumer, other than matters of privacy that may be the subject of a complaint under Part 5 of the Privacy Act 2020 or matters to which subpart 4 of Part 7 of that Act relates.

Provider means a health care provider or disability services provider.

Research means health research or disability research.

Rights includes rights corresponding to the duties in this Code.

Services means health services, or disability services, or both; and includes health care procedures.

Teaching includes training of providers.

5. Other enactments

Nothing in this Code shall require a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

6. Other rights

An existing right is not overridden or restricted simply because the right is not included in this Code or is included only in part.

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REPUBLIC OF CHINA

REPUBLIC OF CHINA

The Constitution of the People's Republic of China provides for the right to healthcare. Specifically, citizens have "the right to material assistance from the state and society" in the event of illness or disability. The state has a responsibility to develop medical services, health services, and social insurance that are necessary for people to utilize that right. China has embarked upon the establishment of a national Electronic Health Records (EHRs) system since 2009. The ongoing transition from the traditional paper based medical records to a centralised EHRs system was expected to bring about significant improvement in safety, quality, integration and efficiency of the healthcare system. The provisions of the Tort Law, 2009 address the issues related to a Patients' privacy. In addition to the Tort Law, Chapter 4 of the Cyber Security Law of the People's Republic of China regulates personal information protection and legally establishes several basic data protection principles which are in accordance with international data protection measures.

The National Health Commission has been promoting the construction of the EHRs with various policies and financial support since 2009 and has issued the latest requirements on the definition and implementation timeline of EHRs in August 2018. The "Technical Specifications for Hospital Information Platforms based on EMRs" issued by the National Health Commission in 2015 defines Electronic Medical Records (EMRs), corresponding to a hospital's EHRs, as complete and detailed clinical information resources that are created, stored and used electronically by medical institutions and are generated and recorded for citizens in all visits to medical institutions. In China, EMRs are therefore legal records created in hospitals and outpatient environments that constitute the data source of EHRs. In June 2016, in order to promote data integration and utilization, China's State Council issued opinions on Promoting and Regulating the Development of Big Data Applications in healthcare. It aims to accelerate the construction of a unified population healthcare information platform including four levels - national, provincial, municipal, and county.

With the assistance of technology and statutory frameworks, China is in the process of establishing an integrated system of electronic health records. The rights of being informed and of accessing medical records have been ensured to the patients through the Law of the People's Republic of China on Medical Practitioners which came into force on May 1, 1999. Chapter V of the statute lays down the legal

responsibility of medical practitioners and hospitals under Articles 36 to 42. Apart from this, the Medical Care Act which was promulgated on November 24, 1986 and was last amended on 15th January, 2020 lays down the patients' right to be informed under Article 63 and the right to access medical records under Article 71.

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MEDICAL CARE ACT

[The complete document can be viewed at the following link https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021]

Amended Date: 2020-01-15

Category: Ministry of Health and Welfare

Chapter I : General Principles

Article 1:

The Medical Care Act (hereinafter referred to as—the Act") is enacted for the purpose of advancing the comprehensive development of the medical care industry, reasonably distributing medical care resources, improving the quality of medical care, to protect the rights of the patient, and to promote national health. Any matter not provided for in the Act shall be governed by the provisions of other relevant laws.

Chapter IV : Medical Practices

Article 56 :

Medical care institutions shall have appropriate locations for medical care and safety facilities in accordance with the nature of the services provided.

Medical care institutions shall ensure comprehensive provision of aseptic needles on progressive percentages within five years, starting from 2012, for their medical personnel who are working on care and treatment that require direct contact with a patient's body fluids or blood.

Article 57 :

Medical care institutions shall supervise their medical personnel to conduct practices in accordance with the related provisions of each professional medical practice law.

Medical care institutions shall not employ or keep someone without proper medical personnel qualification for execution of duties that should be carried out solely by specialized medical personnel.

Article 58 :

Medical care institutions shall not establish clinical assistants to conduct medical practices.

Article 59 :

Hospitals shall appoint an appropriate number of physicians in accordance with the scope and practical needs of the hospital, to treat hospitalized and emergency patients during on-clinic hours.

Article 60 :

Hospitals and clinics shall first provide emergency patients with proper emergency treatment and offer remedies or undertake necessary measures within the capability of their personnel and facilities, and shall not delay without cause.

In the case that the emergency patients referred to in the preceding paragraph are low- or middle-income patients or were found to have collapsed on streets, and they or their supporters are unable to afford the medical costs, the social administrative competent authority at the municipal or county (city) level shall provide subsidies in accordance with the law.

Article 61:

Medical care institutions shall not solicit patients through improper manners proclaimed and prohibited by the central competent authority.

Medical care institutions and its staff shall not take advantage of opportunities resulting from medical practice to gain improper interests.

Article 62 :

Hospitals shall establish medical care treatment quality control systems, and review and assess the quality.

For the purpose of improving medical care service quality, the central competent authority shall establish regulations regarding the applicable symptoms, qualification of technical personnel, conditions, and other observances for medical technology, examination, laboratory testing, medical devices.

Article 63 :

Medical care institutions shall explain the reasons for surgical operation, success rate, possible side-effects and risks to the patient or his/her legal agent, spouse, kin, or interested party, and must obtain his/her consent and signature on letter of consent for surgery and anesthesia before commencing with surgical procedure. However, in case of emergency, the provisions above shall not apply.

The legal agent, spouse, kin, or interested party may sign the letter of consent referred to in the preceding Paragraph in the case that the patient is a minor or unable to affix the signature personally.

The format of the letter of consent for surgery and anesthesia referred to in the first Paragraph shall be determined by the central competent authority.

Article 64 :

Medical care institutions shall explain the invasive examination or treatment regulated by the central competent authority to the patient or his/her legal agent, spouse, kin, or interested party, and must obtain his/her consent and signature on the letter of consent before commencing with the procedure. However, in case of emergency, the provisions above shall not apply.

The legal agent, spouse, kin, or interested party may sign the letter of consent referred to in the preceding Paragraph in the case that the patient is a minor or unable to affix the signature personally.

Article 65 :

The tissue specimens collected or organs taken in operations by the medical care institutions shall be sent in pathological examinations, and shall notify the patient or his/her legal agent, spouse, kin, or interested party of the examination result.

Medical care institutions shall analyze, review, and assess the clinical or pathological examination result of the tissue specimens or organs from operations mentioned in the preceding Paragraph.

Article 66 :

When dispensing medicaments to the patients, a hospital or clinic shall clearly indicate the patient's name and sex, the name, dosage, quantity, method of administration, actions or indications, warnings or side effects of the medicament, the name and location of the medical institution, the name of dispenser and the date of dispensation on the container or package.

Article 67 :

Medical care institutions shall establish clear, accurate, and complete medical records.

The medical records referred to in the preceding Paragraph shall include the following information:

1. Medical records produced by the physician in accordance with the Physicians Act;
2. Each examination and inspection report;
3. Other records made by medical personnel during practice.

Hospitals shall make an index and statistical analysis of medical records for the purpose of research and reference.

Article 68 :

Medical care institutions shall instruct its medical personnel to personally make documentation of medical record, affix signature or seal, and add the year, month and date of inspection when conducting medical practices.

In the case that the medical records referred to in the preceding Paragraph is revised or amended, the signature or sign and date shall be affixed to the revised or amended portions. Amended records shall be drawn out with a line, and not deleted.

The physician's orders shall be clearly stated in the medical record or in written form. However, in case of emergency, the physician's orders may be given orally, and documented within 24hours.

Article 69 :

Medical care institutions which document and store medical records by means of electronic record shall be exempt from producing another written copy. The regulations regarding the criteria, production method, content, and other observances for electronic medical records shall be determined by the central competent authority.

Article 70 :

Medical care institutions shall designate appropriate location and appoint personnel for the storage of medical records, which shall be retained for at least seven years. However, medical records of minors shall be retained for at least seven years after their coming of age, and medical records for human trials shall be retained indefinitely.

Medical care institutions which cease practice due to certain reasons shall transfer the medical records to the successor for retentions in accordance with the law. In the absence of a successor, the patients or their agents may ask the medical care institution to turn over their medical records, while the rest of the records shall be retained for at least another six months before destruction.

Where a medical care institution becomes unable to keep the medical records

with justified reasons, the local competent authority will keep those records.

Medical care institutions shall ensure that the destruction method of medical records which exceed retention period will not disclose the contents of the medical records.

Article 71 :

Medical care institutions shall provide a copy of the patient‘s medical records or Chinese summary of medical records when necessary in accordance with the patient‘s requests, and shall not delay or refuse without cause. The fee for the copy of medical records shall be paid by the patient.

Article 72 :

Medical care institutions and their staff shall not disclose without cause any information regarding patient’s illnesses or health, which are acquired by virtue of practice.

Article 73 :

Hospitals or clinics which are unable to ascertain the patient‘s illness or provide full treatment due to restrictions of personnel, facilities, or expertise, shall suggest the patient to transfer to another medical care institution. However, hospitals or clinics shall provide emergency medical care in accordance with Paragraph1of Article 60 in the case of emergency patients before transfer to another medical care institution. A summary for transfer medical record shall be filled out and provided to the patient in the case of transfer referred to in the preceding Paragraph, which shall not be delayed or refused without cause.

Article 74 :

When treating a patient, the hospital or clinic may contact any previous hospitals or clinics where the patient was treated for copies of medical records, medical record summary, and other examination reports as necessary, but only after obtaining the consent of the patient or his/her legal agent, spouse, kin, or interested party. The previous hospital or clinic shall not refuse to provide said information. The cost shall be paid by the patient.

Article 75 :

Hospitals shall provide appropriate medical care facilities and personnel to

provide continuing care for discharged patients per their requests.

Hospitals shall obtain a signed discharge form from the patient or his/her legal agent, spouse, kin, or related party in the case that the patient demands to be discharged prior to completion of his/her treatment.

Patients shall immediately process the discharge or transfer upon notification of discharge by diagnosis or physician order.

Article 76 :

Hospitals and clinics shall not refuse to provide the patient with birth certificate, certificate of diagnosis, death certificate, or stillbirth certificate without cause as stipulated in the laws or regulations. When issuing the various certificates, caution shall be exerted as much as possible, especially when related to the cause of death.

If the certificate of diagnosis mentioned in the preceding paragraph is issued for the patient's insurance claim, it shall be written in Chinese. In the event that the name of disease indicated is different from the one that appears in the insurance policy, a remark shall be made.

Hospitals and clinics shall report cases of death not caused by illness, or suspected not to be caused by illness, to the procuratorial authority for investigation in accordance with the law.

Article 77 :

Medical care institutions shall accept entrustment by the government in medical care service related affairs, such as assisting in conducting public health, continuing education, on-the-job training, disaster relief, emergency relief, community welfare, and civil defense.

Article 78 :

For the purpose of improving the level of medical care or prevention of disease in the country, teaching hospitals may conduct human research after formulating a plan and obtaining approval from the central competent authority, or upon entrustment of the central competent authority. Notwithstanding the foregoing, the approval of the central competent authority is not required for human research with aim of evaluating the bioavailability and bioequivalence of generic drugs.

Non-teaching hospitals may not conduct human research. However, the preceding paragraph may apply mutatis mutandis to medical care institutions with

specific expertise and having obtained the approval of the central competent authority.

The plan for human research by a medical care institution shall be first reviewed and approved jointly by a board consisting of medical technologists, legal experts and impartial citizens or representatives of civil groups; people of either gender shall constitute no less than one third of the board. Members of the review board shall abide by the principle of recusal due to conflicts of interest.

Subsequent changes of the human research plan shall be implemented only after being examined and verified or approved according to the preceding three provisions.

Article 79 :

When conducting human research, medical care institutions shall pay necessary attention to medical procedures, and first obtain a written consent from the research subjects. The subjects of human research must be adults with disposing capacity. The preceding provision however does not apply to human research that is apparently beneficial to the health of specific population or patients with a special disease.

Where a research subject in the proviso of the preceding paragraph is a person with limited disposing capacity, the consents of both the subject and his/her legal representative are required; where the research subject is a person with no disposing capacity, the consent of his/ her legal representative is required.

The medical care institution shall clearly state the following on the written consent referred to in the preceding paragraph, and shall inform the subject or his/her legal representative in a manner comprehensible to him/her before obtaining his/her consent:

1. Purpose and method of research;
2. Possible risks and side effects;
3. Expected results;
4. Explanation of other possible treatment methods;
5. Subject's right to withdrawal of consent at any time;
6. Research-related compensation for damages or insurance coverage;
7. Confidentiality of the subject's personal information; and
8. The preservation and reutilization of the subject's biological samples, personal data or derivatives thereof.

With respect to informing the subjects and obtaining written consent mentioned in the preceding paragraph, the medical care institution shall give the research subjects ample time to consider and shall not use coercion or other improper methods. When a doctor carries out human research in accordance with the preceding four provisions, causing death or injury of a patient because of unforeseeable factors in the research, the provisions concerning intentional or negligent offence as set down in Article 13 or 14 of the Criminal Code shall not apply.

Article 79-1 :

Unless it is otherwise provided by the Act, the application procedure, review criteria and the principle of withdrawal in case of conflict of interest, disclosure of information, supervision and administration, examination, and other information to be disclosed relating to a human trial mentioned in the preceding two articles shall be set forth by the central competent authority.

Article 79-2 :

Medical care institutions shall continue to provide standard care to patients who decline to participate in the trial or who later withdraw their consent without impairing their legitimate right to medical care.

Article 80 :

Medical care institutions shall submit trial report in accordance with notification by the central competent authority during human trial period. If the central competent authority feels there is concern for safety, the medical care institutions shall cease trial immediately.

Medical care institutions shall submit trial report to the central competent authority at the completion of the human trial.

Article 81 :

When treating the patient, the medical care institution shall inform the patient or his/her legal agent, spouse, kin, or interested party of his/her condition, course of treatment, disposition, medication, expected condition, and possible ill effects.

Article 82 :

Those conducting medical practices shall exercise due care in carrying out a medical procedure.

Only in the event that medical personnel cause harm to patients in conducting

medical practices intentionally or breach of medical due care, which goes beyond reasonable exercise of professional clinical discretion, the medical personnel shall be bound to compensate for such harm.

Only in the event that medical personnel negligently cause injury or death to patients in conducting medical practices due to a breach of medical due care, which goes beyond the reasonable exercise of professional clinical discretion, the medical personnel shall assume criminal responsibility.

The extent of the breach of the duty of due care and professional clinical discretion, as set forth in the preceding two paragraphs, shall be determined based on objective conditions such as the customary medical practice, medical level, medical facilities, working conditions, and level of emergency or urgency in the locality at the time of practice in the medical field concerned.

Medical care institutions shall be liable for compensation only for such harm that causes to patients in the course of medical practices, whether deliberately or negligently.

Article 83 :

The Judicial Yuan shall appoint courts to establish professional medical courts, in which a judge with related professional medical knowledge and trial experience shall handle medical disputes and litigation.

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DENMARK

DENMARK

Denmark has a comprehensive legal framework protecting patients' rights that encompasses both fundamental and consumer-oriented rights. Denmark signed the European Convention on Human Rights and Biomedicine on 4th April 1997 and ratified the Convention by Parliamentary decision of 11th May 1999. At that moment, the most important Act in Denmark relating to patients' rights was Law No. 482 of 1st July 1998. According to the provisions of the Law, all persons are entitled to know any information collected about his or her health. However, the wishes of individuals not to be informed shall be observed. Additionally, there are a number of other Acts which contain provisions related to patients' rights (for example - the Act on Abortion, the Act on Assisted Reproduction, the Act on Transplantation). The Danish legislature adopted the Health Act - Law No. 546 of 24 June 2005, putting together different Acts related to patients' rights. This new Act came into force on 1st January, 2007.

The Health Act (Consolidating Act No. 1202 of 14 November 2014) is complemented by a series of more specific laws (for example - the Consolidating Act No. 1113 of 7 November 2011 on Complaints and Compensation within the Healthcare Services; the Consolidating Act No. 877 of 4 August 2011 on Authorization of Healthcare Professionals and on Healthcare Services) and the application of general legal provisions (for example - administrative and criminal law). This is the result of a steady development process in Danish health law over the last 30 years that started in 1988 with the establishment of a special Patients' Complaints Board. Next to the ratification process of the Biomedicine Convention, changes in the general Danish data protection regulation also contributed in strengthening rights of patients by ensuring their right to access their medical file. More consumer-oriented rights, such as access to treatment, waiting time and free choice of provider, no-fault compensation to the patients became more prominent partly through general policies promoting more efficiency in the public sector. Most of the provisions in the new Act are similar to the provisions contained in the previous Acts including the Patient Rights Act of 1998. There are only a few minor changes in the new Health Act. It contains inter alia the right to complain and compensation and the legal status of patients. It also recognizes a Patients' right of joint involvement in decisions through the right to informed consent and the right to self-determination in certain cases such as in connection with hunger-strikes and the refusal to receive blood. The Consolidating Health Act No. 1202 (2014) also contains the Patients' Rights and stipulates that no treatment may be initiated or

continued without a Patients' informed consent, unless otherwise provided by law or provisions laid down by law. This relates to any patient who is receiving or has received treatment by healthcare professionals.

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PATIENTS' RIGHTS

(Original text taken from "Patients' Rights" in "Heathcare in Denmark - An Overview" published by the Ministry of Health, Denmark)

All residents in Denmark have access to the public healthcare system, and most services are provided free of charge. National legislation ensures that diagnosis and treatment are provided within certain time limits and establishes a free choice of hospital for patients. A comprehensive set of legal rights governs complaint procedures and compensation for injuries caused by services provided in the healthcare system.

The right to treatment, diagnosis and free choice of hospital

Citizens in need of hospital care may, within certain limits, freely choose any public and some private hospitals.

If the region cannot ensure that treatment will be initiated within 30 days, patients have the right to a so called 'extended free choice of hospital'. This means that patients may choose to go to a private hospital in Denmark or to a public or private hospital abroad.

The regions are also required to ensure that any patient referred to a hospital is assessed with a view to diagnosis within one month from the date of referral. If, for medical reasons, it is not possible to determine the condition of the patient within one month, the patient must receive a detailed plan to ensure further investigation of his/her health problem, including, for example, further examinations at another hospital. If, for reasons of capacity, the region is not able to provide an assessment with a view to diagnosis within 30 days, the extended free choice of hospital applies, i.e. the patient may go to a private hospital or a hospital abroad to be diagnosed.

The right to treatment, diagnosis and free choice of hospital applies to both mental and physical illness.

Treatment abroad and reimbursement

The regions may refer patients in need of highly specialised treatment to treatment abroad if the treatment is not available in Denmark. The referral is subject to the approval of the Danish Health Authority. The regions may also refer patients to receive research-related treatment abroad if relevant treatment is not available in Denmark.

The regions may also refer patients suffering from life-threatening diseases to

receive experimental treatment in private hospitals in Denmark or abroad if public hospitals are unable to offer further treatment. The referral is subject to the approval of the Danish Health Authority.

Denmark is a Member of the European Union and as such subject to the EU-Regulation on the coordination of social security systems[1] and the directive on cross-border healthcare[2].

The regulation lays down detailed rules on the coordination of health insurance for citizens travelling to or residing in EU/EEA Member States and Switzerland. Pursuant to the Directive, residents in Denmark have the right to reimbursement of the costs of healthcare provided in other EU/EEA Member States. This right covers both hospital treatment and treatment provided by GPs, medical specialists in private practice, physiotherapists, chiropractors, dentists and other healthcare providers. In some cases, patients may need prior authorisation from their home region before receiving the treatment abroad.

Regional patient advisers, complaints and compensation

The legal rights of patients are protected by a number of laws which aim to ensure that patients receive the best possible care and regulate complaint procedures and compensation for injuries caused by services provided in the healthcare system.

Regional patient advisers have been established in each region to assist and guide patients in relation to diagnosis, treatment, choice of hospital, waiting time, access to treatment abroad and the procedures for submitting complaints and receiving compensation. The assistance provided by the patient advisers is free of charge and advisers work independently of the region and the staff at the hospital in question.

The Danish Patient Safety Authority serves as a single point of entry for all patients who wish to complain about healthcare professionals and/or treatment provided in the healthcare system (public and private). The Danish Patient Safety Authority is also responsible for making sure that knowledge gained from patient complaints and compensation claims is used preventively. Particularly serious cases may be submitted to the public prosecutor with a view to bringing the case before a court.

The Disciplinary Board of the Danish Healthcare system is an impartial public authority which may express criticism of healthcare professionals not acting in

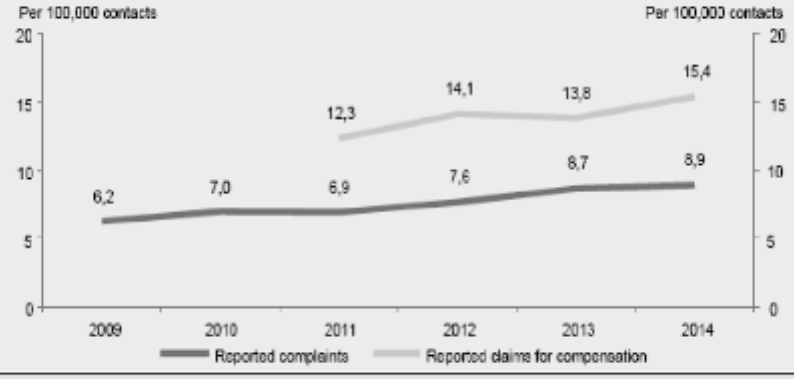
1 EU-Regulation (EC) 883/2004 on the coordination of social security system.
2 Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

accordance with commonly agreed professional standards.

Patients who have sustained injuries caused by treatment in hospitals or by authorised healthcare professionals may be entitled to compensation, and patients can seek compensation by reporting injuries to the Danish Patient Compensation Association. The Danish Patient Compensation Association is responsible for applying the legislation that deals with injuries occurring in connection with treatment in the public and private healthcare system.

The Danish Patient Compensation Association may also award compensation in injuries related to pharmaceutical products, i.e. in cases where patients are injured because of side effects of medicines. Compensation is given for losses and expenses as a consequence of the injuries.

Figure 2
Reported complaints and claims for compensation per 100,000 contacts, 2009-2014



Notes: All contacts and reports in the Danish healthcare system are included, both private and public.
Source: Danish Patient Safety Authority, Danish Patient Compensation Association

The regions cover the costs of compensation except for some treatments provided in the private healthcare system where the insurance company will pay. The Ministry of Health covers the costs of compensation in cases related to injuries caused by pharmaceuticals.

If either the patient or the other party in a case, i.e. the region, disagree with the decision made by the Danish Patient Compensation Association, they can appeal it to the Patient Compensation Appeals Board.

If either the patient or the other party in a case, i.e. the region, disagree with the decision made by the Patient Compensation Appeals Board, the case may be brought before a court.

It is free of charge for patients to seek compensation.

Inspections and sanctions

The Danish Patient Safety Authority supervises the activities carried out by healthcare professionals within the healthcare system. The authority makes inspections based on general supervisory cases and current patient complaints submitted to the independent Disciplinary board of the Danish Healthcare System. If after an inspection the authority finds reason to criticise or sanction the actions and activities of healthcare professionals, the case is brought before the Disciplinary Board of the Danish Healthcare System.

The Danish Patient Safety Board also follows up on organisational circumstances leading to adverse events to ensure that aspects of patient safety are considered and given priority by the hospital management. If general safety issues exposing patients to risks are identified, the Danish Patient Safety Authority has the legal capacity to issue instructions and guidelines for healthcare professionals.

In 2017, the supervisory measures will shift towards a risk-based approach, implying that more resources will be allocated to those institutions and healthcare providers where patients are exposed to the highest risks in order to improve the quality of healthcare services in general.

Efforts are currently being made to adjust the relevant systems in order to provide the necessary register date to support such a risk-based approach.

Adverse events

Denmark was one of the first countries in the world to introduce a compulsory system for reporting adverse events in healthcare. This task was initiated in 2004 for public hospitals and was expanded to include primary healthcare services in the municipalities in 2010. In 2011, patients were given the opportunity to report adverse events.

Healthcare professionals are obliged to report adverse events, but also patients, nursing home residents and their relatives can submit reports. The reporting system is confidential and non-punitive, and reports can be submitted anonymously. The aim of the system is to improve patient safety through the monitoring, analysis and knowledge sharing of adverse events.

The Danish Patient Safety Authority is responsible for the administration of the register of adverse events. After receiving the analysed and anonymised reports from the regions and municipalities, the Danish Patient Safety Authority looks for patterns

and trends in selected areas and provides feedback and information to the regions and municipalities regarding specific risk situations. The information is distributed in newsletters, alerts and in reports on specific subjects. All publications are available on the website www.dpsd.dk.

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Patient Empowerment through Involvement

Patient Empowerment is about strengthening patients' own resources and abilities with the aim of improving their capacity to develop, control and apply their own resources. The mapping of patient experiences also provides inputs to the work on quality improvement in the healthcare system. Every year, 250,000 patients are invited to participate in the National Survey of Patient Experience. The survey is conducted on behalf of the five regions and gives hospitals the opportunity to receive systematic feedback from their patients.

The survey includes both inpatients and outpatients in hospitals and covers different aspects such as clinical services, patient safety, patient and staff member continuity, involvement and communication, information, discharge, intersectorial cooperation, free hospital choice and waiting time.

The overall objectives are :

- to identify and compare the differences in patient experiences,
- to provide input to quality improvements,
- to follow the development of patient experiences and assessments systematically over time.

The National Survey of Patient Experience consists of four studies focusing respectively on somatic hospitals, maternity rooms, emergency rooms and psychiatry.

National Survey Among Elderly People

Every second year, a survey is conducted among elderly people (aged 67+) who receive either care in their own home or in a nursing facility. The survey includes questions on satisfaction with the quality of the services, satisfaction with the number of care workers, the stability of the help and whether citizens feel more self-sufficient after receiving help. The participants are also asked if they know about their right to choose between different service providers.

IT-based self-service solutions

eSundhed.dk :

The webpage www.esundhed.dk provides citizens with information about the quality of healthcare services in order to enable patients to make an informed choice of hospital, see page 7. The webpage offers comprehensive information about the clinical

and organisational quality as well as studies of patient experience.

Sundhed.dk:

On this webpage, citizens can access a number of personal services and data such as patient records from hospitals (e-journals) as well as general information on health, diseases and patient rights.

Patient reported outcome

Patient reported outcome (PRO) is used as a common term for information about a patient's health condition that is reported directly by the patient. As part of chemotherapy treatment, for example, a cancer patient will reply to a questionnaire about side effects of medicine or functional capacity.

Potentials for a more patient-centred approach

PRO has the potential to support a more patientcentred approach to healthcare. The healthcare professional can use the patients' replies to assess the need for a consultation or use it as an instrument for dialogue and decision making. PRO also has the potential to support patient-centred quality improvement and management.

National initiatives to support the use of PRO

The Danish government, regions and municipalities have agreed to support the use of PRO in daily clinical practice and in quality development. A new national working group will manage processes to harmonise PRO questionnaires and guidelines for use as well as contribute to knowledge sharing about the use of PRO.

The Danish government and regions have agreed to initiate nationwide spread of the use of PRO at hospitals towards 2019 within three disease areas: prostate cancer, breast cancer and epilepsy.

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FINLAND

FINLAND

In Finland, the enactment of law related to patients' rights was a result of 20 years long debate. In 1979, the National Health Board made a proposal to the Ministry of Social Affairs and Health to draft a compact text on patients' rights. A Committee on the Protection of Legal Rights in the Field of Healthcare, set up by the Ministry for Social Affairs and Health, proposed a law in 1982. The Committee also considered the need to state clearly what a Patients' responsibilities in general were. Some of the responsibilities proposed were that the patients follow the rules of hospitals and other healthcare units and for failing to do so pay for healthcare services ordered but not used where there was no sufficient reason. There is a universal public health system in Finland. The responsibilities with respect to a Patients' right were not felt to be suitable for inclusion in a proposal for a law on patients' rights. Legislations on healthcare in Finland regulate separately a Patients' responsibility to submit himself/herself to care in certain situations regardless of his/her will. The Law on Patients' Rights regulates the principles central to patient care and treatment. An exhaustive law covering all possible patients' rights was not considered feasible, for example, in Finland, a Patients' right to economic support during illness is regulated under the Social Security Law. In addition, the position of the patient would still be regulated by other special legislations in the field of healthcare that would remain in force.

The Act on the Status and Rights of Patients was issued in Helsinki on 17th August 1992 and applies to the status and rights of patients in healthcare and medical care. Section 5 of the Act deals with a Patients' right to be informed and provides that a patient shall be given information about his/her state of health, the significance of the treatment, various alternative forms of treatment and about other factors related to his/her treatment that are significant when decisions are made on the treatment given to him/her. But such information shall not be given against the will of the patient or when it is obvious that giving the information would cause serious hazard to the life or health of the patient. However, the language used to communicate such information should be understandable to the patient. Regarding the right of the patient to check the data concerning himself/herself in the patient documents, the provisions of sections 26 to 28 of the Personal Data Act apply.

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[1] *Paula Kokkonen, The New Finnish Law on the Status and Rights of a Patient, 1 Eur. J. Health L. 127 (1994).*

ACT ON THE STATUS AND RIGHTS OF PATIENTS

Issued in Helsinki on 17th August 1992

Chapter 1: General provisions

Section 1: Application

This Act shall apply to the status and rights of patients in health care and medical care unless otherwise provided by statute.

Section 2 : Definitions

In this Act:

1. the term patient is used of a person who uses health care services or is otherwise an object of them;
2. the terms health care and medical care mean measures taken by health care professionals or in a health care unit in order to assess the state of health of a person or to restore or maintain it.
3. the term health care professionals means persons referred to in section 2 of the Health Care Professionals Act (559/1994); (560/1994)
4. the term health care unit means health centres and other municipal units in charge of tasks as referred to in the Act on Primary Health Care (66/1972), hospitals and medical care units separate from hospitals and other entities responsible for providing care as decided by the joint municipal board for a hospital district referred to in the Specialized Medical Care Act (1062/1989), units providing health care services as referred to in the Private Health Care Act (152/1990), the Finnish Institute of Occupational Health as far as it provides health and medical care services referred to in the Act on the Activities and Financing of the Institute of Occupational Health (159/1978), State mental hospitals referred to in the Act on State Mental Hospitals (1292/1987), medical care institutions referred to in the Act on Arranging Health Care in the Defence Forces (322/1987), and health care units referred to in the Act on Criminal Sanctions Agency (953/2009); and (741/2011)

5. the term patient documents means the documents or technical records used, drawn up or arrived when the treatment of the patient is arranged and carried out and which contain information on his/her state of health or otherwise personal information about the patient.

Section 2 a (658/2009): National Advisory Board on Social Welfare and Health Care Ethics

The National Advisory Board on Social Welfare and Health Care Ethics operates in conjunction with the Ministry of Social Affairs and Health. The Government appoints it for four years at one time. The task of the Advisory Board is to deal, at the level of principle, with ethical issues relating to social welfare and health care and the status of patients and clients as well as to issue recommendations concerning them.

Further provisions on the composition of the Advisory Board and its tasks are laid down by Government decree.

Chapter 2 : The rights of patients

Section 3 : The right to good health care and medical care and related treatment of patients

Every person who is permanently resident in Finland is without discrimination entitled to health and medical care required by his state of health within the resources available to health care at the time in question. Concerning the right to treatment of persons who are staying in Finland temporarily, what has specially been provided for or what has been agreed upon between states reciprocally shall apply. Provisions on the obligation of municipalities and the state to provide health care services are laid down, in addition, in the Act on Primary Health Care, the Specialized Medical Care Act, the Health Care Act (1326/2010), the Communicable Diseases Act (583/1986), the Mental Health Act (1116/1990), the Act on Criminal Sanctions Agency and the Act on Arranging Health Care in the Defence Forces (322/1987). (1335/2010)

The patient has a right to good quality health care and medical care. The care of the patient has to be arranged so and he/she shall also otherwise be treated so that his/her human dignity is not violated and that his/her conviction and privacy is respected.

The mother tongue, individual needs and culture of the patient have to be taken into account as far as possible in his/her care and other treatment.

Provisions on the patients' right to use the Finnish or Swedish language, to be heard and to obtain their documents containing decisions in Finnish or Swedish and

their right to interpretation when using these languages while dealing with authorities are laid down in sections 10, 18 and 20 of the Language Act (423/2003). Provisions on the responsibilities of the municipalities and joint municipal boards for providing health and medical care services in Finnish and Swedish are laid down in section 6 of the Health Care Act. (1335/2010)

Section 4 (1335/2010) : Access to treatment

The patient shall be informed of the date of access to care or treatment. If that date will be altered, the patient must be immediately informed of the new date and the reason for the alteration. Separate provisions on the access to care and provision of care in primary health care and specialized medical care units are laid down in the Health Care Act.

Provisions on providing help to and admitting to care a person in need of urgent treatment are laid down in section 50 of the Health Care Act and in section 15 of the Health Care Professionals Act.

Section 4 a (857/2004)

The plan concerning examinations, treatment or medical rehabilitation

When organizing health care and medical care, as necessary, a plan concerning examinations, treatment, medical rehabilitation or comparable shall be drawn up. The provision of care for the patient and the time schedule for it must appear from the plan. The plan shall be drawn up in mutual understanding with the patient, his/her relatives or significant others or his/her legal representative. In addition, the content of the plan and the parties concerned are subject to separate provisions.

Section 5 : Patients' right to be informed

A patient shall be given information about his/her state of health, the significance of the treatment, various alternative forms of treatment and their effects and about other factors related to his/her treatment that are significant when decisions are made on the treatment given to him/her. However, this information shall not be given against the will of the patient or when it is obvious that giving the information would cause serious hazard to the life or health of the patient.

Health care professionals should try to give the information in such a way that the patient can understand it. If the health care professional does not know the language used by the patient or if the patient because of a sensory handicap or speech defect cannot be understood, interpretation should be provided if possible.

Concerning the right of the patient to check the data concerning himself/herself

in the patient documents, the provisions of sections 26 to 28 of the Personal Data Act (523/1999) shall apply. Concerning the patient's right of access to information, the relevant provisions of sections 11 and 12 of the Act on the Openness of Government Activities (621/1999) shall apply in addition. (653/2000)

Section 6 : Patients' right to self-determination

The patient has to be cared in mutual understanding with him/her. If the patient refuses a certain treatment or measure, he/she has to be cared, as far as possible, in other medically acceptable way in mutual understanding with him/her.

If a major patient because of mental disturbance or mental retardation or for other reason cannot decide on the treatment given to him/her, the legal representative or a family member or other close person of the patient has to be heard before making an important decision concerning treatment to assess what kind of treatment would be in accordance with the patient's will. If this matter cannot be assessed, the patient has to be given a treatment that can be considered to be in accordance with his/her personal interests.

In cases referred to in paragraph 2, the patient's legal representatives, a close relative, or other person closely connected with the patient, must give their consent to the treatment. In giving their consent, the patient's legal representatives, close relative, or other person closely connected with the patient must respect the patient's previously expressed wishes or, if no wishes had been expressed, the patient's well-being. If the patient's legal representatives, close relative, or other person closely connected with the patient forbid the care or treatment of the patient, care or treatment must, as far as possible in agreement with the person who refused consent, be given in some other medically acceptable manner. If the patient's legal representatives, close relative, or other person closely connected with the patient disagree on the care or treatment to be given, the patient shall be cared for or treated in accordance with his or her best interests. (489/1999)

Provisions on treatment given irrespective of the will of the patient are included in the Mental Health Act (1116/1990), the Act on Social Work with Substance Abusers (41/1986), the Communicable Diseases Act (583/1986) and in the Act on Special Care for the Mentally Handicapped (519/1977).

Section 7: The status of minor patients

The opinion of a minor patient on a treatment measure has to be assessed if it is possible with regard to his/her age or level of development. If a minor patient owing to

his/her age and level of development can decide on the treatment given to him/her, he/she has to be cared in mutual understanding with him/her. If a minor patient cannot decide on the treatment given to him/her, he/she has to be cared in mutual understanding with his/her guardian or legal representative.

Section 8 : Emergency treatment

A patient has to be given treatment necessary to ward off a hazard imperilling his/her life or health even in case it is not possible to assess the patient's will because of unconsciousness or other reason. However, if the patient has earlier steadfastly and competently expressed his/her will concerning treatment given to him/her, he/she must not be given a treatment that is against his/her will.

Section 9 : The right to be informed and the powers of the patient's representative

In the circumstances referred to in paragraphs 2 and 3 of section 6, the patient's legal representative, close relative, or other person closely connected with the patient shall be entitled to receive any information regarding the patient's state of health that may be required to enable them to express an opinion and give their consent. (489/1999)

If a minor patient because of his/her age or level of development can decide on the treatment given to him/her, he/she has a right to forbid providing his/her guardian or other legal representative with information on his state of health and care.

The information meant above in paragraphs 1 and 2 of section 5 shall in the case meant in section 7, paragraph 2, be given to the guardian or other legal representative of a minor patient. The guardian or other legal representative of a minor patient do not have the right to forbid treatment necessary to ward off a threat to the life or health of the patient.

The guardian or other legal representative of a minor or a patient referred to in paragraph 2 of section 6 shall not have the right to forbid any care which may be required to avert a threat to the patient's life or health. (489/1999)

Chapter 3 : Objections and patient ombudsman

Section 10 : Objections

A patient who is not satisfied with the health care or medical care and the related treatment received by him/her has the right to submit an objection on the matter to the director responsible for health care in the health care unit in question. Decision on the objection has to be given in a reasonable time from the submitting it.

Submitting an objection does not restrict the right of a patient to appeal to the authorities controlling health care or medical care about the care or related treatment received by him/her.

If, when the objection is dealt with, it becomes obvious that the care or other treatment of the patient may cause liability for patient injury meant in the Patient Injury Act (585/1986), indemnification liability meant in the Act of Torts (412/1974), taking legal action, cancelling or restricting the right of vocational practise or disciplinary proceedings meant in the legislation on vocational practise of health care staff or disciplinary proceedings meant in other law, the patient shall be advised as to how the matter can be initiated in a competent authority or organ.

Section 11: Patient ombudsman

A patient ombudsman shall be appointed for health care units. The patient ombudsman may also be common to two or more units.

The tasks of a patient ombudsman are :

1. to advise patients in issues concerning the application of this Act;
2. to help patients in the matters meant in paragraphs 1 and 3 of section 10;
3. to inform patients of their rights; and
4. to act also otherwise for the promotion and implementation of patients' rights.

Chapter 4 : Patient documents and material related to care and treatment

Section 12 (653/2000): Patient documents and other material related to care and treatment

Health care professionals shall record in patient documents the information necessary for the arranging, planning, providing and monitoring of care and treatment for a patient.

Health care units and health care professionals practising their profession independently shall keep the patient documents as well as the samples containing biological material that arise in the context of examinations and care and models of organs for a period necessary for arranging and providing care and treatment for a patient, for investigating possible claims for compensation related to care, and for scientific research. Patient documents, samples and models shall be disposed of immediately after there are no grounds as referred to above for keeping them.

Further provisions on the drawing up of patient documents and on keeping them and the samples and models referred to in paragraph 1, and on the periods of keeping them determined on the basis of their use shall be issued by a Decree of the Ministry of Social Affairs and Health. Patient documents, samples and models may be kept after the period prescribed by a Decree of the Ministry of Social Affairs and Health has expired, if that is necessary for arranging or providing care for a patient. The need for keeping them after the period prescribed by a Decree of the Ministry of Social Affairs and Health has expired shall be assessed at least at five years' intervals, unless otherwise provided elsewhere in the law, or in the permission granted by the Data Protection Board as referred to in paragraph 2 of section 43 of the Personal Data Act.

Provisions on retention of documents on a permanent basis are laid down in the Archives Act (831/1994).

Section 13 (653/2000) : Confidentiality of information in patient documents

The information contained by patient documents shall be confidential.

Health care professionals or other persons working in a health care unit or carrying out its tasks shall not give information contained by patient documents to outsiders without a written consent by the patient. If a patient is not capable of assessing the significance of the consent, information may be given by his/her legal representative's written consent. In this Act outsiders refer to persons other than those who participate in the care of the patient or in carrying out jobs related to it in the health care unit in question or by its order. The secrecy obligation remains in force after termination of the employment relationship or the job.

The 2nd paragraph notwithstanding :

1. information included in patient documents may be given if there are express provisions on giving it or on the right of access to it in the law;
2. information necessary for the arranging of examination and treatment of the patient may be given to another health care unit or health care professional, and a summary of the treatment provided may be given to the health care unit or the health care professional that referred the patient for treatment and to a physician possibly appointed to be responsible for the care of the patient in accordance with the patient's or his/her legal representative's orally given consent or consent that is otherwise obvious from the context; and

3. information necessary for arranging and providing the examination and care of a patient may be given to another Finnish or foreign health care unit or health care professional, if the patient, owing to mental health disturbance, mental handicap or for comparable reason is not capable of assessing the significance of the consent and he/she has no legal representative, or if the patient cannot give the consent because of unconsciousness or for comparable reason;

4. information about the identity and state of health of a patient may be given to a family member of the patient or to other person close to the patient, if the patient is receiving treatment because of unconsciousness or for other comparable reason, unless there is reason to believe that the patient would forbid this; and

5. information on the health and medical care of a deceased person provided when the person was still living may be given upon a justified written application to anyone who needs the information in order to find out his/her vital interests or rights, to the extent the information is necessary for that purpose; the acquiring party may not use or forward the information for some other purpose.

What is provided in the Act on the Openness of Government Activities, the Act on National Personal Data Registers for Health Care (5561989) and in the Personal Data Act shall apply to the supplying of information contained in patient documents for scientific research and compilation of statistics. Furthermore, the National Institute for Health and Welfare may, in individual cases, grant permission to obtain information that is needed for purposes of scientific research from patient documents of more than one municipality or joint municipal board providing health and medical care services, from patient documents of a unit providing health care services referred to in the Act on Private Health Care and from patient documents of self-employed health care professionals. The permission may be granted if it is obvious that the supplying of the information does not violate the interests for the protection of which the secrecy obligation has been prescribed. When considering the granting of permission it must been taken care that the freedom of scientific research is secured. The permission can be issued for a fixed period of time, and necessary regulations for the protection of private interests must be appended to it. The permission can be cancelled if considered justified. (795/2010)

The consent obvious from the context referred to in point 2 of paragraph 3 refers to a consent given in some other way than in writing or orally, which the patient has given voluntarily, conscious of the giving of information, of the acquiring party and the use of the information given, as well of the significance of giving it.

The giving of information referred to in paragraphs 2 and 3, and the grounds for it shall be recorded in the patient documents.

Section 13 a (1230/2010): National information system services

Provisions on passing on information contained in patient documents by means of the national information system services are laid down in the Act on the Electronic Processing of Client Data in Social and Health Care (159/2007). Provisions on passing on information contained in the prescriptions recorded in the prescription centre maintained by the Social Insurance Institution are laid down in the Act on Electronic Prescriptions (61/2007).

Section 13b (690/2012): Reference to other legislation

Provisions on the use of the biological samples generated in connection with the examination and treatment of patients for scientific research are also laid down in the Medical Research Act (488/1999), the Act on the Medical Use of Human Organs, Tissues and Cells (101/2001) and the Biobank Act (688/2012).

Chapter 5: Miscellaneous provisions

Section 14 (653/2000): Breach of the secrecy obligation

Punishment for breaching the secrecy obligation referred to in paragraph 2 and in point 5 of paragraph 3 of section 13, shall be imposed according to section 1 or 2 of Chapter 38 of the Penal Code, unless the offence is punishable under section 5 of Chapter 40 of the Penal Code, or unless a more severe punishment is prescribed for it elsewhere in the law.

Section 15 : Right of appeal

A decision on an objection meant in paragraph 1of section 10 may not be appealed.

Section 16 : Further provisions

If needed, further provisions on the implementation of this Act shall be issued by Decree.

Section 17: Entry into force

This Act enters into force on 1 March 1993 and it abrogates :

1) paragraph 4 in section 33 in the Specialized Medical Care Act (1062/1989) issued on 1st March 1989;

2) section 18 in the Act on Primary Health Care (66/1972) issued on 28th January 1972; and

3) section 11 in the Act on Private Health Care (152/1990) issued on 9th February 1990, as this section reads in the Act issued on 17th January 1991 (79/1991) after having been partially amended.

Measures necessary for the implementation of this Act may be undertaken before its entry into force.

Entry into force of Amended Acts :

795/2010 :

This Act enters into force on 1 October 2010.

The applications regarding supplying of information referred to in section 13 (4) for scientific research that are being processed at the Ministry of Social Affairs and Health at the entry into force of this Act are transferred to the National Institute for Health and Welfare.

Measures necessary for the implementation of this Act may be undertaken before its entry into force.

1335/2010 :

This Act enters into force on 1 May 2011.

Measures necessary for the implementation of this Act may be undertaken before its entry into force.

741/2011:

This Act enters into force on 1 September 2011.

690/2012 :

This Act enters into force on 1 September 2013.

ISRAEL

ISRAEL

The enactment of the Patients' Rights Law in Israel in 1996 was an essential turning point in Israeli medical law. Section 13 of the new law explicitly establishes the requirement of informed consent and the details which a doctor must relate to a patient in order to reach an agreement. Nevertheless, the law does not state the standard according to which it should be assessed whether the disclosure was proper.

The Patients' Rights Law defines the rights of the patients and the obligations on medical care providers (including hospitals, clinics, doctors, nurses and other medical professionals). Care providers, under Section 17 and 28(b) of the Patients' Rights Law, are responsible for the on-going management, updating and maintenance of patients' medical records in the proper legal manner and for the period of time required by law. When a patient is treated in a medical facility, the management is responsible for the records. Medical records may not be taken out of a hospital without written approval from the relevant authority in the hospital. If medical records are given to a patient to keep, this must be documented by the care provider or medical facility. The relevant department in the hospital must keep a copy of the records. All patients, under the Patients' Rights Law, are entitled to receive medical information from the medical record from their care provider or from the relevant medical facility. This includes the right to make personal copies. Per patient request, all care providers and medical facilities are obligated to provide patients with medical information from the medical record and allow patients to receive copies of medical records. According to section 18 of the Patients' Rights Law, a patient is entitled to get medical information from the medical records of the doctor or institution. The request can be submitted by the patient, his family member or an external party that has power of attorney to make the request (such as a lawyer). There may be fees for receiving copies of medical records. The fees vary based on the type of record and the identity of the person requesting it. If a request to take information from the medical record is for purposes of continuing medical treatment (an illness summary or results from tests that were performed during hospitalization), patients should contact their attending physician at their primary care clinic. There is no cost for receiving information ordered by an attending physician. Patients wishing to obtain information independently, and not through an attending physician, must contact the relevant department related to medical records on their own. Any violation of the right to access medical records can be addressed through the authorities under the Patients' Rights Law. The official website of Ministry of Health, State of Israel has enlisted the rights of a patient as "Patients' Bill of Rights".

PATIENTS' BILL OF RIGHTS

(Original text as available on the official website of the Ministry of Health, State of Israel)

The right to receive proper medical care

You have the right to receive professional and quality health care and to be treated with respect and consideration, without any discrimination on grounds of religion, race, gender, nationality, country of origin, sexual orientation and so on. If you came to the emergency room, it is your right to be examined by a doctor.

Identity of care-provider

You have the right to know the name and position of any healthcare team member providing your care, and care- providers must identify themself, and carry clear identification tag.

Consent for medical treatment

You have the right to receive an appropriate and clear explanation about your medical condition, about treatment options that are available for you and their alternatives, risks, prospects and potential side effects, including those relating to refraining from treatment. It is important that you will provide the care provider with information about your medical history, so that the diagnosis and treatment offered to you will be appropriate.

You have the right to refuse treatment to which you did not give consent (except for exceptional cases prescribed by law).

You have the right to appoint a proxy, who will have the authority to consent to medical treatment in the event that you become unable to do so.

Maintaining the dignity and privacy

You have the right that all care providers and all employees of the medical institution will retain your dignity and privacy at all stages of treatment. In certain medical examinations, you have the right to have additional person in the room, at your request.

Medical confidentiality

You have the right to keep the confidentiality of your medical information, and care providers must ensure the confidentiality of medical information relating to you

and to your treatment which they received due to their positions.

Disclosing of medical information

You have the right that medical information about you will be disclosed only with your consent, or where by law it is permitted or not required.

Second opinion

You have the right to initiate receiving a second medical opinion (from a care provider within or outside the medical institution) about your condition and the recommended treatment. The medical staff at the institution has the obligation to assist you.

Continuity of care

In transition between care providers or between medical institutions, you have the right to request that care providers and medical institutions will cooperate in order to ensure your continued proper medical care.

Receiving visitors

During hospitalization, you have the right to receive visitors during visiting hours designated to this purpose by the hospital administration.

Receiving medical information

You have the right to receive from the care provider or medical institution, medical information contained in your medical records, or a copy of the medical record (receiving a copy of the record may be subject to a fee).

At the time of your release, you have the right to receive a summary of the course of treatment or hospitalization, in writing.

Public Inquiries

You have the right to contact the person responsible for public inquiries and rights of patients at the medical institution in any comment, complaint, question or recommendation.

You have the right to receive findings and conclusions of the investigation of your complaint.

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SINGAPORE

SINGAPORE

One of the first primary healthcare laws of Singapore is the Private Hospitals and Medical Clinics Act (PHMCA) of 1980. This Act was designed for ensuring patient safety through licensing of physical premises delivering healthcare such as hospitals, medical clinics, clinical laboratories and other related establishments. The Medical Registration Act of 1997 is another legislation which governs licensing of doctors in Singapore and requires all medical practitioners to register themselves with the Medical Council of Singapore and hold a practicing certificate to work as doctors.

The Singapore Medical Council (SMC) has the role of promulgating the Ethical Code and Ethical Guidelines on acceptable professional practice and behavior and has the responsibility to exercise its duty to discipline members of the profession who fail to uphold the high standards demanded by society. The SMC issued an Ethical Code and Ethical Guidelines (ECEG) that lays down principle-based guidelines and values for doctors. The Ethical Code and Ethical Guidelines (ECEG) were first revised in 2002. Ethical code represents the fundamental tenets of conduct and behavior expected of doctors practicing in Singapore. The ethical guidelines elaborate on the application of the Code and are intended as a guide to all practitioners as to what SMC regards as the minimum standards required of all practitioners in the discharge of their professional duties and responsibilities. The Ethical Code requires doctors to act for patients' best interest while giving them advice and offering treatment. When doctors are faced with financial interests that compete with their professional duty towards the patient, the conflict must always be resolved in the best interests of the patient. The Singapore Medical Council's (SMC) jurisdiction in relation to professional conduct over persons registered under the Medical Registration Act is governed by the provisions of the Act and the Medical Registration Regulations. Section 4.1.2 of the code provides that medical records kept by doctors should be clear, accurate, legible and be made available at the time when the consultation takes place and not long afterwards. Medical records shall be of sufficient detail so that any other doctor reading them would be able to take over the management of a case. All clinical details, investigation results, discussion of treatment options, informed consents and treatment by drugs or procedures should be documented.

Section 4.2.4.1 stipulates that a doctor shall provide adequate information to a patient so that he can make informed choices about his further medical management. A

doctor shall provide information to the best of his abilities, communicate clearly and in a language that is understood by the patient. A doctor shall respect a Patients' choice of accepting or rejecting advice/ treatment that is offered after steps have been taken to ensure that there is no language barrier and the patient understands the consequences of his choice. He shall also facilitate a patient obtaining a second opinion if he so desires. If a doctor wishes to enter a patient into a clinical trial, adequate information must be given to the patient and informed consent must be obtained. The doctor needs to familiarize himself with the relevant sections of the current Guidelines on Good Clinical Practice and inform the patient accordingly before he or she joins the trial.

The Singapore Medical Council with the assistance of a Working Committee updated the 2016 Ethical Code and Ethical Guidelines (ECEG) with considerable input from the medical profession. ECEG 2016 provides for maintenance of clear and accurate medical records for enhancing good patient care. Patient autonomy has been considered a fundamental principle in medical ethics and has to be respected. Patients are entitled to have accurate and sufficient information to be able to make their own decisions about their medical management.

Recently the Healthcare Services Act 2020 (HCSA) came into being after it was assented to by the President on 29th January 2020. The HCSA repealed the existing Private Hospitals and Medical Clinics Act (PHMCA) and made consequential and related amendments to a number of other Acts. The HCSA seeks to address such changes by: -

a. introducing a services-based licensing regime for providers of healthcare services, replacing the premises-based licensing regime under the PHMCA;

b. strengthening the safeguards for the safety and welfare of patients who receive healthcare services;

c. Improving the governance requirements for providers of healthcare services, including the requirements for the board of directors and key management personnel of these providers; and

d. enhancing the regulatory powers in relation to providers of healthcare services, including allowing intervention in failing providers in order to stabilize operations and ensure continued patient care.

SINGAPORE MEDICAL COUNCIL'S ETHICAL CODE AND ETHICAL GUIDELINES (2016)

[The complete document can be viewed at the following link https://www.healthprofessionals.gov.sg/smc/guidelines/smc-ethical-code-and-ethical-guidelines-(2002-and-2016-editions)-and handbook-on-medical-ethics-(2016-edition)]

THE ETHICAL CODE

(1) Patients and the public must be able to trust you implicitly with their lives and wellbeing. To justify this trust, you have to maintain a good standard of care, conduct and behaviour. The SMC prescribes the Ethical Code which you are required to uphold. These principles are applicable to a wide variety of circumstances and situations. Adherence to the Ethical Code will enable society to have trust and confidence in the profession.

(2) You should also recognise that when ethical conflicts arise, you can and should consult your colleagues, Ethics Committees or other experts to help you resolve the conflicts.

(3) In general, you must :

(a) Ensure beneficence and non-maleficence:

(i) Maintain due respect for human life.

(ii) Uphold patients' welfare and best interests as your highest consideration.

(iii) Be dedicated to providing medical care that is competent, compassionate and of a quality that is accepted by the profession.

(iv) Be an advocate for patients' care and well-being and endeavour to ensure that patients' are not harmed or suffer minimum harm for maximum possible medical benefit.

(v) Within your ability, treat patients in emergency situations with the urgency and timeliness necessary to save lives or prevent adverse outcomes.

(vi) Work with colleagues where necessary and appropriate in ways that serve the best interests of patients.

(vii) Maintain competence by keeping abreast of medical knowledge relevant to practise and ensure that your clinical and technical skills are current.

(viii) Maintain your fitness to practise and to be cognisant (where your own insight is preserved) of your own impairments and inability to manage patients to the required standards and refrain from continuing to manage patients if you know you are impaired.

(ix) Act to prevent harm or risk of harm to patients, whether due to a colleague's performance or wider systemic issues.

(x) Abide by the ECEG when utilising new technology or treatment modalities and where ethical application is unclear, seek counsel from colleagues or Ethics Committees.

(b) Respect autonomy:

(i) Maintain the highest standards of moral integrity and intellectual honesty.

(ii) Treat patients with honesty, dignity, respect and consideration, upholding their desire to be adequately informed and (where relevant) their desire for self-determination.

(iii) Maintain a professional relationship with patients and their relatives and not abuse this relationship through inappropriate personal relationships or for personal gain.

(iv) Keep confidential (apart from legitimate disclosures) all medical information about patients.

(v) Maintain good communications, whether written, verbal or in any other form, between you and your patients or colleagues.

(vi) Be open, truthful, factual and professionally modest in communications with other members of the profession, with patients and with the public at large.

(vii) Maintain professionalism in informing the public about services,

ensuring that information projected is devoid of any exaggerated or deceptive content.

(c) Uphold justice :

(i) Provide access to good medical care and treat patients without unfair discrimination, prejudice or personal bias against any characteristic of patients, for example, gender, race, religion, creed, social or economic standing, disability or sexual orientation.

(ii) Treat patients fairly and not allow moral bias or prejudices made on account of patients' habits or lifestyles to influence the way you manage them.

(iii) Strive to use resources efficiently and balance your duty of care to patients with your duty of care to the community and wider population (distributive justice).

(iv) Regard all fellow professionals as colleagues, treat them with dignity, accord them respect and manage those under your supervision with professionalism, care and nurturing.

(v) Do what you can to protect and promote the health of individuals and the community, including contributing to patient and public education.

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THE ETHICAL GUIDELINES

A Good clinical care

A1. Duty of care

In clinical practice, the care of your patient is your primary concern. To provide the best possible care means:

(1) You must provide competent, compassionate and appropriate care to your patients.

(2) You must, to the extent that it is within your ability or control, provide care in a timely manner to prevent suffering or deterioration of patients' conditions.

(3) You must avail your patients of supporting medical services required by them that are licensed or accredited by the relevant authorities and of which you have reasonable confidence in their standard and reliability.

(4) You must provide a standard of medical care that is rational and based on a balance of evidence and accepted good clinical practice.

(5) You must offer your patients treatments that are beneficial. Treatments are not legitimate just because there is little evidence of harm or because they are widely employed. You must have sufficient reason to believe that they are beneficial to your patients.

A2. Clinical evaluation of patients

Good clinical care requires adequate evaluation of patients, so that you are able to make appropriate management plans. This means:

(1) You must ensure that you have sufficient information about your patients, derived from good history-taking, adequate clinical examination and other relevant investigations or information sources, before you offer any opinion, make management plans or offer treatment.

(2) When contacted remotely by previously unknown patients and without the intermediation of attending doctors or healthcare professionals who can provide good quality information, you must inform your patients that your opinion is qualified and limited to what you can assess from information that is presented.

(3) If the remote consultation with previously unknown patients is facilitated by or

intermediated through attending doctors or other healthcare professionals, you may offer definitive opinions or management plans if you deem the information provided by these intermediary healthcare professionals to be satisfactory.

(4) Remote follow-up of patients well-known to you is acceptable but you must ensure that there is no evidence to suggest that your patients have any clinically serious deterioration or developed new problems or complications, in which case you must assess them in person, or ensure that they are assessed by doctors or other appropriate healthcare professionals to whom you can delegate this responsibility.

A3. Practising within competence, maintaining and improving performance, and offering the current standard of care

Good medical practice requires you to provide patients competent services. This means:

(1) You must practise within the limits of your own competence. You must not engage in unsupervised practice of an area of medicine without having the appropriate knowledge and skills or the required experience.

(2) You must keep your knowledge and skills up to date throughout your working life, so as to always provide care that is generally accepted as current.

(3) You must provide information to your patients of options for their care that are generally accepted to be more beneficial to them than what are available to them where you practise.

(4) If you cannot provide services that are necessary for your patients, or most beneficial for your patients, you must offer to refer them to other doctors or institutions which can provide the most appropriate services.

A4. Delegation and referral of patients

Shared care of patients involving other healthcare professionals is often needed for good clinical care. Providing good clinical care in the context of shared care means:

(1) If you delegate another person to provide some aspect of care to your patients, you retain overall responsibility for your patients and you must take reasonable care to ensure that the other person is capable of providing care to the required quality and standards.

(2) If you are delegated the care of patients, you must provide an appropriate standard

of care to them, according to the aspects of care you accept responsibility for.

(3) When making referrals to other doctors, you must inform your patients of the reasons for the referral and provide relevant information about the other doctors.

(4) If you make referrals or transfers of care to other doctors, you must provide sufficient documentary medical information, either directly to the other doctors or through the patients, to enable good quality continued care.

(5) In making referrals or transfers of care, you must continue to provide care as needed for the patients until they are seen by the doctors they are referred or transferred to.

A5. Working in teams

Patients are often cared for by teams of doctors and other healthcare professionals. Care is improved when there is mutual respect, good communications and clear understanding of roles between team members and among the different teams. Maximising the benefit to patients of team care means :

(1) You must communicate with other team members as necessary for the team to provide the best care possible.

(2) In the context of structured or formal teams of which you are a part, you must do what you can to improve the team's performance, correct deficiencies and improve quality of care.

(3) If you are a team leader, you must ensure that the overall performance of the team meets the required standard of care for the patients, including, if necessary, arranging for the redeployment or substitution of team members who are unable to perform to the required standard.

(4) If you work as part of a team, you must ensure that the care you provide does not exceed your capabilities and meets the quality and standard of care expected, for the part of the patient's care which you are responsible for. If the care you are asked to provide is beyond your capability, you must inform your team leader.

(5) For patients that require handing over to another team for continued care, you must ensure the same standards as for referring or transferring patients.

(6) In teams where you are associated with allied health professionals, if you have any material financial interest with respect to the services of the allied health professionals, you must disclose this conflict of interest to your patients.

A6. Telemedicine

Telemedicine can improve patient access to medical care. Yet, it is not equal to conventional in-person care and has to be provided in a responsible manner. Providing telemedicine responsibly means :

(1) If you engage in telemedicine, you must endeavour to provide the same quality and standard of care as in-person medical care. This includes ensuring that you have sufficient training and information to manage patients through telemedicine. Otherwise, you must state the limitations of your opinion.

(2) If you perform remotely guided medical procedures or give remote guidance to others to perform procedures, you and the person you guide must have the necessary expertise to provide and follow the remote guidance unless there are exceptional circumstances that justify a departure from this guideline.

(3) If you avail your patients of robotic procedures performed by other doctors remotely, you have only delegated an aspect of care but still retain responsibility for the overall management of the patients. If you perform robotic surgery on a patient remotely, the standard of care you are required to provide to the patient is no different than if you were to perform the operation in person.

(4) You must give patients sufficient information about telemedicine for them to consent to it. You must also ensure that your patients understand any limitations of telemedicine that may affect the quality of their care in relation to their specific circumstances.

(5) You must take reasonable care to ensure confidentiality of medical information shared through technology and ensure compliance with any applicable existing legislation and regulations governing personal data.

(6) If you ask your patients to operate telemedicine equipment from their locations, you must ensure that they are sufficiently trained to do so. You must also ensure that prompt assistance is available in case of equipment failure or inability of the patients to operate the systems, where such failure or inability poses material risks to patients.

A7. End-of-life care

Doctors have an important role in helping patients, their families and the community to deal with the consequences of irreversible or fatal illnesses and the

reality of impending death. Providing good end-of-life care to patients means :

(1) Despite the complex nature of end-of-life care, you must ensure that patients' welfare is not compromised, patient autonomy is preserved where possible, their best interests are upheld and they do not suffer harm inappropriate to their clinical conditions and the natural course of disease.

(2) You must engage patients through good communications to elicit their preferences and goals of treatment, while helping them to understand the limits of medical treatment. You must offer good palliative care where necessary to minimise suffering in the course of life-limiting illnesses.

(3) You must respect patients' wishes not to receive specific treatments. At the same time, you are not obliged to provide or continue treatments that you deem inappropriate, nonbeneficial or even harmful in view of the natural course of the underlying disease.

(4) If patients do not have the capacity to decide what end-of-life care they want for themselves and have not previously expressed their wishes, you must act only in the patients' best interests. This may include consulting family members or those close to them to help you determine what would be the patients' best interests.

(5) You must not commit or participate in any act where your primary intentionis to hasten or bring about death.

B Good medical practice

B1. Decisions about providing services

In deciding the care and treatment you provide and avail to patients, you have a responsibility to make your decisions in an objective manner and in the patients' best interests.

This means :

(1) You must not unfairly discriminate against patients, or show prejudice or personal bias against any patient characteristic, for example, gender, race, religion, creed, social standing , disability, sexual orientation or socio-economic status.

(2) You must not allow personal moral bias or prejudices about patients' habits or lifestyles to influence your decisions on treatment. Your decisions must be based on an objective assessment of clinical needs and the likely effectiveness of

treatment options.

(3) You must not purely out of fear or prejudice refuse to treat patients who have infectious diseases and in such a way as to leave them without timely care. You have the right to ensure that you have adequate personal protection to minimise any risk of infection before you treat such patients.

(4) You must not provide care to yourself or those close to you where this involves controlled drugs, drugs with significant potential for dependence or psychiatric care. In addition, you must not issue medical certificates to yourself.

(5) Generally, you may provide care to yourself and those close to you when it is for routine continued care for stable conditions, minor conditions, or in an urgent/emergency situation when no other suitable doctor is available in a timely manner. If you choose to provide significant care such as major surgery to those close to you, you must ensure that your objectivity, judgment and professionalism in medical decision making are not compromised to patients' detriment due to your emotional proximity.

(6) You must never prescribe or dispense medicines or treatments to third parties of whom you have no personal knowledge and with whom you have no professional relationships, even if relatives or close friends request for you to do so on behalf of these persons.

(7) When you participate in managed care, you must maintain your professional independence. You must not allow any financial or other arrangements inherent in managed care to pressure you into making decisions that would compromise the required standard of care.

(8) Even if you are acting in a policy-making, management or administrative capacity in a healthcare system, as a registered doctor, you continue to have professional responsibility. You must ensure, to the best of your ability, that your colleagues who directly manage patients do not find it impossible to uphold the ethical requirements detailed in the ECEG and are able to provide or facilitate access to the required standard of care.

(9) If you are alerted to a credible medical emergency while you are working or on duty, you must respond and try to help unless you are indisposed due to caring for other patients and cannot reasonably disengage to respond.

(10) If you are working in epidemics, pandemics, disasters and mass casualty

situations anywhere, it is acknowledged that the circumstances are less than ideal. Yet, you must do your best in the circumstances and within your ability. You must, as far as it is reasonably within your ability to do so, ensure that patient welfare is sustained and you do nothing that would disrupt the ability of medical teams to provide care.

B2. Medical investigations

Medical tests are part of good clinical evaluation if appropriately employed and the results correctly handled. Good use of medical tests means :

(1) When you avail your patients of medical investigations, you must take reasonable care to ensure the competency of the service providers. You must check that they are licensed or accredited by the relevant authorities and also be reasonably confident of the quality and timeliness of the service offered.

(2) You must communicate clearly why tests are needed and explain important results to patients in a timely manner. You must ensure that patients are offered follow-up care as necessary.

(3) If results are clinically significant or important to act on to prevent harm to patients or others but patients are difficult to contact, you must make reasonable efforts to trace them, the effort being in proportion to the urgency of the situation.

(4) If you accept patients directly for laboratory, imaging or other tests without them being referred by other doctors, you are deemed to have entered into patient-doctor relationships with them, with all the responsibilities that this entails. You must ensure that important results are communicated to the patient in a timely manner so that they may seek medical care.

(5) If you offer health screening tests to your patients, you must ensure that they are validated and clinically appropriate. You must ensure that your patients (or legal guardians or, where relevant, persons with legal authority to make decisions for them) are informed of important results and their implications in a timely manner and those patients are offered follow-up care if needed.

(6) If you advertise health screening services, you must abide by the ethical requirements for medical advertising. The advertisements must be objective and not exploit the public's vulnerability to unreasonable and unjustifiable anxiety about their current or future health and longevity.

B3. Medical records

Maintaining clear and accurate medical records enhances good patient care and ensures high quality continuity of care. Keeping good medical records means :

(1) You must maintain clear, legible, accurate and contemporaneous medical records of sufficient detail to enable a high quality of continuing care.

(2) You must make your records at the time of your engagement with patients, or as soon as possible afterwards.

(3) Your medical records must include all clinical details about your patients, discussions of investigation and treatment options, informed consents, results of tests and treatments and other material information. If you are delegated an aspect of care, you may confine your records to what is relevant to your portion of care.

(4) If patients request for information not to be documented, you may accede to their requests but you must be sure that this does not adversely impact their care or the safety of others.

(5) Medical notes must be written or entered in objective language without showing disrespect for patients, or otherwise disparaging or insulting patients in any way.

(6) You must not amend medical records in order to hide anything, or to otherwise mislead. You may only amend medical records to make genuine corrections or amplifications.

(7) If the medical records are made on your behalf, you must take reasonable steps to ensure that the quality of the records is up to the required standards.

(8) You must, within your ability, ensure that your medical records are kept safely and securely and are not at risk of unauthorised access and breach of medical confidentiality. If you are not in control of the medical record systems, then your duty is to use the systems responsibly and abide by all the security protocols in place.

(9) Patients have a right to their medical information (though not the physical medical records or the original digital records) and when requested, unless there are exceptional circumstances, you must make such information from their records available to them, communicating it in a way that best suits the patients' needs, such as in a medical summary or report.

B4. Medical certificates

The community places trust in doctors and authorises you to certify illnesses or disability through medical certificates. Good practice in writing medical certificates means :

(1) Medical certificates must be issued to patients only on proper medical grounds arrived at through good clinical assessment. You must not take into consideration extraneous factors such as who pays for the consultation, what benefits the patients may receive or what employers' preferences may be.

(2) Where possible, medical certificates must be handed over only to patients themselves. When patients request or consent to it, you may send the medical certificates directly to employers.

(3) Medical certificates must be written objectively, accurately and in good faith, must cover an appropriate duration and where relevant, must provide an accurate account of patients' limitations during the periods covered.

(4) If you are certifying that the patients are fit to return to work but with limitations on their level of activity at work, you must first ensure that the patients' work conditions allow this and, to the best of your ability, ensure that appropriate light duties are in fact available to the patients at their place of work.

(5) You must not post-date or back-date the date of issue of your medical certificates. The date of issue must be that of the day of consultation or treatment. The date you begin coverage may be before the date of issue only if it is clear to you that the patients' absence from work prior to the date of issue is consistent with their clinical presentation.

(6) You must not amend the particulars on medical certificates issued by other doctors. If you disagree with the provisions of other doctors' medical certificates, you may issue new medical certificates. However, you must only do this after assessing the patients yourself to determine that this is justified on medical grounds and where appropriate and possible, consulting the other doctors before you do so.

(7) Diagnoses must not be stated on the medical certificates unless patients have consented to this.

(8) As medical certificates are documents that carry professional and legal implications, you must sign the certificates personally at the time of consultation

and if another person has filled in the details on your behalf, you must satisfy yourself that the details are correct before signing.

(9) When medical certificates are generated electronically and where you are in control of the systems, you must ensure that there are security protocols to prevent fraudulent issuance of the certificates. If you are not in control of the systems, you must use the systems responsibly and abide by the security protocols in place.

B5. Prescription of medicine

Doctors have the unique privilege of prescribing medicine and treatments. This is a serious responsibility and must never be abused. Prescribing responsibly means :

(1) You must prescribe, dispense or supply medicines only to patients under your care.

(2) You must prescribe, dispense or supply medicines only on clear medical grounds arrived at through sufficient clinical information and after considering the available evidence and what is accepted by the profession as good clinical practice.

(3) You must ensure that patients are informed of the purpose of the medicine prescribed and the expected results. You must ensure that patients know the more common and important drug interactions and side effects, or those likely to be significant to specific patients.

(4) You must always elicit a history of drug allergy. If this history is unclear, you must justify the material risks of prescribing the drug or class of drug and the patients must understand and consent to the risks.

(5) Prescriptions, no matter how they are made, must be legible and unambiguous. If you give remote or verbal orders, you must be satisfied with the information about the patients and you must be satisfied that such prescription is in the patients' best interests

(6) You may provide repeated prescriptions or dispense medicine without consultations if patients' clinical situations are reasonably believed to be stable and the patients require only replenishment of medicines.

(7) You must not prescribe or dispense drugs with potential for dependence or addiction in disregard of patients' circumstances or patterns of usage that ought to raise suspicions.

(8) If the drugs you prescribe have the potential for abuse, dependency or addiction, you must ensure that you have good clinical indications for using them; prescribe only the smallest appropriate amount of the drugs to patients so as to ensure that patients are reviewed at short intervals and refer patients to addiction specialists if abuse, dependency or addiction is suspected.

(9) If you use "off-label" drugs, you must ensure that it is in the patients' best interests, there is rational basis, patients have justifiable medical indications, you have assessed the risks and benefits of such use and patients' consent to such use has been obtained if they are able to give it.

(10) You must not use unlicensed drugs, devices or instruments on your patients unless you have obtained the necessary approvals. You must ensure that such usage is in patients' best interests and you must obtain patients' (or their legal representatives') consent, where possible, before using such unlicensed treatment modalities.

(11) You must not knowingly abet or participate in the trafficking, supply or administration of any drugs, substances or treatments (listed in the World Anti-Doping Agency ("WADA") Prohibited List) to sports persons for the primary purpose of enhancing their sports performance or to obtain an unfair competitive advantage for them.

(12) You may use such drugs or treatments listed in the WADA Prohibited List for legitimate medical indications, but you must not prescribe or dispense performance enhancing drugs or treatments to sports persons in disregard of patients' circumstances or patterns of usage that ought to raise suspicions.

B6. Untested practices

Patients expect doctors to offer only treatments or therapies that will benefit them while minimising harm. Offering appropriate treatment to patients means :

(1) You must treat patients only according to generally accepted methods, based on a balance of available evidence and accepted best practices.

(2) Variances in treatment based on individual patients' needs are legitimate in clinical practice. Yet, these variances must not be so significant that they render the techniques novel and unclear in their risk profiles, thereby becoming not generally accepted.

(3) Except for innovative therapy, treatments that are not generally accepted must be

offered to patients only in the context of formal and approved clinical trials which would be subject to the ethics of research.

(4) Innovative therapy may be offered when conventional therapy is unhelpful and it is a desperate or dire situation. There must be professional consensus on the use of innovative therapy in the particular clinical situation and consent must be obtained from patients if they are able to give it.

B7. Non-treating doctors performing assessments for third parties

When you are contracted by third parties to provide medico-legal, insurance or other assessments of patients, no patient-doctor relationship arises between you and the patients concerned. However, you still have professional responsibilities and discharging these well means :

(1) As a non-treating doctor, you must exercise due diligence, professional competence and skill to make sure that any documents written or signed by you are not false or misleading.

(2) You must ensure that your recommendations serve the patients' best interests and if followed, do not result in harm to the patients through consequent inappropriate restriction of treatment options or inappropriate work assignments.

(3) If in the process of the assessments, you discover medical information that is significant and important to act on to prevent harm, which you know the patients are not aware of, you must take reasonable steps to ensure that patients are informed of such information so that they may seek medical care in a timely manner.

B8. Medical research

Medical research is vital to improve patient care, reduce uncertainty to patients and improve the health of the community. Good research practice means :

(1) You must conduct medical research with honesty, objectivity and integrity.

(2) You must not allow commercial, financial or other extraneous considerations to influence the integrity of your patient recruitment methods, research protocols, results, findings or plans to publish the results regardless of the outcome.

(3) You must not conduct or authorise any research on human subjects or trials of any treatment on patients not approved by the Institutional Review Board or Ethics

Committee and are contrary to current Good Clinical Practice Guidelines, or other existing guidelines on human biomedical research.

(4) You must provide competent research subjects or patients with sufficient information for them to understand the research you are inviting them to participate in so that they can give informed consent.

(5) You must not conduct research on persons with diminished mental capacity or minors who do not have the capacity to understand information sufficiently to decide for themselves, unless you have reasonable grounds to believe that research of comparable effectiveness cannot be carried out without the participation of such persons.

(6) For persons with diminished mental capacity, you must determine whether they have sufficient residual capacity to understand and retain information for the purpose of making informed decisions for themselves. If so, you must take consent from these persons. If these persons do not have sufficient mental capacity to decide, you may take consent from legally appointed persons with the authority to make decisions for them or failing that, those closest to the subjects.

(7) For minors with the capacity to understand information sufficiently to decide for themselves, you must involve them in making the decision to be a research subject. Consent from one parent or legal guardian is also required unless an Institutional Review Board has given exemption to waive the requirement of consent from a parent or legal guardian.

(8) For minors who do not have the capacity to understand information sufficiently to decide for themselves, consent must be taken from at least one parent or legal guardian. Even then, you must, as far as possible, engage and explain the research to the minors in ways that they can comprehend, so that any concerns may be addressed to minimise possible distress.

(9) If you are conducting research on persons who are under military command or other subordinate situations, you must take reasonable steps to ensure that they are not participating under coercion.

(10) You must not engage in research on any method that is designed to injure or harm human beings as the primary objective.

(11) If you know or reasonably believe that a colleague is engaged in scientific misconduct, you must report this to the relevant authorities.

B9. Complementary and alternative medicine

There are many systems for diagnosis and healing of the body that are based on theories and beliefs that are vastly different from conventional medicine. As a registered doctor, you are obliged to practise complementary and alternative medicine ("CAM") in an ethical manner. This means:

(1) If you practise or avail your patients of CAM, you must restrict this to only those modalities that are specifically approved by SMC.

(2) If you practise SMC-approved CAM, you must be duly trained (through the full qualification courses that non-doctor practitioners have to undergo), certified and accredited.

(3) You must not, through taking advantage of patients' trust in your medical qualifications and SMC registration status, mislead patients as to the appropriateness of use and expected benefits of CAM.

(4) You must not claim superiority of your service merely because you offer SMC-approved CAM alongside conventional medicine.

(5) You must ensure that you are acting in patients' best interests and have medical reasons for offering SMC-approved CAM services to them. In addition, you must ensure that there are no medical contraindications to do so.

(6) You must not use SMC-approved CAM on your patients in disregard of medical needs of your patients that are better met through conventional medicine. Harm caused to patients through failure to offer necessary conventional medical treatment is not defensible on the grounds that your management is legitimate under an alternative health system or philosophy.

(7) You must give patients sufficient information about the SMC-approved CAM that you are offering them, for them to give informed consent.

(8) If you avail your patients of SMC-approved CAM practised by non-doctors, you are regarded as having only delegated care. You must retain responsibility for the patients' overall care (unless patients discharge themselves from your care) and must send patients only to those CAM practitioners with approved credentials and of whom you have reasonable confidence in their competence.

B10. Aesthetic practice

Aesthetic practice differs from other areas of medical practice in that the objective is not the improvement of patients' health but appearance. Patients who seek aesthetic procedures may be more vulnerable than others. Ethical aesthetic practice means :

(1) As aesthetic practice is not a recognised specialty, you must not mislead the public into thinking you are a specialist in aesthetic medicine. You must continue to make yourself known to the public only by the relevant SMC-approved designations.

(2) If you engage in aesthetic practice, you must ensure that the aesthetic procedures you offer go beyond mere non-maleficence (doing no harm). The treatments must be shown to be effective and safe and your practice must be licensed to provide them.

(3) You must take reasonable care to ensure that your patients do not have psychological or psychiatric illnesses involving self and body image before you provide aesthetic procedures to them.

(4) Because aesthetic practices do not cure or ameliorate disease and illness and aesthetic treatments are not medically necessary, the usual acceptable balance between benefit and harm to patients is modified and you must advise patients of side effects and adverse outcomes beyond those that are more common. For the purpose of obtaining consent, you must disclose risks that are lower than those required to be disclosed in conventional medicine.

(5) As all aesthetic procedures are elective, for the more invasive and surgical procedures, there must be a reasonable "cooling off" period between patients giving consent and the treatment, the duration being proportional to the invasiveness of the procedures and whether deep sedation or general anaesthesia is needed.

(6) You must not exploit patients' vulnerabilities and insecurities about self- esteem and perception of body image. When advertising or advising on aesthetic procedures, you must recognise patients' expectations and give objective and comprehensive information to patients about the procedures as well as what outcomes may be reasonably expected.

(7) You must not offer to or perform aesthetic procedures on minors or persons with diminished mental capacity, unless you have independent professional

assessments indicating that these procedures are indeed in these patients' best interests.

C Relationships with patients

C1. Attitude towards patients

A good patient-doctor relationship requires doctors to display a high standard of professional conduct in their dealings and interactions with patients. This means :

(1) You must treat patients with courtesy, consideration, compassion and respect and without coercion, discrimination, harassment or exploitation.

(2) You must always respect patients' right to privacy and dignity.

(3) You are not obliged to be subjected to abuse of any kind by patients or those with them. Yet, you must maintain a professional demeanour towards patients at all times. Except in cases of self-defence against physical harm, you must not retaliate but seek to end the engagement with the patients as quickly as possible.

C2. Good and effective communication

(1) An important part of the patient-doctor relationship is good communication to support patient autonomy, facilitate decision making by patients and to maximise the potential for patient benefit. Communicating well with patients means :

(2) You must engage in good communication with patients based on openness, truthfulness and honesty.

(3) You must not communicate in such a manner that your patients' welfare becomes compromised, patients are deprived of autonomy or suffer harm as a result of poor communication.

C3. Personal beliefs

(1) Doctors, as with all individuals would have your own personal beliefs. However, patients expect you to be objective when you provide medical care. This means setting aside prejudices when exercising clinical judgment. Responsibly handling your personal beliefs means :

(2) You must not foist your personal beliefs upon patients or express your beliefs in ways that exploit patients' vulnerabilities or are likely to cause distress or offence.

(3) If you have beliefs or conscientious objections that interfere with your ability to

offer otherwise legitimate or legal treatments, you must explain this to patients in an inoffensive and non-judgmental manner and inform them that they are free to seek medical treatment elsewhere. You may offer information to patients to help them if they request, so as not to leave them with nowhere to turn.

(4) In general, it is better not to personally provide spiritual counselling to your patients, to prevent misunderstanding and loss of objectivity. But if patients request it from you and you decide to personally provide spiritual counselling or support to your patients, you must ensure that your objectivity, judgment and professionalism in medical decision making are not compromised to patients' detriment.

(5) If patients out of their own beliefs request treatment which you deem not to be in their best interests or decline treatments which you deem to be in their best interests, you must first ensure that they have sufficient information to base their decisions upon. If patients continue to refuse necessary treatment despite your explanations, you must respect their decisions.

(6) If despite your best explanations patients persist in demanding treatment that you strongly disagree with, you may find yourself unable to continue providing care. In such a situation, you may terminate your relationship with the patients and offer to refer them to other doctors.

C4. Propriety and sexual boundaries

In order to uphold the trust that patients and the community repose in doctors, it is critical that you maintain propriety and observe appropriate boundaries in your relationships with patients. Having an inappropriate or sexual relationship with patients is unprofessional as it exploits the patient-doctor relationship and may cause profound psychological harm to patients and compromise their medical care. Maintaining propriety means :

(1) You must not breach sexual boundaries with your patients by inappropriate physical contact or any sexualised behaviour of any kind through words, gestures, actions or other behaviour designed to arouse sexual feelings or desires.

(2) When you need to ask intimate questions or examine intimate parts of the body, you must explain the need to do so and be sensitive to any discomfort or hesitancy on patients' part and reconsider your approach if they express discomfort.

(3) You must ensure that during clinical examination, your approach would leave

reasonable patients feeling safe, secure and comfortable in your presence, without any misconception or fear that their modesty is being compromised or that you are taking advantage of them for your own gratification.

(4) If your patients indicate that they would be more comfortable having a chaperone for clinical examination, or you assess them to be so, you must have a chaperone present. If in your judgment of the situation you are better protected if there is a chaperone, you may insist on having one present. If despite your explanations and reassurances patients object, you may decline to examine them until a mutually acceptable chaperone is available.

(5) When you need patients to undress for clinical examination, you must ensure their privacy.

(6) If patients exhibit sexualised behaviour towards you, you must not reciprocate. You must discourage such behaviour and if ultimately necessary, you may formally end the patientdoctor relationship.

C5. Patients' right to information and self-determination

Patient autonomy is a fundamental principle in medical ethics and must be respected. Patients are entitled to have accurate and sufficient information to be able to make their own decisions about their medical management. Respecting patients' autonomy means :

(1) You must provide adequate information in a manner that patients can understand so as to allow them to make informed choices.

(2) You must accept patients' decisions whether to accept any of the management options you offer even if you disagree with them, but you must ensure that patients have sufficient information to understand the consequences of their decisions.

(3) You must not deliberately deceive patients on any aspect of their diagnosis or management, but you must ensure that the information you give is presented in terms and at a pace that allows patients to assimilate, thereby enabling them to make informed decisions about their management.

(4) If family members request withholding of information from patients, you must not do so unless you assess that the patients will react in an extreme way which would cause them serious harm. You must explain to the family members your obligation not to deceive patients while being sympathetic to their concerns and

assuring them of your sensitivity in how you divulge information.

C6. Consent

An important part of patient autonomy involves ensuring that patients give their valid consent (if they are able to do so) to any treatment or procedure prior to their undergoing such treatment or procedure. This involves the patients making voluntary decisions on their medical care after having known and understood the benefits and risks involved. Good consent taking is essential and this means :

(1) Consent must be obtained for all aspects of medical care, whether it is minor interventions with minimal risks or major interventions with significant risks or side effects. For minor tests, treatments or procedures that have low risks, oral consent or implied consent through compliance is sufficient.

(2) You must take valid and adequately documented consent from patients for tests, treatments or procedures that are considered complex, invasive or have significant potential for adverse effects.

(3) You must ensure that patients are made aware of the purpose of tests, treatments or procedures to be performed on them, as well as the benefits, significant limitations, material risks (including those that would be important to patients in their particular circumstances) and possible complications as well as alternatives available to them.

(4) You must (to the best of your knowledge) inform patients about the persons who will be performing the tests, treatments or procedures that are invasive and carry higher risks. The more invasive or risky a test, treatment or procedure, the more specific and detailed must be the information about the persons conducting it.

(5) If patients consent to you performing any test, treatment or procedure under anaesthesia, you must not engage other persons to carry out the procedures on your behalf, or support your performance in a material way (excepting routine assistant surgeons), without patients' knowledge, unless it is an urgent or emergency situation.

(6) You must be clear about the scope of patients' consent. If there are likely to be further tests or treatments that are contingent upon your initial findings, you must explain this to your patients. Advance or anticipatory consent for such further procedures must be obtained if patients are going to be unable to participate in decision making at the time of your initial findings. You must be

clear about the limits to the range of options or alternatives that patients set in their consent.

(7) Patients must be made to understand that they may withdraw or modify their consent at any time. Unless you have reasons to believe that their judgment is impaired by illness, anaesthesia or temporary mental incapacity, you must respect patients' decisions to withdraw or change consent.

(8) You must either take consent personally or if it is taken for you by a team member, you must, through education, training and supervision of team members, ensure the quality of the consent taken on your behalf. In any case, you must ensure adequate documentation of the consent taking process where this involves more complex or invasive modalities with higher risks.

(9) You must ensure that patients understand the information you give for the purpose of consent. If there are language difficulties, you must use interpreters.

(10) Except in emergency situations, consent must be taken before a test or treatment, such that patients have sufficient time to think over their decisions and to clarify any doubts.

(11) You may proceed with treatment without consent in emergency situations when patients are not capable of giving consent and where you deem treatment is necessary in patients' best interests.

(12) If during a procedure you encounter situations in which you want to perform further procedures (that are not reasonable extensions of the procedure within the parameters of the consent) at the same sitting but the patient is unable to consent to it, you may proceed if you deem that the patient's life is at risk unless the further procedure is done immediately.

(13) You must respect patients' right to refuse consent for tests, treatments or procedures, except when it is evident that their judgment is impaired or their mental capacity so diminished that they cannot make choices about their own care.

(14) Despite it being standard practice that consent for minors is taken from parents or legal guardians, you must give consideration to the opinions of minors who are able to understand and decide for themselves.

(15) If there is disagreement about consent between minors with the capacity to consent and their parents or legal guardians, you must, to the best of your ability,

provide them with information and explain in a way that helps them to make more informed decisions.

(16) If minors who have the capacity to understand ultimately refuse to undergo tests, treatments or procedures consented to by parents or legal guardians, but you have good reasons to believe it is medically imperative for you to proceed, you may do so if it is feasible.

(17) If parents or legal guardians object to tests, treatments or procedures that you deem necessary despite your best explanations, you must act in the best interests of the minors and not of the parents. You may then have to take steps (such as going through independent advocates or the courts) in order to prevent harm to the minors.

(18) If patients are too young to understand but there are no parents or legal guardians available within reasonable time to give consent, you may proceed according to your best judgment of the patients' best interests.

(19) Taking consent from patients with diminished mental capacity must take into account the patients' residual or fluctuating cognitive ability. If patients can demonstrably understand, retain and use your information and explanations to make clear and consistent decisions and communicate them in a coherent manner, you must obtain consent from the patients themselves.

(20) If patients have such diminished mental capacity that they cannot give consent, you must obtain consent from persons with the legal authority to make such medical decisions for them unless such persons are not contactable within reasonable time depending on the urgency of the situation. Otherwise, you must proceed according to your best judgment of the patients' best interests.

C7. Medical confidentiality

Patients have a right to expect that any information provided to you in the context of clinical care be kept confidential, unless there are very good reasons for sharing the information. Upholding medical confidentiality means :

(1) You must maintain medical confidentiality unless patients consent for specific disclosure to other parties, save where the exceptions below apply.

(2) You must take reasonable care to ensure the security of the systems you use for storing medical records. If you are not in control of the systems, your duty is to use

the systems responsibly and comply with all the security protocols in place.

(3) You must not access confidential patient information if you are not involved in any aspect of the patients' care.

(4) You must not allow patients' confidential information to be disseminated knowingly or unknowingly through your carelessness or through your participation in social media.

(5) You must have sound justifications if you decide to disclose patients' information without consent. Disclosure without consent is generally defensible when it is mandated by law, it is necessary in order to protect patients or others from harm, when the involvement of parents and legal guardians is beneficial to minors or where such disclosure is in patients' best interests.

(6) When you disclose medical information, as you often must, in any court of law or SMC disciplinary proceedings or formal inquiries, you must do so only to the extent it is relevant to the discussion at hand. You must not disclose anything more than is necessary in the context of the case and must not use such information as a means to embarrass or otherwise pressurise any party involved.

(7) You must not refer to your patients' information beyond what is reasonable and relevant when you need to defend your reputation in the public domain.

(8) In the recruitment for and conduct of research, you must abide by the confidentiality requirements imposed by the Institutional Review Boards, and any other requirements under the ECEG, when handling information relating to research subjects.

(9) In teaching, you must make every reasonable effort (such as by clear briefings and instructions as to their obligations) to ensure that students or trainees only access patients' information for legitimate educational purposes. However, you must respect the rights of patients, or those legally responsible for making decisions for them, to decline to participate in teaching or give access to their information.

(10) Patients' information may be shared between those involved in their care to facilitate the best possible care. This includes providing information to one another when you delegate or refer patients, or when you give replies to your referring colleagues.

(11) If patients request withholding of information from those involved in their care, you must advise them of the possible adverse consequences of doing so. If they are

adamant, you must comply unless it is necessary to disclose this information to prevent harm to the patients, other healthcare professionals or the public.

(12) You must maintain the medical confidentiality of deceased patients except when: next of- kin or executors of the estates ask for information and you have no reason to believe that this would be against the wishes of the patients to divulge it; disclosure is required for legitimate clinical audit, education or research or disclosure is required in connection with Coroners' or other official inquiries.

C8. Caring for minors (persons below age 21)

Caring for minors comes with additional responsibilities due to concerns over their lack of ability to understand medical diagnoses and advice. This may affect their ability to make informed decisions on their care and to give valid consent. Minors may also be vulnerable and need protection. Providing good care to minors means :

(1) You must respect and uphold the minors' desire for privacy, their need to know about their medical conditions, to be heard, and to participate in decisions on their care.

(2) You must, together with parents or legal guardians, facilitate the minors' understanding, give them time to express themselves and then make decisions based on their best interests.

(3) You must maintain the medical confidentiality of minors except when you deem that it is in their best interests for their parents or legal guardians to be informed.

(4) If you have reasonable grounds to believe that the minors under your care are suffering from abuse or neglect, or while managing adult patients realise that minors in their care are so suffering, you must take steps necessary (such as reporting to the relevant authorities responsible for child protection) to protect the minors.

C9. Caring for patients with diminished mental capacity

Caring for patients with diminished mental capacity comes with additional responsibilities. Apart from their increased vulnerability arising from their diminished mental capacity, they may have fluctuating mental capacity (as opposed to an irreversible loss of such capacity) and this needs to be taken into account when decision making is required. Providing good care to patients with diminished mental capacity means :

(1) You must treat patients with diminished mental capacity with respect and recognise their rights, values and preferences.

(2) You must assess how much patients can understand given that they may have fluctuating or residual cognitive function that may well be sufficient to allow them to participate in decision making.

(3) If you determine that patients do not have sufficient cognitive function, you may consider the views of family, carers or those with legal authority to represent them, but in all cases, you must ascertain as best as you can what is in the patients' best interests and decide accordingly.

(4) You must be aware of the vulnerability of such patients to abuse, neglect or self-harm and if you have reasonable grounds for suspicions, you must either offer assistance to rectify this or report this to the relevant authorities.

C10. Visual or audio recordings of patients

Visual or audio recordings of patients are often made for legitimate purposes such as medical records, research or education. Ethical handling of such recordings means :

(1) You must ensure that visual or audio recordings do not compromise patients' privacy, dignity, confidentiality and autonomy.

(2) You must obtain patients' consent for recordings except where the recordings are an integral part of clinical assessment or treatment. You must allow patients to view or hear the recordings if they wish. If patients modify or withdraw their consent, you must abide by this.

(3) If you wish to use audio or visual patient recordings of patients for legitimate purposes that advance healthcare for the community, such as medical education and research, if there is any risk that patients can be identified, you must obtain specific consent. However, if you wish to use such recordings for these purposes without specific consent, you must take every reasonable measure to remove all identifiable characteristics and ensure that patient confidentiality and privacy will not be breached.

(4) You must obtain specific consent if you wish to use audio or visual recordings of patients anywhere in the public domain (such as advertising, public lectures or any kind of media output). On top of the need to obtain specific consent for such use, unless patients further consent to be identifiable, you must ensure that

patients' confidentiality and privacy will not be breached.

(5) You must within your ability ensure that the storage or transmission of the recording is secure and that no unauthorised persons have access to it. Such recordings must be accorded the same level of confidentiality protection as medical records.

(6) If patients are minors or have diminished mental capacity, you must where possible still obtain their consent. If that is not possible, you may obtain consent from parents, guardians or those with the legal authority to decide for them.

(7) You must not make surreptitious recordings (without patient knowledge or consent) unless there are special circumstances and it is in patients' best interests.

(8) You must not make surreptitious recordings of consultations or treatments with patients merely for the purpose of protecting yourself from possible complaints. If patients or accompanying persons ask to record your consultation, you may accede to this according to your judgment of the situation. If you suspect that you are being surreptitiously recorded, you have the right to refuse this.

(9) Where this is under your control, you must not place security cameras where patients' privacy and dignity will be compromised. If you control the use of security cameras for routine surveillance, you must ensure that the presence of the cameras is obvious in which case no specific consent need be taken from patients. You must ensure that access to the recordings is limited to authorised persons for legitimate purposes only (such as security staff or agencies) and that they keep the recordings confidential.

C11. Third parties in attendance

Occasionally, third parties may be present during your care of your patients. Such third parties must have legitimate reasons to be there. Responsible handling of such third party presence means:

(1) You must ensure that patients are comfortable with the presence of third parties during your care of patients and that such presence would not disrupt the patients' care.

(2) Unless the third parties are an obvious part of the healthcare team, you must explain to patients who the third parties are, why they are present and you must be sensitive to patients expressing discomfort about their presence and exclude the third parties if patients request to.

(3) Chaperones are a special category of third parties in attendance. If in your judgment of the situation you want a chaperone present for clinical examinations, you may insist on having one present. If, despite your explanations and reassurances, patients object, you may decline to examine them until another time when chaperones acceptable to both you and the patients are available.

C12. Relationships with patients and those close to them

To merit the trust reposed in you by your patients, you must not take advantage of your patients but must display a standard of behaviour towards them and those close to them that warrants their trust and respect. This means :

(1) You must not have personal relationships that are sexual, romantic or emotionally intimate with current patients.

(2) You must not enter into such personal relationships with ex-patients when they are still vulnerable to your influence.

(3) You must not discharge patients for the express purpose of entering into such relationships with them.

(4) You must not use your patient-doctor relationships as the means of entering into exploitative associations with patients and those close to patients.

(5) You must not breach professional boundaries by initiating social media relationships with your patients.

(6) If you choose to accept social media relationships with your patients who initiate this, you must not compromise your patient-doctor relationship by sharing anything that would breach patient confidentiality or privacy or through inappropriate words or behaviour towards patients.

(7) If you are active in social media, you must ensure that exposure of your personal life and your words and behaviour do not diminish your professional standing before patients or the public, or bring the profession as a whole into disrepute.

(8) You must not allow any business or financial relationships with patients, their families or those close to patients to jeopardise the patient-doctor relationship.

(9) You must not abuse or exploit the trust and confidence that patients, their families and those close to patients repose in you for your personal gain or gratification.

C13. Dealing with adverse outcomes and medical errors

When something goes wrong during your care of patients, you have a responsibility to put things right as quickly as possible. Responsible handling of such situations means :

(1) When an adverse outcome is identified, you must ameliorate harm, openly and honestly inform patients as soon as possible of the adverse outcome and possible consequences, report the outcomes as appropriate and not allow any complaint or investigation to prejudice your further care of the patients.

(2) You must take steps to understand the wider implications, if any, of the outcomes, and if possible, address them to prevent recurrences.

(3) You must not apportion blame in advance of a formal inquiry and if one is called, you must cooperate with the investigation and the inquiry procedures.

(4) If the patient's trust in you is lost due to an adverse outcome and it is the patient's wish, you may terminate the professional relationship. In such a situation, you must offer a smooth handover of care to another doctor.

C14. Termination of a patient-doctor relationship

You must strive to maintain good relationships with your patients where possible. In situations where it is impossible to continue your professional relationship with a patient, or if you are retiring or reducing your patient list, you may terminate the relationships properly. This means :

(1) If the patient-doctor relationship is so compromised or rendered so ineffective that you feel unable to continue to provide care for the patients, you must explain this to patients before terminating the relationship.

(2) You must offer to refer the patients to other doctors and facilitate a smooth handover of care by providing the new doctors with the necessary medical information and continuing to provide essential care, if patients want, until the care has been properly taken over.

(3) If you are retiring or withdrawing from practice, or reducing your patient list, you must where possible ensure that patients that require continued care are informed in advance so that they can make arrangements to transfer their care to another doctor. You must offer to facilitate this process by transferring medical records (or providing medical reports), with patients' consent, to their new doctors and making provisions for continued care until such transfer is effected.

INDIA

INDIA

The Constitution of India does not expressly guarantee a fundamental right to health. There are however multiple references in the Constitution to public health and on the role of the State for providing adequate healthcare to all the citizens. The subject of "public health and sanitation; hospitals and dispensaries" falls under the State list of the 7th Schedule of the Constitution of India, which means that State Governments enjoy constitutional directives to adopt, enact and enforce public health regulations. The laws governing rights of people who approach healthcare establishments or medical professionals in India include:-

- ***The Constitution of India, 1950***
- ***Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002***
- ***Drugs and Cosmetics Act, 1940***
- ***Clinical Establishment (Registration and Regulation) Act, 2010***
- ***Indian Penal Code, 1860 and Code of Criminal Procedure, 1973.***

These laws guide medical health professionals in maintaining a standard of care and treatment for patients. The Ministry of Health and Family Welfare, in 2018, released the Charter of Patients' Rights that contains 17 basic rights of patients. This Draft Charter was prepared by the National Human Rights Commission (NHRC) and draws its inspiration from various national and international legislations, relevant rules and standards framed under different charters and judgments delivered by various legal forums. This was done with a view to help the patients identify their rights through a single, more accessible document. Each of the patient rights is accompanied by a detailed description, reference documents giving justification for the same and identification of the duty bearer responsible for fulfilling this right in the context of any healthcare establishment.

In June 2019, the Charter of Patients' Rights was forwarded to the State Governments by the Ministry of Health and Family Welfare, Government of India recommending its adoption so that the basic and common grievances of patients and clinical establishments are addressed. Many State Governments and hospitals have adopted the Charter of Patients' Rights but the Charter is not legally enforceable

throughout India. The rights contained therein however, have been enforced through different legal forums under various statutes. The Supreme Court and the High Courts have enforced the rights through their writ jurisdictions under the Constitution of India. The Consumer Forums recognize some of the violations of patients' rights enumerated in the Charter as deficiency of service under the Consumer Protection Act. Under the Right to Information Act, the right to be informed and the right to access medical records have been recognized as being covered under the ambit of the Act and all the government hospitals are therefore bound by the Act to provide information and medical records to a patients under the Act.

In September 2019, a High-Level Group on the health sector constituted under the 15th Finance Commission recommended declaration of right to health as a fundamental right. It also suggested shifting the subject of 'health' from State list to Concurrent List. The recommendation to declare right to health as a fundamental right, if implemented, will strengthen people's access to healthcare facilities.

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CHARTER OF PATIENTS' RIGHTS

(As drafted by the NHRC)

Patients' Rights are Human Rights!

Preamble

The Universal Declaration of Human Rights (1948) emphasizes the fundamental dignity and equality of all human beings. Based on this concept, the notion of Patient Rights has been developed across the globe in the last few decades. There is a growing consensus at international level that all patients must enjoy certain basic rights. In other words, the patient is entitled to certain amount of protection to be ensured by physicians, healthcare providers and the State, which have been codified in various societies and countries in the form of Charters of Patient's Rights. In India, there are various legal provisions related to Patient's Rights which are scattered across different legal documents e.g. The Constitution of India, Article 21, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002; The Consumer Protection Act 1986; Drugs and Cosmetic Act 1940, Clinical Establishment Act 2010 and rules and standards framed therein; various judgments given by Hon'ble Supreme Court of India and decisions of the National Consumer Disputes Redressal Commission.

This Charter of Patient's Rights adopted by the National Human Rights Commission draws upon all relevant provisions, inspired by international charters and guided by national level provisions, with the objective of consolidating these into a single document, thereby making them publicly known in a coherent manner. There is an expectation that this document will act as a guidance document for the Union Government and State Governments to formulate concrete mechanisms so that Patient's Rights are given adequate protection and operational mechanisms are set up to make these rights functional and enforceable by law. This is especially important and an urgent need at the present juncture because India does not have a dedicated regulator like other countries and the existing regulations in the interest of patients, governing the healthcare delivery system is on the anvil, some States have adopted the national Clinical Establishments Act 2010, certain other States have enacted their own State level legislations like the Nursing Homes Act to regulate hospitals, while a few other States are in the process of adopting / developing such regulation. The Charter of Patient's Rights has been drafted with the hope that it shall be incorporated by policy

makers in all existing and emerging regulatory legislations concerning the health care sector. This charter would also enable various kinds of health care providers to actively engage with this framework of patients' rights to ensure their observance, while also benefiting from the formal codification of patients responsibilities.

Another objective of this Charter is to generate widespread public awareness and educate citizens regarding what they should expect from their governments and health care providers-about the kind of treatment they deserve as patients and human beings, in health care settings. NHRC firmly believes that informed and aware citizens can play a vital role in elevating the standard of health care, when they have guidance provided by codified rights, as well as awareness of their responsibilities.

NHRC believes that this Charter of Patients' Rights will be an enabling document to nsure the protection and promotion of Human rights of those who are among some of the most vulnerable sections of society – ordinary patients and citizens seeking health care across India.

1. Right to information

Every patient has a right to adequate relevant information about the nature, cause of illness provisional / confirmed diagnosis, proposed investigations and management, and possible complications To be explained at their level of understanding in language known to them.

The treating physician has a duty to ensure that this information is provided in simple and intelligible language to the patient to be communicated either personally by the physician, or by means of his / her qualified assistants.

Every patient and his/her designated caretaker have the right to factual information regarding the expected cost of treatment based on evidence. The hospital management has a duty to communicate this information in writing to the patient and his/her designated caretaker. They should also be informed about any additional cost to be incurred due to change in the physical condition of the patient or line of treatment in writing. On completion of treatment, the patient has the right to receive an itemized bill, to receive an explanation for the bill(s) regardless of the source of payment or the mode of payment, and receive payment receipt(s) for any payment made.

Patients and their caretakers also have a right to know the identity and professional status of various care providers who are providing service to him / her and to know which Doctor / Consultant is primarily responsible for his / her

care. The hospital management has a duty to provide this information routinely to all patients and their caregivers in writing with an acknowledgement

References

(1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

(2) MCI Code of Ethics

(3) Patients Charter by National Accreditation Board for Hospitals (NABH)

(4) The Consumer Protection Act, 1986

2. Right to records and reports

Every patient or his caregiver has the right to access originals / copies of case papers, indoor patient records, investigation reports (during period of admission, preferably within 24 hours and after discharge, within 72 hours). This may be made available wherever applicable after paying appropriate fees for photocopying or allowed to be photocopied by patients at their cost. The relatives / caregivers of the patient have a right to get discharge summary or in case of death, death summary along with original copies of investigations. The hospital management has a duty to provide these records and reports and to instruct the responsible hospital staff to ensure provision of the same are strictly followed without fail.

References

(1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

(2) MCI Code of Ethics section1.3.2

(3) Central Information Commission judgment, Nisha Priya Bhatia Vs. Institute of HB&AS, GNCTD, 2014

(4) The Consumer Protection Act, 1986

3. Right to Emergency Medical Care

As per Supreme Court, all hospitals both in the government and in the private sector are duty bound to provide basic Emergency Medical Care, and injured persons have a right to get Emergency Medical Care. Such care must be initiated without demanding payment / advance and basic care should be provided to the

patient irrespective of paying capacity.

It is the duty of the hospital management to ensure provision of such emergency care through its doctors and staff, rendered promptly without compromising on the quality and safety of the patients.

References

(1) Supreme court judgment Parmanand Katara v. Union of India (1989)

(2) Judgment of National Consumer Disputes Redressal Commission Pravat Kumar Mukherjee v. Ruby General Hospital & Others (2005)

(3) MCI Code of Ethics sections 2.1 and 2.4

(4) Article 21 of the Constitution 'Right to Life'

4. Right to informed consent

Every patient has a right that informed consent must be sought prior to any potentially hazardous test/treatment (e.g. invasive investigation / surgery / chemotherapy) which carries certain risks.

It is the duty of the hospital management to ensure that all concerned doctors are properly instructed to seek informed consent, that an appropriate policy is adopted and that consent forms with protocol for seeking informed consent are provided for patients in an obligatory manner.

It is the duty of the primary treating doctor administering the potentially hazardous test / treatment to explain to the patient and caregivers the main risks that are involved in the procedure, and after giving this information, the doctor may proceed only if consent has been given in writing by the patient / caregiver or in the manner explained under Drugs and Cosmetic Act Rules 2016 on informed consent.

References

(1) MCI Code of Ethics section 7.16

(2) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

(3) The Consumer Protection Act, 1986

(4) Drugs and Cosmetic Act 1940, Rules

(5) 2016 on Informed Consent

5. Right to confidentiality, human dignity and privacy

All patients have a right to privacy, and doctors have a duty to hold information about their health condition and treatment plan in strict confidentiality, unless it is essential in specific circumstances to communicate such information in the interest of protecting other or due to public health considerations.

Female patients have the right to presence of another female person during physical examination by a male practitioner. It is the duty of the hospital management to ensure presence of such female attendants in case of female patients. The hospital management has a duty to ensure that its staff upholds the human dignity of every patient in all situations. All data concerning the patient should be kept under secured safe custody and insulated from data theft and leakage.

References

(1) MCI Code of Ethics sections 2.2, 7.14 and 7.17.

(2) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

6. Right to second opinion

Every patient has the right to seek second opinion from an appropriate clinician of patients' / caregivers' choice. The hospital management has a duty to respect the patient's right to second opinion, and should provide to the patients caregivers all necessary records and information required for seeking such opinion without any extra cost or delay.

The hospital management has a duty to ensure that any decision to seek such second opinion by the patient / caregivers must not adversely influence the quality of care being provided by the treating hospital as long as the patient is under care of that hospital. Any kind discriminatory practice adopted by the hospital or the service providers will be deemed as Human Rights' violation.

References

(1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

(2) The Consumer Protection Act, 1986

7. Right to transparency in rates, and care according to prescribed rates wherever relevant

Every patient and their caregivers have a right to information on the rates to be charged by the hospital for each type of service provided and facilities available on a prominent display board and a brochure. They have a right to receive an itemized detailed bill at the time of payment. It would be the duty of the Hospital / Clinical Establishment to display key rates at a conspicuous place in local as well as English language, and to make available the detailed schedule of rates in a booklet form to all patients / caregivers.

Every patient has a right to obtain essential medicines as per India Pharmacopeia, devices and implants at rates fixed by the National Pharmaceutical Pricing Authority (NPPA) and other relevant authorities. Every patient has a right to receive health care services within the range of rates for procedures and services prescribed by Central and State Governments from time to time, wherever relevant. However, no patient can be denied choice in terms of medicines, devices and standard treatment guidelines based on the affordability of the patients' right to choice.

Every hospital and clinical establishment has a duty to ensure that essential medicines under NLEM as per Government of India and World Health Organisation, devices, implants and services are provided to patients at rates that are not higher than the prescribed rates or the maximum retail price marked on the packaging.

References

(1) MCI Code of Ethics section 1.8 regarding Payment of Professional Services

(2) Section 9(i) and 9(ii) of Clinical establishments (Central Government) Rules 2012

(3) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

(4) Various Drug price control orders

(5) The Consumer Protection Act, 1986

(6) Drugs Price Control Order (DPCO) section 3 of the Essential Commodities Act, 1955

8. Right to non-discrimination

Every patient has the right to receive treatment without any discrimination based on his or her illnesses or conditions, including HIV status or other health condition, religion, caste, ethnicity, gender, age, sexual orientation, linguistic or geographical /social origins.

The hospital management has a duty to ensure that no form of discriminatory behaviour or treatment takes place with any person under the hospital's care. The hospital management must regularly orient and instruct all its doctors and staff regarding the same.

References

(1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

9. Right to safety and quality care according to standards

Patients have a right to safety and security in the hospital premises. They have a right to be provided with care in an environment having requisite cleanliness, infection control measures, safe drinking water as per BIS/FSSAI Standards and sanitation facilities. The hospital management has a duty to ensure safety of all patients in its premises including clean premises and provision for infection control. Patients have a right to receive quality health care according to currently accepted standards, norms and standard guidelines as per National Accreditation Board for Hospitals (NABH) or similar. They have a right to be attended to, treated and cared for with due skill, and in a professional manner in complete consonance with the principles of medical ethics. Patients and caretakers have a right to seek redressal in case of perceived medical negligence or damaged caused due to deliberate deficiency in service delivery.

The hospital management and treating doctors have a duty to provide quality health care in accordance with current standards of care and standard treatment guidelines and to avoid medical negligence or deficiency in service delivery system in any form.

References

(1) Clinical establishments (Central Government) Rules 2012

(2) The Consumer Protection Act, 1986

10. Right to choose alternative treatment options if available

Patients and their caregivers have a right to choose between alternative treatment / management options, if these are available, after considering all aspects of the situation. This includes the option of the patient refusing care after considering all available options, with responsibility for consequences being borne by the patient and his/her caregivers. In case a patient leaves a healthcare facility against medical advice on his / her own responsibility, then notwithstanding the impact that this may have on the patient's further treatment and condition, this decision itself should not affect the observance of various rights mentioned in this charter.

The hospital management has a duty to provide information about such options to the patient as well as to respect the informed choice of the patient and caregivers in a proper recorded manner with due acknowledgement from the patient or the caregivers on the communication and the mode.

References

(1) Annexure 8 of standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical Establishment Act 2010

(2) The Consumer Protection Act, 1986

11. Right to choose source for obtaining medicines or tests

When any medicine is prescribed by a doctor or a hospital, the patients and their caregivers have the right to choose any registered pharmacy of their choice to purchase them. Similarly when a particular investigation is advised by a doctor or a hospital, the patient and his caregiver have a right to obtain this investigation from any registered diagnostic centre/laboratory having qualified personnel and accredited by National Accreditation Board for Laboratories (NABL).

It is the duty of every treating physician / hospital management to inform the patient and his caregivers that they are free to access prescribed medicines / investigations from the pharmacy / diagnostic centre of their choice. The decision by the patient / caregiver to access pharmacy / diagnostic centre of their choice must not in any ways adversely influence the care being provided by the treating physician or hospital.

References

(1) Various judgments by the National Consumer Dispute Redressal Commission

(2) The Consumer Protection Act, 1986

12. Right to proper referral and transfer, which is free from perverse commercial influences

A patient has the right to continuity of care, and the right to be duly registered at the first healthcare facility where treatment has been sought, as well as at any subsequent facilities where care is sought. When being transferred from one healthcare facility to another, the patient / caregiver must receive a complete explanation of the justification for the transfer, the alternative options for a transfer and it must be confirmed that the transfer is acceptable to the receiving facility. The patient and caregivers have the right to be informed by the hospital about any continuing healthcare requirements following discharge from the hospital. The hospital management has a duty to ensure proper referral and transfer of patients regarding such a shift in care.

In regard to all referrals of patients, including referrals to other hospitals, specialists, laboratories or imaging services, the decision regarding facility to which referral is made must be guided entirely by the best interest of the patient. The referral process must not be influenced by any commercial consideration such as kickbacks, commissions, incentives, or other perverse business practices.

References

(1) Medical Council of India code of ethics section 3.6

(2) World Health Organisation – Referral Notes

(3) Various IPHS documents

13. Right to protection for patients involved in clinical trial

Every person / patient who is approached to participate in a clinical trial has a right to due protection in this context. All clinical trials must be conducted in compliance with the protocols and Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organisation, Directorate General of Health Services, Govt. of India as well as all applicable statutory provisions of Amended Drugs and Cosmetics Act, 1940 and Rules, 1945, including observance of the following provisions related to patients rights:

a) Participation of patients in clinical trials must always be based on informed consent, given after provision of all relevant information. The patient must

be given a copy of the signed informed consent form, which provides him / her with a record containing basic information about the trial and also becomes documentary evidence to prove their participation in the trial.

b) A participant's right to agree or decline consent to take part in a clinical trial must be respected and her/his refusal should not affect routine care.

c) The patient should also be informed in writing about the name of the drug / intervention that is undergoing trial along with dates, dose and duration of administration.

d) At all times, the privacy of a trial participant must be maintained and any information gathered from the participant must be kept strictly confidential.

e) Trial participants who suffer any adverse impact during their participation in a trial are entitled to free medical management of adverse events, irrespective of relatedness to the clinical trial, which should be given for as long as required or till such time as it is established that the injury is not related to the clinical trial. In addition, financial or other assistance must be given to compensate them for any impairment or disability. In case of death, their dependents have the right to compensation.

f) Ancillary care may be provided to clinical trial participants for non-study/trial related illnesses arising during the period of the trial. This could be in the form of medical care or reference to facilities, as may be appropriate.

g) Institutional mechanisms must be established to allow for insurance coverage of trial related or unrelated illnesses (ancillary care) and award of compensation wherever deemed necessary by the concerned Ethics Committee.

h) After the trial, participants should be assured of access to the best treatment methods that may have been proven by the study.

Any doctor or hospital who is involved in a clinical trial has a duty to ensure that all these guidelines are followed in case of any persons / patients involved in such a trial.

References

(1) Protocols and Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organisation, Directorate General of Health Services, Govt. of India

(2) Amended Drugs and Cosmetics Act, 1940 and Rules, 1945 especially schedule Y

(3) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research, New Delhi, 2017

(4) World Medical Assembly Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects available at www.wma.net/ en/ 30publications/ 10policies/b3/17c.pdf

14. Right to protection of participants involved in biomedical and

Every patient who is taking part in biomedical research shall be referred to as research participant and every research participant has a right to due protection in this context. Any research involving such participants should follow the National Ethical Guidelines for Biomedical and Health Research Involving Human health research Participants, 2017 laid down by Indian council for Medical Research and should be carried out with prior approval of the Ethics Committee.

Documented informed consent of the research participants should be taken. Additional safeguards should be taken in research involving vulnerable population. Right to dignity, right to privacy and confidentiality of individuals and communities should be protected.

Research participants who suffer any direct physical, psychological, social, legal or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability.

The benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant. New Delhi, 2017 Any doctor or hospital who is involved in biomedical and health research involving patients has a duty to ensure that all these guidelines are followed in case of any persons / patients involved in such research.

References

(1) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Indian Council of Medical Research,

(2) World Medical Assembly Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects available at www.wma.net/en/ 30publications/ 10policies/b3/17c.pdf

(3) Drugs & Cosmetic Act, Rules 2016 on Clinical Trails

15. Right to take discharge of patient, or receive body of deceased from hospital

A patient has the right to take discharge and cannot be detained in a hospital, on procedural grounds such as dispute in payment of hospital charges. Similarly, caretakers have the right to the dead body of a patient who had been treated in a hospital and the dead body cannot be detailed on procedural grounds, including nonpayment/dispute regarding payment of hospital charges against wishes of the caretakers.

The hospital management has a duty to observe these rights and not to indulge in wrongful confinement of any patient, or dead body of patient, treated in the hospital under any circumstances.

References

(1) Prohibition of wrongful confinement under Sec. 340-342 of IPC. Statements of Mumbai High Court.

(2) Consumer Protection Act 1986

16. Right to Patient Education

Patients have the right to receive education about major facts relevant to his/her condition and healthy living practices, their rights and responsibilities, officially supported health insurance schemes relevant to the patient, relevant entitlements in case of charitable hospitals, and how to seek redressal of grievances in the language the patients understand or seek the education.

The hospital management and treating physician have a duty to provide such education to each patient according to standard procedure in the language the patients understand and communicate in a simple and easy to understand manner

References

(1) The Consumer Protection Act, 1986

(2) Standards for Hospital level 1 by National Clinical Establishments Council set up as per Clinical

(3) Establishment Act 2010

17. Right to be heard and seek redressal

Every patient and their caregivers have the right to give feedback, make comments, or lodge complaints about the health care they are receiving or had received from a doctor or hospital. This includes the right to be given information and advice on how to give feedback, make comments, or make a complaint in a simple and user-friendly manner.

Patients and caregivers have the right to seek redressal in case they are aggrieved, on account of infringement of any of the above mentioned rights in this charter. This may be done by lodging a complaint with an official designated for this purpose by the hospital / healthcare provider and further with an official mechanism constituted by the government such as Patients' Responsibilities rights Tribunal Forum or Clinical establishments regulatory authority as the case may be. All complaints must be registered by providing a registration number and there should be a robust tracking and tracing mechanism to ascertain the status of the complaint resolution.

The patient and caregivers have the right to a fair and prompt redressal of their grievances. Further, they have the right to receive in writing the outcome of the complaint within 15 days from the date of the receipt of the complaint.

Every hospital and clinical establishment has the duty to set up an internal redressal mechanism as well as to fully comply and cooperate with official redressal mechanisms including making available all relevant information and taking action in full accordance with orders of the redressal body as per the Patient's Right Charter or as per the applicable existing laws.

References

(1) The Consumer Protection Act, 1986

(2) NHS - Charter of Patient Rights and Responsibilities of patients and caretakers

Along with promoting their rights, patients and caretakers should follow their responsibilities so that hospitals and doctors can perform their work satisfactorily.

1) Patients should provide all required health related information to their doctor, in response to the doctor's queries without concealing any relevant information, so that diagnosis and treatment can be facilitated.

2) Patients should cooperate with the doctor during examination, diagnostic tests and treatment, and should follow doctor's advice, while keeping in view their right to participate in decision making related to treatment.

3) Patients should follow all instructions regarding appointment time, cooperate with hospital staff and fellow patients, avoid creating disturbance to other patients, and maintain cleanliness in the hospital.

4) Patients should respect the dignity of the doctor and other hospital staff as human beings and as professionals. Whatever the grievance may be, patient / caregivers should not resort to violence in any form and damage or destroy any property of the hospital or the service provider.

5) The Patients should take responsibility for their actions based on choices made regarding treatment options, and in case they refuse treatment.

Recommended mechan ism for implementation of Charter of Patient's Right s and Grievance redressal mechanism

NHRC recommends to the Government of India, all State Governments and Administration of all the Union Territories that they should seriously consider the adoption of the charter and incorporate this Charter of Patients' Rights in the entire range of existing and emerging regulatory frameworks concerning the health care sector, under their jurisdiction.

Further NHRC recommends that all State Human Rights Commissions should adopt the Charter of Patients' Rights to be treated as a reference document in all cases related to human rights violations concerning patients and all users of health care

services.

NHRC further recommends that all administrative and regulatory authorities completely or partially related with the healthcare sector, including but not limited to the following should incorporate and promote implementation of the Charter of Patient's Rights within their jurisdiction wherever applicable.

1. Ministry of Health and Family Welfare, Government of India
2. Public Health and Family Welfare Departments in all States and UTs
3. Medical Education Department of States and UTs, wherever they exist
4. Executive/Managing authorities of all publicly funded healthcare insurance schemes and Public-Private-Partnership arrangements in healthcare by Government of India, all State Governments and administrations in all UTs
5. National Council for Clinical Establishments
6. State Councils for Clinical Establishments, wherever applicable
7. Authorities established under State Nursing Home Acts or equivalent acts, wherever applicable
8. Medical Council of India / National Medical Commission or equivalent body
9. State Medical Councils in all States and UTs
10. Central Council of Indian Medicine
11. State Councils for Indian Medicine in all States and UTs
12. Any other healthcare related statutory councils established in all States and UTs
13. Central Consumer Protection Council, all State and District consumer protection councils
14. Registrar of Societies in all States and UTs, in the context of non-profit clinical establishments
15. Charity Commissioner in those States wherever applicable, in the context of non-profit clinical establishments
16. Department of Religious and Charitable Endowments in those States wherever applicable, in the context of non-profit clinical establishments
17. Registrar of Companies, in the context of for-profit hospitals run by companies and nonprofit clinical establishments run by companies registered under Section 25

18. Central Drugs and Standard Control Organisation, Ministry of Health & Family Welfare, Government of India

19. Quality Council of India, New Delhi

20. Department of Consumer Affairs, Ministry of Consumer Affairs, Food & Public Distribution, Government of India

Once the Patients' Rights Charter has been adopted by the Govt. of India, State Governments and the Administration of the Union Territories, they may stipulate/ensure that all types of Clinical Establishments (both therapeutic and diagnostic) display this Charter prominently within their premises, orient all their staff and consultants regarding the Charter, and observe the Charter of Patients' Rights in letter and spirit irrespective of whether such clinical establishment is owned, controlled or managed by

i. the Government or a department of the Government;

ii. a trust, whether public or private;

iii. a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government;

iv. a privately owned enterprise;

v. a local authority

Further, NHRC recommends to the Government of India, all State Governments and administration of Union Territories to ensure the setting up of a grievance redressal mechanism for patients, as a component of their existing or emerging regulatory frameworks for clinical establishments, by making required modifications in rules, regulations and acts where required. Observance of patients' rights and setting up of grievance redressal mechanism for protection of these Rights should be made an integral component of the implementation of Clinical Establishment (Registration and Regulation) Act 2010 in those states who have adopted it, or as a component of state specific regulatory frameworks for clinical establishments in other states, which have equivalent state specific legislations, or are planning to enact state specific legislations to regulate clinical establishments.

NHRC recommends that Patients' rights grievance redressal mechanisms should have the following components-

1. Every clinical establishment should set up an internal grievance redressal mechanism. First, patients may file a complaint with an authorized representative

who can be named 'Internal Grievance Redressal Officer' of the clinical establishment, either individually in person through an authorized representative or collectively through a consumer group or civil society organization. The clinical establishment's Internal Grievance Redressal Officer shall consider the complaint and try to find an appropriate solution, keeping in view the provisions of the Patients' Rights Charter and promptly acknowledge the receipt of the complaint within 24 hours by assigning a registration number for tracking and tracing the status of the complaint.

2. If a solution acceptable to the patient is not found at the level of the clinical establishment and the patient/representative is not satisfied, then he/she may approach the office of the district level registering authority set up under Clinical Establishment (Registration and Regulation) Act 2010 in those States who have adopted it, or equivalent district level authorities created under the State specific clinical establishments act or similar regulatory frameworks for clinical establishments in other states which have other State specific legislations. The district level registering authority shall verify the facts of the matter, and where there is clear violation of patient's rights as brought out facts, the registering authority may issue necessary executive orders to the clinical establishment for rectification. If there is any dispute over interpretation of Charter of Patient's Rights and provisions in the regulatory framework, the registering authority may clarify the procedure, rules, regulations and attempt to resolve the complaint through mediation between both parties within 30 days from the date of receipt of the appeal.

3. In case of any particular complaint, if even after completing the above mentioned procedure, the patient or his/her representative is not satisfied, then he/she can file appeal before the State Council of Clinical Establishments under Clinical Establishment (Registration and Regulation) Act 2010 in those states who have adopted the Act. Section 8(5)(e) empowers the 'State Council for Clinical Establishments' to hear appeals against the orders of the District Registering Authority set up under CEA 2010. 'State Council of Clinical Establishment' can set up a three or five member sub-committee / cell (with multi-stakeholder participation) which can be named as 'Healthcare Grievance Redressal Authority' for resolution of patient's grievances, and pass rectification orders or disciplinary orders or punitive orders which would be binding upon the clinical establishments within the framework of CEA within 30 days from the date of

receipt of the appeal. The complaints procedure to be set up under the State Council of Clinical Establishments should explicitly state that it is not intended as a means of achieving monetary compensation.

4. Apart from the above mentioned grievance redressal mechanisms, patients/ representatives would always be free to approach the State Medical Council to seek disciplinary action against unethical conduct of any specific doctor, and also free to approach Consumer Forums at various levels to seek financial compensation, or approach Civil/Criminal Courts keeping in view the nature of the complaint i.e., creation of a separate grievance redressal machinery to deal with violations of Patients' Rights Charter shall in no way either extinguish or affect adversely the existing legal remedies both civil and criminal available to patients and their caregivers under the existing legal framework.

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CHAPTER - II

JUDICIAL TREND CONCERNING PATIENTS' RIGHTS

RIGHT TO BE INFORMED

A UNITED STATES OF AMERICA

I. Canterbury v. Spence 464 F.2d. 772 (1972)

Court : **United States Courts of Appeals, District of Columbia Circuit**

Coram : **Wright, Leventhal and Robinson, Circuit Judges**

Facts

Jerry Watson Canterbury suffered a ruptured disk in 1958 and was operated by Dr. William T. Spence who was a well-known neurosurgeon. As a result of the surgery and a subsequent fall from his bed while hospitalized, Canterbury ended up paralyzed below the waist and incontinent.

Canterbury sought damages for personal injuries sustained as a result of an operation negligently performed, a negligent failure to disclose the risk of serious disability inherent in the operation and negligent post-operative care. The district court decided in favour of the physicians on the grounds that the patient had failed to produce any medical evidence indicating negligence on the physicians' part in diagnosing the Patients' malady or in performing the operation. The patient sought review of the judgment entered in the District Court on verdicts directed for the two physicians at the conclusion of the Patients' case in chief.

On appeal, the court held that Canterbury in his testimony and that of his mother, made out a prima facie case that the physician violated his duty to disclose the risk of paralysis from the operation. The physician's non-compliance with a professional custom to reveal like any other departure from prevailing medical practice, may give rise to liability to the patient. The court held that there was testimony from which the jury could have found that the physician negligently performed the operation. The record also contained sufficient evidence to submit to the jury the issues of whether and to what extent any such negligence causally related to the Patients' post-operative condition. The court held that these considerations entitled the patient to a new trial. Accordingly, the court reversed the judgment of the district court.

Decision

Allowing the application, the Court held -

It is well established that the physician must seek and secure his Patients' consent before commencing an operation or other course of treatment. It is also clear that the consent, to be efficacious, must be free from imposition upon the patient. It is the settled rule that therapy not authorized by the patient may amount to a tort -- a common law battery -- by the physician. And it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the Patients' edification. Thus the physician has long borne a duty, on pain of liability for unauthorized treatment, to make adequate disclosure to the patient. The evolution of the obligation to communicate for the Patients' benefit as well as the physician's protection has hardly involved an extraordinary restructuring of the law.

Once the circumstances give rise to a duty on the physician's part to inform his patient, the next inquiry is the scope of the disclosure the physician is legally obliged to make. The courts have frequently confronted this problem but no uniform standard defining the adequacy of the divulgence emerges from the decisions. Some have said "full" disclosure, a norm we are unwilling to adopt literally. It seems obviously prohibitive and unrealistic to expect physicians to discuss with their patients every risk of proposed treatment -- no matter how small or remote and generally unnecessary from the Patients' viewpoint as well.

In our view, the Patients' right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the Patients' need, and that need is the information material to the decision. Thus the test for determining whether a particular peril must be divulged is its materiality to the Patients' decision: all risks potentially affecting the decision must be unmasked. And to safeguard the Patients' interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure.

II. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261

Court: **United States District Court for the Western District of Pennsylvania**

Coram: **Rehnquist, C.J., White, O'Connor, Scalia, Kennedy, Brennan, Marshall, Blackmun, Stevens, JJ.**

Facts

In 1983, Nancy Cruzan lost control of her vehicle and was thrown into a ditch with standing water. She was found lying face-down in the water, and no vital signs were initially observed by the paramedics who came to the scene. The paramedics resuscitated Cruzan, and she received further treatment from hospital staff as she spent the next three weeks in a coma. Doctors told her family that she was likely to remain permanently in a vegetative state, but her life could be preserved for a substantial time by using a feeding tube, generally, a condition in which a person exhibits motor reflexes but evinces no indications of significant cognitive function. The State was bearing the cost of her care. Hospital employees refused, without court approval, to honour the request of Cruzan's parents to terminate her artificial nutrition and hydration, since that would result in death. A state trial court authorized the termination, finding that a person in Cruzan's condition has a fundamental right under the State and Federal Constitutions to direct or refuse the withdrawal of death-prolonging procedures, and that Cruzan's expression to a former housemate that she would not wish to continue her life if sick or injured unless she could live at least halfway normally suggested that she would not wish to continue on with her nutrition and hydration which would be a consent on her part to refuse treatment.

Decision

The Court held -

6. *At common law, even the touching of one person by another without consent and without legal justification was a battery. Before the turn of the century, this Court observed that "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." Union Pacific R. Co. v. Botsford, 141 U.S. 250 (1891). This notion of bodily integrity has been*

embodied in the requirement that informed consent is generally required for medical treatment. Justice Cardozo, while on the Court of Appeals of New York, aptly described this doctrine: "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 Patients' consent commits an assault, for which he is liable in damages." Schloendorff v. Society of New York Hospital, 211 N.Y. 125 (1914). The informed consent doctrine has become firmly entrenched in American tort law.

7. *The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment. Until about 15 years ago and the seminal decision in In re Quinlan, 70 N.J. 10, Garger v. New Jersey, 429 U.S. 922 (1976), the number of right-to-refuse-treatment decisions was relatively few. Most of the earlier cases involved patients who refused medical treatment forbidden by their religious beliefs, thus implicating First Amendment rights as well as common-law rights of self-determination. More recently, however, with the advance of medical technology capable of sustaining life well past the point where natural forces would have brought certain death in earlier times, cases involving the right to refuse life sustaining treatment have burgeoned.*

32. *No doubt is engendered by anything in this record but that Nancy Cruzan's mother and father are loving and caring parents. If the State were required by the United States Constitution to repose a right of "substituted judgment" with anyone, the Cruzans would surely qualify. But we do not think the Due Process Clause requires the State to repose judgment on these matters with anyone but the patient herself. Close family members may have a strong feeling-a feeling not at all ignoble or unworthy, but not entirely disinterested, either-that they do not wish to witness the continuation of the life of a loved one which they regard as hopeless, meaningless, and even degrading. But there is no automatic assurance that the view of close family members will necessarily be the same as the Patients' would have been had she been confronted with the prospect of her situation while competent. All of the reasons previously discussed for allowing Missouri to*

require clear and convincing evidence of the Patients' wishes lead us to conclude that the State may choose to defer only to those wishes, rather than confide the decision to close family members.

61. *The right to be free from medical attention without consent, to determine what shall be done with one's own body, is deeply rooted in this Nation's traditions, as the majority acknowledges. This right has long been "firmly entrenched in American tort law" and is securely grounded in the earliest common law. "Anglo-American law starts with the premise of thorough-going self determination. It follows that each man is considered to be master of his own body, and he may, if he be of sound mind, expressly prohibit the performance of lifesaving surgery, or other medical treatment." Natanson v. Kline, 186 Kan. 393 (1960). "The inviolability of the person" has been held as "sacred" and "carefully guarded" as any common-law right. Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251-252, 11 S.Ct. 1000, 1001, 35 L.Ed. 734 (1891). Thus, freedom from unwanted medical attention is unquestionably among those principles "so rooted in the traditions and conscience of our people as to be ranked as fundamental." Snyder v. Massachusetts, 291 U.S. 97 (1934). "That there may be serious consequences involved in refusal of the medical treatment at issue here does not vitiate the right under our common-law tradition of medical self determination. It is "a well-established rule of general law . . . that it is the patient, not the physician, who ultimately decides if treatment-any treatment-is to be given at all. . . . The rule has never been qualified in its application by either the nature or purpose of the treatment, or the gravity of the consequences of acceding to or foregoing it." Tune v. Walter Reed Army Medical Hospital, 602 F.Supp. 1452, 1455 (DC 1985).*

B. UNITED KINGDOM

I. Bolam v. Friern Hospital Management Committee (1957) 1 WLR 582

Court : **Queen's Bench Division**

Coram : **McNair J.**

Facts

Hector Bolam was a psychiatric patient who went to Friern Hospital as a voluntary patient for issues related to recurrent depression. After diagnosis, the doctors decided that he has to be treated with ECT (Electroconvulsive Therapy) and Bolam agreed to the same. Bolam was given an unmodified ECT (in which no muscle relaxant or anesthesia is administered to the patient) and he was not even restrained during the procedure. He was given an unmodified ECT for 7 to 10 times a day during each session. In the 3rd session his depression improved, but at the same time since he was not administered with any muscle relaxant or anesthesia and he developed muscle fracture called acetabulum (both sides of pelvis bone fractured). When he came to know about this he filed a suit for damages against the hospital.

Judge McNair called upon experts from the medical field and set up an expert board to determine the issue related to the administration of muscle relaxant or anaesthesia during ECT. One group of experts stated that anaesthesia and muscle relaxant are considered dangerous and consist of high risk to the patient, hence use of anaesthesia should be avoided. The other expert group said that the hospital should have given anaesthesia and muscle relaxant to Bolam, because then the pelvis fracture could have been avoided and also they should have warned Bolam of the probable outcome of the treatment.

Decision

One of the grounds for the case was that the doctors were negligent in failing to give Bolam a warning of the risks involved in the treatment, so that he might have a chance to decide whether he was going to take those risks or not. The Jury decided the case in doctors' favour. On the ground of failure to give warning to the patient, the Court made the following observations for the Jury -

> *Having considered the evidence on this point, you have to make up your minds whether it has been proved to your satisfaction that when the defendants adopted the practice they did (namely, the practice of*

saying very little and waiting for questions from the patient), they were falling below a proper standard of competent professional opinion on this question of whether or not it is right to warn. Members of the jury, though it is a matter entirely for you, you may well think that when dealing with a mentally sick man and having a strong belief that his only hope of cure is E.C.T. treatment, a doctor cannot be criticized if he does not stress the dangers which he believes to be minimal involved in that treatment.

If you do come to the conclusion that proper practice requires some warning to be given, the second question which you have to decide is: If a warning had been given, would it have made any difference? At any rate, whether that is right or wrong, as it seems to me, you might well take the view that unless the plaintiff has satisfied you that he would not have taken the treatment if he had been warned, there is really nothing in this point.

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II. Hunter v. Hanley (1955) SLT 213

Court : **Scottish Court of Session**

Coram : **Lord President Clyde**

Facts

Mrs. Hanley took legal action against Hunter, a medical practitioner alleging professional negligence on his part. It was alleged that she suffered injury as a result of the breaking of hypodermic needle while she was receiving an injection. Part of the needle was lodged in the soft tissues requiring hospital treatment to remove it. Hanley contended that the accident had been caused by the fault and negligence of Hunter in failing to exercise the standard of care and competence which it was his duty to display in giving the injection. She specifically alleged that the type of needle used by Hunter was not suitable having adequate strength for that type of injection.

Decision

The Court held -

> *To establish liability by a doctor where departure from normal practice is alleged, three facts are required to be established. First of all it must be proved that there is a usual and normal practice; secondly it must be proved that the defender has not adopted that practice; and thirdly (and this is of crucial importance) it must be established that the course the doctor adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care.*

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III. Sidaway v. Bethlem Royal Hospital (1985) 1 All ER 643, HL

Court : **House of Lords**

Coram : **Lord Scarman, Lord Diplock, Lord Keith of Kinkel, Lord Bridge of Harwich, Lord Templeman**

Facts

Sidaway was warned by the surgeon of the possibility of disturbing a nerve root while advising him of an operation on the spinal column to relieve shoulder and neck pain. He did not however mention the possibility of damage to the spinal cord. Though the operation was performed without negligence, the Sidaway sustained damage to the spinal cord resulting in partial paralysis. He alleged that the surgeon was negligent in failing to inform her about the said risk and that had she known the true position, she would not have accepted the treatment. The trial Judge and Court of Appeal applied the Bolam test and concluded that the surgeon had acted in accordance with a practice accepted as proper by a responsible body of medical opinion, in not informing the plaintiff of the risk of damage to spinal cord. Consequently, the claim for damages was rejected.

Decision

Affirming the decision of the Court of Appeal, the Court held -

> *To the extent that I have indicated I think that English law must recognise a duty of the doctor to warn his patient of risk inherent in the treatment which he is proposing: and especially so, if the treatment be surgery. The critical limitation is that the duty is confined to material risk. The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the Patients' position would be likely to attach significance to the risk. Even if the risk be material, the doctor will not be liable if upon a reasonable assessment of his Patients' condition he takes the view that a warning would be detrimental to his Patients' health.*
>
> *The 'prudent patient' test calls for medical evidence. The materiality of the risk is a question for the court to decide on all the evidence. Many factors call for consideration. The two critically important medical factors are the degree of probability of the risk materialising*

and the seriousness of possible injury if it does. Medical evidence will be necessary so that the court may assess the degree of probability and the seriousness of possible injury. Another medical factor, on which expert evidence will also be required, is the character of the risk. In the event of an operation is the risk common to all surgery, eg sepsis, cardiac arrest, and the other risks associated with surgery and the administration of an anaesthetic? Or is it specific to the particular operation under consideration? With the worldwide development and use of surgical treatment in modern times the court may well take the view that a reasonable person in the Patients' situation would be unlikely to attach significance to the general risks; but it is not difficult to foresee circumstances particular to a patient in which even the general risks of surgery should be the subject of a warning by his doctor, eg a heart or lung or blood condition. Special risks inherent in a recommended operational procedure are more likely to be material. The risk of partial paralysis, as in this case where the purpose of the operation was not to save life but merely to relieve pain, illustrates the sort of question which may face first the doctor and later the court. Clearly medical evidence will be of the utmost importance in determining whether such a risk is material but the question for the court is ultimately legal, not medical, in character.

If the doctor admits or the court finds that on the prudent patient test he should have disclosed the risk, he has available the defence that he reasonably believed it to be against the best interest of his patient to disclose it. Here also medical evidence, including the evidence of the doctor himself, will be vital. The doctor himself will normally be an essential witness; and the reasonableness of his assessment may well need the support of independent medical testimony.

My conclusion as to the law is therefore this. To the extent that I have indicated, I think that English law must recognise a duty of the doctor to warn his patient of risk inherent in the treatment which he is proposing and especially so if the treatment be surgery. The critical limitation is that the duty is confined to material risk. The test of

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materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the Patients' position would be likely to attach significance to the risk. Even if the risk be material, the doctor will not be liable if on a reasonable assessment of his Patients' condition he takes the view that a warning would be detrimental to his Patients' health.

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IV. Montgomery v. Lanarkshire Health Board (2015) UKSC 11

Court: **United Kingdom Supreme Court**

Coram: **Lord Neuberger, President Lady Hale, Deputy President, Lord Kerr, Lord Clarke, Lord Wilson, Lord Reed, Lord Hodge**

Facts

Mrs. Montgomery was a pregnant woman of short stature and was suffering from diabetes. Women suffering from diabetes are likely to have babies that are larger than normal which brings with it an increased risk of approximately 10 percent of shoulder dystocia during delivery. Shoulder dystocia is a situation whereby the width of the baby's shoulders are such that they cannot pass down the birth canal and so the baby cannot be born vaginally unless the baby's shoulders are somehow freed is an obstetric emergency for the mother with serious potential adverse consequences for the baby. Mrs. Montgomery was told that she was having a larger than usual baby. Even though Mrs. Montgomery expressed concern about the size of her baby the doctor did not warn her of the risk of 'shoulder dystocia'. However, in a perhaps crucial piece of testimony, the attending advising obstetrician did say at trial that it was her practice not to discuss or advise of the risk of shoulder dystocia because she believed, if she did so, most expectant mothers in the situation of Mrs. Montgomery would opt for a caesarean section. She was also of the view that caesarean sections were not in the maternal interest. In 1999, while delivering her baby shoulder dystocia occurred. It took some 12 minutes between the baby's head appearing and the effecting of delivery. As a result,the baby was deprived of oxygen and he suffered cerebral palsy with all four of his limbs being affected.

Decision

The Court held

> *[81] The social and legal developments which we have mentioned point away from a model of the relationship between the doctor and the patient based upon medical paternalism. They also point away from a model based upon a view of the patient as being entirely dependent on information provided by the doctor. What they point towards is an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors (and then being prone to sue their doctors in the event of a disappointing outcome),*

treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.

[82] In the law of negligence, this approach entails a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks of injury that are inherent in treatment. This can be understood, within the traditional framework of negligence, as a duty of care to avoid exposing a person to a risk of injury which she would otherwise have avoided, but it is also the counterpart of the Patients' entitlement to decide whether or not to incur that risk. The existence of that entitlement, and the fact that its exercise does not depend exclusively on medical considerations, are important. They point to a fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.

[83] The former role is an exercise of professional skill and judgment: what risks of injury are involved in an operation, for example, is a matter falling within the expertise of members of the medical profession. But it is a non sequitur to conclude that the question whether a risk of injury, or the availability of an alternative form of treatment, ought to be discussed with the patient is also a matter of purely professional judgment. The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the Patients' entitlement to decide on the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a person's rights rests with the courts, not with the medical professions.

[84] Furthermore, because the extent to which a doctor may be inclined to discuss risks with a patient is not determined by medical

learning or experience, the application of the Bolam test to this question is liable to result in the sanctioning of differences in practice which are attributable not to divergent schools of thought in medical science, but merely to divergent attitudes among doctors as to the degree of respect owed to their patients.

[85] A person can of course decide that she does not wish to be informed of risks of injury (just as a person may choose to ignore the information leaflet enclosed with her medicine); and a doctor is not obliged to discuss the risks inherent in treatment with a person who makes it clear that she would prefer not to discuss the matter. Deciding whether a person is so disinclined may involve the doctor making a judgment; but it is not a judgment which is dependent on medical expertise. It is also true that the doctor must necessarily make a judgment as to how best to explain the risks to the patient, and that providing an effective explanation may require skill. But the skill and judgment required are not of the kind with which the Bolam test is concerned; and the need for that kind of skill and judgment does not entail that the question whether to explain the risks at all is normally a matter for the judgment of the doctor. That is not to say that the doctor is required to make disclosures to her patient if, in the reasonable exercise of medical judgment, she considers that it would be detrimental to the health of her patient to do so; but the "therapeutic exception", as it has been called, cannot provide the basis of the general rule.

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V. Chester v Afshar [2004] 4 All ER 587

Court : **House of Lords**

Coram: **Lord Bingham, Lord Steyn, Lord Hoffmann, Lord Hope and Lord Walker**

Facts

Ms. Chester suffered from severe back pain and was referred to Mr. Afshar, an eminent consultant neurosurgeon, who advised her to undergo surgery. Three days later, the surgeon conducted the operation with the Patients' consent. The operation was properly performed; however, it resulted in significant nerve damage and left her partially paralyzed. The particular surgery was known to have a 1-2% risk of worsening the symptoms even if performed safely and competently. Mr Afshar had a duty of care to warn Miss Chester of this risk but he did not. Chester initiated proceedings for negligence and alleged that the surgeon failed to advise her of risk, and that breach of duty entitled her to damages. The judge found that the surgeon had indeed not informed the patient of the risk before the operation and was negligent. If the patient had known the risk she would not have consented to the operation taking place at that time and would instead have sought a second or third opinion before deciding what to do. It was held on that basis that the patient had established a causal link between the breach of duty and the injury. The decision was affirmed by the Court of Appeal. The surgeon appealed to the House of Lords, contending that, in order to establish causation in the case of a surgeon's failure to warn a patient of a significant risk of injury, the patient had to prove not only that she would not have consented to run the relevant risk then and there, but also that she would not at any time have consented to run the relevant risk.

Decision

Dismissing the appeal filed by Mr. Afshar, the House of Lords held -

> *[86] I start with the proposition that the law which imposed the duty to warn on the doctor has at its heart the right of the patient to make an informed choice as to whether, and if so when and by whom, to be operated on. Patients may have, and are entitled to have, different*

views about these matters. All sorts of factors may be at work here - the Patients' hopes and fears and personal circumstances, the nature of the condition that has to be treated and, above all, the Patients' own views about whether the risk is worth running for the benefits that may come if the operation is carried out. For some the choice may be easy - simply to agree to or to decline the operation. But for many the choice will be a difficult one, requiring time to think, to take advice and to weigh up the alternatives. The duty is owed as much to the patient who, if warned, would find the decision difficult as to the patient who would find it simple and could give a clear answer to the doctor one way or the other immediately.

[87] To leave the patient who would find the decision difficult without a remedy, as the normal approach to causation would indicate, would render the duty useless in the cases where it may be needed most. This would discriminate against those who cannot honestly say that they would have declined the operation once and for all if they had been warned. I would find that result unacceptable. The function of the law is to enable rights to be vindicated and to provide remedies when duties have been breached. Unless this is done the duty is a hollow one, stripped of all practical force and devoid of all content. It will have lost its ability to protect the patient and thus to fulfil the only purpose which brought it into existence. On policy grounds therefore I would hold that the test of causation is satisfied in this case. The injury was intimately involved with the duty to warn. The duty was owed by the doctor who performed the surgery that Miss Chester consented to. It was the product of the very risk that she should have been warned about when she gave her consent. So I would hold that it can be regarded as having been caused, in the legal sense, by the breach of that duty.

[88] The reasoning of Kirby J in Chappel v Hart, 195 CLR 232, para 95, which I would respectfully endorse, supports this approach. I am encouraged too by the answer which Professor Honoré gave to the question which he posed for himself in his case note on that case at p 8: "is this a case where courts are entitled to see to it that justice is done

despite the absence of causal connection?" I would hold that justice requires that Miss Chester be afforded the remedy which she seeks, as the injury which she suffered at the hands of Mr Afshar was within the scope of the very risk which he should have warned her about when he was obtaining her consent to the operation which resulted in that injury.

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VI. Gold v Haringey Health Authority [1987] 2 All ER 888

Court : **Court of Appeal, Civil Division**

Coram : **Watkins, Stephen Brown and Lloyd L, JJ.**

Facts

Mrs. Phyllis Gold underwent an operation for sterilization at the North Middlesex Hospital. It was on the day after the birth of her third child. The operation did not succeed and in October 1982 she gave birth to her fourth child. In October 1984 she commenced these proceedings against the Haringey Health Authority, despite the fact that she gave birth to her fifth child in November 1984. It was alleged that the Health Authority had been negligent in not warning her of the risk of failure of the operation and that a statement made to her that the operation would be 'irreversible' amounted to negligent misrepresentation. The judge held that the operation itself had not been negligently performed but having regard to the fact that the contraceptive advice had been given in a non-therapeutic context, the Health Authority had been negligent in failing to warn Mrs. Gold of the possibility of failure of the operation. Damages to the tune of £19,000 were awarded. Subsequently an appeal was filed.

Decision

Allowing the appeal, the Court held -

> *the judge decided against the defendants on two grounds. First, he held that the Bolam test did not apply at all in a contraceptive context. Instead he applied his own judgment as to what should have been mentioned in that context. Second, if the Bolam test did apply, then he found as a fact that there was no body of responsible medical opinion which would not, in a contraceptive context, have warned of the risk of failure. I have reversed these two grounds, since the first ground raises a question of considerable general importance.*
>
> *Counsel for the plaintiff did his best to argue that the Bolam test is confined to doctors. For the reasons I have given, I cannot accept that argument. I can see no possible ground for distinguishing between doctors and any other profession or calling which requires special skill, knowledge or experience. To be fair to the judge, it was not, I think, on this ground that he regarded the Bolam test as exceptional.*

passing, I should mention that the Bolam test is often thought of as limiting the duty of care. So in one sense it does. But it also extends the duty of care, as the second of the two passages I have quoted from McNair J's summing up in the Bolam case makes clear. The standard is not that of the man on the top of the Clapham omnibus, as in other fields of negligence, but the higher standard of the man skilled in the particular profession or calling.

In the second place, a distinction between advice given in a therapeutic context and advice given in a non-therapeutic context would be a departure from the principle on which the Bolam test is itself grounded. The principle does not depend on the context in which any act is performed, or any advice given. It depends on a man professing skill or competence in a field beyond that possessed by the man on the Clapham omnibus. If the giving of contraceptive advice required no special skill, then I could see an argument that the Bolam test should not apply. But that was not, and could not have been, suggested. The fact (if it be the fact) that giving contraceptive advice involves a different sort of skill and competence from carrying out a surgical operation does not mean that the Bolam test ceases to be applicable. It is clear from Lord Diplock's speech in Sidaway that a doctor's duty of care in relation to diagnosis, treatment and advice, whether the doctor be a specialist or general practitioner, is not to be dissected into its component parts. To dissect a doctor's advice into that given in a therapeutic context and that given in a contraceptive context would be to go against the whole thrust of the decision of the majority of the House of Lords in that case. So I would reject the argument of counsel for the plaintiff under this head, and hold that the judge was not free, as he thought, to form his own view of what warning and information ought to have been given, irrespective of any body or responsible medical opinion to the contrary.

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VII. Pearce v. United Bristol Healthcare NHS Trust 48 BMLR 118

Court : **Court of Appeal, Civil Division**

Coram : **Lord Woolf MR, Roch and Mummery LJJ.**

Facts

This case was brought by Mr & Mrs Pearce with regards to the obstetric advice she was given during her fifth pregnancy which ended with the stillbirth of her daughter, Jacqueline, in December 1991. She met her consultant two weeks before her due date to seek his advice to either go for induced labour or a Caesarean section. The consultant thought it appropriate to let nature take its course, and advised her to have a normal birth without any medical intervention. He explained that it would be very risky to induce the birth, and that it would take longer for her to recover if she had a caesarian section. She accepted the advice. The advice from the consultant, following an examination and discussion of the risks of induction and Caesarean, was that Mrs. Pearce awaited the natural onset of labour.

On 2nd December, 1991 her daughter was found to have died in the uterus. Mrs Pearce was not informed of the 0.1-02% risk of this happening as it was not felt to constitute a significant risk. Claim for negligence was brought by Mr and Mrs Pearce at the law court of Bristol where Mrs. Pearce argued that had she been informed of this risk she would have opted for a Caesarean section. The Bristol court dismissed the claim and an appeal was subsequently preferred.

Decision

Dismissing the appeal, the Court held -

> *In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law, as indicated in the cases to which I have just referred, that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to*

inform the patient of that significant risk, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.

Obviously, the doctor, in determining what to tell a patient, has to take into account all the relevant considerations, which include the ability of the patient to comprehend what he has to say to him or her and the state of the patient at the particular time, both from the physical point of view and an emotional point of view. There can often be situations where a course different from the normal has to be employed. However, where there is what can realistically be called a 'significant risk', then, in the ordinary event, as I have already indicated, the patient is entitled to be informed of that risk.

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C. AUSTRALIA

I. Rogers v. Whitaker (1992) 109 ALR 625

Court : **High Court of Australia**

Coram : **Mason CJ, Brennan, Dawson, Toohey, Gaudron and McHugh JJ**

Facts

Mrs. Whitaker suffered a penetrating eye injury in her right eye when she was a young girl. When she was in early middle age she was referred to Dr. Christopher Rogers who told her that he could clear up some of the scarring over her eye which would ultimately improve her sight as well as the aesthetic appearance of the eye. The operation went ahead as planned but unfortunately Ms. Whitekar suffered a condition known as sympathetic ophthalmia and was left completely blind in both her eyes. Whitaker commenced proceedings against Christopher Rogers for failing to warn her of the possibility of sympathetic ophthalmia. The Supreme Court of New South Wales decided in her favor and awarded a compensation of $808,564.38. The New South Wales Court of Appeal confirmed the decision and dismissed Dr. Roger's appeal. This was subsequently challenged in the High Court of Australia.

Decision

Dismissing the appeal, the Court held -

> *We agree that the factors referred to in F v R by King CJ must all be considered by a medical practitioner in deciding whether to disclose or advise of some risk in a proposed procedure. The law should recognise that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the Patients' position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it. This duty is subject to therapeutic privilege.*
>
> *Diagnosis and treatment are but particular duties which arise in the doctor-patient relationship. That relationship also gives rise to a duty to provide information and advice. That duty takes its precise*

content, in terms of the nature and detail of the information to be provided, from the needs, concerns and circumstances of the patient. A patient may have special needs or concerns which, if known to the doctor, will indicate that special or additional information is required. In a case of that kind, the information to be provided will depend on the individual patient concerned. In other cases, where, for example, no specific inquiry is made, the duty is to provide the information that would reasonably be required by a person in the position of the patient.

Whether the position is considered from the perspective of the individual patient or from that of the hypothetical prudent patient and unless there is some medical emergency or something special about the circumstances of the patient, there is simply no occasion to consider the practice or practices of medical practitioners in determining what information should be supplied. However, there is some scope for a consideration of those practices where the question is whether, by reason of emergency or the special circumstances of the patient, there is no immediate duty or its content is different from that which would ordinarily be the case.

Leaving aside cases involving an emergency or circumstances which are special to the patient, the duty of disclosure which arises out of the doctor-patient relationship extends, at the very least, to information that is relevant to a decision or course of action which, if taken or pursued, entails a risk of the kind that would, in other cases, found a duty to warn. A risk is one of that kind if it is real and foreseeable, but not if it is "far-fetched or fanciful". Certainly, the duty to warn extends to risks of that kind involved in the treatment or procedures proposed.

***

II. Sheppard v. Swan [2004] WASCA 215

Court : **Supreme Court of Western Australia**

Coram : **Malcolm, CJ, McLure and Em Heenan JJ.**

Facts

Between 15 January 1998 and 8 August 1998 Mrs. Sheppard attended upon the doctor on at least 13 occasions for antenatal care and assessment. During the course of the antenatal visits it was evident that the appellant had experienced significant weight gain during the course of her pregnancy. By 3 August 1998 she was overdue. Her doctor arranged for her to attend at Saint John of God Hospital, Murdoch ("hospital"), for a CTG trace, which was non-reactive. She stayed in the hospital overnight. On 4 August 1998, Dr. Hugo was consulted about her. The appellant returned home. On 8 August 1998, she was admitted to the hospital under the care for assessment and if appropriate for induction delivery of the baby. She commenced experiencing contractions at about 11.45 pm on 8 August 1998. At about 7.30 am on 9 August 1998 the hospital augmented her labour by commencement of a Syntocinon drip. At various times the rate of administration of the Syntocinon was increased at the doctor's direction. Between 2.30 pm and 6 pm on 9 August she slowly progressed to full cervical dilation and the descent of the baby was progressing. She complained of significant and unrelenting pain in this period. She had had an epidural block administered earlier that day. The doctor authorised an epidural top up at 4.30 pm but refused further top ups from 6.10 pm and thereafter. About 7.30 pm, after informing the appellant of her intention, the doctor proceeded to perform an assisted delivery by using vacuum suction. During this process the baby's heart rate dropped as a result of which the doctor performed an episiotomy after injecting her perineum with local anaesthetic. The baby's head emerged but his shoulders were impacted. They were dislodged and the baby was delivered. It was Mrs. Sheppard's contention that during labour, the doctor should have offered or informed her of the option of having a caesarean section rather than proceeding with the vaginal delivery. She contended that if the doctor had so advised her, she would have proceeded by way of caesarean section and thus avoided the personal injuries associated with the vaginal delivery which included an episiotomy, pelvic floor injury and nerve damage.

Decision

It was held by the Court as follows :-

42. *On proper analysis, this is not a duty to warn case. The duty to warn relates to communicating relevant risks of adverse outcomes of proposed treatment. However, the appellant says that the policy of patient autonomy underlying the duty to warn gives rise in this case to a duty on the respondent to offer or inform the appellant during the course of labour of the option of a caesarean section. The formulation of the duty is too specific. It is necessary to step back and take a broader perspective starting with the High Court formulated duty on a medical practitioner to provide information to a patient in an appropriate case, mindful of the public policy in favour of patient autonomy. However, I accept as a general rule that in ordinary circumstances a medical practitioner owes a duty to advise his or her patient of the medical or treatment options available to achieve the relevant outcome. I acknowledge that a statement at this level of abstraction is of little assistance in answering the duty question in this case. I also accept that at least some of the principles developed in relation to the duty to warn would apply by way of analogy. In particular, the timing and content of any advice the subject of the duty will be affected by objective and subjective considerations.*

44. *On the issue of whether the respondent was under a relevant duty, I propose to start by addressing the relevance of the fact that at the material time a caesarean section was not medically necessary, indicated or desirable. This is a relevant negative factor in the sense that if it were otherwise there would (or may) be a duty to inform the patient of the situation. It may be seen as a positive factor as well in this way. There being no medical or clinical reason for a caesarean section, the medical practitioner would not recommend that course and would (of course) have to inform the patient of the risks of proceeding with a caesarean. In those circumstances, it is unlikely that a reasonable patient would do other than follow the medical practitioner's recommendation. On this scenario a caesarean section is not an objectively material option (to borrow from the duty to warn*

formulation) that requires communication to the patient. However, a similar proposition did not receive endorsement by the High Court in Rosenberg v Percival and is inconsistent with the public policy of giving paramountcy to the Patients' right to make decisions. The trial Judge's approach was even more direct. He said that unless a medical practitioner intended to positively recommend a caesarean, there was no duty to inform a patient of the treatment option. Such a proposition is too broadly stated and is inconsistent with accepted principle.

45. *However, although the trial Judge erred in his statement of principle, I am satisfied that he was correct in his conclusion that the alleged duty did not arise on the facts for the following reasons. After receipt of relevant information and discussion with the respondent in the antenatal phase, the appellant to the respondent's knowledge determined that she would deliver the baby naturally at least to the extent that was medically appropriate. The respondent managed the pregnancy and labour to that end. Nothing of medical significance happened in the course of the labour (at least until after the point of no return) that required the respondent to alter, or consider altering, the planned course of a vaginal delivery or that materially altered the risks of proceeding in that way. Matters of non medical significance are likely to be primarily (if not solely) relevant to whether subjective considerations activate a duty to inform. As I understand the evidence, there was no other significant matter of which the appellant was unaware. She was aware in general terms that the baby was big and of her ordeal, matters relied on by the appellant as triggering the duty. The appellant gave no indication that she wanted to change course or to discuss the option of doing so. Although the appellant was suffering significant pain and distress and was feeling exhausted, her situation was not exceptional by objective standards. On the facts there were no objective or subjective grounds for the respondent to revisit with the appellant during the course of labour the options available to the appellant for the delivery of her child.*

***

III. Paul v Cooke [2013] NSWCA 311

Court : **Supreme Court of New South Wales**

Coram : **Basten, Ward and Leeming JJ**

Facts

In 2003, Ms Paul underwent a scan to determine whether she had an intracranial aneurysm. Her radiologist Dr Cooke negligently failed to diagnose the aneurysm. In 2006, following a further scan, the aneurysm was diagnosed. On the advice of her treating practitioners and informed of the risks involved, Ms Paul underwent an operation to remove it. During the course of that operation, and without any lack of skill or care on the part of the surgeons, the aneurysm ruptured, causing her to have a stroke and suffer serious injuries. It was contended that if Dr Cooke had diagnosed the aneurysm in 2003, Ms Paul would have undergone surgery then. The procedure Ms Paul underwent in 2006 (endovascular surgery) was different to the procedure she would have undergone in 2003 (open neurosurgery). Based on statistical evidence that the overall risk of stroke following rupture during either procedure was less than 1%, it was highly likely that Ms Paul would have suffered no harm had a procedure been performed in 2003; that is, "but for" Dr Cooke's failure to diagnose the aneurysm in 2003, Ms Paul would have had the aneurysm safely removed in 2003 and therefore would not have had the surgery and suffered the harm in 2006. The delayed diagnosis did not of itself increase the risks associated with surgery, in that the aneurysm did not change in size, shape or propensity to rupture during those three years. Ms Paul claimed damages from Dr Cooke for his negligence in failing to diagnose the aneurysm in 2003.

Decision

Dismissing the appeal, the Court held :-

> *93. Ms Paul submitted that the "duty to diagnose cannot be, and should not be, partitioned from the duty to inform" because the Patients' right to know what he or she is suffering from, and to decide for himself or herself to undergo treatment, depended upon both diagnosis and warning. I do not agree. The duty to warn is treated differently by the Act, just as it was treated differently by the common law. In my view, neither Chappel v Hart nor Chester v Afshar assists the appellant. Those cases are failure to warn cases. The common law attaches considerable value to the individual's autonomous, and*

informed, choices, and vindicates the negligent denial of a right to informed choice by attaching liability. That is the right to an informed and therefore rational choice to which the High Court referred in Wallace v Kam at [8]:

"The policy underlying the imposition of that component of the duty is to equip the patient with information relevant to the choice that is the Patients' to make. The duty to inform the patient of inherent material risks is imposed to enable the patient to choose whether or not to run those inherent risks and thereby 'to avoid the occurrence of the particular physical injury the risk of which[the]patient is not prepared to accept'."

94. But the present case is the opposite of the case where a poorly informed patient subjects himself or herself to a medical procedure involving a risk which he or she would have been unwilling otherwise to run. The negligent failure to diagnose means there is no medical procedure. The case therefore turns on whether there has materialised a risk other than from the medical procedure by reason of the delay, and the evidence in the present case was that Ms Paul's condition did not worsen between 2003and 2006.

98. The High Court has repeatedly acknowledged the importance attributed by the common law to the Patients' right to choose, so that there is informed decision-making before undergoing medical procedures which have unavoidable risks. The central difficulty Ms Paul faces is that she was fully warned in 2006, so that common law policy is not available to support her claim based on Dr Cooke's 2003 negligence.

100. The appellant said, correctly, that the failure to warn cases highlight the fundamental right of patients to make informed, free choices about what treatment to undergo and when to undergo it. But that does not subtract from the key difference that diagnosis is not so much apart of informing a patient of his or her choices before an activity is undertaken, but an anterior step, and that the occasion for a warning in a case like the present one only arises upon the (non-negligent) performance of the diagnosis.

102. I respectfully agree with the entirety of the reasons of the primary judge on this issue. The appellant submitted that the primary judge erred by defining foreseeability too narrowly. The appellant said that the relevant and foreseeable risk was not intra-procedural rupture, or intra-procedural rupture occasioning stroke, but stroke simpliciter (whether in hospital or spontaneous). But I cannot agree that those risks should be conflated. Intra-procedural rupture is a risk which occurs at the time and place chosen by the patient, presumably following his or her fully informed and autonomous choice, because of an invasive procedure undertaken under general anaesthetic. Spontaneous rupture may be a risk chosen by a patient (whose aneurysm is diagnosed but who has chosen conservative management) or it may be risk run unknowingly, as it was by Ms Paul for at least three years prior to 2006(and for all that is known perhaps many years longer). The causal mechanism leading to spontaneous rupture is poorly understood. It seems entirely artificial to my mind to conflate such different things, even though the ultimate harm (stroke)is the same. And the appellant provides no basis for concluding that stroke is the appropriate level of abstraction. Why not more generalized harm (such as the mortality and morbidity assessed in the Lancet article)? That is supported not only by commonsense, but also by the discussion of principle by Lord Caplan in Moyes v Lothian Health Board 1990 SLT 444 at 447 which the High Court endorsed in Wallace v Kam."

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IV. Chappel v Hart (1998) 156 ALR 517

Court : **High Court of Australia**

Coram : **Gaudron, McHugh, Gummow, Kirby and Hayne JJ**

Facts

Mrs. Hart underwent surgery at the hands of Dr Chappel without warning as to the possible consequences that her oesophagus may get perforated and infection may set in. That is what happened and, in consequence, Mrs Hart suffered damage to her laryngeal nerves, paralysis of her right vocal cord and voice loss. During the operation, her oesophagus was perforated and there ensued an infection which resulted in damage to one of her vocal cords and consequential partial loss of her voice. The operation was elective for her at the time although, if it was not performed then, it was eventually inevitable. Dr. Chappel did not perform the operation negligently. However, he failed to warn her as to the possible consequences that her oesophagus may get perforated and infection may set in. She commenced proceedings against the doctor in the Supreme Court of New South Wales. It was established at trial that, if she had been warned of the risk of the operation, she would not have undergone the surgery when she did. Instead, she would have taken steps to have the operation carried out by the most experienced surgeon with a record and reputation in the field. It was also established at trial that, prior to the operation, she had asked the doctor about the risks of the operation, and that the infection which set in after the operation and led to the injuries which she sustained was a random event which might occur no matter when or by whom the surgery was performed. The trial judge held that the doctor had breached the duty he owed to Mrs. Hart to warn her of material risks in respect of the operation. The trial judge also held that the appellant's breach of duty caused her injury. An appeal to the Court of Appeal against this order was dismissed and thus the present appeal was filed.

Decision

The Court, dismissing the appeal, held :-

Per Kerby, J.

98. In judging the performance of a health care or other professional, the law does not require perfection. It recognises the variability of professional skills. Even an expert, acting at the highest standards of the profession, may turn in a less than perfect performance on a

particular day. However, the requirement to warn patients about the risks of medical procedures is an important one conducive to respect for the integrity of the patient and better health care. In Australia, it is rigorous legal obligation. Its rigour was not challenged in this appeal. It must be accepted that, by establishing the requirement to warn patients of a risk to which they would be likely to attach significance, or of which they should reasonably be aware, the law intends that its obligations be carefully observed. Breaches must be treated seriously. Because in some cases the failure to warn would have no, or no relevant, consequences, proof of a breach will not of itself be sufficient to establish an entitlement to damages for every harm that thereafter occurs to the patient. To reason in such a way would involve the logical fallacy of post hoc ergo propter hoc. The plaintiff's legal obligation to show the causal connection remains throughout the proceedings.

Per Gaudron, J.

8. *It was not disputed in this court that Dr. Chappel was under a duty to inform Mrs. Hart of the possible consequences in the event of the perforation of her oesophagus and subsequent infection, including the possibility of damage to her voice. The duty was called into existence because of the foreseeability of that very risk. The duty was not performed and the risk eventuated.*

9. *Where there is a duty to inform it is, of course, necessary for a plaintiff to give evidence as to what would or would not have happened if the information in question had been provided. If that evidence is to the effect that the injured person would have acted to avoid or minimise the risk of injury, it is to apply sophistry rather than common sense to say that, although the risk of physical injury which came about called the duty of care into existence, breach of that duty did not cause or contribute to that injury, but simply resulted in the loss of an opportunity to pursue a different course of action. The matter can be put another way. If the foreseeable risk to Mrs. Hart was the loss of an opportunity to undergo surgery at the hands of a more experienced surgeon, the duty would have been a duty to inform her that there*

were more experienced surgeons practising in the field. Because the risk was a risk of physical injury, the duty was to inform her of that risk. And that particular duty was imposed because, in point of legal principle, it was sufficient, in the ordinary course of events, to avert the risk of physical injury which called it into existence.

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D. CANADA

I. Chen v. Ross

Court : **British Columbia Court of Appeal**

Coram : **Saunders, Garson, and Savage JJ.**

Facts

Chen had multiple vision problems over the years. Dr. Lee who was Chen's general ophthalmologist referred him to Dr. Ross, a retinal subspecialist. In the year 2000, Dr. Ross performed surgery on Chen's left eye. Within days, Chen experienced a dramatic loss of vision in his eye, and was eventually diagnosed as blind in that eye. He took legal on the ground of medical negligence against Drs. Lee and Ross. Chen alleged that he had undiagnosed pre-existing glaucoma that made the surgery inappropriate and greatly increased the risk of vision loss. Chen maintained that both physicians were negligent in failing to diagnose him with glaucoma and in failing to obtain his informed consent to the surgery. The trial judge dismissed the action against Drs. Lee and Ross and found that Chen had provided his informed consent to perform the surgery. In January 2000, Dr. Ross had a discussion with Chen about the surgical risks and benefits. Following the meeting with Chen, Dr. Ross had recorded in his chart the risks and benefits that had been explained to Chen. The trial judge accepted this evidence. Chen appealed the dismissal of his claim.

Decision

The Court held -

> *The trial judge did not err in finding that Chen gave his informed consent to Drs. Lee and Ross. Dr. Lee was the referring physician and did not have a duty to obtain informed consent from Chen with respect to surgery performed by Dr. Ross. There was evidence to support the trial judge's findings that Chen gave his informed consent to Dr. Ross. Chen did not establish any error in law on the question of informed consent.*
>
> *Further, a balanced consideration of the evidence as a whole supports the conclusion that the nature of the potential benefits and risks that could be expected, including the risk of Mr. Chen going blind in his left eye, and the relative chances of them occurring were accurately and sufficiently disclosed to Mr. Chen by Dr. Ross on January 26, 2000, and that Mr. Chen provided his informed consent to Dr. Ross to perform the Membrane Surgery.*

II. Tiglao v. Sleightholm, 2012 ONSC 3092

Court : **Ontario Superior Court of Justice**

Coram : **L. Snowie J.**

Facts

Susan Tiglao, underwent a breast augmentation and a tummy tuck with liposuction surgery. The surgery was performed at the Brampton Civic Cosmetic Surgery and Laser Clinic. Dr. Sleightholm was the director of the said clinic and performed the surgery. Susan Tiglao, and her husband Keith Fraser sued both Dr. Sleightholm and his clinic for negligence and lack of an informed consent as they were dissatisfied with the results of the plastic surgery. It was alleged that the risks of these surgeries were never fully explained to them. Tiglao was born in the Philippines and had been in Canada for approximately 17 years. She spoke Tagalog and did not speak or read English.

According to Tiglao all the consultations and office visits at the Clinic were done in English. Sleightholm on the other hand testified that in 15 minutes he explained to Tiglao and her English-speaking husband all the risks of the two surgeries and all the different methods of doing implants. Tiglao and her husband denied that they were informed of any such risks by Sleightholm. Instead she was made to sign all the consent forms immediately before the surgery.

Decision

The Court held -

> *Sleightholm failed to obtain informed consent from Tiglao for either of the surgeries. Tiglao was not a sophisticated consumer and she lacked the ability, due to her lack of fluency in English, to comprehend much of what Sleightholm claimed that she understood. Tiglao may have looked at the consent forms but she did not read and/or comprehend them because she could not read English. The Patients' illiteracy and/or ability to comprehend and/or fluency in English were significant factors to be considered when the doctor explained to the patient the risks related to the surgery to be performed.*
>
> *There was a special duty placed on the doctor in these circumstances to be certain that the patient understood the risks and the available*

alternatives. A doctor could not relegate his obligation to ensure informed consent was given to an employee or a spouse of the patient. Sleightholm was not able to rely unduly on Tiglao's husband to explain the risks second hand. He had to satisfy himself that he was proceeding with the informed consent of his own patient. Tiglao was never told properly and/or had not been able to comprehend due to her inadequate fluency in English, that the slight asymmetry of her breasts would be magnified by the use of breast implants.

***

III. Stepita v. Dibble 2020 ONSC 3041

Court : **Ontario Superior Court of Justice**

Coram : **Ferguson J**

Facts

Stepita, a 56-year-old pharmacist, underwent heart surgery to remove a mass found in her heart after a routine echocardiogram in the course of her treatment for breast cancer. The mass could only be definitively identified based on a tissue analysis. Surgery was done and a tissue analysis showed the mass to be thrombus. Stepita and her family brought an action for negligence against the physicians involved in her heart surgery on the basis that they ought to have known that her mass was likely to be thrombus, and therefore should have treated it medically with anticoagulants. Stepita argued the physicians did not meet the standard of care because they did not seek further diagnostic testing or refer her to a hematologist to treat the mass as a blood clot. She also argued that the physicians did not provide enough information to obtain informed consent from her, by failing to disclose the possibility of the mass being a blood clot and discuss alternatives to surgery.

Decision

Dismissing the action, the Court held -

> *The standard of care requires that a physician exercise the reasonable degree of care and skill of a normal, prudent practitioner of the same experience in the same circumstances. The doctor met the standard of care in all aspects of his care for Stepita. It was appropriate for the doctor to consider the opinion of the referring cardiologist, to perform an assessment of Stepita, and to remove the atrial mass. The doctor met the standard of care and a referral for surgery was still appropriate in light of other clinical circumstances.*
>
> *Stepita's informed consent claim also failed. The standard of care did not require the doctor to divulge that the mass could be a clot. That was a diagnosis he did not find likely. The experts agreed that surgery, not medical therapy, was the appropriate treatment for a suspected*

myxoma. An alternative treatment which is not appropriate for the anticipated problem is not required to be disclosed to the patient in those circumstances. Doctor met the full disclosure standard for informed consent. A reasonable person, in light of Stepita's previous choices for medical treatment, would more likely than not have chosen the mass' removal through surgery even if they were told the mass was a clot and there was an option to treat it with nonsurgical alternatives.

***

IV. Solomon v. Abughaduma 2018 ONSC 3287

Court : **Ontario Superior Court of Justice**

Coram : **J.M. Wilson J.**

Facts

Solomon was a competitive golf player and golf teacher who had an elective total wrist fusion surgery at age 73 that was not successful. At the time of the surgery, he had problems for several years with pain and with cocking his wrist. Abughaduma was an orthopedic surgeon with a specialty in upper extremity surgery. The surgery completely ended flexion and extension of the wrist joint and rendered the joint essentially immobile as a metal plate was placed over the joint secured by screws. The plaintiff could no longer play golf and developed chronic regional pain syndrome, a rare risk inherent with all surgeries. Post surgery, he had no movement in his wrist and also lost the functional use of his fingers. He had a second corrective surgery which resulted in some improvement.

Solomon argued he was not provided with adequate disclosure prior to the elective surgery of the risks and benefits of a total wrist fusion. He thought he was getting a different fusion operation without a metal plate.

Decision

The Court held -

> *The plaintiff's consent to a total wrist fusion was not an informed consent. During the consultation with the defendant, conservative treatment options and alternative surgical options other than a total wrist fusion were not discussed as options for treatment. The defendant did not spend time to explore the needs and objectives of the patient for this surgery. The plaintiff was not told that he would lose all mobility in his wrist as a result of this procedure and that a metal plate would be inserted in his wrist. The plaintiff thought he was getting the procedure that he saw on the internet that did not involve a metal plate. The responsibility for the vague and uninformative disclosure about the nature of the surgery lay with the defendant. The plaintiff was not told what the chances of success or failure were for the proposed elective surgery, nor was he told that he*

could be worse off after the elective surgery. He was not told of the risk of chronic regional pain syndrome. Had the plaintiff been properly informed of the options, the plaintiff would not have had a total wrist fusion with a metal plate inserted in his wrist eliminating all movement. A reasonable person in the shoes of the plaintiff properly informed would not have chosen a total wrist fusion. Damages were awarded to the plaintiff.

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RIGHT TO ACCESS MEDICAL RECORDS

A. UNITED STATES OF AMERICA

I. Wallace v. University Hospitals of Cleveland 172 N.E. 2d 459(Ohio, 1961)

Court : **The Supreme Court of Ohio**

Coram : **Weygandt, C. J., Zimmerman, Gillen, Matthias, Bell, Herbert and O'neill, JJ.**

Facts

Wallace had instituted this case praying before the Court to grant mandatory injunction directing the Hospital to permit her attorney, pursuant to her authorisation, to inspect the records of the Hospital pertaining to her stay and treatment at the Hospital and to furnish her or her attorney with a photocopy of the records.

Decision

Dismission the application, the Court held -

> *It is obvious that the plaintiff has obtained all that she asks for in this action and no order could be made by this court that would give her more than she already has. As between these parties, therefore, the case is moot.*
>
> *In any other case, when a request therefor is made, a hospital may permit a former patient to see such of his records as the hospital deems to be in the beneficial interest of that patient. If unsatisfied with what he considers only half a loaf, that former patient may commence an action to require the furnishing of the entire record. The court in which such action is instituted, or a Court of Appeals, could well follow the decision of the Court of Appeals herein to deny a mandatory injunction. If this court then still believed there was a debatable constitutional question involved, and that there was in the case a question of public or great general interest, it would overrule a motion to dismiss the appeal as of right and allow the motion to certify the record. And again the case pending in this court could be rendered moot by the hospital's mere furnishing to the plaintiff of his complete hospital record.*

II. Pyramid Life Insurance Co. v. Masonic Hospital Association of Payne Count 171 F.Supp. 51 (W.D. Okla, 1961)

Court : **United States District Court, W.D. Oklahoma**

Coram : **Chandlar, Chief Justice**

Facts

This case was filed by an Insurance Company which issued among other types, policies of insurance covering hospital, doctors' and medical bills. The case was filed for a mandatory injunction enjoining and restraining the Masonic Hospital from preventing inspection and copying of hospital and medical records of patient-policyholders of the Insurance Company who had been confined in the Cushing Municipal Hospital, Cushing, Oklahoma, by representatives of the Insurance Company armed with authorizations signed by the patients or their representatives; and for discovery and accounting of any amount due and owned by the hospital association to the Insurance Company because of claims paid by the Company to the hospital through fraud of such hospital or mistake of fact by the insurance Company.

Decision

Allowing the application, the Court held -

> *As to the second proposition, the defendant hospital association is required by statute in the State of Oklahoma to keep and retain accurate and complete medical records of its patients. 63 O.S.1951 § 326.7; License Law and Standards for Hospitals and Related Institutions, Hospital Division, Oklahoma State Department of Health. Records required to be kept and retained by the force of statute, regulation, or judicial decision are at least quasi-public. The right to inspect such records is not one which may be exercised only by persons having a legal interest therein. Inspection can be made by any person who has an interest such as would enable him to maintain or defend an action for which the document or record sought can furnish evidence or necessary information.*
>
> *Insurance companies have a legitimate interest in determining whether claims made under their policies are claims which they are obligated to pay, and whether those already paid were in fact claims*

for which they were liable. Since they are expected to pay claims promptly, they should not be forced to make payment without such investigation as they deem necessary.

The court finds that the paper or other material on which the quasi-public medical records maintained by Cushing Municipal Hospital pertaining to care and treatment of patients and to expenses incurred by patients appear or are portrayed is the property of the hospital. But the keeper of the records does not have the right to possess and use the information constituting the records to the exclusion of the patient, his representatives, or those standing in his shoes. 27 C.J.S. Discovery 72c, p. 232. Nor can it with impunity disclose such information without permission of the patient. 70 C.J.S. Physicians and Surgeons 36, pp. 941, 942; 41 Am.Jur. pp. 196, 197, Sec. 75. Accordingly, the keeper of the records is only the custodian and not the owner of that information constituting the medical records of the patient.

The patient has a property right in the information appearing or portrayed on the records and he, or those authorized by him, including an insurance company representative armed with authorization signed by the patient, is entitled to make such inspection and/or to copy such records without resort to litigation.

As to the third proposition, the court finds that plaintiff's representatives submitted to the hospital authorizations executed by the patient-policyholders or by representatives of the patient-policyholders. It is, therefore, an unlawful interference with plaintiff's business for the defendants or their agents to deny plaintiff's representatives the right to inspect and copy the Patients' hospital and medical records and such interference will be enjoined.

That defendants now concede plaintiff's right to inspect, copy or reproduce the records does not divest the court of jurisdiction to issue a mandatory injunction. With respect to the fourth proposition, the court finds that plaintiff was denied access to the records prior to litigation. Accordingly, it was entitled to discovery. If, as a result of a discovery a plaintiff finds that it has paid claims through fraud or mistake of fact, it is entitled to an accounting.

III. Gotkin v. Miller 379 F.Supp. 859 (E.D.N.Y., 1974)

Court : **US District Court for the Eastern District of New York**

Coram : **Travia, J.**

Facts

Janet Gotkin was a voluntary mental patient at Brooklyn State Hospital, Long Island Jewish-Hillside Medical Center and at Gracie Square Hospital between 1962 to 1970. The main cause of her voluntary hospitalization was a series of threatened suicide attempts. Upon recovery, Janet Gotkin was not hospitalized or treated for any mental disorder since September 1970. Janet Gotkin and her husband, Paul Gotkin co-authored a book dealing with Janet Gotkin's experiences with psychiatry and more specifically, with her medical treatment at the aforementioned hospitals. In an attempt to verify some of the factual data contained in their book and to compare her recollection of certain incidents with the hospitals' version of what had transpired, Janet Gotkin wrote to both the hospitals where she had been treated and requested access to any medical records which might relate to her. Each of these hospitals, however, refused to grant her request. Aggrieved by the refusals, she approached the Court on the ground that such refusals violated her rights under the first, fourth, ninth and fourteenth Amendments to the United States Constitution.

Decision

Dismissing the petition, the Court inter alia addressed the question, whether a hospital's refusal to grant a former mental patient access to its medical records constitutes a violation of that former Patients' constitutional rights, as follows -

The "right to receive information and ideas" has always been used as a necessary corollary to the right of free speech. Outside the sphere of public or controversial issues, the "right to receive information and ideas" loses much of its vitality and justification. Moreover, the "right to receive information" has never been used by the courts as a constitutional cudgel to compel an unwilling "speaker" to impart information or ideas to any individual who requests him to. Thus, plaintiffs' attempt to invoke the "right to receive information" in the context of this case, would seem to be an overly broad extension of the right and an unprecedented interpretation of the First Amendment.

Plaintiffs advance the claim that the refusal to permit former mental patients an opportunity to inspect and copy the hospitals' medical records which pertain to them amounted to an intrusion of their "right to privacy" under the Ninth Amendment. Such a claim is patently without merit. This court fails to see how the "right of privacy" is in any way germane to the facts presented herein. It would be an entirely different matter if one of the defendants was attempting to publish material which referred to the plaintiff Janet Gotkin; then, invocation of the Ninth Amendment would have some justification. But such is not the case and this court cannot visualize how the withholding of an undisputably confidential medical record constituted a deprivation of the plaintiffs' right to privacy. It is possible that the records sought here contain references to and statements by other mental patients, which are entitled to some degree of confidentiality. Given the fact that the plaintiffs' purpose for requesting these records is to publish a book, it is ironic that plaintiffs' success in this action could conceivably violate the very right to privacy which the plaintiffs rely upon.

A more intricate question to be resolved by this court is whether the defendants' actions constituted a deprivation of plaintiffs' property without due process of law. Such a claim is necessarily dependent upon a threshold finding that former mental patients have a property interest in hospital medical records concerning them. The establishment of any property interest is substantially the result of state, rather than constitutional, law.Therefore, in order to assert a property interest in a hospital record, a former patient must demonstrate some legitimate claim of entitlement to it under state or contractual law.

Turning first to the statutory law of New York, this court is unable to discern a single legislative enactment which even implicitly recognizes a former mental Patients' entitlement to hospital records concerning him. The only statute which relates to the disclosure of a mental hospital's medical records, Section 15.13 of the Mental Hygiene Law, would seem to indicate that patients or former patients are precluded from gaining direct access to their records. The silence of

Section 15.13 as to whether mental patients themselves might be entitled to access to their medical files, should not be construed as a tacit legislative imprimatur. Quite the contrary, the statute establishes a general rule of nondisclosure and only permits access to a mental hospital's medical files in a limited number of enumerated situations.

Similarly, the regulations and policy of the New York Department of Mental Hygiene recognize no right of a former patient to gain direct access to his medical records. Departmental policy, however, does permit a former patient to designate any licensed physician to receive the records for him. This procedure, on the one hand, allows a former patient to gain indirect access to his medical files and, on the other hand, it also insures that a licensed medical practitioner will have an opportunity to review the hospital records before turning them over to the former patient.

Granting a former patient access to medical records without resort to litigation is the exception rather than the rule in an overwhelming majority of our states. In sum, neither the statutory, administrative nor decisional law of New York recognizes a former Patients' entitlement to his medical files in the absence of pending litigation.

In light of the aforementioned discussion, this court concludes that the plaintiffs cannot show a sufficient property interest in the hospitals' medical records which would entitle them to constitutional protection under the Fourteenth Amendment.

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IV. Fox v. Namani 622 N.Y.S. 2d 842

Court : **Supreme Court of New York, Tompkins County**

Coram : **Phillip R. Rumsey, J.**

Facts

Matthew C. Fox was treated by Binghamton Psychiatric Center for a psychiatric problem. The patient filed a malpractice action against the hospital. The patient initially tried to obtain his medical records from the hospital in order to proceed with his malpractice action, but was denied access by the hospital for access to his records because it would be antitherapeutic at that time for Mr. Fox.

Decision

The Court held :-

"Under Mental Hygiene Law, the party seeking disclosure must make a threshold showing that the "interests of justice significantly outweigh the need for confidentiality". That criteria is not the standard applied in a motion for disclosure under CPLR 3101 . CPLR 3101 (a) requires, in part, that "There shall be full disclosure of all matter material and necessary in the prosecution or defense of an action, regardless of the burden of proof, by ... a party". The court is called upon here to balance the best interests of a former patient (as viewed by his physicians) in precluding access to his medical records, against the Patients' right as a litigant to disclosure of his medical records.

Mr. Fox is no longer a patient at the Binghamton Psychiatric Center. As a pro se litigant he has the need to view those medical records pertinent to his claim; without that access he could not proceed to have his claim heard. The material sought is material and relevant.

Mr. Fox is entitled to access to that portion of his hospital record at Binghamton Psychiatric Center covering his admission and treatment in July 1991 which is the subject of his complaint. He is directed to pay the usual cost of photocopying such record prior to its release. Counsel for defendants are directed to submit an order in accordance with this decision upon notice to Mr. Fox within 60 days pursuant to Uniform Rules for Trial Courts."

V. Collins v. Haines 2002 WL 1346794

Court: **United States District Court for the Northern District of California**

Coram : **William H. Alsup**

Facts

The patient, who was currently hospitalized at Napa State Hospital, alleged the psychiatrist had violated his constitutional rights by refusing him permission to see his mental health records covering a month in 2000. Allegedly, the psychiatrist refused the patient access to the records based on the psychiatrist's concern that seeing the records would be harmful to the Patients' mental condition.

Decision

Dismissing the claim, the Court held :-

"To state a claim under 42 U.S.C. § 1983, a plaintiff must allege two essential elements:

(1) that a right secured by the Constitution or laws of the United States was violated, and

(2) that the violation was committed by a person acting under the color of state law.

Haines is the psychiatrist who refused plaintiff's request to see his records. Plaintiff alleges that this refusal was because Dr. Haines concluded that seeing the records would be harmful to plaintiff's mental condition.

There is no constitutional right for a patient to see his own medical records. The federal Freedom of Information and Privacy Acts, although containing provisions regarding access to records, apply only to federal, not state, agencies. Plaintiff has thus failed to state a federal claim, and because no amendment could cure this, the federal claims will be dismissed without leave to amend.

A California statute provides a right of access to one's own medical records, Cal. Health & Safety Code § 123110, but contains an exception for mental health records if the health care provider

determines that seeing the records would present a substantial risk of significant adverse or detrimental consequences to the patient, Cal. Health & Safety Code § 123115(b). In the absence of any federal basis for plaintiff's suit, the court declines to exercise supplemental jurisdiction over this state claim, if indeed it is actionable at all. The state claims, if any, will be dismissed without prejudice."

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VI. Clouser v. Johns Manville Corp. 48 Pa. D. & C.3d 667

Court : **Common Pleas Court of Philadelphia County, Pennsylvania**

Coram : **Richard B. Klein**

Facts

Asbestos Claims Facility requested access to chest X-rays taken of Paul Clouser at York Hospital to send to their physician-experts to evaluate. Mr. Clouser had no objection but the hospital refused to release the original X-rays. The hospital only agreed to allow Asbestos Claims Facility (or Mr. Clouser) expert physicians to come to the hospital to view the X-rays there, or, in the alternative, to make copies of the X-rays at the expense of the defense and send the copies.

Decision

The Court held :-

"While the authorities are scanty in this area, it can be stated as a broad principle that the X-rays, like all medical records, are the property of the hospital. They have the right to keep them as part of an intact medical file. Although the physical film may remain the property of the hospital, the patient has the right of access to these films. The hospital may not hold the films hostage to interfere with the Patients' right to use the X-rays of his or her body for further diagnoses and treatment or for purposes of litigation. The present paranoia of hospitals fearing potential malpractice claims cannot be interposed to cause harm to its patients, either physically or economically.

The common law has long held that a physician is duty-bound to cooperate not only in further medical care of a patient but also in protecting his legal rights. Further, there is a statutory right to access to records granted by the "Patients' Bill of Rights." According to Pennsylvania Admistrative Code: "Patients or patient designees shall be given access to or a copy of their medical records, or both, in accordance with section 103.22(b)(15)," which provides: "The hospital shall provide the patient, or patient designee, upon request, access to all information contained in his medical records, unless access is specifically restricted by the attending physician for medical reasons."

Access must be taken in its common-sense meaning. It must be realistic access. Hospitals cannot impose roadblocks to frustrate the Patients' right to see his or her own records. Likewise, hospitals cannot impose financial obstacles in the way of Patients' access to his or her X-rays. It is an onerous burden to require busy physicians to leave their offices to travel to a hospital to review an X-ray "on site." Likewise, if a patient requires an original X-ray for further diagnoses for medical or legal reasons, upon a proper release and an agreement to ultimately return the films, he or she should be given the original films. If the hospital wants to protect itself further, it can make and retain a copy at its own expense.

While recognizing the problems of malpractice suits and general financial difficulties of hospitals, the bottom line is that hospitals are to serve their patients. Applying a balancing test, the rights of the patients to ready access to their medical records outweighs the relatively minimal financial demands placed on the hospital by this order."

VII. Mantica v. New York State Dep't of Health 94 N.Y. 2d 58

Court : **Court of Appeals of New York**

Coram : **Judith S. Kaye, C.J., Bellacosa, Levine, Ciparick, Wesley and Rosenblatt, JJ.**

Facts

During 1993, James Mantica received allegedly deficient medical care at St. Peter's Hospital in Albany, New York, resulting in the amputation of his legs. On January 21, 1994, his wife, Ruth Mantica, filed a complaint with the New York State Department of Health (DOH). By letter dated February 22, 1995, DOH replied by indicating the results of its investigation.

In May 1995, James Mantica and his wife commenced a medical malpractice action in Supreme Court against several physicians and St. Peter's Hospital. In conjunction with that action, by letter dated September 27, 1995, they requested from the DOH a copy of "your complete file concerning the investigation of the above-captioned complaint, including all communications, notes of interviews, reports, conclusions, Statements of Deficiencies issued, and other pertinent documents." On October 10, 1995, the DOH responded by providing redacted versions of some of the documents requested. In January 1996, James submitted a second, more detailed request for the DOH file, this time invoking Freedom of Information Law (FOIL). The DOH denied the request, claiming to have previously provided all information properly subject to FOIL disclosure. The results of an administrative appeal, dated February 3, 1997, which were sent to James by the DOH, disclosed additional information, cited statutory exemptions to FOIL and stated that the medical records should be obtained directly from the hospital pursuant to Public Health Law.

Decision

The Court held :-

> *"DOH argues that Public Health Law § 18 (6), which limits the instances in which third parties who have obtained confidential medical records may disclose them, provides an exemption from disclosure under FOIL.*
>
> *While a Patients' right of access to his or her own medical records should ordinarily not be denied, that right is not absolute. Public*

Health Law § 18 (3) permits a health care provider to deny a patient access to records if the information contained therein can cause such "substantial and identifiable harm" to the patient or others as to outweigh the Patients' right of access, or if the records contain privileged doctors' notes. In addition, section 18 (3) and (4) provide a detailed mechanism of administrative and judicial review when access is denied for these reasons. Therefore, in cases where the records are potentially harmful, or where privileged medical notes are involved, section 18 (3) and (4) might provide a specific statutory exception to FOIL, and the patient might be required to obtain the records directly from the health care provider pursuant to section 18. Here, however, there has never been any allegation that the records sought by petitioner contain harmful information or privileged doctors' notes. Accordingly, section 18 (3) and (4) do not provide an exemption to FOIL in the case at hand. Finally, the fact that petitioner could obtain his records from the hospital pursuant to section 18 does not diminish his right to obtain them under FOIL."

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B. UNITED KINGDOM

I. Gaskin v. the United Kingdom (1989) 11 EHRR CD 402

Court: **The European Commission of Human Rights**

Coram: **R. Ryssdal, President, J. Cremona, Thór Vilhjálmsson, Dindschedler-Robert, F. Gölcüklü, F. Matscher, L.-E. Pettiti, B.Walsh, Sir Vincent Evans, R. Macdonald, C. Russo, R. Bernhardt, A. Spielmann, J.de Meyer, J.a. Carrillo Salcedo, N. Valticos, S. K. Martens, Maeissen, Registrar, H. Petzold, Deputy Registrar**

Facts

Graham Gaskin was a British citizen who was born in 1959 and following the death of his mother, he was received into care by the Liverpool City Council under section 1 of the Children Act 1948 ("the 1948 Act") on 1 September 1960. He remained in voluntary care until 18 June 1974 when he appeared before the Liverpool Juvenile Court and pleaded guilty to a number of offences including burglary and theft. The court made a care order in respect of him under section 7 of the Children and Young Persons Act 1969. The applicant ceased to be in the care of the Liverpool City Council on attaining the age of majority on 2 December 1977. During the major part of the period while he was in care, he was boarded out with various foster parents, subject to the provisions of the Boarding-Out of Children Regulations 1955 ("the 1955 Regulations"). Under the terms of those regulations the local authority was under a duty to keep certain confidential records concerning the applicant and his care.

Gaskin contended that he was ill-treated in care, and since his majority had wished to obtain details of where he was kept and by whom and in what conditions in order to be able to help him to overcome his problems and learn about his past. Wishing to bring proceedings against the local authority for damages for negligence, he made an application under section 31 of the Administration of Justice Act 1970 ("the 1970 Act") for discovery of the local authority's case records made during his period in care. The local authority objected to the grant of discovery of the records on the ground that disclosure and production would be contrary to the public interest. He was refused access to his records and even after several rounds of litigation, when he was permitted the access, it was restricted. The Council also promulgated Regulations enlisting restrictions on access to records. Aggrieved by these, Gaskin approached the Commission on the ground that such refusal was in breach of his right to respect for his private and family life.

Decision

Allowing the application, the Court held -

49. In the Court's opinion, persons in the situation of the applicant have a vital interest, protected by the Convention, in receiving the information necessary to know and to understand their childhood and early development. On the other hand, it must be borne in mind that confidentiality of public records is of importance for receiving objective and reliable information, and that such confidentiality can also be necessary for the protection of third persons. Under the latter aspect, a system like the British one, which makes access to records dependent on the consent of the contributor, can in principle be considered to be compatible with the obligations under Article 8 (art. 8), taking into account the State's margin of appreciation. The Court considers, however, that under such a system the interests of the individual seeking access to records relating to his private and family life must be secured when a contributor to the records either is not available or improperly refuses consent. Such a system is only in conformity with the principle of proportionality if it provides that an independent authority finally decides whether access has to be granted in cases where a contributor fails to answer or withholds consent. No such procedure was available to the applicant in the present case.

51. The Commission found that Article 10 (art. 10) did not, in the circumstances of the case, give the applicant a right to obtain, against the will of the local authority, access to the file held by that authority. The Government agreed.

52. The Court holds, as it did in its aforementioned Leander judgment, that "the right to freedom to receive information basically prohibits a Government from restricting a person from receiving information that others wish or may be willing to impart to him." (Series A no. 116, p. 29, para. 74).

***

II. R. v. Mid Glamorgan Family Health Services Authority and Anr. (1993) P.I.Q.R. P426

Court : **Queen's Bench Division**

Coram : **Popplewell J.**

Facts

In this case, the applicant at the time of filing the case was 45 years old and wanted to access the medical records maintained during his childhood. He had an unhappy and loveless childhood. He suffered depression and/or psychological problems over a period of years since at least 1966. In 1969 he was diagnosed as suffering from catatonic schizophrenia, psychopathy and accelerated intellectual maturity. In 1966 he received psychotherapy from a consultant psychiatrist and a social worker. He fell in love with her but during the course of treatment she was withdrawn as an act of clinical judgment prompted by his relationship with her. Ever since 1966 the applicant has continued to request sight of records of his diagnosis and of the decision to withdraw her. On August 25, 1969, the applicant was detained at Whitchurch Hospital under the Mental Health Act 1959. As part of his treatment he received group therapy from a team led by consultant psychiatrists and a psychiatric social worker. During the course of this treatment the psychiatric social worker was withdrawn from the team and following the withdrawal the applicant between 1969 and 1972 bombarded the respondents with letters and personal visits requesting the records; the requests were repeated again most recently in 1990. He was refused access to his medical records and on one occasion when he was permitted, there were restrictions and conditions. Aggrieved by these, the applicant approached the Court.

Decision

The Court formulated the following question -

> *The question which arises in this case is whether a patient has an unconditional right of access at common law to his medical records.*
>
> *Dismissing the application and holding that "this applicant has no right of access to his records", the Court held -*
>
> *It will be seen therefore by reason of s 5(1)(b) Access to Health Records Act 1990 does not govern the facts of this case because the records were made before the commencement of the Act. The reason*

for this has not been discovered by counsel.

It seems clear that this Act came into existence as a result of the decision of the European Court of Human Rights in Gaskin v United Kingdom (1990) 12 EHRR 36.

The Data Protection Act 1984 gives an individual a right of access in information held about him in computerised form. In relation to health records regulations were issued under s 29 of the Act. They were the Data Protection (Subject Access Modifications) (Health) Order 1988, SI 1987/1903. By art 3 the Order applies to personal data consisting of information as to physical or mental health of the Data subject if the data are held by a health professional. By art 4(2) access provisions of the Data Protection Act do not apply where this would be either likely to cause serious physical or mental harm to the data subject or be likely to disclose to the data subject the identity of another individual.

It is pertinent to observe that the Act and orders have no limitation as to the time when the records were made. Thus if the records with which we are concerned in this case had been put on to the computer subject to the question of serious harm, and identity the applicant would have had a right of access. It may be thought somewhat illogical that a hospital who chooses to put all its written records on to a computer to bring it into the modern world should then be subject to a claim for access by a patient but the hospital who chooses to keep all its records in an old fashioned file can maintain, so it is argued, its right to refuse access.

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III. Re AB (Disclosure of Medical Records) [2020] EWHC 691 (Fam)

Court : **High Court of Justice Family Division**

Coram : **Sir Andrew McFarlane**

Facts

AB was the brother of CD. CD died two years before the initiation of this proceeding. AB was the personal representative of his deceased brother's estate. According to AB, some five or more years prior to his death, CD made arrangements for a fertility clinic ("BC") in England for the freezing and storage of his sperm. Following CD's death, AB, as his personal representative, had requested the fertility clinic to provide him with a copy of all records relating to the arrangements for the storage and use of CD's sperm and/or any embryos created using his sperm. The clinic, conscious of the need to maintain confidentiality unless there is a clear duty of disclosure, had declined that request. AB, therefore, applied to the court for a declaration as to the lawfulness of the request and an order requiring the clinic to disclose the relevant records.

Decision

The Court, after referring to the provisions of the Access to Health Records Act, 1990 (AHRA 1990) and Human Fertilisation and Embryology Act 1990 (HFEA 1990), held as follows :-

> *44. The outcome of this application turns upon a short and straightforward issue of statutory interpretation, namely, does AHRA 1990, s 5(4) , which limits disclosure that is otherwise permitted under s 3(1)(f) , apply to both of the categories of individual identified in that subsection or only to "any person who may have a claim arising out of the Patients' death"?*
>
> *45. The starting point is that it is common ground between the parties for this court that s 3(1)(f) does establish two distinct categories of individual: (a) the Patients' personal representatives and (b) any person who may have a claim arising out of the Patients' death.*
>
> *46. I accept the submission made by Ms Richards that the wording of s 3(1)(f) is plain on its face. The two categories are, indeed, disjunctive and the reference to "a claim arising out of the Patients' death" is*

expressly tied to the second, and not to a personal representative. I also accept that, if all those claiming under this subsection where required to establish that they had a claim arising out of the Patients' death, there would be no need to identify a personal representative specifically for inclusion in the provision.

47. Section 5(4) is in the form of a proviso which provides a reasonable and proportionate limitation on the degree of access to a deceased's medical records which is to be afforded to an individual who seeks to make a claim arising out of the Patients' death. Such an individual can only see records on a "need to know" basis, rather than being given open-ended disclosure of the entire content of the record.

49. By section 33A(2)(r) of the HFEA 1990, the prohibition on disclosure in s 33A(1) is disapplied with respect to disclosure that 'is made under section 3 of the AHRA 1990 '. This application is one that is made under AHRA 1990, s 3 where, by s 3(1)(f) , for the reasons that I have given, a 'personal representative' may make an application for access to the health record of a patient who has died. A personal representative is expressly identified as a category of applicant. There is no requirement for that individual to prove that the deceased's estate has vested in them. All that is required is for that individual to establish that they are deceased Patients' 'personal representative' and there is no dispute in the present case that AB does, indeed, have that status.

50. It follows from the conclusions that I have reached that the Applicant has made out his case. He has made a valid application for disclosure of the deceased's medical records held by the Respondent clinic, subject to the agreement that information relating to, or provided by, third parties should, at least at this stage, be redacted. Under the terms of the legislation the clinic was obliged to provide the disclosure that was sought."

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IV. Madden & Finucane (a firm) v. Causeway Health and Social Services Trust (1997) NI 20

Court : **Queen's Bench Division**

Coram : **Pringle J.**

Facts

A firm named Madden & Finucane applied under the Access to Health Records (Northern Ireland) Order 1993, SI 1993/1250, to the medical records department of Coleraine Hospital for copies of the hospital records relating to Miss Shona McCorry's treatment. The firm, along with the demand letter enclosed a cheque of £12, representing £10 for the administration fee under the 1993 Order and £2 for the cost of copying and a form of authority signed by Miss McCorry. The hospital records officer replied stating that the department's policy was to ask for the payment of £41·13, (£35 plus value added tax), for requests for information by legal advisers for the purposes of litigation and that the 1993 Order was not intended as a replacement for the existing system which had allowed legal advisers to obtain records at an economic cost.

Decision

Allowing the appeal, the Court held -

The 1993 Order contained no express exclusion where litigation was intended and there was no basis for such exclusion being implied. The English equivalent of the 1993 Order had come into existence as a result of a case in which a person who had been in care as a child was seeking medical records for the purpose of possible litigation. Therefore Parliament must have had it in mind that a person making use of that Act or the 1993 Order might be an intending litigant. If the intention was to exclude intending litigants so they would have to rely on pre-existing legislation, such intention could have been expressed. An applicant could say that he wanted to see his medical records and it was only when he read them that he realized that he might have a possible claim. It would be difficult to disprove such an assertion. Accordingly, it was impossible to read into the 1993 Order any exclusion of intending litigants from the persons entitled to rely on its provisions and the applicants were therefore entitled to a copy of Miss McCorry's medical records for a fee of £10 plus a fee not exceeding the cost of making the copy and the cost of posting it to them.

V. Bluck v. Information Commissioner and Anr. 98 BMLR 1

Court : **Information Tribunal**

Coram : **C Ryan (Dy. Chairman), R Tatam and M Hake (Lay Members)**

Facts

In June 1998, Ms. Bluck's daughter, Karen Davies died at the Epsom General Hospital. Ms. Bluck was provided certain information about the treatment her daughter had received but was not informed of any deficiencies in the standard of care. Approximately five years later she discovered that the hospital's treatment of her daughter had not been satisfactory and that it had admitted liability for her daughter's death and reached a settlement with her widower, on behalf of himself and two children of the marriage. Under the settlement a substantial compensation payment was made. Since that time the applicant tried her level best to obtain further information about Karen Davies' death from the hospital and from the Epsom and St Helier University Hospital NHS Trust, which managed the hospital. The trust was not prepared to disclose or share any details concerning her daughter's treatment without the consent of Karen Davies' widower, as next of kin. A request for information under the Freedom of Information Act 2000 was then made by Ms. Bluck.

Decision

Dismissing the appeal, the Tribunal held -

> *The medical records should not be disclosed because they fell within the scope of the absolute exemption in Section 41 of the Freedom of Information Act. The records contained a body of non-disclosed information which retained the necessary quality of confidence and would be capable of forming the basis of a claim for breach of confidence. This duty of confidence was capable of surviving the death of the patient. The public interest in maintaining the confidentiality in the medical records of the deceased outweighed, by some way, the countervailing public interest in disclosure. If a patient was aware that the information they gave to their doctor might be made public after their death they might not make full disclosure, with the result that medical staff might be unable to make a correct diagnosis or provide appropriate treatment. If disclosure would be contrary to an individual's reasonable expectation of maintaining confidentiality in respect to his or her private information the absence of detriment was not relevant.*

C. AUSTRALIA

I. Breen v. Williams (1996) 138 ALR 259

Court : **High Court of Australia**

Coram : **Brennan CJ, Dawson, Toohey, Gaudron, Mchugh and Gummow JJ**

Facts

In 1977, Ms. Breen underwent breast enhancement surgery. She subsequently endured severe pain. Dr Williams performed a corrective procedure on Ms Breen, but did not remove the existing implants or insert new ones. Ms Breen asked Dr Williams about removing the implants entirely but this did not occur. It was found later that her left breast's implants had leaked silicon. Ms Breen later sued the implants' US manufacturers and required her medical records from Dr Williams. She asked Dr Williams for the records but he refused to provide the records to her on acceptable terms. Ms Breen initiated proceedings claiming a qualified right to her own medical records. Ms Breen appealed to the High Court from a decision of the NSW Court of Appeal, which had dismissed her appeal. Her appeal was based on the ground mainly on four grounds - implied contractual term, Patients' proprietary right in the information in the medical records, fiduciary relationship between patient and doctor and a Patients' right to know all necessary information regarding the treatment.

Decision

Dismissing the appeal, the Court held -

Regarding proprietary right to access medical records,

A claim that a patient has a right of access to his or her medical records is a question of great social importance. But absent a contractual term, such a claim has no foundation in the law of Australia. Nevertheless, every possible argument that could be made in support of the claim by Ms Breen was put. The doctor-patient relationship, like that of valuer and client, is not one of agent and principal. Dr Williams' notes were prepared to assist him to fulfil his professional duties. The property in the medical records relating to Ms Breen which he prepared belongs to him; Ms Breen has no proprietary right in respect of those records. The right of ownership of Dr Williams is, statute or contract apart, good against the world and entitles Dr

Williams to prevent any person from having access to those records.

Although Dr Cashman conceded that Ms Breen did not own the records, he contended that she had a proprietary right or interest in the documents that entitled her to access to them. The premise of this argument was that the records were not owned by anybody. However, the idea that an item of personal property that has not been abandoned has no owner is ill-founded. Ownership may be divisible in the sense that one or more of the collection of rights constituting ownership may be detached and vested in a number of persons. Ownership may also be divorced from possession in numerous circumstances. But the notion that personal property that has not been abandoned may have no owner is one that is foreign to the common law. Statute or contract apart, medical records, prepared by a doctor, are the property of the doctor. That property right entitles the doctor to refuse other persons access to the records. Dr Cashman's argument based on Ms Breen having a proprietary right or interest in the records must fail.

Regarding right of access as can implied contractual term

Even if Australian law implied a term in the contract between doctor and patient that the doctor would act in the Patients' best interests in the sense that Lord Templeman propounded in Sidaway, it would not assist Ms Breen's claim to a right of access to medical records concerning her. Lord Templeman was not asserting that a doctor owed a general duty to act in the best interests of the patient. He used the term in the context of medical advice and treatment. In the paragraph preceding the statement upon which Dr Cashman relies, Lord Templeman had said that " a doctor offers a patient diagnosis, advice and treatment". It was in that context that his Lordship went on to say that the doctor "impliedly contracts to act at all times in the best interests of the patient". The duty was not one applying in respect of all matters arising out of the doctor-patient relationship and subsisting for an indefinite period. Only within the context of "diagnosis, advice and treatment" was the duty to act in the "best interests" of the patient active. Moreover, "it is difficult to see how a

duty to act in the Patients' `best interests' can differ in any substantive way from a doctor's duty to exercise reasonable care in practising the skills of medicine". In addition, Lord Templeman was not formulating an objective test of "best interests". The whole point of his speech in Sidaway was that it was primarily a matter for the doctor to determine what was in the Patients' best interests. He said that "the doctor, bearing in mind the best interests of the patient and bearing in mind the Patients' right of information which will enable the patient to make a balanced judgment must decide what information should be given to the patient and in what terms that information should be couched".

For these reasons, the common law did not imply a term in the contract between Dr Williams and Ms Breen that he would always act in her best interests or that she had a right of access to his record of her treatment. So far as advice and treatment were concerned, the only relevant contractual term implied by law was to exercise reasonable care and skill.

Finally, no ground exists for implying a "best interests" term as a matter of fact. The term was not "so obvious that `it goes without saying'?", nor was it "necessary to give business efficacy to the contract".

Regarding a doctor's fiduciary duty towards patient to grant him access to records,

Dr Cashman contends that the doctor-patient relationship is fiduciary in nature and that a doctor who denies a patient reasonable access to medical files concerning that patient is in breach of this fiduciary duty. In our opinion, this submission must be rejected.

Australian courts have consciously refrained from attempting to provide a general test for determining when persons or classes of persons stand in a fiduciary relationship with one another. As the law stands, the doctor-patient relationship is not an accepted fiduciary relationship in the sense that the relationships of trustee and beneficiary, agent and principal, solicitor and client, employee and

employer, director and company and partners are recognised as fiduciary relationships. Some aspects of the doctor-patient relationship exhibit characteristics that courts have used to find a fiduciary relationship. But that does not mean that their relationship would be fiduciary for all purposes. A consideration of the fundamental obligations of a fiduciary shows that Dr Williams owed no fiduciary duty to Ms Breen to give her access to the records that he had created. In the present case, it is impossible to identify any conflict of interest, unauthorised profit or any loss resulting from any breach of duty.

II. Woollard v Medical Board of Australia [2015] WASC 332

Court : **Supreme Court of Western Australia**

Coram : **Allanson J**

Facts

Keith Victor Woollard, was a medical practitioner. On 2 November 2011, a patient suffered a stroke during a coronary angioplasty performed by Dr Woollard. In May 2014, the Medical Board of Australia brought an allegation of unsatisfactory professional performance against Dr Woollard.On 29 August 2014, a panel of the Medical Board of Australia found that Dr Woollard had behaved in a way that constitutes unsatisfactory professional conduct, and cautioned him. Dr Woollard challenged the finding by this application for judicial review. The allegations against Dr Woollard were that he:

- failed to obtain informed consent from the Patient for the coronary angioplasty, in that he:
    - did not adequately inform the Patient of the possible risks and potential complications; and/or
    - failed to confirm the Patients' understanding of the risks and potential complications.

    and, or in the alternative,
- failed to maintain clear, appropriate, accurate and detailed clinical records of his discussions with the Patient regarding the risks and potential omplications of the coronary angioplasty.

Decision

Dismissing the application, the Court held :-

> *11. The Medical Board of Australia had approved a code: "Good Medical Practice: A Code of Conduct for Doctors in Australia" (the Code). Section 3.3 is headed "Effective communication". It states a number of matters involved in effective communication in the doctor/patient relationship, including:*
>
> - *3.3.3 Informing patients of the nature of, and need for, all aspects of their clinical management, including examination*

and investigations, and giving them adequate opportunity to question or refuse intervention and treatment.

- *3.3.4 Discussing with patients their condition and the available management options, including their potential benefit and harm.*
- *3.3.5 Endeavouring to confirm that your patient understands what you have said.*
- *3.3.6 Ensuring that patients are informed of the material risks associated with any part of the proposed management plan.*

16. *Finally in s 8, "Professional Behaviour", the Code deals with medical records. Section 8.4 states:*

Maintaining clear and accurate medical records is essential for the continuing good care of patients. Good medical practice involves:

- *8.4.1 Keeping accurate, up-to-date and legible records that report relevant details of clinical history, clinical findings, investigations, information given to patients, medication and other management in a form that can be understood by other health practitioners*
- *8.4.2 Ensuring that your medical records are held securely and are not subject to unauthorised access.*
- *8.4.3 Ensuring that your medical records show respect for your patients and do not include demeaning or derogatory remarks.*
- *8.4.4 Ensuring that the records are sufficient to facilitate continuity of patient care.*
- *8.4.5 Making records at the time of the events, or as soon as possible afterwards.*
- *8.4.6 Recognising patients' right to access information contained in their medical records and facilitating that access.*
- *8.4.7 Promptly facilitating the transfer of health information when requested by the patient.*

48. *The obligation to give reasons ensures that a person whose interests may be adversely affected by a decision understands why the decision has been made, and allows a party dissatisfied with a decision to determine whether there has been a reviewable error. In general, the adequacy or sufficiency of reasons is assessed by reference to their function and purpose.*

52. *There is no express statutory prescription of what the reasons must contain, for example by requiring a statement of reasons to set out the findings on material questions of fact, referring to the evidence or other material on which those findings were based.*

62. *The facts relating to the records kept by Dr Woollard were not in dispute. The undisputed fact is that the clinical notes did not record any discussion with the patient on any occasion on which Dr Woollard said he discussed risks and complications. Dr Woollard relied upon the consent forms as being part of the clinical record, and on the submission that the NHMRC General Guidelines for Medical Practitioners on Providing Information to Patients suggests doctors should normally discuss material risks but says nothing about recording the risks discussed.*

64. *There was no controversy about the applicable standard. The briefing submission, which was provided to Dr Woollard before the hearing, clearly identified the issue as whether Dr Woollard maintained appropriate clinical records of his discussion(s) with the patient; identified the Code as the standard, under the National Law, of what constitutes appropriate professional conduct or practice; and identified the relevant sections of the Code.*

65. *Whether a practitioner has complied with the Code is conduct which shows knowledge, skill or judgment possessed, or care exercised by the practitioner, or the want of those matters. The*

finding of unsatisfactory professional performance necessarily implies that the panel found a failure to comply. This is explicit in the statement of the panel at para 43 that the practitioner should have included reference in his notes to having provided a consent form and the booklet, and having discussed the potential risks and complications.

***

III. Dezfouli v Justice Health [2006] NSWADT 274

Court : **New South Wales Administrative Decisions Tribunal**

Coram : **Pearson (Member Judicial)**

Facts

On 18 May 2005, Dezfouli applied under the Freedom of Information Act 1989 (FOI Act) for access to the following documents:

"Entire medical records from the beginning to 15/01/05 and from 01/04/05 to 18/05/05."

On 5 September 2005, it was informed to him that a total of 130 documents had been identified as being within the scope of the application, and that partial access was granted in accordance with clauses 2(1)(d) and (e), 4(1)(c), 4(3), 6, and 11(c) of Schedule 1, and s 25(1)(c) of the FOI Act. Full access had been granted to 60 documents, partial access had been granted to 59 documents and access had been refused to 11 documents. Dezfouli requested internal review, and on 26 September 2005, the original decision was upheld. Aggrieved by this, Dezfouli approached the Tribunal.

Decision

It was held as follows :-

> *10. The first issue is to define the scope of the applicant's request. The applicant requested access to "entire medical records" for a defined period. The term "medical records" is not defined in any relevant legislation. In other legislation which might be thought to shed some light, different terms are used. I consider that the term "medical records" covers a broad range of documents, including records of medication prescribed or administered, observations or reports of medical practitioners and other health professionals, and other matters relating to the health, medical condition, and treatment of the person to whom those records relate.*
>
> *13. I have examined the documents provided by the respondent, and find that documents 1-12, 14, 16-33, 36-45, 47-54, 56, 57, 59-61, and 63-70 fall within the scope of the applicant's request.*
>
> *17. In order to determine whether the agency has established that*

these documents are exempt to the extent to which they contain information which would identify staff, I first considered the context within which these records were created.

32. I am satisfied, based on the witness statements, that the nature of the Long Bay Hospital environment, being a forensic hospital dealing with patients with acute and chronic conditions, many of whom have records of violent behaviours, is such that staff employed there are particularly vulnerable. I am satisfied, based on the witness statements, that there is a possibility that disclosure of the surnames of staff employed by the respondent to provide health care at Long Bay Forensic Hospital could endanger the physical safety of those individuals. I am satisfied that this possibility is a reasonable one, and that there is a realistic possibility of the harm occurring, in relation to disclosure to the applicant in particular, and disclosure more generally. The respondent has discharged its onus of proving that disclosure of the surnames of staff to the applicant "could reasonably be expected" to endanger the life or physical safety of staff working at Long Bay Forensic Hospital.

39. The decision of the respondent to delete material which would identify staff in documents 1-9, 11, 12, 16-20, 22-33, 36-45, 47-54, 56, 57, 59-61, and 63-69, should be affirmed.

40. The respondent claims that documents 10 and 21 are exempt, under cl 4(1)(c) and cl 16(a)(iv) of Schedule 1, in their entirety.

44. I am not satisfied that the respondent has discharged its onus of establishing that disclosure of the content of documents 10 or 21 could reasonably be expected to have a substantial adverse effect on the performance of the respondent of its functions. The documents are, to the extent that they contain material which would identify any of the staff who created them, or who are otherwise identified in them, exempt under cl 4(1)(c). Access should be given to these documents with identifying material deleted.

49. In the particular context of the Long Bay Hospital environment, being a forensic hospital dealing with patients with acute and chronic conditions, many of whom have records of violent behaviours, I am

satisfied that disclosure of information that would identify inmates other than the applicant, particularly in contexts of incidents involving the applicant and those other inmates, would involve disclosure of information concerning the personal affairs of those other persons. That information would include the name of the inmate, and the MIN of that inmate.

50. The next issue to consider is whether disclosure of this information would be "unreasonable". This requires "consideration of all the circumstances, including the nature of the information that would be disclosed, the circumstances in which the information was obtained, the likelihood of the information being information that the person concerned would not wish to have disclosed without consent, and whether the information has any current relevance".

51. Having regard to the circumstances in which the information was obtained, I am satisfied that disclosure of this information to the applicant would be unreasonable. The decision of the respondent to provide access to these documents with the identifying information deleted under s 25(4) should be affirmed.

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D. CANADA

I. McInerney v. MacDonald (1992) S.C.J. No. 57

Court : **Supreme Court of Canada**

Coram : **La Forest, L'Heureux-Dubé, Gonthier, Stevenson and Iacobucci JJ**

Facts

Mrs. Margaret MacDonald was the patient of Dr. Elizabeth McInerney. Before seeking consultations with Dr. McInerney, Mrs. MacDonald was treated by various physicians over a period of years. She became concerned about her medical care that she received. Therefore, she requested copies of the contents of her complete medical file. The doctor delivered copies of all notes, memoranda and reports she had prepared herself but refused to produce copies of consultants' reports and records she had received from other physicians, stating that they were the property of those physicians and that it would be unethical for her to release them. An application was then made on behalf of Mrs. MacDonald to the New Brunswick Court of Queen's Bench for an order directing Dr. McInerney to provide a copy of her entire medical file relating to Mrs. MacDonald. The application was granted. Therefore, an appeal was filed raising two issues:

1. Are patients' medical records prepared by a physician the property of that physician or of the patient?
2. If a Patients' medical records are the property of the physician who prepares them, does a patient nevertheless have the right to examine and obtain copies of all documents in the physician's medical record, including records that the physician may have received which were prepared by other physicians?

Decision

Dismissing the appeal, the Court held -

> *25. I find it unnecessary to reify the Patients' interest in his or her medical records and, in particular, I am not inclined to go so far as to say that a doctor is merely a "custodian" of medical information. The fiduciary duty I have described is sufficient to protect the interest of the patient. The trust-like "beneficial interest" of the patient in the information indicates that, as a general rule, he or she should have a right of access to the information and that the physician should have a*

corresponding obligation to provide it. The Patients' interest being in the information, it follows that the interest continues when that information is conveyed to another doctor who then becomes subject to the duty to afford the patient access to that information.

26. There is a further matter that militates in favour of disclosure of patient records. As mentioned earlier, one of the duties arising from the doctor-patient relationship is the duty of the doctor to act with utmost good faith and loyalty. If the patient is denied access to his or her records, it may not be possible for the patient to establish that this duty has been fulfilled. As I see it, it is important that the patient have access to the records for the very purposes for which it is sought to withhold the documents, namely, to ensure the proper functioning of the doctor-patient relationship and to protect the well-being of the patient. If there has been improper conduct in the doctor's dealings with his or her patient, it ought to be revealed. The purpose of keeping the documents secret is to promote the proper functioning of the relationship, not to facilitate improper conduct.

27. Disclosure is all the more important in our day when individuals are seeking more information about themselves. It serves to reinforce the faith of the individual in his or her treatment. The ability of a doctor to provide effective treatment is closely related to the level of trust in the relationship. A doctor is in a better position to diagnose a medical problem if the patient freely imparts personal information. The duty of confidentiality that arises from the doctor-patient relationship is meant to encourage disclosure of information and communication between doctor and patient. In my view, the trust reposed in the physician by the patient mandates that the flow of information operate both ways.

28. While patients should, as a general rule, have access to their medical records, this policy need not and, in my mind, should not be pursued blindly. The related duty of confidentiality is not absolute. In Halls v. Mitchell, supra, at p. 136, Duff J. stated that, prima facie, the patient has a right to require that professional secrets acquired by the practitioner shall not be divulged. This right is absolute unless there is

some paramount reason that overrides it. For example, "there may be cases in which reasons connected with the safety of individuals or of the public, physical or moral, would be sufficiently cogent to supersede or qualify the obligations prima facie imposed by the confidential relation". Similarly, the Patients' general right of access to his or her records is not absolute. The Patients' interest in his or her records is an equitable interest arising from the physician's fiduciary obligation to disclose the records upon request. As part of the relationship of trust and confidence, the physician must act in the best interests of the patient. If the physician reasonably believes it is not in the Patients' best interests to inspect his or her medical records, the physician may consider it necessary to deny access to the information. But the patient is not left at the mercy of this discretion. When called upon, equity will intervene to protect the patient from an improper exercise of the physician's discretion. In other words, the physician has a discretion to deny access, but it is circumscribed. It must be exercised on proper principles and not in an arbitrary fashion. Where a person, in this case a doctor, is under a fiduciary duty to inform another, equity acts in personam to prevent that person from acting in a manner inconsistent with the interests of the person to whom the duty is owed.

30. In my view, the onus properly lies on the doctor to justify an exception to the general rule of access. Not only is the information in some fundamental sense that of the patient; the doctor has primary access to it. In comparison, the records are unavailable to the patient. To some extent, what the documents contain is a matter of speculation for the patient. Consequently, there is a marked disparity in the ability of each party to prove its case. The burden of proof should fall on the party who is in the best position to obtain the facts.

39. In the absence of regulatory legislation, the patient is entitled, upon request, to inspect and copy all information in the Patients' medical file which the physician considered in administering advice or treatment. Considering the equitable base of the Patients' entitlement, this general rule of access is subject to the superintending jurisdiction of the court.

II. Rousseau v. Canada (Privacy Commissioner), 2008 FCA 39

Court : **Federal Court of Appeal**

Coram : **Décary, Nadon, and Trudel JJ.**

Facts

Rousseau was receiving long-term disability benefits from Maritime Life, an Insurance company. The insurer questioned Rousseau's continued eligibility for benefits and required Rousseau to undergo an independent psychiatric medical examination. The examination was performed and Rousseau signed consent for disclosure of the report to the insurer. As a result of the report, the insurer terminated Rousseau's benefits. The insurer later sent Rousseau a copy of the report. Rousseau requested a copy of the doctor's file, which consisted only of the doctor's notes taken during the examination. The doctor refused and Rousseau complained to the Office of the Privacy Commissioner. The Commissioner allowed the complaint recommending disclosure, but the doctor refused. Pursuant to section 14 of the Personal Information Protection and Electronic Documents Act, Rousseau successfully applied for an order for access to the notes. The doctor appealed. The question to be decided was whether the handwritten notes of a doctor, taken during an independent medical examination (IME) of an insured person performed in Ontario by the doctor at the request of an insurance company, are personal information under the Personal Information Protection and Electronic Documents Act?

The appeal was allowed in part. Rousseau was held entitled to access the notes to the extent that they constituted "personal information" but not to those parts of the notes that did not constitute "personal information".

Decision

The Court held -

> *In light of the Privacy Commissioner's recognition that there are in the notes information which is personal to Mr. Rousseau and information which is not, it may be said that in the end, Mr. Rousseau has a right of access to the information he gave the doctor, and to the final opinion of the doctor in the form of the report to the insurer. In accordance with Principle 4.9.1. of Schedule I to the PIPED Act, this enables Mr. Rousseau to correct any mistakes in the information he gave the*

doctor or which the doctor noted, as well as any mistakes in the doctor's reasoned final opinion about his medical condition. But the process of getting to that final opinion from the initial personal information of Mr. Rousseau belongs to the doctor'

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CHAPTER - III

HEALTHCARE JURISPRUDENCE IN INDIA

1. Dr Laxman Balkrishna Joshi v. Dr Trimbak Bapu Godbole & Anr. (1969) 1 SCR 206

Court : **Supreme Court of India**

Coram : **R.S. Bachawat , J.M. Shelat and A.N. Grover, JJ.**

Facts

Dr. Trimbak Bapu Godbole's son met with an accident which resulted in the fracture of the femur of his left leg. After some primary treatment by a local physician, the injured was taken to a hospital in Pune. Dr. Laxman Balkrishna Joshi (surgeon) prescribed two injections of morphia and hyoscine hydrobromide at an hour's interval but only one injection was administered. After the x-ray, the boy was taken to the operation theatre where his injured leg was put in plaster splints and then he was moved to a room. Subsequently, the boy developed difficulty in breathing and cough and his condition deteriorated. He expired the same night, in spite of the emergency treatment administered to him. Dr. Joshi issued a certificate stating that the cause of death was fat embolism. Dr. Trimbak filed a case of tortuous damage against the surgeon inter alia alleging that his son's leg was put in plaster using manual traction and excessive force (with the help of three men) though such traction is done under proper general anaesthesia and never under morphia alone. The surgeon denied the allegation of excessive force and submitted that given the Patients' condition, general anaesthesia was not found to be desirable and that he had therefore decided to delay the reduction of fracture and instead carried out only immobilization of the leg for the time being with light traction. The trial court and in appeal, the Bombay High Court gave concurrent findings in favour of Dr. Trimbak and held that the Dr. Joshi had undertaken reduction of the fracture without caring to give anaesthesia and that excessive force was used in the process which resulted in shock causing the Patients' death and awarded damages.

In appeal by special leave, the Supreme Court considered the evidence relied upon by the appellant and held that there was no ground for interference in the findings of the lower Courts. The Court also took into account that Dr. Trimbak was himself a medical practitioner of standing though not an expert in surgery and would understand the treatment given, to which he was a witness.

Decision

The Hon'ble Court held as follows :-

> *11. The duties which a doctor owes to his patient are clear. A person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties, viz., a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or a duty of care in the administration of that treatment. A breach of any of those duties gives a right of action for negligence to the patient. The practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor a very low degree of care and competence judged in the light of the particular circumstances of each case is what the law requires: (cf. Halsbury's Laws of England 3rd ed. vol. 26 p. 17). The doctor no doubt has discretion in choosing treatment which he proposes to give to the patient and such discretion is relatively ampler in cases of emergency".*

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2. Rakesh Chandra Narayan v. State of Bihar (1989) 1 Supp SCC 644

Court : **Supreme Court of India**

Coram : **Ranganath Misra and M.N.Venkatachaliah, JJ.**

Fact

A letter was addressed to the then Chief Justice of India by two residents of Patna highlighting the deplorable condition of a mental hospital in Kanke, Ranchi. The application was considered as public interest litigation and registered under Article 32 of the Indian Constitution. Supreme Court of India called upon the State of Bihar to file its counter affidavit and ordered the Chief Judicial Magistrate of Ranchi to visit the hospital and submit a report about the conditions prevailing there. The Chief Judicial Magistrate (CJM) visited the hospital and after thoroughly investigating the situation submitted a detailed report on 15th July, 1986.

The outcome of the report by the CJM highlighted the sorry state of affairs prevailing in the hospital. The sanctioned strength of medical officers was 16 but only 9 had been filled-up and there were 7 vacancies. There was acute shortage of water in the Hospital and none of the toilets within the hospital complex were in order. Only 300 beds were available for 1580 patients. Some patients were found naked in the absence of clothing and others were wearing torn shirts and pants. The amount sanctioned for daily meal was found to be wholly inadequate. There was no account of the stock of medicines; life-saving drugs were not stored properly. The medical equipments were not in working condition. Some of the patients had to pay for their treatment while the treatment to the general category was intended to be free. Several doctors were not available in the Hospital for days together. Close to 300 patients who had recovered were not in a position either to return back to their homes or to any employment in the absence of any facility.

Decision

The Hon'ble Apex Court held -

> *29. In a welfare State - and we take it that the State of Bihar considers itself to be one such - it is the obligation of the State to provide medical*

attention to every citizen. Running of the mental hospital, therefore, is in the discharge of the State's obligation to the citizens and the fact that lakhs of rupees have been spent from the public exchequer (perhaps without or inadequate return) is not of any consequence. The State has to realize its obligation and the Government of the day has got to perform its duties by running the hospital in a perfect standard and serving the patients in an appropriate way'.

32. We are cognizant of the position that it is difficult for the Court to monitor the management of a hospital- particularly when it is located a thousand kilometers away; but since there have been some improvements with the Court's intervention, to get out of the picture at this stage would only mean that the situation will again deteriorate no sooner the Court's attention is withdrawn. As we have already pointed out mere restoration of the hospital to its old position would only bring into existence an archaic institution sans modernism. In our opinion, it will be much better if a Committee of Management is appointed with full powers to look after all aspects of the institution'.

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3. Parmanand Katara v. Union of Indian & Ors (1989) 4 SCC 286

Court : **Supreme Court of India**

Coram : **Ranganath Misra and G.L.Oza, JJ.**

Facts

Parmanand Katara, a human rights activist filed an application under Article 32 of the Constitution with a prayer that every injured citizen brought for treatment should instantaneously be given medical aid and thereafter the procedural criminal law may be allowed to operate. In his writ petition he appended a report titled 'Law helps the injured to die' published in the leading daily 'Hindustan Times'. In the said publication it was alleged that a scooterist was knocked down by a speeding car and started bleeding profusely. A person, who was on the road, picked up the injured and took him to the nearest hospital. The doctors refused to attend him and told the man that he should take the victim to a different hospital located 20 kms away that was authorized to handle medico-legal cases. The victim was immediately rushed to the other hospital but before he could reach there he succumbed to the injuries.

Decision

The Hon'ble Apex Court held -

7. There can be no second opinion that preservation of human life is of paramount importance. That is so on account of the fact that once life is lost, the status quo ante cannot be restored as resurrection is beyond the capacity of man. The patient whether he be an innocent person or be a criminal liable to punishment under the laws of the society, it is the obligation of those who are in-charge of the health of the community to preserve life so that the innocent may be protected and the guilty may be punished. Social laws do not contemplate death by negligence to tantamount to legal punishment.

8. Article 21 of the Constitution casts the obligation on the State to preserve life. The provision as explained by this Court in scores of decisions has emphasized and reiterated with gradually increasing

emphasis that position. A doctor at the Government hospital positioned to meet this State obligation is, therefore, duty-bound to extend medical assistance for preserving life. Every doctor whether at a Government hospital or otherwise has the professional obligation to extend his services with due expertise for protecting life. No law or State action can intervene to avoid/delay the discharge of the paramount obligation cast upon members of the medical profession. The obligation being total, absolute and paramount, laws of procedure whether in statutes or otherwise which would interfere with the discharge of this obligation cannot be sustained and must, therefore, give way.

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4. Indian Medical Association v. V.P. Shantha & Ors. (1995) 6 SCC 651

Court : **Supreme Court of India**

Coram : **Kuldip Singh, S.C.Agarwal and B.L.Hansaria, JJ.**

Facts

A series of decisions led to confusion and contradictions in the judiciary regarding the scope and application of the Consumer Protection Act in cases of medical negligence. Conflicting approaches were taken in various judgments of the National Consumer Disputes Redressal Commission also. Owing to the lack of uniformity in judicial interpretation a series of appeals, special leave petitions and the writ petitions were filed against the contradictory decisions of the High Courts and subordinate courts. Supreme Court heard these matters in this case and decided the following important issues:-

i. Whether a medical practitioner, hospital, or nursing home can be regarded as rendering 'service' under Section 2(1)(o) of the Consumer Protection Act, 1986?

ii. Under what circumstances can the service rendered at a hospital/nursing be regarded as 'service' under Section 2(1)(o) of the Consumer Protection Act, 1986?

Decision

The Hon'ble Supreme Court held the following at para 55 of the judgment :-

(1) Service rendered to a patient by a medical practitioner (except where the doctor renders service free of charge to every patient or under a contract of personal service), by way of consultation, diagnosis and treatment, both medicinal and surgical, would fall within the ambit of 'service' as defined in Section 2(1) (o) of the Act.

(2) The fact that medical practitioners belong to the medical profession and are subject to the disciplinary control of the Medical Council of India and/or State Medical Councils constituted under the provisions of the Indian Medical Council Act would not exclude the services rendered by them from the ambit of the Act.

(3) A 'contract of personal service' has to be distinguished from a 'contract for personal services'. In the absence of a relationship of master and servant between the patient and medical practitioner, the service rendered by a medical practitioner to the patient cannot be regarded as service rendered under a 'contract of personal service'. Such service is service rendered under a `contract for personal services' and is not covered by exclusionary clause of the definition of 'service' contained in Section 2(1) (o) of the Act.

(4) The expression 'contract of personal service' in Section 2(1) (o) of the Act cannot be confined to contracts for employment of domestic servants only and the said expression would include the employment of a medical officer for the purpose of rendering medical service to the employer. The service rendered by a medical officer to his employer under the contract of employment would be outside the purview of 'service' as defined in Section 2(1) (o) of the Act.

(5) Service rendered free of charge by a medical practitioner attached to a hospital/Nursing home or a medical officer employed in a hospital/Nursing home where such services are rendered free of charge to everybody, would not be "service" as defined in Section 2(1) (o) of the Act. The payment of a token amount for registration purpose only at the hospital/nursing home would not alter the position.

(6) Service rendered at a non-Government hospital/Nursing home where no charge whatsoever is made from any person availing the service and all patients (rich and poor) are given free service - is outside the purview of the expression 'service' as defined in Section 2(1) (o) of the Act. The payment of a token amount for registration purpose only at the hospital/Nursing home would not alter the position.

(7) Service rendered at a non-Government hospital/Nursing home where charges are required to be paid by the persons availing such services falls within the purview of the expression 'service' as defined in Section 2(1) (o) of the Act.

(8) Service rendered at a non-Government hospital/Nursing home where charges are required to be paid by persons who are in a position to pay

and persons who cannot afford to pay are rendered service free of charge would fall within the ambit of the expression 'service' as defined in Section 2(1) (o) of the Act irrespective of the fact that the service is rendered free of charge to persons who are not in a position to pay for such services. Free service, would also be "service" and the recipient a "consumer" under the Act.

(9) Service rendered at a Government hospital/health centre/dispensary where no charge whatsoever is made from any person availing the services and all patients (rich and poor) are given free service - is outside the purview of the expression 'service' as defined in Section 2(1) (o) of the Act. The payment of a token amount for registration purpose only at the hospital/nursing home would not alter the position.

(10) Service rendered at a Government hospital/health centre/dispensary where services are rendered on payment of charges and also rendered free of charge to other persons availing such services would fall within the ambit of the expression 'service' as defined in Section 2(1) (o) of the Act irrespective of the fact that the service is rendered free of charge to persons who do not pay for such service. Free service would also be "service" and the recipient a "consumer" under the Act.

(11) Service rendered by a medical practitioner or hospital/nursing home cannot be regarded as service rendered free of charge, if the person availing the service has taken an insurance policy for medical care where under the charges for consultation, diagnosis and medical treatment are borne by the insurance company and such service would fall within the ambit of 'service' as defined in Section 2(1) (o) of the Act.

(12) Similarly, where, as a part of the conditions of service, the employer bears the expenses of medical treatment of an employee and his family members dependent on him, the service rendered to such an employee and his family members by a medical practitioner or a hospital/nursing home would not be free of charge and would constitute 'service' under Section 2(1) (o) of the Act.

5. Paschim Banga Khet Mazdoor Samity v. State Of West Bengal & Anr. (1996) 4 SCC 37

Court : **Supreme Court of India**

Coram : **S.C.Agarwal and G.T.Nanavati, JJ.**

Facts

Hakim Seikh was a member of Paschim Banga Khet Mazdoor Samity, an organization of agricultural labourers. On 08.07.1992 at about 7.45 pm he fell off a train at Mathurapur station of West Bengal and suffered severe head injuries. He was immediately taken to the Primary Health Centre, Mathurapur for treatment. The Medical Health in-charge Officer, Mathurapur referred him to some other state health hospital having better medical facilities. Hakim Sheikh was taken to NRS Medical College, Calcutta where the Emergency Medical Officer after examining him and taking X-Ray prints of his skull recommended his immediate admission in the hospital for further treatment. Due to non-availability of bed, Hakim Sheikh was not admitted in that hospital. Subsequently, he was taken to Calcutta Medical Hospital but there also he was denied admission due to non-availability of bed. He was then taken to Shambhu Nath Pandit Hospital but he was not admitted there on the ground that the hospital had no ENT Emergency or Neuro Emergency Department. Hakim Sheikh was thereafter taken to Calcutta National Medical College Hospital where he was once again denied admission due to non-availability of bed. Two more hospitals where he was taken, denied admission as there was no facility of neurosurgery. Hakim Sheikh was ultimately admitted in Calcutta Medical Research Institute, a private hospital as an indoor patient where an expenditure of approximately Rs. 17,000/- was incurred in his treatment.

Feeling aggrieved by the callous attitude of the medical authorities in different state run hospitals in Calcutta in providing treatment for the serious injuries, a writ petition under Article 32 of the Indian Constitution was filed. During the pendency of the writ petition, Government of West Bengal appointed an enquiry Committee to report on why Hakim Seikh was repeatedly denied treatment and to give

recommendations to avoid similar incidents from occurring again.

Several remedial measures to rule out recurrence of such incidents in future and also for ensuring immediate medical attention and treatment to persons in real need were broadly enumerated by the Hon'ble Court.

Decision

Allowing the writ petition, the Hon'ble Court held -

9. The Constitution envisages the establishment of a welfare state at the federal level as well as at the state level. In a welfare state the primary duty of the Government is to secure the welfare of the people. Providing adequate medical facilities for the people is an essential part of the obligations undertaken by the Government in a welfare state. The Government discharges this obligation by running hospitals and health centers which provide medical care to the person seeking to avail those facilities. Article 21 imposes an obligation on the State to safeguard the right to life of every person. Preservation of human life is thus of paramount importance. The Government hospitals run by the State and the medical officers employed therein are duty bound to extend medical assistance for preserving human life. Failure on the part of a Government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his right to life guaranteed under Article 21. In the present case there was breach of the said right of Hakim Seikh guaranteed under Article 21 when he was denied treatment at the various Government hospitals which were approached even though his condition was very serious at that time and he was in need of immediate medical attention. Since the said denial of the right of Hakim Seikh guaranteed under Article 21 was by officers of the State in hospitals run by the State the State cannot avoid its responsibility for such denial of the constitutional right of Hakim Seikh. In respect of deprivation of the constitutional rights guaranteed under Part III of the Constitution the position is well settled that adequate compensation can be awarded by the court for such violation by way of redress in proceedings under Articles 32 and 226 of the Constitution.

6. Raghunath G. Raheja v. Maharashtra Medical Council AIR 1996 Bom 198

Court : **Bombay High Court**

Coram : **M.Shah and A. Savant, JJ.**

Facts

Raghunath Raheja's wife was admitted in Nanavati Hospital, Bombay on 18th October 1989 after she complained of a heart ailment viz. "acute left ventricular failure" and "diabetes mellitus". Upon receiving necessary treatment she was discharged on 27th October 1989. She was re-admitted in the said Hospital on 22nd November 1989 and was referred to the Dr. Pahlajani, a cardiologist who after consulting Dr. Sharad Pande, a heart surgeon decided to operate upon her for a bypass surgery. Accordingly, on 7th December 1989 by-pass surgery was performed by Dr. Pande and subsequently was discharged on 18th December 1989. Thereafter she suffered myocardial infraction and despite treatment being given to her, she expired on 23rd January 1990. Raghunath Raheja approached the Maharashtra Medical Council alleging medical negligence against the doctors. The Council after holding an inquiry exonerated the doctors. Against this decision, Raghunath approached the Bombay High Court challenging the decision of the Council and also sought appropriate directions on the Council for regulating its procedure and practice for getting speedy disposal of the complaints made to it.

Decision

The Court upheld the decision of the Council but regarding access to medical records, held as follows:

> *15. We have already referred to the scheme of the provisions of the Maharashtra Medical Council Act 1965 and the 1967 Rules framed thereunder. We are of the view that when a patient or his near relative demands from the Hospital or the doctor the copies of the case papers, it is necessary for the Hospital authorities and the doctors concerned to furnish copies of such case papers to the patient or his near relative. In our view, it would be necessary for the Medical Council to ensure*

that necessary directions are given to all the Hospitals and the doctors calling upon then to furnish the copies of the case papers and all the relevant documents pertaining to the patient concerned. The hospitals and the doctors may be justified, in demanding necessary charges for supplying the copies of such documents to the patient or the near relative. We, therefore, direct the first respondent Maharashtra Medical Council to issue necessary circulars in this behalf to all the hospitals and doctors in the State of Maharashtra. We do not think that the hospitals or the doctors can claim any secrecy or any confidentiality in the matter of copies of the case papers relating to the patient. These must be made available to him on demand, subject to payment of usual charges. If necessary, the Medical Council may issue a press-note in this behalf giving it wide publicity in all the media.

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7. Rajappan v. Sree Chitra Tirunal Institute for Medical Science & Technology 2004 SCC Online Ker 410

Court : **Kerala High Court**

Coram : **C.N. Ramachandran Nair, J.**

Facts

Rajappan's daughter was admitted in a hospital established by the Government of Kerala for treatment of epilepsy. During the course of treatment she died on 17.04.2003. After the death of his daughter, Rajappan applied for medical records pertaining to the treatment of his daughter. The husband of the deceased however was given case summary and discharge record and investigation report by the Hospital. Thereafter, Rajappan's request for copies of medical records was declined.

Decision

After referring to the provisions of Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002, the Court held as follows :

> *5. It is also to be noticed that Regulations do not provide any immunity for any medical record to be retained by any medical practitioner of the hospital from being given to the patient. On the other hand it is expressly provided that a patient should be given medical records in Appendix 3 with supporting documents. Therefore in the absence of any immunity either under the Regulations or under any other law, the respondent-Hospital is bound to give photocopies of the entire documents of the patient. Standing counsel for the respondent-Hospital submitted that the documents once furnished will be used as evidence against the hospital and against the doctors concerned. I do not think this apprehension will justify for claiming immunity against furnishing the documents.*
>
> *6. If proper service was rendered in the course of treatment, I see no reason why the hospital, or staff, or doctors should be apprehensive of any litigation. A patient or victim's relative is entitled to know*

whether proper medical care was rendered to the patient entrusted with the hospital, which will be revealed from case sheet and medical records. There should be absolute transparency with regard to the treatment of a patient and a patient or victim's relative is entitled to get copies of medical records. This is recognised by the Medical Council Regulations and therefore petitioner is entitled to have copies of the entire medical records of his daughter which should be furnished in full. The respondent Hospital is entitled to retain the original for their purpose and need furnish only the true certified copy of the originals.

7. W.P. is therefore disposed of directing the respondents to give photocopies of the entire case records of the deceased to the petitioner, within three weeks from the date of production of a copy of this judgment by the petitioner. If there is no provision for issuing photocopies at the cost of the Hospital, the petitioner will remit the photocopying charges.

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8. State of Punjab v. Shiv Ram and Ors. (2005) 7 SCC 1

Court : **Supreme Court of India**

Coram : **R.C.Lahoti, C.J., C.K. Thakker, J., P.K. Balasubrmaniam, J.**

Facts

In this case a man and his wife filed a suit against the State of Punjab and a lady surgeon who was in the State Government's employment at the relevant time, for recovery of damages to the tune of Rs 3,00,000 on account of a child having been born to them in spite of the wife having undergone a tubectomy operation performed by the lady surgeon. According to the husband and wife, they already had a son and two daughters from the wedlock lasting over 17 years. In response to a publicity campaign carried out by the Family Welfare Department of the State, the wife with the consent of her husband, underwent a sterilisation operation on 1-8-1984. A certificate in this regard duly signed by the lady surgeon who performed the said surgery, was issued to her. On 4-10-1991, the wife gave birth to a female child attributing the birth of the child to carelessness and negligence of the lady surgeon. The District Court had awarded damages to the couple which was upheld by the High Court.

Decision

The Supreme Court, after referring to medical documents and literature, judgments of various courts and the relevant statutory provisions, reversed the orders of the District Court and the High Court holding that the pregnancy even after sterilization operation could not be attributed to the negligence on the part of the lady surgeon. However, the Court made the following observations with respect to the duties of a doctor -

> *In recent times the self-regulatory standards in the profession have shown a decline and this can be attributed to the overwhelming impact of commercialisation of the sector. There are reports against doctors of exploitative medical practices, misuse of diagnostic procedures, brokering deals for sale of human organs, etc. It cannot be denied that black sheep have entered the profession and that the profession has been unable to isolate them effectively. The need for*

external regulation to supplement professional self-regulation is constantly growing. The high costs and investments involved in the delivery of medical care have made it an entrepreneurial activity wherein the professionals look to reaping maximum returns on such investment. Medical practice has always had a place of honour in society; currently the balance between service and business is shifting disturbingly towards business and this calls for improved and effective regulation, whether internal or external. There is need for introspection by doctors - individually and collectively. They must rise to the occasion and enforce discipline and high standards in the profession by assuming an active role.

***

9. Samira Kohli v. Dr. Prabha Manchanda & Anr (2008) 2 SCC 1

Court : **Supreme Court of India**

Coram : **B. N. Agarwal, P. P. Naolekar, R. V. Raveendran, JJ.**

Facts

Samira Kohli visited the clinic of Dr. Prabha Manchanda complaining of prolonged menstrual bleeding for nine days. She was accompanied by her mother. The doctor advised her for a laparoscopy test under general anesthesia for making an affirmative diagnosis. Admission Card of the clinic showed that admission was for diagnostic and operative laparoscopy. The consent form for surgery filled by the doctor's assistant described the procedure to be undergone as "diagnostic and operative laparoscopy. Laparotomy may be needed". Thereafter, Samira Kohli was put under general anesthesia and subjected to a laparoscopic examination. When she was unconscious, the assistant came out of the operation theatre and took the consent of her mother for performing hysterectomy under general anesthesia. Upon obtaining consent Dr. Prabha performed abdominal hysterectomy (removal of uterus) and bilateral salpingo oophorectomy (removal of ovaries and fallopian tubes). On 15.05.1995 Samira Kohli got herself discharged at the behest of a friend without settling the bill.

Dr. Prabha Manchanda lodged a complaint against Samira Kohli alleging that on 15.5.1995 her friend abused and threatened her and against medical advice she got herself discharged without clearing the bills. On the other hand, Samira Kohli filed a complaint against Dr. Prabha alleging that her uterus, ovaries and fallopian tubes were removed without her consent when she was under general anesthesia for a Laparoscopic test. Due to removal of her reproductive organs she had suffered premature menopause necessitating a prolonged medical treatment and a Hormone Replacement Therapy (HRT) course apart from making her vulnerable to other health problems.

Decision

The Hon'ble Court held -

18. Consent in the context of a doctor-patient relationship, means the grant of permission by the patient for an act to be carried out by the doctor, such as a diagnostic, surgical or therapeutic procedure. Consent can be implied in some circumstances from the action of the patient. For example, when a patient enters a Dentist's clinic and sits in the Dental chair, his consent is implied for examination, diagnosis and consultation. Except where consent can be clearly and obviously implied, there should be express consent.

65. When a patient is a competent adult, there is no question of someone else giving consent on her behalf. There was no medical emergency during surgery. The appellant was only temporarily unconscious, undergoing only a diagnostic procedure by way of laparoscopy. The respondent ought to have waited till the appellant regained consciousness, discussed the result of the laparoscopic examination and then taken her consent for the removal of her uterus and ovaries. In the absence of an emergency and as the matter was still at the stage of diagnosis, the question of taking her mother's consent for radical surgery did not arise. Therefore, such consent by mother cannot be treated as valid or real consent. Further consent for hysterectomy, is not consent for bilateral salpingo - ophorectomy.

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10. Malay Kumar Ganguly v. Dr. Sukumar Mukherjee (2009) 9 SCC 221

Court : **Supreme Court of India**

Coram : **S.B.Sinha and Deepak Verma, JJ.**

Facts

Anuradha, a Child Psychologist by profession, was settled in United States of America with her husband Dr. Kunal Saha. They left for a vacation to India on 24-3-1998. They arrived at Calcutta on 1-4-1998. While in Calcutta, Anuradha developed fever along with skin rash on 25-4-1998. Dr. Sukumar Mukherjee, who attended and examined Anuradha at her parental residence on a professional call, did not prescribe her any specific medicine. However, two weeks thereafter i.e. on 7-5-1998, the skin rash reappeared more aggressively. Dr. Mukherjee was again contacted who then prescribed depomedrol injection 80 mg twice daily for the next three days. Anuradha's condition deteriorated rapidly. Accordingly, she was admitted at Advanced Medicare Research Institute (AMRI) in the morning of 11-5-1998 under Dr. Mukherjee's supervision. Anuradha was also examined by Dr. Baidyanath Halder and later by Dr. Abani Roy Chowdhury. Anuradha was later shifted to Breach Candy Hospital, Mumbai as her condition further deteriorated. She breathed her last on 28-5-1998. Kunal sent a lawyer's notice to 26 persons on 30-9-1998. On 1911-1998 one of Kunal's relatives, Malay Kumar Ganguly filed a criminal complaint in the Court of the Chief Judicial Magistrate, 24 Parganas at Alipore against Dr. Sukumar Mukherjee, Dr. Baidyanath Halder and Dr. Abani Roy Chowdhury, for commission of the offence under Section 304-A of the Penal Code, 1860. The learned Chief Judicial Magistrate, Alipore by his judgment and order dated 29-5-2002 found Dr. Sukumar Mukherjee and Dr. Baidyanath Halder guilty of commission of an offence under Section 304A of the Penal Code and sentenced them to undergo simple imprisonment for three months and to pay a fine of Rs 3000 each and in default to undergo a further simple imprisonment for fifteen days. Dr. Abani Roy Chowdhury was, however, acquitted.

Decision

The Court held -

142. The patients by and large are ignorant about the disease or side or adverse affect of a medicine. Ordinarily the patients are to be informed about the admitted risk, if any. If some medicine has some adverse affect or some reaction is anticipated, he should be informed thereabout. It was not done in the instant case.

143. The law on medical negligence also has to keep up with the advances in the medical science as to treatment as also diagnostics. Doctors increasingly must engage with patients during treatments especially when the line of treatment is a contested one and hazards are involved. Standard of care in such cases will involve the duty to disclose to patients about the risks of serious side effects or about alternative treatments. In the times to come, litigation may be based on the theory of lack of informed consent.

144. A significant number of jurisdictions, however, determine the existence and scope of the doctor's duty to inform based on the information a reasonable patient would find material in deciding whether or not to undergo the proposed therapy.

145. In this respect, the only reasonable guarantee of a Patients' right of bodily integrity and self-determination is for courts to apply a stringent standard of disclosure in conjunction with a presumption of proximate cause. At the same time, a reasonable measure of autonomy for the doctor is also pertinent to be safeguarded from unnecessary interference.

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11. Union of India v. Moolchand Kharaiti Ram Trust (2018) 8 SCC 321

Court : **Supreme Court of India**

Coram : **Arun Mishra and U.U.Lalit, JJ.**

Facts

The validity of Circular issued by the Government of NCT of Delhi (GNCTD) on 2-2-2012 was in issue before the Apex Court, whereby it was intimated to the hospitals to implement the judgment of the Delhi High Court with regard to free treatment to the weaker sections of the society in terms of the judgment dated 22-3-2007 in Social Jurists v. State (NCT of Delhi). Thereafter, the Land & Development Officer (in short "L&DO") passed an order dated 2-2-2012 wherein it was stated that the Government of India had taken a policy decision that all the hospitals which have been provided land by L&DO have to strictly follow the policy of providing free treatment as provided in it. The said conditions were applicable to Moolchand Hospital and St. Stephen's Hospital as they were allotted land by L&DO. The issue before the Apex Court was as follows:

> *Whether by virtue of fact that Moolchand Kharaiti Ram Trust and St. Stephen's Hospital have obtained the land for charitable purposes at a concessional rate, it was open to the Government to impose a condition of 10% in IPD and 25% in OPD services to be provided free of cost to patients of economically weaker sections?*

Decision

The Court held -

> *68. In our opinion, the State can also impose such obligation when the government land is held by such hospitals and it is the constitutional obligation imposed upon such hospitals. Under Article 47, State has to make constant endeavour to raise the level of nutrition and the standard of living and to improve public health. It is also one of the fundamental duties enshrined in Article 51-A(h) to develop the scientific temper, humanism and the spirit of inquiry and reform. It would be inhuman to deny a person who is not having sufficient means or no means, the life-saving treatment, simply on the ground*

that he is not having enough money. Due to financial reasons, if treatment is refused, it would be against the very basic tenets of the medical profession and the concept of charity in whatever form we envisage the same, besides being unconstitutional would be violative of basic human rights. In our opinion, when the State largesse is being enjoyed by these hospitals in the form of land beside it is their obligation by the very nature of the medical services to extend the reciprocal obligation to the public by providing free treatment as envisaged in the impugned order. In case they want to wriggle out of it and not to comply with it, they have to surrender the land and ogre out the benefit which they have received by virtue of holding the government land in an aforesaid manner.

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12. Federation of Obstetrics and Gynecological Societies of India (FOGSI) v. Union of India (2019) 6 SCC 283

Court : **Supreme Court of India**

Coram : **Arun Mishra and Vineet Saran,JJ.**

Facts

The Federation had approached the Apex Court seeking decriminalizing of anomalies in paperwork/ record keeping/clerical errors in regard of the provisions of the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 [PCPNDT Act] contending that the same is violative of Articles 14, 19(1)(g) and 21 of the Constitution of India. The Federation was essentially aggrieved with Section 23 equating, what they term as 'clerical errors' on the same footing with the actual offence of sex determination. According to them the Act does not distinguish between criminal offences and the anomalies in paperwork like incomplete 'F'-Forms, clerical mistakes such as writing NA or incomplete address, no mentioning of the date, incomplete filling of Form 'F', indication for sonography not written, faded notice board and not legible, striking out details in the Form 'F' etc. Even the smallest anomaly in paperwork which is in fact an inadvertent and unintentional error has made the obstetricians and gynecologists vulnerable to the prosecution by the Authorities all over the country, it was contended. Section 23(2) of the Act empowers the State Medical Council to suspend the registration of any doctor indefinitely, who is reported by the Appropriate Authority for necessary action, during the pendency of trial.

Decision

The Court held -

> *15. As the sex determination is hatched in secrecy and committed in privacy and as both the parties are hand in glove with each other, therefore it becomes difficult to detect the commission of the offence, hence traps are usually laid or raids are conducted by the inspecting authorities and sometimes non maintenance of records or incomplete records may provide substantial evidence towards the commission of offence. It is further submitted that the Act specifically provides for the record keeping under*

Rule 9 of the Preconception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996 (hereinafter referred to as 'the Rules') and any deficiency or inaccuracy in record keeping amounts to violation of Sections 5 and 6 of the Act.

20. The respondents have also drawn our attention to the provisions of Regulation 1.3 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002; Regulation 6.2 of Pharmacy Practice Regulation, 2015; and Transplantation of Human Organs and Tissues Act, 1994, which contains the provisions with respect to maintenance of proper records.

58. The Act and Rules are not the only regulatory framework which requires the medical fraternity to keep proper record. The medical profession has highly specialised nature and considering the nature of services rendered by medical professional, proper maintenance of records is an integral part of the medical services. It is contended on behalf of Medical Council of India that the Medical Council of India (MCI) under Section 33 of the Indian Medical Council Act, 1956 has framed the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, which also placed a burden on physicians to observe the law of the country. By the said Regulations, it is mandatory for every doctor to maintain the records of the patients treated by him/her and nonmaintaining of records is a misconduct.

98. Non maintenance of record is springboard for commission of offence of foeticide, not just a clerical error. In order to effectively implement the various provisions of the Act, the detailed forms in which records have to be maintained have been provided for by the Rules. These Rules are necessary for the implementation of the Act and improper maintenance of such record amounts to violation of provisions of Sections 5 and 6 of the Act, by virtue of proviso to Section 4(3) of the Act. In addition, any breach of the provisions of the Act or its Rules would attract cancellation or suspension of registration of Genetic Counselling Centre, Genetic Laboratory or Genetic Clinic, by the Appropriate Authority as provided under Section 20 of the Act.

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13. Maaysha Singh v. State of Maharashtra & Anr (Writ Petition No. 1958/2021)

Court : **Bombay High Court**

Coram : **K. K. Tated, Abahay Ahuja, JJ.**

Facts

Sudha Bhardwaj's medical records were not provided to her daughter Maaysha Singh by the prison Authorities. She was also not allowed to make a phone call to the approved family member/s after consultation with the medical officer or after any visit to the hospital.

Decision

The Hon'ble Court held -

> *3. In our view prisoners have a right to obtain their medical records from the prison Authorities under Article 21 of the Constitution of India. In view thereof, all the medical records including medicines prescribed and the test reports shall be provided to the Petitioner on request. In fact, we would go a step further and say that this direction should be followed by the prison Authorities qua all the prisoners. We also agree that the Petitioner should be allowed to make a phone call in the presence of a jail official to the approved family member/s after any of them visits the hospital.*

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CHAPTER - IV

RIGHT TO ACCESS MEDICAL RECORDS: SIGNIFICANCE AND ENFORCEABILITY

SIGNIFICANCE OF MEDICAL RECORDS

One of the most important rights of a patient is the right to have access to his medical records. Medical records include a variety of documents such as a Patients' medical history, clinical findings, diagnostic test results, preoperative care, operation notes, post operative care and daily notes of his progress and medications. A Patients' medical records enable different medical care professionals to provide them with continuous, consistent and proper care. The precise description of a Patients' condition at various times along with the test results is important for keeping track of the development of an illness and the effects of treatment. The medical records have great legal importance and are used as evidence of the particulars of the treatment given to any patient. In case a patient brings a legal action and there is no proper medical record provided to him/her then the burden of proof regarding disputed facts is placed on the doctor or medical facility provider.

For Doctors

- Helps in the scientific evaluation of their Patients' profile, analyzing the treatment results and also to plan treatment protocols
- Helps the other doctors for reference in future treatments of the patient
- Helps in planning governmental strategies for future medical care
- Can be helpful in medical training and education
- In cases of alleged medical negligence, the maintenance and availability of medical records would form important evidence and would lead to transparency thereby reducing the suspicion of medical negligence which, in some cases, results in violence and litigation. A properly written operative note can protect a surgeon in case of alleged negligence due to operative complications. The maintenance of medical records and the fact that it has been made available to the patient throughout his treatment will also help in speedy disposal of cases.

For Patients

- Keeps them informed about the treatment
- Patients can have access to second opinion based on their medical records

- It can be used in giving informed consent in cases where the consent of the patient or his representative is required
- Helps the patient or his representative to make an informed decision regarding the continuation of the treatment or in taking the next step in treatment
- Addresses the problem of last-minute information to the patient or his representative about the condition of the patient, particularly in cases where time is of the essence
- The insurance companies also require properly maintained records for proving the Patients' demand for medical expenses

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MAINTENANCE OF HEALTH RECORDS AND PATIENTS' RIGHT TO ACCESS

A. UNITED STATES OF AMERICA

The Health Information Technology for Economic and Clinical Health Act, 2009 (HITECH Act) provides the United States Department of Health and Human Services with the authority to establish programs to improve healthcare quality, safety, and efficiency through the promotion of health IT, including electronic health records and private and secure electronic health information exchange.

The right of a patient to access his medical records was first recognized in 1959 when the court held that though hospital records are the property of the hospital nevertheless, the patient has a property right to the information contained in the record and is, therefore, entitled to a copy of the record[1]. Similarly, in another case[2], the court regarded the physician as the custodian, rather than the owner of the information constituting the records and declared that the information contained therein cannot be used to the exclusion of the patient or his representative and since the keeper of the medical record is only the custodian of the information, the patient can inspect and/or copy the records without resorting to litigation.

The Health Insurance Portability and Accountability Act, 1996 (HIPAA), under its Privacy Rules with limited exceptions provides individuals with a legal, enforceable right to see and receive copies upon request of the information in their medical and other health records maintained by their health care providers. An individual does not have a right to access 'protected health information' (PHI) that is not part of a designated record set because the information is not used to make decisions about individuals. This may include certain quality assessment or improvement records, patient safety activity records or business planning, development, and management records that are used for business decisions more generally rather than to make decisions about individuals. For example, a hospital's peer review files or practitioner or provider performance evaluations, or a health plan's quality control records that are used to improve customer service or formulary development records may be generated

[1]. *Wallace v. University Hospitals of Cleveland, 172 N.E.2d 459 (Ohio 1961).*

[2]. *Pyramid Life Insurance Co. v. Masonic Hospital Association of Payne County, 191 F. Supp. 51 (W.D. Okla. 1961).*

from and include an individual's PHI but might not be in the covered entity's designated record set and subject to access by the individual.

Two categories of information are expressly excluded from the right of access:-

- Psychotherapy notes, which are the personal notes of a mental health care provider documenting or analyzing the contents of a counseling session maintained separately from the rest of the Patients' medical record.
- Information compiled in reasonable anticipation of, or for use in a civil, criminal, or administrative action or proceeding.

In case of a violation of the statutory right of access to medical records, the aggrieved person can file a complaint at the Office for Civil Rights (OCR), United States Department of Health and Human Services (HHS).

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B. UNITED KINGDOM

The Department of Health released the "NHS Code of Practice" for Records Management which is a guide to the required standards of practice in the management of records for those who work within or under contract to NHS (National Health Services) organizations in England. The NHS Confidentiality Code of Practice is a guide to required practice for those who work within or under contract with NHS organizations concerning confidentiality and patients' consent to use their health records. "Information Governance" managed by the Department of Health Informatics Directorate, ensures the necessary safeguards for, and appropriate use of patient and personal information.

The main legislative measures that give rights of access to health records include:

- The Data Protection Act, 1998 - It provides for the rights for living individuals to access their records. The right can also be exercised by an authorized representative on the individual's behalf. The Data Protection Act gives individuals (known as data subjects) or their authorized representative, the right to apply to see certain personal data held about them, including health records. These rights are known as "subject access rights", and are contained in sections 7, 8 and 9 of the Act. The Information Commissioner's Office (ICO) is the United Kingdom's independent public body that is responsible for governing data protection compliance. Data protection legislation is not confined to health records held for National Health Service purposes. It applies equally to all relevant records relating to living individuals; this includes the private health sector and health professionals' private practice records. Responsibility for dealing with a request for an access to health record lies with the "data controller". The data controller is the legal entity that determines the purposes for which and the manner in which personal data is processed.
- The Access to Health Records Act 1990 - This Act was a result of the judgment delivered in *Gaskin v. The United Kingdom* reported in (1990) 12 EHRR 36. The Act provides for the right of access to deceased Patients' health records by specified persons. The Access to Health Records Act 1990 (AHRA) provides a small cohort of people with a statutory right to apply for access to information contained within a deceased person's health record. The Access to Health Records Act (AHRA) 1990 provides certain individuals with a right of access to the health records of a deceased individual. These individuals are defined under

Section 3(1)(f) of that Act as, 'the Patients' personal representative and any person who may have a claim arising out of the Patients' death'. A personal representative is the executor or administrator of the deceased person's estate. The personal representative is the only person who has an unqualified right of access to a deceased Patients' record and is not required to give any reason for applying for access to a record. Individuals other than the personal representative have a legal right of access under the Act only where they can establish a claim arising from a Patients' death.

- The Access to Medical Reports Act 1988 - This Act gives the right to individuals to have access to reports, relating to them, provided by medical practitioners for employment or insurance purposes.
- The Freedom of Information Act 2000 (FOI) - It is an Act making provision for the disclosure of information which is held by public authorities and those who provide services to public authorities. The information includes the information contained in a medical record with certain exceptions contained under Sections 40 and 41.

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C. INDIA

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 under Regulation 1.3 lays down the following regarding the maintenance of medical records:-

1.3 Maintenance of Medical Records :

1.3.1 Every physician shall maintain the medical records pertaining to his / her indoor patients for a period of 3 years from the date of commencement of the treatment in a standard proforma laid down by the Medical Council of India and attached as Appendix 3.

1.3.2. If any request is made for medical records either by the patients / authorized attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours.

1.3.3 A registered medical practitioner shall maintain a Register of Medical Certificates giving full details of certificates issued. When issuing a medical certificate he / she shall always enter the identification marks of the patient and keep a copy of the certificate. He/she shall not omit to record the signature and/or thumb mark, address and at least one identification mark of the patient on the medical certificates or report. The medical certificate shall be prepared as in Appendix 2.

1.3.4 Efforts shall be made to computerize medical records for quick retrieval.

Electronic Health Record Standards, 2016 (EHR Standards)

An Electronic Health Record (EHR) is a unique longitudinal electronic record of a person's health over the life course that comprises patient demographics, progress notes, clinical problems, medications, past medical history, laboratory data etc. and can be accessed instantly and securely by authorized users. It is a collection of various medical records that get generated during any clinical encounter or events. A unique identifier for each person, provider and clinical establishment delivering the care is essential for EHR, so as to enable the sharing of records across different healthcare providers.

The Ministry of Health and Family Welfare notified Electronic Health Record

(EHR) Standards Version 2016 for India in December 2016 (whilst the earlier version of EHR Standards was notified in September 2013) with intent to bring standardization and homogeneity, interoperability in capture, storage, transmission & use of healthcare information across various Health IT systems. The purpose of collecting medical records, as outlined by the Ministry of Health in the EHR Standards notified in 2016, is improved care that is evidence based, accurate and faster diagnosis that translates into better treatment at lower cost of care, avoidance of repeating unnecessary investigations, robust analytics including predictive analytics to support personalized and contextualized care, improved health policy decisions based on better understanding of the underlying challenges, all translating into improved personal and public health outcomes.

The Government of India intended to introduce a uniform system for maintenance of Electronic Medical Records/Electronic Health Records (EMR/EHR) by the Hospitals and healthcare providers in the country. An Expert committee was set up to develop EMR/EHR Standards for adoption/implementation in the country. Draft EMR/EHR Standards were hosted on the website of the Ministry soliciting comments from the stakeholders and general public. After due consideration of the recommendation of the Committee and the comments received thereon, the 'Electronic Health Record Standards for India' have been finalized and approved by the Ministry of Health and Family Welfare, Government of India. In cases of computerization or digitization of medical records, these are the standards which can be followed by the States.

The creation of a database of Health Records in India is still in its nascent stage. Currently, **"My Health Record"** is going to be launched soon under the National Health Portal programme and the proposal of implementing **"National Health Stack"**[3] is under way.

In India, there is an increase in the magnitude of digitization of healthcare services in various healthcare delivery institutions. It has been claimed by practitioners and clinicians that electronic health records (e.g. personal health records) have the ability to enhance quality and safety of care besides improved management of health information and clinical data. Electronic health records also increase portability of clinical information including better interaction between patient and health service providers. This has helped public health experts to understand disease trends and better diagnose diseases. Also, from the patients' perspective, it enables improved services and has reduced the redundant clinical tests. However, these medical records are more institution centric as they are limited to specific/defined healthcare delivery institutions only. Further, the clinical data resides in silos and usually, access of this data is not extended to the patients, who often struggle with paper based record keeping. To bring about a shift from a citizen centric healthcare system to an institution centric healthcare system, the Ministry of Health and Family Welfare jointly with the Ministry of Electronics and IT, Govt. of India has developed a Personal Health Record Management System (titled My Health Record) for citizens of India. A few private Hospitals such as **Max Healthcare, Shankar Netralaya, Fortis** have implemented EHR.

The Ethical, Legal, Social Issues (ELSI) Guidelines under the Electronic Health Record Standards, 2016 (EHR Standards) lays down "access to medical records" as a privilege of a patient as the same is not legally enforceable by a Central Act. Some of the privileges mentioned therein are as follows:-

- *Patients will have the privilege to carry out the activities detailed below, personally, or through their appointed representative.*
- *Patients can demand from a healthcare provider a copy of their medical records held by that healthcare provider, which should be provided within 30 days of receipt of communication of request.*
- *Patients can demand from a healthcare provider that stores/maintains their medical records, to withhold, temporarily or permanently, specific*

information that they do not want disclosed to other organizations or individuals.

- *Patients can demand information from a healthcare provider on the details of disclosures performed on their medical records for any reason whatsoever. When demanded, following details are to be provided for each instance of disclosure :*
    - *Date of the disclosure*
    - *Name and address of the entity or person who received the information*
    - *Brief description of the medical information disclosed*
    - *Brief summary of the purpose of the disclosure*

As discussed in the previous chapter, the right of a patient and his relatives to access his medical records has been recognized by the Courts in India. In *Raghunath G. Raheja v. Maharashtra Medical Council,*[4] the Bombay High Court and in *Rajappan v. Sree Chitra Tirunal Institute for Medical Science & Technology* ,[5] the Kerala High Court have held that there must be absolute transparency with regard to the treatment of a patient and he has a right to demand access to his medical records to which the doctors or the hospitals cannot claim any secrecy or exclusive authority.

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[4]. *1996 SCC OnLine Bom 5.*

[5]. *2004 SCC Online Ker 410.*

ENFORCEABILITY OF THE RIGHT TO ACCESS MEDICAL RECORDS IN INDIA

Writ : In India, the right of access to medical records, though not a fundamental right specifically, can be enforced through a writ petition either on the ground of arbitrariness or on the ground that it is also a facet of the fundamental right to health. In a recent case, *Maaysha Singh v. State of Maharashtra & Anr.,* W.P. No. 1958/2021, the Hon'ble Bombay High Court through its writ jurisdiction held that prisoners have a right to access their own medical records under Article 21 and all medical records, details of tests, medicines prescribed etc., should be given to the petitioner.

Consumer Protection Laws : In India, the non-availability of medical records even after the request of the patient has been considered to be a "deficiency in service", such as in the cases of *P.P. Ismail v. K.K. Radha* and *Dr. Shyam Kumar v Rameshbhai Harmanbhai Kachiya* decided by the National Commission for Consumer Dispute Redressal Forum and, therefore, relief under the Consumer Protection Act is often granted to the aggrieved patient.

Right to Information : In India, for Government hospitals, the patient can also approach the hospital for medical records under the Right to Information Act but the same is not available for private hospitals or for private clinics. It has also been held by the Central Information Commission in a catena of cases, such as in *Nisha Priya Bhatia v. Institute of Human Behavior and Allied Sciences, GNCTD,*[6] *Mrs. Anita Singh v. GNCTD* and *Prabhat Kumar v. GNCTD,* that the patients have a right to access their medical records under the Right to Information Act.

In India, though the patients can enforce their rights of access to medical records through different forums including the Supreme Court and the High Courts, the process is not effective because of the following reasons :-

- The grievance redressal mechanisms require that the aggrieved patient first establishes his right of access to medical records as a right which is covered under the statute under which he has approached the particular forum.
- The process is time consuming and by the time the outcome of the case is decided, the relief might become infructuous.
- It overburdens the already burdened courts in India, as even for simple rights such as the right of access to medical records the aggrieved person has to approach the regular courts and even the writ courts.

[6]. *2014 SCC OnLine CIC 3155.*

CHAPTER - V

RIGHT TO ACCESS MEDICAL RECORDS : GOOD PRACTICES

1. STATUTORY AUTHORITIES

As discussed in previous Chapters, a Patients' right to be informed and to have access to his medical records are governed by specific statutes in some countries such as in United States and United Kingdom and, therefore, the redressal of any violation of the right is addressed through the grievance redressal mechanism provided in the statute. For example, in United States, in case of a violation of the statutory right of access to medical records, the aggrieved person can file a complaint at the Office for Civil Rights (OCR), United States Department of Health and Human Services (HHS).

2. OMBUDSMAN

In countries such as in Israel and Canada, the system of ombudsman has been established which addresses any complaint related to medical service including the violation of the right of access to medical records. The system of Ombudsman is the most effective and may prove to be efficient for India also as it is evident from the scheme of Banking Ombudsman, which not only provides a grievance redressal mechanism for both public sector and private sector banks but also covers a myriad of issues giving speedy and effective resolutions to the grievances of the bank customers. Only in a few cases, the customers find it necessary to approach the regular courts for the redressal of their issues.

In India, there can be an internal system for the redressal of patients' grievances in every clinical establishment and when the complaints or grievances of a patient are not resolved by the internal grievance redressal system, the patient can approach the Ombudsman.

3. MOBILE APPS AND HOSPITAL MANAGEMENT SOFTWARES

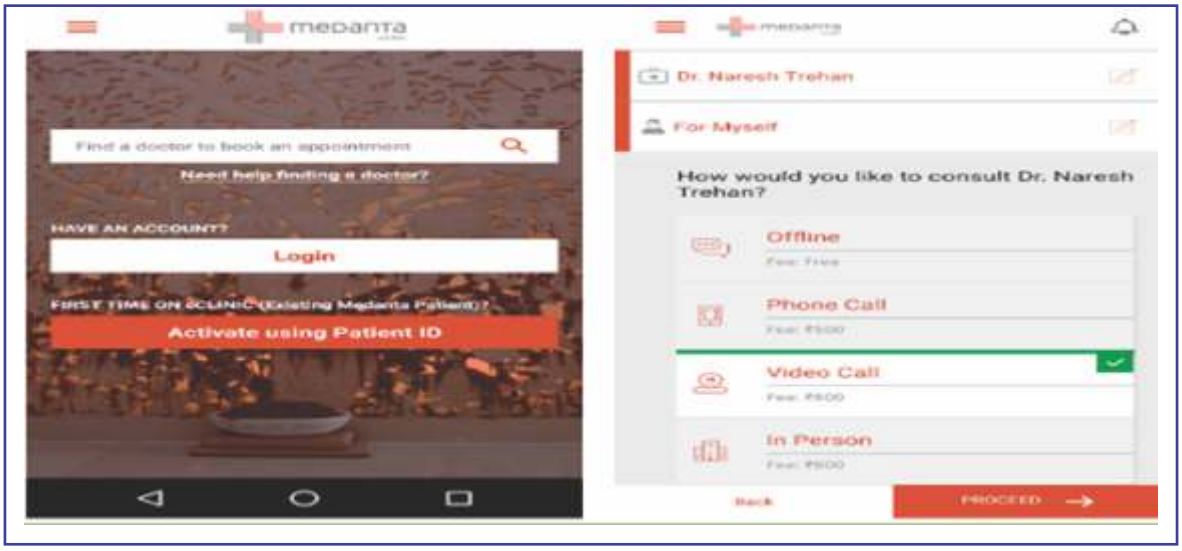
The doctors and hospitals can, themselves, engage in the maintenance of medical records which would be available to the patient through an App or through a portal requiring login credentials exclusively accessible to the patients. During the preparation of this research paper, several hospitals had been contacted for their inputs on the subject. In this regard, the team from **TATA Main Hospital, Jamshedpur** under the guidance of Air Marshal (Dr) Rajan Chaudhry, Advisor, Medical Services, Tata Steel, Dr. Deb Sanjay Nag, Senior Consultant, Dept. of Anaesthesiology, Tata Main Hospital, Jamshedpur and Mr. Gyanendra Karn (Head, Legal), Tata Steel demonstrated the functioning of "Vishwas" App through a detailed presentation. The App creates a profile of each of its patients and all the details related to the treatments and the tests of a patient are made available in the App with real-time updates which the patient can access by putting his patient ID or other such unique ID. Some of the portions from the presentation demonstrating the App have been shared below.

Slide : 1

Slide : 2

Slide : 3

Hospitals such as Medanta create separate profiles of each of its patients which can be accessed by the patients through website login. Such practices can be adopted by hospitals and doctors throughout India as it will be beneficial both for the doctors and the patients and can be created simply through a mobile App. Medanta has also launched **"eCLINIC"** which is a mobile and web-based telemedicine for patients. A patient can search our doctors by name, specialty, ailment, procedure or treatment and book their consult online for in-person, video, phone or email consultation and even do pre-payments. Patients can also access their previous reports, prescriptions and discharge summaries from the comfort of their home. As per Medanta, presently, per annum, over 20 lakh reports have been downloaded, two lakh appointment requests made and 50 thousand telemedicine consultations done across 50+ countries.



It is claimed that while Medanta eCLINIC is patient-centric, equivalent app for doctors is 'Mobile EMR' with access to patient medical history from mobile phones and the ability to securely place lab, radiology and diagnostic orders, thereby reducing transcription errors and ensuring better turnaround time. With provisions to define care plans, report and track incidents, it sends notification for time-bound tasks with due and overdue alerts including timely discharges and a lot more to help clinicians make more informed decisions.

Similarly, **ATTUNE,** a health company has developed Attune Mobile EMR App, which records patient history and examination details including personal, family & social history, vitals, chief complaints & duration with auto complete and clickable events. Many doctors and hospitals now prefer to take assistance from Apps and Hospital Management Softwares such as "MocDoc" to maintain and access patients' records.

The Government of Jharkhand has released ***"Manual for Preparation, Prevention and Planning for COVID-19 Third Wave in Jharkhand - The Way Forward"*** in May, 2021. The Manual focuses primarily on the dissemination of correct, accurate and updated information regarding COVID-19. As a part of this, the Manual inter alia suggests the maintenance of medical records with timely updation of the status of the patient and his treatments. One of the important roles of the District Health authorities enumerated in the manual is as follows:-

> *"Details about the child under home isolation should also be updated on COVID-19 portal and facility app (with DSO as user) or any other prevailing local method(s). The records updation should be regularly monitored."*

There are other instances also where the manual stresses the relevance of medical records. According to the manual, WHO has an established platform for standardized, anonymized clinical data and contributors can enter data into the web-based WHO COVID-19 Clinical Data Platform, which captures all COVID-19 variables listed in the case report forms (CRFs). Using the WHO platform facilitates aggregation, tabulation, and analysis across different settings globally and provides a secure, access-limited, password-protected, electronic database hosted in a secure server at WHO. WHO will maintain appropriate technical and organizational security measures to protect confidentiality and prevent the unauthorized disclosure of the anonymized COVID-19 data. The manual further clarifies that as the COVID data collection is not considered a

research study, but rather surveillance of public health importance, patient or parent/guardian consent is not expected to be required in most settings; additionally, information is likely to be collected retrospectively through extraction from medical records in most cases.

All public hospitals, charitable hospitals with public obligations, and private hospitals involved in health insurance schemes (like Ayushman Bharat-PMJAY) must display the charter in their premises. This will set the stage for all private hospitals to implement this charter. The entire set of 17 patients' rights can be recognised in the standards related to the Central Clinical Establishments Act (CEA) which would ensure that all healthcare facilities in 11 states, which have adopted this Act, will observe patients' rights. If the state has its own Clinical Establishments Act then the charter of rights framed by the NHRC must be incorporated in it.

Hospitals should have committees to ensure that patients' rights are protected in hospitals. These committees need not examine the routine working of the hospital, but should review all complaints from patients and direct physicians to take proper care to protect patients' rights.

The Charter must act as a guiding document for the Union Government and State Governments to formulate concrete mechanisms so that Patients' Rights are given adequate protection and operational mechanisms are set up to make these rights functional and enforceable by law. This is especially important and an urgent need at the present juncture because India does not have a dedicated regulator like other countries and the existing regulations in the interest of patients, governing the healthcare delivery system is on the anvil. Some States have adopted the national Clinical Establishments Act, 2010, certain other States have enacted their own State level legislations like the Nursing Homes Act to regulate hospitals, while a few other States are in the process of adopting /developing such regulation.

The Charter of Patients' Rights has been drafted with the hope that it shall be incorporated by policy makers in all existing and emerging regulatory legislations concerning the health care sector. This charter would also enable various kinds of health care providers to actively engage with this framework of patients' rights to ensure their observance, while also benefiting from the formal codification of patients' responsibilities.

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