Title : Analysis of the Regulating Laws and Legal Defences against Medical Malpractices in Different Jurisdictions: Informed Consent

Author(s) : Anastacia binti Ezral

Institution : International Islamic University Malaysia

Category : Article, Competition

Topics : Health

ANALYSIS OF THE REGULATING LAWS AND LEGAL DEFENCES AGAINST MEDICAL MALPRACTICES IN DIFFERENT JURISDICTIONS: INFORMED CONSENT

By

ANASTACIA BINTI EZRAL

Ahmad Ibrahim Kuliyyah of Laws (AIKOL),

International Islamic University Malaysia (IIUM)

Submission is for

DR. MUH ENDRIYO SUSILA

Universitas Muhammadiyah Yogyakarta

Summer School on Law and Sharia 2021

Medical Law and Ethics

1.0 INTRODUCTION

There is an approximate aggregate of 14,549 known drugs in the world[1], each was scientifically approved, experimented, withdrawn and investigated before it was made use of to cure and prevent illnesses and diseases, and each of these medicines and treatments play a cardinal role, especially with regards to the top 10 causes of death globally that was identifiable by the United Nations (UN). It was made known to the public in December 2020 that these illnesses are radiused from kidney diseases, Alzheimer's, cancerous illness to heart diseases, at which are non-communicable diseases (NCD)[2]. This actively demonstrated a degree of importance that modern medicines possess over these 21st Century world health problems.

1.1 SETTING A CONTEXT

These circumstances in medicines and treatments have given rise to the establishment of statutory laws that regulates medical practices, and this includes a systematically-structured guideline on medical ethics and disciplines to ensure that these treatments are being administered within the ambit of permissible premises as per deemed acceptable and necessary by ministries of health globally. They also serve as a yardstick to measure the extent of interference that the law possesses over medical practitioners as well as their patients and is bound to follow the purpose of its design which was to protect either of these party(s) from any sort of medical malpractice, be it from the health service provider or the receiver of the treatment themselves. Also taking into account of the distinguishable existing legal systems, it is apparent that there would be a contrast in the regulating laws from one jurisdiction to another, regardless of how, these differences are principally designed to incorporate the primary beliefs of medical practitioners.

This paper aims to discuss on divergence between these regulations, particularly on the issue of informed consent that is considered to be the starting point before the administration of any sort of medical procedure. Chronologically, this paper will briefly explain on the material subject that is the ground of its institution itself (read: informed consent, including its definitive meaning, requirements that validates an informed consent and a discussion on the popular issue that is given rise to in relation to the material subject, followed by a comparative discussion on the regulating laws with respect to informed consent in different jurisdictions and will conclude with propositions on how these regulations can be ameliorated to provide a more all-rounded coverage on the particularised material subject.

1.2 OUTLINE OF PAPER

1.2.1 HISTORICAL BACKROUND OF JURISDICTION

[1] Statistics | DrugBank Online. (2021). Retrieved 29 July 2021, from https://go.drugbank.com/stats

[2] Disease that is not transmissible directly from one person to another

Its explanation is aimed to enhance understanding on the origin of a particular jurisdiction or legal system as well as how it may be different or indifferent with each other.

1.2.2 DEVELOPMENT OF JURISDICTION

Objectively to enable a comparative perspective on the *then* and *now* aside from identifying its degree of adaptability towards the change of circumstances.

1.2.3 REGULATING LAWS

To magnify comparative knowledges on how each jurisdictions grasp the issue of the material subject (read: informed consent) statutorily and judicially and to demonstrate analysation skills with logical clarity.

1.2.4 LEGAL IMPROVEMENTS

Addressing this particular section helps one comprehend the legal complexity that was the contributing factor to the improvements of a regulating laws.

1.2.5 LEGAL IMPLICATIONS

Designed to make uncertainties and ambiguities on the legal implications (other than lawsuits) against medical practitioners that had conducted a medical malpractice more identifiable. It also allows us to determine the suitability of the existing regulated punishments for medical violations, disciplinarily, ethically and criminally as well as the organisations that are responsible to sanction them.

1.2.6 LEGAL DEFENCES

This section explains on the defensive legal tools that can be used against allegations of medical malpractices to highlight on the importance of legal protection for medical practitioners.

2.0 INFORMED CONSENT

One has to first understand the concept of informed consent to enable themselves to a degree of comprehension that this article aimed to accomplish. Consent in the context of medical law primarily refers to a patients' consent to undergo a prescribed treatment and so, it functions to kick-start the process of administrating treatment to a patient. In addition to that, it can also be interpreted as a persons' agreement to allow something to happen made with full knowledge on the risks involved and the alternatives[3].It is also an embodiment of human right on which it enables a person to exercise their freedom to decide and act according to their own choices.

Essentially, a person whom are consenting to a medical treatment have got to understand the types of consent as well as the elements that makes it a valid consent in order to be able to communicate their acceptance to that particular treatment *per se* at which will be discussed accordingly. Principally, there are expressed and implied consent and it need not be restricted to a statement and a form of writing only, the mere gesture of nodding to convey acceptance and shaking the head to convey negation is sufficient to make the doctor(s) aware of your decision. Speculatively, in spite of consent forms as the most ordinary methodological that signifies patient consent, a patient could have easily given their signature to a medical staff without completely apprehending the risks and probable outcomes of a treatment which would consequently had them proceeding into a treatment without all proper information and this may subsequently lead to a legal action had the doctor and patient stumble upon an unprecedented or unanticipated outcome; at which case, the consent form would circumstantially be the defending evidence against a medical malpractice cause of action and this can be illustratively substantiated by a statement from a member of the Malaysian Medical Council (MMC), Dr. Milton Lum whom expressly opined in a newspaper article that a signed consent form may not have been sufficient to prove that the patient validly consented to the treatment[4].

Another authority that supports our case can be evidently seen in the case of **Ngiao Jong Nian v Lee Chan Foo & Anor** [5]. Briefly, the plaintiff filed an action against the defendant-doctor for medical negligence for the defendants' failure to obtain the plaintiffs' consent to undergo a different surgical procedure than the one that the patient initially consented to after the plaintiff had discovered a bile leakage from a linen ligature that was tied across the remaining part of the plaintiffs' gall bladder from another doctor. Zamani A. Rahim JC in the High Court of Alor Star dismissed the plaintiffs' claims on the basis that the plaintiff was made known of that he was scheduled for a gall bladder operation to which he had voluntarily consented to its removal along with other surgical operations that was deemed necessary by the attending surgeon and so the plaintiff should have instead filed a cause of action under the Tort of Trespass to person (battery). Simply, the Court was of the opinion that in accordance to the English leading case

[3] Black's Law Dictionary (10th ed. 2014)

[4] Chin, C. (2013). A consent form may not be binding for medical treatment. *The Star*. Retrieved from https://www.thestar.com.my/news/nation/2013/11/24/a-consent-form-may-not-be-binding#close

[5] [2011] 1 MLJ 565

of **Chatterton v Gerson and another**[6] - a consent is vitiated by fraud and would have been considered to be expressed in form only and not in reality if information on the nature of the medical procedure was withheld in bad faith; the plaintiff is restricted from basing their claim on the lack of consent since the decision to perform another surgical procedure was made during the course of the surgery and not earlier.

There are three (3) fundamental elements that forges a valid consent; (i) the consent would have to be *real* – this places a magnitude of obligation onto doctors to disclose the necessary information in regards to the prescribed medical treatment procedurally to capacitate the patient to exercise their right to consent to said treatment with confidence. In Malaysia, this was made obligatory by the Malaysian Medica Council when it was expressly provided that – A medical practitioner is ethically obligated to disclose every information in regards to the patients' diagnosis and potential prognosis as well as warn the patients of the material risks in relation to its treatments before said patient is required to decide on whether or not to undergo the proposed procedure, surgery, examination or treatment[7]. (ii) the patient would have to possess the *capacity to consent* – in the common sense that a person would have to be sane followed with the full capacity to consider all the information that they had priorly acquire in order to make a justified decision. That being said, those whom are incapable to do so (i.e., children or people with mental incapacities) would have to resort to having their family members or guardians decide for them on the basis that a consent is not a consent if it was given by a person whom are of unsound mind or intoxication because it would mean that they are unable to understand the nature and consequence that they are consenting to[8]. Lastly, (iii) the consent would have to come from the patient *voluntarily* – simply, it refers to a persons' ability to exercise free will as a patient without confrontation to any sort of coercion or threat that might rise doubt to their consideration. Statutorily, a voluntarily act includes the causing of a circumstance with the intention of wanting to orchestrate it[9]. These are the three (3) universally applicable elements that signifies a valid informed consent.

2.1 IMPORTANCE OF INDIVIDUAL AUTONOMY[10]

It was formerly mentioned that the deliverance of an informed consent is an embodiment of human right on which it enables a person to exercise their freedom to

---

[6] [1981] QB 432

[7] Malaysian Medical Council Guideline: Consent for Treatment by Patients by Registered Medical Practitioners, Provision 3 – "Necessity to Warn Patients about Material Risks"

[8] Penal Code (Act 574) s. 90(b) (MY) - "Consent known to be given under fear or misconception and consent of a child or person of unsound mind

[9] Penal Code (Act 574) s.39 (MY) - "Voluntarily"

[10] Definition of AUTONOMY. (2021). Retrieved 3 August 2021, from https://www.merriam-webster.com/dictionary/autonomy - *"The autonomy of children is almost always limited by their parents. But when those parents are elderly and begin driving poorly and getting confused about their finances, their children may see the need to limit their autonomy in much the same way"*

decide and act according to their own choices. Conceptually, a person can only give their consent to an entity or an act, or, *for the sake of the material subject of this paper*, a treatment, once they are able to rationally comprehend the weight of the risks that they are consenting to. The vitality that a patient fully understands the treatment along with the risks that comes before consenting to it was laid down in the case **Gurmit Kaur a/p Jaswant Singh**[11]. In the instant case, the plaintiff filed a medical negligence action against the second defendant-doctor for their failure to obtain the plaintiffs' consent for the hysterectomy that was performed subsequent to the polyp removal surgery that the plaintiff had initially requested the defendant to performed. It was then decided by Rosilah Yop JC in the High Court of Kuala Lumpur that it was not sufficient that the defendant-doctor proceeded the hysterectomy without first making sure that the plaintiff understood the risks that follow that removal surgical procedure, the defendants' defence that the plaintiff expressly consented to the surgery for the reason that the plaintiff had signed the consent form was then considered doubtful by the Court on account of the defendants' failure to present a witness (read: the staff nurse that witnessed the signing and explaining of the consent form) at which consequently had the Court invoking an adverse inference against the defendants. Conclusively, the Court held that the defendant-doctor was liable for medical negligence since it was discovered by the Court that the plaintiff had only consented to the laparoscopic myomectomy and not the hysterectomy, this was owing to the plaintiffs' contention that she herself was shocked after discovering the facts of the latter surgical procedure that she had not consented to. The aforementioned case also equally discusses on spousal consent when it was discovered by the Court that the plaintiffs' husband, in spite being present at the premise at the material time, was not called in by the medical staff nor the defendant to consent to the latter surgical procedure that was performed on his wife. Principally, it is evidently pointed out on the gravity that a patient fully comprehends a particular treatment together with the risks and probable outcomes to avoid suppressing the patient of their right to autonomy, at which in this context, to undergo a medical treatment.

[11] [2012] 4 MLJ 260

3.0 MALAYSIA – COMMON LAW

3.1 HISTORICAL BACKGROUND ON COMMON LAW

Malaysia is one out of the 232 countries[12] that practices the common law legal system or the Anglo-Saxon law which, during its establishment, a judicial-centric legal system that criminalises civil misconducts and practiced compensatory remedies for victims of said misconducts at which was established by the Anglo-Saxons that had incorporated the sets of rules that was, *at the material time*, used by the Germanics[13]. It was historically incorporated by the common-law courts of England at which can be dated back to the King's Court, *Curia Regis*[14] in the Middle Ages[15]. Judicial-centric involves reference to be made to legal precedents of decided cases in law reports depending on its suitability to the material facts of an instant case that was brought to the courts at which is still being practice today.

3.2 DEVELOPMENT OF COMMON LAW

The Common Law was primarily developed by one Sir William Blackstone whom was the first English law lecturer in 1758. His most paramount academical scripture was the Commentaries on the Laws of England that was acknowledged as an authoritative exposition of the common law. In fact, his work was then referred to by Jeremy Bentham, an English utilitarian philosopher whom then published "An Introduction to the Principles of Morals and Legislation in 1789. Today, countries that practices the Common law judicially would refer to binding legal precedents from decided cases that compasses an analogous material fact.

3.3 REGULATING LAWS IN MALAYSIA

The **Medical Act 1971 (Act 50)** Malaysia provides on matters including – (i) the Malaysian Medical Council, "Majlis Perubatan Malaysia" (hereafter, 'MMC'), which was established by the aforementioned parliamentary act with the objective of ensuring a high-standard medical ethics, education and practice, in the interest of patients, public and the medical profession through fair and effective administrations, (ii) registration of medical practitioners and (iii) disciplinary proceedings. In relation to that, the MMC had published a guideline that was meant for public reference that included clarifications on the defining concept of consent in the medical context within the statutes' prerogative – "Consent is the voluntary acquiescence by a person to the

[12] Common Law Countries 2021. (2021). Retrieved 31 July 2021, from https://worldpopulationreview.com/country-rankings/common-law-countries

[13] Historical group of people living in Central Europe and Scandinavia

[14] A small, permanent council that was introduced during the Norman Conquest

[15] A period in European history

proposal of another or the act or result of reaching an accord"[16]. It was also explained in the guidelines that medical procedures cannot be undertaken on a patient without the patients' consent[17] at which actively demonstrates a degree of necessitation on the part of MMC to ensure that medical practitioners are performing their medical obligations ethically.

The leading case in Malaysia that discussed on the material subject (read: informed consent) is the case of **Foo Fio Na v Dr. Soo Fook Mun & Anor[18].** In that case, the appellant (then plaintiff) filed a medical negligence action against the respondent – orthopaedic surgeon (then defendant) for their failure to obtained the appellants' consent to undergo additional surgical procedures that was initially aimed to reduce the dislocated cervical vertebrae that was caused by an accident that the appellant was involved in. Subsequent to the former procedure, the respondents then had to perform a removal of wire loop that was pressuring the spinal cord that was the cause of the appellants' paralysis without the presence of the neurosurgeon that first discovered the loop. The case was first heard in the High Court where the appellant had successfully proved that her paralysis was caused by the first surgical operation performed by the respondent and that the subsequent surgical procedures was not consented for. It was held in the appellants' appeal by Siti Norma Yaakob FCJ (now CJ (Malaya) in the Federal Court of Putrajaya that the first operation that the appellant had expressly consented to the performance of the first and second surgical procedure; (i) signed by the appellant during the admission when there was no possible way to medically decide that a second surgical procedure would be necessary and (ii) thumb printed by the appellant on the consent forms after the first operation. Another case that we can refer to is the case of **Hasan bin Datolah v Kerajaan Malaysia [19].** Reference of the aforementioned case of ***Foo Fio Na*** was made in the instant case, particularly in regards to the issue of patients' informed consent. Briefly on the instant case, appellant (then plaintiff) filed a medical negligence action against the respondents (then defendants) for the paralysis that was suffered by the appellant subsequent to two surgical procedures that was performed by a doctor that is, *in the instant case*, vicariously represented by the respondents. The High Court had dismissed the appellants' case on the basis that the appellant had failed to prove a causative link between the damage (read: paralysis) and the surgeon that performed the fenestration and laminectomy followed by a discovery by the Court that the surgeon had explained the risks and probable outcome of the surgical procedure. Following that, the appellant filed for an appeal to which his submission was that the trial judge (read: the High Court judge) had failed to take into consideration the fact that, in the instant case, the latter surgical procedure was circumstantially should be performed priorly than the former

[16] Malaysian Medical Council Guideline: Consent for Treatment of Patients by Registered Medical Practitioners, Provision 1 – "Definition"

[17] Ibid, Provision 2 – "Necessity for Obtaining Consent"

[18] [2007] 1 MLJ 593

[19] [2010] 2 MLJ 646

and that the appellant did not consent to undertook the surgical procedures since he was not informed of the risks associated with the procedures. However, the Court of Appeal of Putrajaya dismissed the appellants' case for the reason that the circumstances of the appellant suffering from 'cauda equina compression' had allowed the applicability of the exception to the duty of disclosure as per imposed upon a doctor in a doctor-patient relationship because it had meant that the appellant required an urgent and immediate operation at which what the first surgical operation was for and thus would have immaterialised the need for the surgeon to disclose the risks to the second surgical procedure as the appellant was already paralysed before the latter surgical procedure was performed.

3.4 IMPROVEMENTS

With reference to the abovementioned case ***Gurmit Kaur a/p Jaswant Singh***[20] , the Malaysian Medical Council ('MMC') had set forth at the minimum three (3), including previously-explained, (i) "Consent for Treatment of Patients by Registered Medical Practitioners" guideline, necessary guidelines in relation to a patients' consent to undergo treatment. This includes – (ii) **Code of Professional Conduct of the Malaysian Medical Council 2019** that covers on subject matters including – the forms of serious professional misconduct (i.e., neglect, abuse and derogatory of the professional responsibilities) in addition to a section on disciplinary procedures. In the context of patients' consent, it was promulgated in the Code of Professional Conduct 2019[21] on the notability of obtaining a valid consent followed by the requirements that has to be performed by a doctor procedurally (i.e., using an interpreter to deliver the treatment procedures, its alternatives and known complications). Another guideline by the MMC is the (ii) **Good Medical Practice 2019** that is complementary to the aforementioned Code of Professional Conduct and encompasses moral, ethical and professional obligations expected from medical professionals and which are considered safe, effective and trustworthy by the medical profession and the community. It was explained in the section with respect to the doctor and his practice, that implied consent is merely perception and cannot be taken for granted by doctors against patients whom seeks their consult[22]. It moreover includes explanation on tools that can help doctors deliver their briefing on the treatment procedures to patients methodologically – drawing blood for investigations, diagnostic imaging procedures, local infiltrations and injections, and that patients' refusal to treatment should be written down in the patients' record[23]. However, discussions concerning the treatment procedure and possible post-operative complications is advised to be concise and detailed but not too detailed that

[20] [2012] 4 MLJ 260

[21] Code of Professional Conduct of the Malaysian Medical Council 2019 – 1.4, "Consent for Medical Examination and Treatment"

[22] Good Medical Practice of the Malaysian Medical Council 2019 – 4.4, "Consent"

[23] 4.4.2, *ibid*

it gets a patient discouraged or fearful of the complications, to undergo the procedure[24], especially when it involves major invasive procedures. It was also included that an attending doctor and a colleague, a registered medical practitioner may manage a patient with the inability to give consent due to complications (i.e., intoxication, confusion, comatose) and is without a next-of-kin to the patients' best interest[25].

3.5 LEGAL IMPLICATIONS

Medical malpractices in Malaysia are handled in three stages[26] – (i) **Preliminary Investigation Committee (PIC)**, will form an investigation group of not more than five people to investigate the complaint filed against a medical practitioner as per tasked to them by the Medical Regulation 2017. Among other things, they are responsible to notify on the complaint and forward a copy of the complaint form to the medical practitioner that was complaint against[27]. The PIC will subsequently forward their recommendation to the (ii) **Disciplinary Board**, where the medical practitioner will be inquired and recommendation from the board of at least three people (fully registered medical practitioners of at least 10 years of practising certificates)[28] will finally be forwarded to the (ii) **Malaysian Medical Council (MMC)[29].** The MMC then will then make a decision to either direct a further inquire of appoint a new Board to conduct another hearing[30]. The disciplinary punishments that can be impose by the Council includes striking the medical practitioners' registration from the Councils' register[31] or order a suspension for a period depending on the prerogative of the Council[32]

3.6 LEGAL DEFENCES

There are two (2) most commonly used defences against allegations of medical malpractices (in regards to consent) forwarded to medical practitioners by patients. The first one is the defence of necessity that was introduced by Scott-Baker J in **F v West**

[24] Good Medical Practice of the Malaysian Medical Council 2019 – 4.4.4, "Consent"

[25] 4.4.6, *ibid*

[26] Malaysian Medical Council, Code of Professional Conduct 2019, Part III, "Disciplinary Procedures"

[27] Ibid, S.35 – "Preliminary Investigation Committee"

[28] Ibid, s.36 – "Disciplinary Board"

[29] Medical Act 1971 (Act 50), S.29 (1), (MY) – *"The Council shall have disciplinary jurisdiction over all persons registered under this Act"*

[30] Malaysian Medical Council, Code of Professional Conduct 2019, Part III, "Disciplinary Procedures"; s.45 – "Decision of Council"

[31] Medical Act 1971 (Act 50); Part IV, "Disciplinary Proceedings"; S.30 (i) – "Disciplinary Punishments" (MY)

[32] *Ibid* S.30 (ii) – "Disciplinary Punishments"

Berkshire Health Authority[33]. Briefly, plaintiff-patient had filed a judicial request to the Family Division to provide a declaration of consent for the plaintiffs' sterilisation for reasons that the plaintiff was mentally incapable of consenting to the sterilisation procedure. Reasons behind the plaintiff request was because of an intimate relationship that the plaintiff, at the material time, possessed with another patient at the Borocourt Hospital[34] at which the plaintiffs' doctors was of the opinion that such a relationship would potentially lead to the plaintiff being pregnant and thus may not turn out favourably considering of the plaintiffs' mental condition. For the aforementioned medical opinion, Scott-Baker J granted the declaration that was sought by the plaintiff.

Another applicable defence is the defence of therapeutic privilege that can be evidently seen being applied in the case of **Dr. Ismail Abdullah v Poh Hui Lin**[35]. The respondent-deceased (then plaintiff) filed a medical negligence action against the appellants (then defendants) for their failure to disclose the risks of acute pancreatitis and acute respiratory distress syndrome (ARDS) after a kidney stone removal surgical procedure that was performed by the appellant-doctor. It was later that the appellant contended that information in regards to the surgery had been disclosed and that the deceased had consented to the treatment. It was held by Azahar Mohamed J in the High Court of Johor Bahru that the defence of therapeutic privilege allows a surgeon to withhold disclosure of a material risk in the best interest of a patient, and in the instant case, the evidences presented to the Court demonstrated that there was no surgical procedure that could have caused the pancreatitis and ARDS and it was discovered by the Court that these medical conditions were not established as to be 'material risks to the operation'. Conclusively, the appellants' defence of therapeutic privilege had justified the non-disclosure of the aforementioned risks of medical condition for reasons that the deceased's' passing was because of their severe medical problems and not from the surgical procedure performed by the appellant-doctor.

[33] [1988] Lexis Citation 1563

[34] Previously known as; Borocourt Institution for Mental Defectives

[35] [2009] 2 MLJ 599

4.0 INDONESIA – CIVIL LAW

4.1 HISTORICAL BACKGROUND OF THE CIVIL LAW

The Civil Law legal system was fundamentally known as the *European Continental legal system* or the Romano-Germanic Law for reasons that it is essentially based on a conglomeration of Roman, Germanic, ecclesiastical, feudal, commercial and customary law and is often distinguishable with the Common Law or Anglo-Saxon legal system. The Roman law was rediscovered in the late 11th century and the expansion of its practicability was entrenched from the increasing demand for trained judges and administrators that its teaching and studying finally took its toll in local universities. It was primarily promulgated in the *Corpus Juris Civilis*, "Code of Justinian" between 527 and 565 simply for the reasons that the emperors appreciated the ideology of transpiring as the direct successors of the Roman Caesars. It was not until later that the French had incorporated the principles in the Code of Justinian into their Civil Code of 1804, Napoleonic Code at which was referred to by other Civil law countries for its techniques and arrangements and this had subsequently become a contributing factor to the inauguration of the *Bürgerliches Gesetzbuch für das deutsche Reich* or the German Civil Code after that was only taken into effect in 1900. The codification of the French Civil Code 1804 was contemporarily based on the belief that the law should be codified in a clear language to enhance accessibility among citizens and for that reason, it was organised as a series of short articles that are flexible enough to allow the old principles to be adaptable to new circumstances. The French Civil Code essentially governs on common matters such as – (i) marriage and family, (ii) divorce, (iii) succession and gifts, (iv) property, and (v) contracts and torts. By comparison, the German Civil Code 1896 that was enforced years later than the French Civil Code 1804 is immensely different that its antecedent in the sense that it is more orderly, concise and exacting. Other consequential codifications include – (i) Swiss law; Swiss Civil Code 1907, (ii) Italian law; Italy Civil Code 1942 and (iii) Japanese law; Japanese Civil Code 1898.

4.2 DEVELOPMENT OF CIVIL LAW

Since European law does not necessitate the use of long-established civil-law juridical constructs, it still, however, affects and replaces the substantive rules of the civil law and this had consequentially contributed to breakdowns of the civil codes (e.g., constitutional law, sports law, consumer protection regulations and international law that governs on public-oriented civil fundamental rights). In connection with Civil law, Indonesia is one out of the proximately 100 countries that practices this particular jurisdiction and thus the reason it is exemplary in discussing the subject matter (read: informed consent) within the Civil law legal system.

By comparison, the differences between the Common law and the Civil law are that the former heavily relies on judicial decisions (binding precedent) and the latter make most of its references to statutory provisions (written laws), needless, both these jurisdictions

are kindred in the sense that they both involve judicial statutory interpretation. Simply put, statutory provisions are at times, instituted from cases (local or international) due to the reason that one of the functions of statutory provisions is to enable regulation against precedented circumstances.

4.3 REGULATING LAWS IN INDONESIA

4.4 IMPROVEMENTS

The primary health-related statutory provision in Indonesia is the **Medical Practice Act 2004**[36] that provides on regulations objectively to maintain and enhance the quality of medical practice in Indonesia aside from insuring legal guarantee for both civilians and medical practitioners[37]. Included in this Act are matters being – (i) information on the establishment of the Indonesian Medical Council along with its foundations[38], (ii) the standard for medical practitioners as per legalised by the Indonesian Medical Council[39] and finally, on (iii) disciplinary procedures against medical malpractices by doctors and dentists[40]. Fundamentally, it was expressly asserted, *in the context of the material subject*, that the patients' consent is needed by every registered and licensed medical practitioner before the administration of any medical or dentistry treatment and said consent would have to be taken *after* a comprehensive explanation on the treatment has been delivered to the patient (i.e., diagnosis and procedures, objective of treatment, alternative treatments, risks and complications and prognosis)[41]. Another equivalent provision that can be made reference to is the **Regulation of the Minister of Health of the Republic of Indonesia 2008**[42] that principally touches on the similar aspect as per the priorily-mentioned Act. It essentially explains on consent (i.e. information that needs to be disclosed by medical practitioners, parties that are entitled to consent[43] and refusal to medical treatment by patients[44]) and an exception clause for emergency cases[45]. The subject matter (read: consent) was also regulated in the **Law of the Republic of Indonesia 2009 on**

[36] Law of the Republic of Indonesia, Number 29 Year 2004 regarding the Medical Practice

[37] *Ibid,* Chapter II, "Principles and Objectives", Article 3

[38] *Ibid,* Chapter III, "Indonesian Medical Council"

[39] *Ibid,* Chapter IV, "The Standard for Medical and Dentistry Profession Education"

[40] *Ibid,* Chapter VIII, "The Disciplines of Doctor/Dentist"

[41] *Ibid,* Chapter VV, "The Procedures of Medical Practice"; Part Three, "The Procedure in Giving the Medical Service"; Paragraph two, "The Consent for Medical/Dentistry Treatment", Article 45

[42] Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 concerning Approval of Medical Action

[43] *Ibid*, Article 3, "Parties that are Entitled to Consent"

[44] *Ibid*, Article 5, "Refusal to Medical Action"

[45] Ibid, Article 4, "Medical Action in Emergency Situations"

Hospital[46] and the **Law of the Republic of Indonesia 2009 on Health**[47]. To my way of thinking, it is also important to point out on the professional organisations that are actively superintending the buildout of practice standards for the medical profession being – (i) the Indonesian Medical Council (*Konsil Kedokteran Indonesia*/KKI) for doctors and dentists, and (ii) the Indonesian Nursing Association (*Persatuan Perawat Nasional Indonesia*/ PPNI) for nurses.

4.5 LEGAL IMPLICATIONS

It was to my discovery that there are proximately three agencies that monitors the medical disciplinary law – (i) the **Indonesian Medical Disciplinary Board** which is a supplementary institution to the Indonesian Medical Council at which it was given the responsibility[48] to receive and examine a complaint[49] against a medical practitioner (doctors or dentists) and subsequently decides[50] on the punishment to be sanctioned had the Board discovered that the medical practitioner had violated their disciplinary and ethical obligations in their course of employment. Other than the former is the (ii) **Indonesian Honorary Council of Medical Ethics** (MKEK), whereby it is a formal special board of the Indonesian Doctors Association (IDI) that was formed under the *Ikatan Dokter Indonesia*[51]. Lastly is the (iii) **Indonesian Honorary Council and Medical Discipline** (MKDKI) that collects complaints on disciplinary and ethical violations by medical practitioners as per tasked to them by the Medical Practice Act 2004[52].

---

[46] Law of the Republic of Indonesia, Number 44, Year 2009 – concerning Hospital; Article 4, "Patients' Rights"; Clause. 32; Paragraph (k) – *Patient has the right to consent or refuse medical action that is going to be performed by medical practitioners on the patients' illness"*

[47] Law of the Republic of Indonesia, Number 36, Year 36 – concerning Health; Chapter VI, "Health Effort"; Part Two, "Health Service"; Paragraph two, "Patient Protection"; Article 56 (1) – *Every individual has the right to accept or refuse part or whole of aid action that would be given to him/her after receiving and understanding the information regarding the action completely.*

[48] Law of the Republic of Indonesia, Number 29, Year 2004 – regarding The Medical Practice; Chapter VIII, "The Disciplines of Doctor/Dentist; Part One, "The Indonesian Disciplinary Board"; Article 64

[49] *Ibid*, Part Two, "Complaints"; Article 66 – *"Every one who knows or who suffers from loss due to insufficient medical treatment done by doctor/dentist in conducting his/her medical practice is allowed to send complaint letter to the head of the Indonesian Medical Disciplinary Board"*

[50] Ibid, Part Four, "Investigation"; Article 67

[51] AD/ART IDI; Pasal 16, "Majelis-Majelis" – *Majelis Kehormatan Etik Kedokteran adalah salah satu unsur dalam struktur kepengurusan IDI di tingkat pusat, wilayah, dan cabang yang bertanggunjawab untuk pembinaan and pengawasan pelaksanaan etika kedoktoran*

[52] Law of the Republic of Indonesia, Number 29, Year 2004; Part Two, "Complaints"; Article 66

Punishments against medical practitioners in Indonesia exists in forms of – (i) written warning, (ii) recommendation that the medical practitioners' registration letter and license practice are revoked or (iii) obligatory educational or training programmes[53]. In the direction of criminal action in the field of health, it was explicitly explained that governmental civil servant officers within the health sector can be delegated with a special authority to carry out the functions of an investigator at which their tasks include – conducting investigations and inspections, put in requests for expert assistance or even cease investigations that are insufficiently evidenced[54].

4.6 LEGAL DEFENCES

The applicable legal defences against medical malpractices lawsuits in Indonesia includes – (i) ***Noodtoestand***, a German word for 'emergency situation' and is commonly used for *force majeure*[55] circumstances. It was incorporated into the **Indonesian Penal Code**[56] at which serves as an exception to the requirement of obtaining a patients' consent to undergo treatment. The rationalisation for the employment of a criminal defence in medical malpractice causes of actions is in accordance to several provisions in the Indonesian Penal Code that imposes criminal liability against medical practitioners for their failure to obliged to their ethics and disciplines (read: failure to obtain patients' consent). These circumstances include – negligently caused a patients' death[57] or sufferings to physical injuries[58] in their course of performing medical treatments[59]. Another applicable defence is (ii) ***Zaakwarneming*** at which definitively means "voluntarily undertaking of anothers' affairs", it is a civil

[53] *Ibid*, Part Four, "Decision"; Article 69; Clause 3

[54] Law of Republic of Indonesia, Number 36, Year 2009 – concerning Health; Chapter XIX, "Investigation"; Article 189

[55] French term for "greater force" – unforeseeable circumstances that prevent someone from fulfilling a contract

[56] Penal Code of Indonesia, Article 48 – *"Not punishable shall be the person who commits an act to which he is compelled by force majours"*

[57] Penal Code of Indonesia, Chapter XXI, "Causing death or bodily harm"; Article 359 – *"Any person by whose negligence the death of another person is caused, shall be punished by a maximum imprisonment of five years or a maximum light imprisonment of one year"*

[58] *Ibid*, Article 360 – *"Any person through whose fault is caused the serious physical injury of another person, or such physical injury that temporary illness or an obstacle arises in exercising his official or professional activities, shall be punished by a maximum imprisonment of nine months or a maximum light imprisonment of six months or a maximum fine of three hundred rupiahs"*

[59] *Ibid*, Article 361 – *"If the crimes described in this chapter are committed in exercising an office or profession, the sentence may be enhanced with one third, deprivation of the exercise of the profession in which the crime has been committed may be pronounced, and the judge may order the publication of his verdict"*

legal defence that is adopted in the **Indonesian Civil Code** concerning Contracts[60]. In the context of defensing against a medical malpractice civil action, it circumstantially refers to the voluntary performance of a medical treatment on a patient without said patients' consent that could have potentially be caused by a barrier on part of the patient.

[60] Indonesian Civil Code; Book Three, "Contracts"; Chapter III, "Contracts arising by force of law"; Article 1354 – *"In the event that an individual, voluntarily, without having been assigned thereto, manages a persons' affairs with or without the other persons' knowledge, he shall impliedly bind himself to continue and complete the management, until the person whose interests are managed shall be in a position to manage his own affairs. He shall similarly involve himself in everything related to such affairs. He shall be subject to all the obligations which he would be obliged to comply with, in the event that he had been empowered by a specific authorization"*

5.0 SAUDI ARABIA – ISLAMIC LAW

5.1 HISTORICAL BACKGROUND OF ISLAMIC LAW

The Islamic legal system is interchangeably known as the Shariah law and it is somewhat distinguishable with Western legal systems in the sense that – (i) its parameter is wider for reasons that it principally regulates an individuals' relationship with a community, states and essentially, spiritual connection between themselves and God, (hereafter, Allah) that is manifested through obligatory sanctioned ritual practices (i.e., daily prayers, fasting, pilgrimage and etc). Simply, the Shariah law provides a comprehensive yet elaborated guidelines and rulings on prohibitory and permissible human conducts by way of what is promulgated in the scriptures (Read: Quran) and Prophetical Sunnah(s). It is also dissimilar because of its (ii) universal expressions that are unchangeable but yet adaptable to modernisation with the meaning that the principles that are being uphold within the legal system is somewhat also applicable socially, economically and politically.

5.2 DEVELOPMENT OF ISLAMIC LAW

In spite of its universally applicable principles, the development of different schools of law had unequivocally led to contrasting interpretations of the scriptures and religious teachings, some might be conspicuously more different than others so long as it does not develop against the fundamental Islamic principles. To date, there has been prominent expansion of the traditional Shariah law, substantially, the establishment of Shariah Courts that functions to enforce Shariah law among Muslims (i.e., inheritance, family law, successions etc) and the enactment of supplementary statutory provisions that incorporates Shariah teachings that are only enforceable against Muslims as well as the formation of both governmental and non-governmental institutions that operates towards the empowerment of Shariah compliance.

5.3 REGULATING LAWS IN SAUDI ARABIA

Most countries practice the Shariah law secularly, however, Saudi Arabia is one out of the 45 countries[61] that primarily enforce Shariah law governmentally. In the subject matter of informed consent, the Ministry of Health in the Kingdom of Saudi Arabia (hereafter, 'the Ministry') had released the Saudi Guidelines for Informed Consent purposefully with the intentions to protect patients' rights aside from raising awareness on issues relating to informed consent. Periodically, the Ministry is the predecessor to the Public Health Department that was founded by HRH King Abdul Aziz. Its provinces include the legislating laws and regulations for both governmental

[61] Muslim Majority Countries 2021. (2021). Retrieved 11 August 2021, from https://worldpopulationreview.com/country-rankings/muslim-majority-countries

and private health sectors, monitoring the performance of these health institutions and enforcing health policies (i.e., National Malaria Drug Policy, guidelines on cancerous medical conditions). The **Saudi Guidelines on Informed Consent** contains information, among other things, on informed consent (i.e., definitions, components that makes up an informed consent, types of informed consent and parties that are responsible to obtain informed consent).

Another provision that was legislated by the Ministry is **Law of Practising Health Professions**[62] that provides on the licensing of medical practitioners and, *for the purpose of this paper*, on duties of health practitioner. In respect to patients' consent, is the prohibitory clause on the performance of any treatment procedure without the patients' consent[63] including explanations in emergency situations[64]. Pharmaceutically, the Law also prohibits pharmaceutical facilities from dispensing alternative medications without the patients' consent, among other authorities[65]. In the aspect of ethics, medical practitioners, by virtue of the aforementioned law, is restricted from undermining or discouraging another practitioner or a colleague[66]. To my discovery, there preliminary-explained organisations and laws are adjudicated by the Saudi Health Council that upholds the administrative authority upon health-related laws and institutions.

5.4 IMPROVEMENTS

One most plausible initiative that was coordinated by the Ministry was the awareness campaign on patients' right that was entitled, "It's Your Right" that was motivated by the Saudi 2030 Vision. The Ministry had notably reformulated the policies in regards to patients' informed consent to provide clarity and accessibility to service recipients (read: patients and their families) through periodical meetings and conferences. An unrelated, to the material subject, but yet commendable initiative is the

[62] Law of Practicing Health Professions issued by the Royal Decree No. (M/59), Dated 04/11/1426H and the Implementing Regulations thereof issued by the Ministerial Resolution No. (4080489) dated 02/01/1439H

[63] *Ibid*, Part II, "Duties of Health Practitioner"; Section One, "General Duties of Health Practitioner"; Article (5); Regulation 5.3 (a)

[64] *Ibid*, Section Two, "Duties of Health Practitioner towards Patients"; Article 19 – *"No medical intervention may be performed except with the consent of the patient, its representative or guardian if the patient is legally incompetent. As an exception, the health practitioner must, in cases of accidents, emergencies or critical cases requiring immediate or urgent medical intervention to save the patients' life or an organ thereof or to avert severe damage that might result from delay, where the timely consent of the patient, its representative or guardian is unattainable, intervene without waiting for such consent. Under no circumstances may the life of a terminally ill patient be terminated even if so requested by the patient or its family"*

[65] Ibid, Article 23; Regulation 23.3

[66] Ibid, Section Three, "Professional Courtesy"; Article 24

introduction to Anti-Smoking Law that aims to combat unhealthy smoking habits through the restriction of the manufacturing of tobacco[67].

5.5 LEGAL IMPLICATIONS

A medical practitioner's civil liability was explained statutorily in the Law of Practising Health Professions[68] (hereafter, 'the Law'). Essentially, the failure of a medical practitioner in Saudi Arabia to comply with the regulations and laws, in the context of the material subject, informed consent, will be civilly liable[69] for indemnification[70]. In the aspect of criminal liability, the violation of a medical ethics and disciplines (read: failure to obtain patients' consent) can consequently led to the imprisonment of the medical practitioner or the sanctioning of a fine[71]. In addition to the abovementioned liabilities imposable against medical practitioners, it was also included, in the same Law, on disciplinary liabilities against medical malpractices hierarchically, - (i) warning, (ii) fine not exceeding ten thousand (10,000) Riyals and finally, (iii) revocation of practising license at which reapplication can only be filed two years after its revocation[72]. Informationally, the procedures apropos to the violation of medical ethics and disciplines is also enclosed in the very same Law[73] whereby will be convoyed by a committee publicly recognised as the Medico Legal Committee[74].

5.6 LEGAL DEFENCES

With the existence of the Saudi Patient Center ('SPSC') that performs executive authorities such as – monitoring and analysing medical errors at the national level, to develop proactive interventions to enhance the safety of patients in healthcare facilities; it is important to note that the legal system in Saudi Arabia that is based on Shariah law that applies rules from judges' personal interpretation of jurisprudence texts, unlike the

---

[67] Anti-Smoking Law issued by Royal Decree No. (M/56) dated 28/07/1436H; Article 3

[68] Law of Practicing Health Professions issued by the Royal Decree No. (M/59), dated 04/11/1426 H and the Implementing Regulations thereof issued by the Ministerial Resolution No. (4080489) dated 02/01/1439H

[69] Ibid, Part III, "Professional Liability"; Section One, "Civil Liability"; Article 27

[70] Compensating for harm or loss

[71] *Ibid*, Section Two, "Criminal liability"; Article 28 – *"Without prejudice to any severer punishment provided for in other laws, a person commits any of the following shall be punished by imprisonment of not more than six months and/or a fine not exceeding one hundred thousand Riyals"*

[72] Ibid, Section Three, "Disciplinary Liability"; Article 32

[73] Law of Practicing Health Professions issued by the Royal Decree No. (M/59), dated 04/11/1426 H and the Implementing Regulations thereof issued by the Ministerial Resolution No. (4080489) dated 02/01/1439H; Part IV, "Investigation and Trial"

[74] Ibid, Article 33

Common law and Civil law legal systems that makes reference to legal precedence, *per se*. And for those reasons, we will discuss on how the courts in Saudi Arabia determines a medical practitioners' liability from potential evidences that can be presented to the Court in respect to patients' consent that is within the Quranic texts' conception[75]. These includes – (i) al-Aqrar, or admission of the medical practitioner of their misconduct. Simply, a medical practitioner would not have to admit to an act that they did not commit to and thus is how it can be used against medical malpractices legal actions. Second is the (ii) al-Shahadah or witnesses. As how patients that brings forth medical malpractice legal actions against medical practitioners may present their witnesses to support their allegations, medical practitioners facing these allegations may also present a witness of their own to proof that no medical misconduct was performed as per alleged by the opposition. It also upholds the same sense of utilisation with (iii) Ra'yu al-Khabir or opinions of specialists as per evident in common law cases whereby medical practitioners may call upon specialists that can attest to when a patients' consent is not necessary based on circumstances at the material time of a particular medical treatment, *per se*, in an instant case. Lastly is (iv) al-Kitabah, which translates to written documents that, *in the context of patients' consent*, refers to consent forms.

[75] *Surah An-Naml* 27:64 – translation; *"…. Show me your proof, if what you say is true"*

6.0 CONCLUSION

We now decide on the extent of protection that is legislatively provided to medical practitioners and their patients against medical malpractices. It is apparent in my aforementioned discoveries that as much as there are differences on the requirements that makes up a valid patients' consent in different jurisdictions, there are also differences on how a government protects their medical practitioners against medical malpractice legal actions that is brought forth by patients methodologically, and these protections are somewhat important to ensure the existence of a secure environment for medical practitioners to perform their medical obligations phlegmatically without having to be worried that their actions might potentially harm their stance as a license medical practitioner.

Analytically, there are a somewhat similarity in the legal defences against medical malpractice actions in the above-explained jurisdictions (read: Malaysia, Indonesia and Saudi Arabia). In the context of informed consent, the defence of necessity applies in these jurisdictions, although not in the same sense but ideologically, this defence, in spite having disparate titles, imposes a degree of protections against medical malpractice legal actions whereby the medical practitioners are allowed to make an informed consent for their patients that, at the material time, is unable to do for themselves in emergency situations.

A feature of the Saudi Arabia health policy structure that outstands Malaysia's and Indonesia's is that they are collectively organised in a single database, with the meaning that their health-related policies, regulations, guidelines and organisational framework can be found in the very same website and not to mention that they also have a detailed guideline that pivots on the material subject (read: informed consent). To my mind, this is significant for reasons that it palpably augments accessibilities not only for those looking for information (i.e., to seek medical help) but for those that intend to use it as a research material as myself.

I would also like to submit my two cents on how I personally believe that this area of law (read: medical law) can be more closely-monitored and laboriously-developed, especially with respect to uprising medical issue(s) (ie. the absence of law on traditional medicine). A broad ideology that can be considered is the establishment of a special court that technicalises on medical law whereby an administration of specialists in different areas of medicines are appointed to verify on the genuiness of a medical practice, *per se*. In addition to that, it also within my personal opinion on the promotion of Alternative Dispute Resolutions (ADR) as part of litigations processed to, among other things, conserve doctor-patient relationship aside from offering alternative possible courses of actions for parties that lacks indefatigability to fathom a litigatory procedure.

REFERENCES

- Provisions/Regulations/ Statutes
  AD/ ART ID – Anggaran Dasar Ikatan Doktor Indonesia
  Law of Republic of Indonesia Number 29 Year 2004 regarding The Medical Practice
  Indonesian Civil Code
  Penal Code of Indonesia
  Penal Code of Malaysia (Act 574)
  Medical Act 1971 of Malaysia (Act 50)

- Articles/ Journals
  Mulyadi, D., Danil, E., Chandrawila, W., & Warman, K. (2020). Medical Negligence Dispute Settlement in Indonesia. Retrieved from https://medicopublication.com/index.php/ijfmt/article/view/12304/11308
  Paraati, A., & Agustine, E. (2021). Legal Aspects of Aoutonomousindonesia Medical Discipline Honorary Council in the Completion of Medical Disputes, (2319-7064). Retrieved from https://www.ijsr.net/archive/v9i1/ART20203817.pdf
  The Standard of Medical Care in Malaysia: The Case for Legislative Reform. (2012). Retrieved from https://eprints.utas.edu.au/15885/2/whole-lee-thesis-2012.pdf
  Informed Consent in Indonesia. (2018). *Journal Of Law, Policy And Globalization*, *69*(2224-3240).
  The Role of Indonesian Honorary Council of Medical Discipline in Upholding Indonesian Medical Code of Ethics. (2021), *358*.
  Legal Certainty of Noodweer as an Excuse Justification for the Decision of the Blora District Court Number 109/PID/B/2015/PN/BLA. *Advances In Social Science, Education And Humanities Research*, *478*. Retrieved from http://creativecommons.org/licenses/by-nc/4.0/
  CRITICAL ANALYSIS OF CRIMINAL MEASURES IN THE INDONESIAN NATIONAL POLICE. (2019). *South East Asia Journal Of Contemporary Business, Economics And Law*, *19*(2289-1560).
  Juridical Analysis of CriminalLiabilityby Doctors inMedical Malpractice(Study Analysis of Medical Malpractice Case in General Hospital Prof. Dr. R.D. Kandou Malalayang, Manado, Indonesia). (2017). *International Journal Of Humanities And Social Science Invention*, *6*(6). doi: 2319 – 7722
  Jochemsen, H.. (2001). Update: the legalization of euthanasia in the Netherlands. Ethics & medicine : a Christian perspective on issues in bioethics. 17. 7-12.
  MEDICAL NEGLIGENCE LITIGATION IN MALAYSIA: CURRENT TREND AND PROPOSALS FOR REFORM. (2007).
  THE STANDARD OF MEDICAL CARE IN MALAYSIA: THE CASE FOR LEGISLATIVE REFORM. (2012). Retrieved from https://eprints.utas.edu.au/15885/2/whole-lee-thesis-2012.pdf
- Websites
  MKEK IDI – Website Resmi Majelis Kehormatan Etik Kedokteran. (2021). Retrieved 10 August 2021, from http://mkekidi.id/

Konsil Kedokteran Indonesia::. (2021). Retrieved 10 August 2021, from http://www.kki.go.id/index.php/tentangkami/index/1206/1245/majelis-kehormatan-disiplin-kedokteran-indonesia

'Do Not Resuscitate' Order: The Right to Refuse Medical Treatment. (2020). Retrieved 10 August 2021, from https://mahwengkwai.com/do-not-resuscitate-order-the-right-to-refuse-medical-treatment/

Hartono, S., & Sunandar, T. (2001). The Indonesian Law of Contracts. *Economic And Social Development And Law (Indonesia)*. Retrieved from https://www.ide.go.jp/library/English/Publish/Reports/Als/pdf/10.pdf

Saudi Commission For Health Specialties . (2021). Retrieved 11 August 2021, from https://www.scfhs.org.sa/en/Pages/default.aspx

home page. Retrieved 11 August 2021, from https://www.moh.gov.sa/en/Pages/default.aspx

Kumar, V. (2019). Advantages & disadvantages: pros & cons of medical consumer Protection Act. Retrieved 13 August 2021, from https://extinctdoctorgood.com/2019/05/07/advantages-disadvantages-pros-cons-of-medical-consumer-protection-act/