

The Standard of Disclosure in Informed Consent Decision Making in Medical Practice in Malaysia

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Abstract: *This is a conceptual paper to analyse the standard of disclosure in informed consent decision making in the medical practice in Malaysia. This study reviews literature on the history of the standard applied in the informed consent requirement among patients and its consequences in healthcare practice. It aims to evaluate the crucial elements of patient centricity particularly the factors that affect the voluntariness and competency of the patient in giving consent. This paper reviews the existing literature surrounding the phenomenon of giving consent for medical treatment in the healthcare, particularly on how the concept of shared decision making affects the consent requirement. This study provides an overview of the perplexing nature of disclosure in shared decision making and the various concerns that have surrounded the topic leading to its recognition. Hence in Malaysia, there is no specific law which governs the provisions for shared decision making in informed consent in the healthcare practice. This study aims to explore the Malaysian Medical Council Guideline on Consent for Treatment of Patients by Registered Medical Practitioner (MMC Guideline on Consent) and the current Malaysian laws to determine whether they are sufficient to address the principle of shared decision making requirement patients. The study reviews the existing case laws and literature on the historical development of the elements of shared decision making, subsequently, the findings of the perusal of the MMC Guideline on Consent and the current statutory laws are presented and discussed. Finally, lack of empirical evidence is recognised in this paper and several suggestions are made for future research and recommendation for enactment of a new law pertaining to shared decision making in informed consent to medical treatment.*

Keywords: informed consent, standard of disclosure, shared decision making

1. Introduction

Health professionals need to give patients sufficient information to make an informed decision, in the past, there was a paternalistic approach to healthcare: doctors decided not only what treatment would best fit their patients' needs, but also what information to give to them. Patients would be spared information which their doctor thought they might find upsetting or otherwise did not need to know – for example, a diagnosis of cancer or terminal illness.¹ Patient centred care rest on the adoption of patient centric approach where the patients are regarded as the universe of the health care industries. Partaking this, shared

¹ McCrae N (2013) Person-centred care: rhetoric and reality in a public healthcare system. *British Journal of Nursing*; 22: 19, 1125-1128.

decision-making has been taken as the crux of the patient care centred² where the patient will be made as the team player together with the medical practitioners in medical making decision process, where the role of the medical practitioners is to support whenever possible the patients' self-determination. This partnership concept based on the premise of corroborating two important elements of self-determination and relational autonomy which are individual and interdependency.³

The principle of shared decision- making is modification of informed consent concept with an extension towards consideration of patient's preference, demands, value, choices and decisions. The principle of beneficence, equality and justice will then improve the good medical practice through the proper execution of the concept.⁴ However, these medical phenomena raise questions like what are the legal principles enforcing this concept and will the failure to adhered to this standard of decision making will result in legal consequence.

The acceptance of legal ruling that decided a patient's consent must be a result of sufficient information according to terms and need of the patient has made informed consent to be adopted as patients' right, ethical principle and prevalence practice in medical service.⁵ Thus, it is confirmed that besides social change the legal departure mandates the patients' first approach and shared decision making in health-care industries.⁶

2. Legal Development on Patient Centric Approach

Laws has contribute constitutively towards the evolution of patients' identity and role. In the 1960s and 1970s, the concept of autonomy among patient is enlarged legally by the principle of informed consent. All jurisdiction around the world generally accept and practice the doctrine of informed consent though with slight modifications. According to the doctrine of informed consent, sufficient information must be given to every patient before any medical decision making as it is patients' right which founded based on autonomy principle. This doctrine aims at protecting patient's interest and safeguard physicians' acts against liability in negligence and battery.⁷ The development of this principle on the issue of disclosure brought about the departure of idealized doctor- patient relationship and simultaneously brought changes to the practice of medicine.

Primarily, the doctrine of informed consent was not recognized by the common law in United Kingdom. This position is envision by the decision in *Sidaway v. Bethlem Royal Hospital Governors*⁸ reflects the view that patients cannot be expected to have the same level of knowledge as the doctors treating them, might not be able to objectively balance the risks and

² Wayne Weston, (2001) 'Informed and Shared Decision-Making: The Crux Of Patient-Centered Care', Canadian Medical Association Journal, 165, 438-439 < <http://www.cmaj.ca/content/cmaj/165/4/438.full.pdf> > accessed on 5.7.2019. pg.438

³ Glyn Elwyn, et al. (2012), 'Shared decision making: a model for clinical practice.' Journal Of General Internal Medicine vol. 27,10 1361-7.< <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3445676/>> accessed on 4.7.2019. pg. 1363.

⁴ Ibid n.1

⁵Richard T. Hull, (1985), "Informed Consent: Patient's Right or Patient's Duty?" The Journal of Medicine and Philosophy 10 < https://times.taylors.edu.my/pluginfile.php/3114789/mod_resource/content/2/Informed%20Consent%20-%20Right%20or%20Duty.pdf>accessed on 30.6.2019. pg.184

⁶ Lesley Moody, Brett Nicholls, Hannah Shamji, Erica Bridge, Suman Dhanju and Simron Singh' (2018), "The Person-Centred Care Guideline: From Principle to Practice" Journal of Patient Experience 2018, Vol. 5(4) 282-288 < <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6295806/>> accessed on 27.6.2019. pg. 282

⁷ Schloendorff v Society of New York Hospital (1914) N.E. 92 105.pg.5.

⁸ [1985] 2 WLR 480 pg.643

benefits of a particular intervention, and might place “undue significance” on certain elements of the information they are given. It was thought that giving the patient too much information might “prejudice the attainment of the objective of restoring the patient’s health” and, therefore, conflict with the doctor’s duty to act in the patient’s best interests. The courts considered that patients needed to be protected from making irrational decisions so the House of Lords extended the Bolam test – used to assess negligence – to the information doctors were required to give or disclose to patients. This meant doctors were able to withhold information from their patients and would not be deemed negligent provided they had “acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art as upheld in the case of *Bolam v. Friern Hospital Management Committee*.⁹ In this case the patient who suffered from mental illness was not informed about the possibility of fracture before the treatment of electroconvulsive therapy was given. On the duty and standard of care of a doctor the court held that a medical practitioner 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 area of medicine involved.

There are different views given by competent medical professional in Bolam’s case on whether the risk of fracture before the treatment, which is one in ten thousand to be informed to the patient. The court in Bolam held the doctors would not be negligent if act in accordance at least one accepted practice and applied the principle in *Hunter v Hanley*¹⁰ case which held that medical practitioners’ judgement who decide for the best of the patients should be criticised.

Bolam’s paternalism approach was applied in *Hills v Potter*¹¹ where the court clearly rejected the Doctrine of Informed Consent and held the standard of disclosure is based on medical judgment.¹² In *Sidaway v Board of Governors of Bethlem Royal and the Maudsley Hospital*,¹³ The issue of Informed Consent was discussed in detail. The patient in this case who had a recurrent pain in her neck, right shoulder and arms claims that she was not informed the risk of damage to the spinal column and nerve roots when she underwent the procedure in which she had become severely disabled from with. The risk was assessed at between 1% to 2%. The court held in this case that Bolam’s principle is available in the doctor’s duty to advice and the determination of what risk to disclose is based on accepted practice of prudent medical body.

However, in recent years there has been some departure from Bolam reported in England. The departure starts from dissenting judgement in Sidaway case upholding the patient’s self-determination in risk disclosure for medical decision-making.¹⁴ Lower courts under British jurisdiction applying the dissenting principle had taken more patient approach and made

⁹ [1957] 2 All ER 118 pg.118

¹⁰ [1955] SLT 213 pg.217

¹¹ [1984] 1 WLR 641 pg.646

¹² Nemie J. Kassim, (2007), “*Law and Ethics Relating to Medical Profession*”, International Law Book Service. pg. 26

¹³ Ibid n.7 pg. 643-644

¹⁴ Ibid n.5 pg.8

some modification to Bolam's test. Examples of cases are *Smith v. Tunbridge Wells H.A.*¹⁵, *McAllister v. Lewisham*¹⁶ and *Lybert v. Warrington Health Authority*.¹⁷

Direct modification of Bolam approach was made by the House of Lords in *Bolitho v City & Hackney Health Authority*¹⁸ which stated that any medical opinions will have to stand logical evaluation by the court and if the accepted medical opinion is not capable of withstanding logical analysis, the court can held the opinion as unreasonable or irresponsible. This decision shows the court's approach towards patient favour, where the accepted practice decided by prudent medical body will be evaluated further by the court.

In 1999, Court of Appeal in *Pearce v United Bristol Healthcare NHS Trust*¹⁹ applied both Bolam and Sidaway in deciding on the issue of whether the risk of stillborn in delayed delivery should be informed to the patient held that medical practitioners have duty to inform the patient significant risks that will affect patients' decision. This decision shows England court took a direct shift towards patient centric approach where in this case taking into consideration patient's condition, it was decided that patient would continue with the surgery even after being informed about the risk.

The Pearce decision was applied in *Montgomery v Lanakshire Health Board*.²⁰ In this case the doctor has failed to inform the plaintiff on the risk of shoulder dystocia when plaintiff request for vagina delivery. The court distinguished Bolam's case and upheld that whether the risks are material or not is to be determined by the reasonable man in patient's condition. Therefore the case of Montgomery mark the UK's departure from paternalism to patient centric approach. Montgomery also acknowledged shared decision-making principle when decided that in assessment of disclosure of the risk, patients' sensitive facts should be taken into consideration. The court highlighted that the doctor should act as an advisor engaging patient in discussion to ensure the patient's understanding of technical terms, risks, seriousness of the condition, and alternatives in giving an informed consent.²¹ The test to be applied is "whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

Latest decision in UK in the case *Mills v Oxford University Hospitals NHS Foundation Trust*²² applied patient prudent test was still in deciding the claim of lack of informed consent.

Unlike England, United State are clear on the issue of informed consent. The first principle regarding informed consent in a negligence case was held in *Salgo v. Leland Stanford, Jr.*

¹⁵ [1994] 5 Med. L.R. 334, the court stated that patients' condition should be taken into consideration in deciding the extent of disclosure to the patients. In this case court took into consideration the period of patient's suffered condition.

¹⁶ [1994] 5 Med. L.R. 343, followed Tunbridge in deciding the doctor's liability and acknowledge that the patients would not undergo the surgery if she was informed about the risk of some further deficit in her leg.

¹⁷ [1996] 7 Med. L.R. 71, the Court applied both the subjective test and Tunbridge case and the history of previous 3 caeseran sections and plaintiff's request for hysterectomy was taken into consideration.

¹⁸ [1997] 3 W.L.R. 1151 pg. 771-772

¹⁹ (1998) 48 BMLR 118 pg. 118-119

²⁰ [2015] 2 WLR 768 pg. 768

²¹ Ibid n.18

²² [2019] All ER (D) 85, pg.1

University.²³ The court adopted the informed consent concept provided by the American College of Surgeons which laid down that medical practitioners' failure to tell necessary facts to the patients will be held liable. Later, in *Natanson v. Kline*²⁴ the doctor approach test was used when the doctor decided not to inform about the risk but at the same time court acknowledges patient's self-determination in giving consent. A clear approach toward patient centric in US was made by the court in *Canterbury v. Spence*.²⁵ The decision departed from the prudent doctor standard in disclosure of information and explains that the patient should have the opportunity of evaluating the risks and options available before making a choice in treatment. The case involved the doctor's failure in warning the patient of any risk of paralysis from the procedure of surgery for severe back pain.

The Australian Courts have been very authoritative on the issue of informed where in *Rogers v Whitaker*,²⁶ applying the test of reasonable patient decided that the doctor's failure to properly advise the patient who had only one good eye of the risk of sympathetic ophthalmia amount to negligence. It was also highlight that patient should contribute more in the process of giving consent and the duty to ensure patients' understanding of the risks rests on medical practitioners.

Summarily, latest principle by the courts on informed consent in all over countries are patient focused. Detailed perusal of the cases' facts will shows that in arriving to the new decisions, particular facts of each specific patient were taken into consideration in formulation of the prevailed legal principle. The courts somehow manoeuvred the legal principle to upheld and safeguard patients' interest in order to provide them a suitable remedy from the damages suffered caused by medical practitioner.

Apart from indirectly acknowledge that medical practice should revolve around patient, courts also indirectly adopted the language of shared decision-making. The principle of informed consent directly proposed the active involvement of patient in decision making process²⁷ and for the doctors to ensure patient's understanding in making informed decision. Inadequacy of doctrine of informed consent in term of physician variation on the standard of care and variation in patients' preferences for information disclosure give raised to the need of shared decision-making²⁸ where shared decision-making's objective is to combine both the principle of Bolam²⁹ doctor-approach by encouraging doctors' medical opinion to actively leading the patient and Rogers³⁰ patient-approach by emphasizing on patient's active involvement in decision-making process.

Hence, it is clear that shared decision making has not been made as a legal requirement for standard of disclosure in informed consent or as part of legal duty to advice among the medical practitioners. However, the concept active participation of patients and shared responsibility to achieve informed consent in decision-making has been accepted as a good practice. Recommendations has been for medical and legal system to establish an obligatory

²³ [1957] 317 P.2d 170, The surgeon failed to warn about risk of paralysis.

²⁴ [1960] 186 Kan 393; [1960] 350 P 2d 1093.

²⁵ 464 F.2d at 772, The Canterbury court replaced the physician-based standard with one that acknowledged a larger role for patients in determining whether to proceed with medical treatment.

²⁶ [1992] 175 CLR 479

²⁷ Ibid n. 5 pg.8

²⁸ Jaime S. King and Benjamin W. Moulton, (2006), "Rethinking Informed Consent: The Case For Shared Medical Decision-Making" 32 Am. J.L. & Med. 429 pg. 17-22

²⁹ Ibid n.8

³⁰ Ibid n.27

system which will uphold the principle of patient-centric and also paternalism at the same time. The application of shared-decision is an ethical practice that will improve health care services' effectiveness and efficiency,³¹ patients' satisfaction,³² alleviate the tension of paternalism and autonomy,³³ harmonize the competence elements in medical decisions³⁴ and will increase patient's engagement and understanding.

Thus, the current principle of informed consent theoretically may be modified to add some elements of shared decision making like open communication, input sharing and a mutual agreement to re-establishes the physician-patient relationship. A Singapore's case *Hii Chii Kok v Ooi Peng Jin & Anor*³⁵ clearly stated that it is appropriate to move towards a somewhat more patient-centric approach in respect of disclosure of information and medical practitioner's advice to patients. In adopting the guideline in the case of Montgomery, the court in this case emphasized on the communication between patients and doctors to improve patients understanding in decision making process. The case of Hii shows that the courts somehow are ready to legalize shared decision-making as a legal requirement to ensure that the patient has given an informed consent to medical procedures.³⁶

3. The Position in Malaysia

In Malaysia, as other jurisdictions, there is no direct legal preposition upheld by the court imposing shared decision-making to be practiced or executed by medical institution. But, the doctrine of informed consent is applied by the courts of law.

The primary position in Malaysia was based on Bolam's approach where it was upheld that the doctor would not be held negligence if act in accordance with one of medical accepted practice and disclosure of information is to be determined by the accepted practice of prudent medical body. This doctor- approach was applied in the case of *Liew Sin Kiong v Dr Sharon M Paulraj*³⁷ where the plaintiff who suffered from juvenile glaucoma claims that the doctor has failed to inform him the risks of affection from the operations. The court held that there was no negligent on part of defendant as he acted in accordance with the standards of a competent ophthalmologist.

Later, the Malaysian court shows a little departure from paternalism approach in relation to the case when the patient asked to sign consent forms before any operation but in reality they

³¹ Nan D. Hunter , (2010) "*Rights Talk And Patient Subjectivity: The Role Of Autonomy, Equality, And Participation Norms*" 45 Wake Forest L. Rev. 1525 pg. 6

³² Carlos A. Rodriguez-Osorio and Guillermo Dominguez-Cherit,(2008), "Medical Decision Making: Paternalism Versus Patient-Centered (Autonomous) Care", *Current Opinion in Critical Care* 2008, 14:708–713< https://times.taylors.edu.my/pluginfile.php/3114768/mod_resource/content/2/Medical%20decision%20making%20Paternalism%20versus.pdf> accessed on 30.6.2019

³³ Lucija Murgic, Philip C. Hébert, Slavica Sovic and Gordana Pavlekovic, (2015), "*Paternalism And Autonomy: Views Of Patients And Providers In A Transitional (Post-Communist) Country*", *BMC Medical Ethics* < https://times.taylors.edu.my/pluginfile.php/3114795/mod_resource/content/2/Paternalism%20and%20autonomy%20views%20of.pdf>accessed on 30.6.2019

³⁴ Ibid n.3 pg. 186

³⁵ [2017] SGCA 38, para 142

³⁶ Louise v. Austinsn, (2019) "*Hii Chii Kok v (1) Ooi Peng Jin London Lucien; (2) National Cancer Centre: Modifying Montgomery*" *Med Law Rev* 27 (2): 339, pg. 2

³⁷ [1996] 5 MLJ 193 pg. 194

do not really understand what they are signing.³⁸ This can be seen in *Tan Ah Kau v Government of Malaysia*³⁹ case where the plaintiff claimed that when he signed the consent form he was told that the operation is to ensure he will be able to walk in future and the pain will gone in two weeks after the surgery. Thus, the court held that no consent was actually given by the plaintiff as the risk of paralyse suffered by the plaintiff from the surgery was not disclosed to the patient.

Direct departure from Bolam's approach and a step toward patient-centric decision was taken in the case of *Foo Fio Na v Dr Soo Fook Mun & Anor*.⁴⁰ In that case the patient became totally paralysed after undergoing surgery for neck injuries. One of the appellant's claims was the doctor has failed to disclose the material risk and gave proper advice. For that claim, the court found the defendant guilty by applying the principle of Rogers v Whitaker and held that the paternalism approach in Bolam no longer applicable in duty to advise among medical practitioners.

Subsequently, Malaysia courts on issue of consent at one point has vaguely extend the need of informed consent to include spousal consent. In the case of *Gurmit Kaur a/p Jaswant Singh v Tung Shin Hospital & Anor*,⁴¹ the court decides the failure to obtain patient's husband consent for a hysterectomy as required under the consent form amount to negligence. The scope was further expanded by *Abdul Razak bin Datuk Abu Samah v Raja Badrul Hisham bin Raja Zezeman Shah & Ors*⁴² case when it was held that when the patient depends on their spouse in decision making, spouse's consent is required.

This patient-centric position was later shown and upheld by Federal Court case, *Zulhasnimar Hasan Basri v Kuppu Velumani P*⁴³ where the court analyse all the cases related to adequacy of advice and gave a clear preposition that the test in Rogers v Whitaker⁴⁴ is applicable in term of disclosure of information for informed consent in Malaysia. The Federal Court also held that in the respect of duty to diagnose and to treat the Bolam⁴⁵ test applicable with slight modification subject to qualifications as decided by the case of Bolitho⁴⁶. In this case, the case of Gurmit Kaur and Abdul Razak was referred but nothing mention on the application of spousal consent.

Thus, currently, the Malaysian legal position is patient-centric disclosure where according to the courts adequacy of information disclosed in decision-making is to be determined by the patient. Similar to other countries, the courts in Malaysia has indirectly and unconsciously recognized shared decision-making process by stressing on patients' understanding and extended the principle of informed consent to include the spousal consent.

Unfortunately, up to this date, there is no patient centred care establishment in Malaysia neither shared decision-making policies has been made as part of any medical institution. But a discernible movement towards adapting patient centric approach and upholding share decision-making practice can be seen through the medical policies provided under the

³⁸ Ibid n.10. pg.36

³⁹ [1997] 2 AMR 1382, pg. 1383-1384.

⁴⁰ [2007] 1 MLJ 593, pg.594

⁴¹ [2012] 4 MLJ 260, pg.261

⁴² [2013] 10 MLJ 34 pg.34

⁴³ [[2017] 5 MLJ 438.pg.473

⁴⁴ Ibid n.26

⁴⁵ Ibid n.7

⁴⁶ Ibid n.16

purview of Health Ministry. The directions given by the Malaysia Medical Council have derivatively favouring patient's well-being, best interest and active involvement in decision making.

The duty of obtaining informed consent has been included in several guidelines and directive enforced by the council namely Code of Professional Conduct,⁴⁷ House Officer Guidebook,⁴⁸ Guidelines on Consent⁴⁹, Good Medical Practice,⁵⁰ Guidelines for Clinical Trials & Biomedical Research⁵¹ and in The Malaysian Medical Council's Position on Managed Care Practice.⁵² The doctors also religiously directed by the guidelines and code of conduct to act for the benefit and wellness of patient where the breach of duty to act for patient's well-being will resulted in disciplinary proceeding.

Apart from that in House Officer Guidebook and Guideline for Consent, clear instructions of what information and how disclosure should be made are judiciously provided. An emphasize was made in paragraph 4.12 of the guidebook⁵³ that the patient is the ultimatum decider for their health as it is a matter of human right. The imposition by the MMC Guidelines on detailing each subject of disclosure, who should deal with the patient, additional material for patient's understanding, language of the patient is the priority, environment of obtaining patient's consent, how consent should obtained and partnership and involvement of patient in decision making shows an early adoption of patient-centric approach and shared decision-making in Malaysia.

Theoretically, in Malaysia shared decisions-making has been recommended as a process that would be intrinsically valuable as it enables the patient to exercise inviolable right of self-determination. The recognition was made on the basis that the patient's autonomy can be enhanced after a detailed discussion and explanation by doctors on the risks of treatment and the alternatives.⁵⁴ A compatible approach of decision making need to be found to ensure balance between patients' and doctors' interest will always be maintained by the Malaysia court as we human will always depend on medical profession.⁵⁵

A research was conducted on patient activation program found that the program will help in educating patient in Malaysia to communicate to medical practitioner about their personal condition, preference and value and also overcome the disempowerment of patient.⁵⁶ Even there are worries that shared decision-making principles breach the patient's autonomy on self-determination, it is argued that shared decision-making combined both the tendency of protecting oneself and the dependency in others in decision-making process. Shared decision-

⁴⁷ Malaysian Medical Council Guideline, (1986), "*Code of Conduct of Medical Practitioners*"

⁴⁸ Malaysian Medical Council Guideline, (2010), "*A Guide Book for a House Officer*".

⁴⁹ Malaysian Medical Council Guideline, (2016), "*Consent for Treatment of Patients by Registered Medical Practitioners*"

⁵⁰ Malaysian Medical Council Guideline, (2001), "*Good Medical Practice Ethical Guideline*"

⁵¹ Malaysian Medical Guideline (2006), "*Clinical Trials & Biomedical Research Ethical Guideline*"

⁵² Malaysian Medical Council Guideline, (2012), "*The Malaysian Medical Council's Position on Managed Care Practice*"

⁵³ Ibid n.44

⁵⁴ Nemie J.Kassim, (2003), "*Medical Paternalism Versus Patient Autonomy: Solving Conflicts In Medical Decision-making*", 2 MLJ xxxiv, pg.7

⁵⁵ Ahalya Mahendra, (2013), "*The Law Of Medical Negligence: Where Does It Stand Post Foo Fio Na?*" 1 MLJ cvi pg. 9.

⁵⁶ Nor A. Azizama, Siti N. Maonb, Nor I. S. Abdul Aziz & Nur Z. Abd Hamid, (2016), '*Association of Patient Centered Communication and Patient Enablement*'. Pg1-3 <<https://pdfs.semanticscholar.org/c3da/b3bc491d9e96e008d08548be5601382a4b4e.pdf>> accessed on 2 July 2019

making also held on the reconciliation of doctor-centric and patient-centric and will help in providing more informed consent as it will involve two experts i.e. the doctor and the patient in respective relevant area.

However, on issue whether shared decision-making can be employed in Malaysia medical service, for now the answer would be negative. There is a big gap between theory and reality. Models of implementation of shared decision making requires instalments of medical education, integrated training, information or decision aids tools, new system of patients record, upgraded health care policies, role models and society awareness into a medical service.

Practically, in Malaysia, unfortunately the concept of informed consent has not been fully adhered with. This can be seen in the reported cases discussed above where in the case of Tan Ah Kau,⁵⁷ the consent form was instructed to be signed without any explanation of the risk of paralyse. Similar circumstances occurred in *Foo Fio Na's*⁵⁸ case where the information disclosed only involves the fact that the surgery is minor intended to correct patient's neck problem. During trial, court also question the patient's signature as there was no witness attestation on the form and when the consent was given, patient's limb had lost all sensation.

In *Gurmit Kaur*⁵⁹ the doctor performed an unconsented procedure of hysterectomy while performing surgery to remove a fibroid. The evidence also showed that while the Plaintiff signed the consent form, no information or risk was explained to her and the consent form in this case required husband's signature in case involving major gynaecology operations. Similarly in the case of Abdul Razak,⁶⁰ evidence in trials showed the consent from the patient was obtained by surgical trainee, no witness's signature on the form, no record provided in court to show what information revealed to the patient and the instructions given by the surgical in charge, the 1st defendant to other defendants was through a phone call.

Both situations besides showing lack of adherence to principle of informed consent in Malaysia medical practice, raised a question whether it is a standard procedure in the Malaysian Medical Practice for a consent form involved hysterectomy to request a husband's signature. If it is a standard procedure or an accepted practice, then the question arises where it is provided. It is also clear under the doctrine of informed consent and the concept of patient's autonomy, it is the patient alone that has the right to determine what should be done to his or her body. Thus, these decisions has encroached the principle of informed consent and creates a new duty of care outside the patient-doctor relationship. But looking from another perspective, these two cases also shown an indirect adoption to the principle of shared decision-making which provides that patients' family are entitled to be involved in medical decision-making process.

In Malaysia, sadly, expectations provided by judicial interventions was almost never been practiced. Even, it was provided under the Medical Malaysian Council Consent Guidelines⁶¹ itself from 2013 that informed consent must be obtained by the medical practitioners, in

⁵⁷ Ibid n. 36

⁵⁸ Ibid n. 37 pg.602

⁵⁹ Ibid n. 38 pg.265

⁶⁰ Ibid n. 39 pg.54

⁶¹ Malaysian Medical Council Guideline, (2013), *Consent for Treatment of Patients by Registered Medical Practitioners*.

Malaysia's hospital, in most situations consent are obtained by nurses without clear disclosure of material risks and without witnesses. The medical practitioners also find it difficult to record any communication between them and the patients. The real situation is always 5 minutes consultation due to time limitation caused by flood of patients. The first defendant in Abdul Razak case admitted himself that he have limited time to see the patient and discuss about the risk because he was on call monitoring 6 to 7 wards.⁶²

First example of real occurrences is the recent procedure in National Health Institute where the consent form and the explanation was provided by a nurse, where only medical officer, not the surgeon attended to the patient very early in the morning explained roughly on the angiogram procedure omitted any material risk. After the procedure, the medical officer came again stated that the artery blockages were not totally repaired and the patient has to undergo the procedure again on the reason of possibility of kidney affection. Similarly, in infertility treatment in National University Hospital when patients undergo alternative reproductive treatment, the doctors just explained what is the next step or procedure but never carefully discussed the benefit, risks, costs, affect and future plan with the patient in Malaysia. This practice not only prevailed in government hospitals but also in private hospitals. In a latest federal court case, *Hari Krishnan & Anor v Megat Noor Ishak bin Megat Ibrahim & Anor*⁶³ the doctors were held liable for negligent when failed to disclose the risk of bucking and blindness in retina detachment surgery even patient previously requested for scans to be conducted and enquired on the need for the operation. Summarily, in Malaysia's medical system there are no proper execution and enforcement of the doctrine of informed consent to date.

All the reported and real situations explained shows that there are very little awareness, education and training regarding the concept of patient centred and shared decision-making available in Malaysia. In fact there are only one medical school which included shared decision making as its primary subject, the research on both issues are scarce and practically in Malaysia decisions still paternally done by the medical practitioners.⁶⁴ Malaysia's medical service also faces with unresolved predicament such as time limitation for consultation, shortage of human resources, heavy workload, lack of technology and latest facilities, communication skills among medical practitioners and lack of financial resources.

Research shows that in Asia, lack of knowledge in both approach would be the main hindrance in practicing shared decision-making and there is no basis to find a certainty whether the western guideline will be able to be applied as in Asia particularly in Malaysia patients' decision are always depends on their families' thoughts and opinion which is varied in term of belief, practice and lifestyle.⁶⁵ In fact as for now, there is no research or proposal on the suitable model of shared decision-making can be found for Malaysia's medical framework.

Legitimately, in current situation an establishment of both patient centred care and shared decision practice will require an abundance of change in every aspects including health policy, government's finance, hospital administrations, medical education system, hospital's

⁶² Ibid n.39 pg.43

⁶³ [2018] 3 MLJ 281 pg.305

⁶⁴ Ibid n.53. pg.5

⁶⁵ Chirk J. Ng, PingY. Lee, Yew K. Lee, Boon H.Chew, Julia P Engkasan, Zarina I Irm, Nik S. Hanafi and Seng F. Tong, (2013) "An Overview Of Patient Involvement In Healthcare Decision-Making: A Situational Analysis Of The Malaysian Context", BMC Health Services Research, 13:408 <<https://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-13-408>> accessed on 2 July 2019. pg. 4

standard procedure, staff and officers support system, work mechanism, and technology equipment. The employment of shared decision-making in medical service will need detailed plan and multifaceted strategies with combination of overall cultural changes in all levels of medical institutions, professionals and patients as its establishment will involve a complex intervention.⁶⁶ A good start of it would be creating some awareness among the patients and medical practitioners itself⁶⁷ and researches on predicted issues. Even one of the benefit of shared decision-making is decreasing medico litigation,⁶⁸ in Malaysia if the practice is imposed legally, it is believed that there will be a flood of medico legal cases as there will be lack of adherence to the legal standard of informed consent.

It is prudent to note that after the decisions of Gurmit Kaur and Abdul Razak extended the principle of informed consent to include husband's consent, there have been criticism that unnecessary decision will result in unlimited claims by spouse and will bring extra workload and cost to medical industry.⁶⁹ Thus, even now it seems convenient to the courts to imposed patients centric approach but the court also has to act fairly in favour of doctors and medical service. In Malaysia legal imposition of shared decision-making will bring extra encumbrance and burden to both healthcare and judicial services.

Patient education is an important step towards empowering patient involvement in decision-making. Accessibility to accurate, relevant, and readable health information increases health literacy and engages patients in the discussion of choosing the best option for their health. Low health literacy rate may be an important contributing factor to the lack of patient involvement in decision-making in Malaysia.⁷⁰ The Ministry of Health is the main provider of patient health education resources in Malaysia. It recognises the importance of disseminating “accurate, appropriate, and relevant information in a timely, equitable, and innovative manner” and “empowerment of individuals and communities to enable them to take action on the determinants of health.”⁷¹ The Ministry has established a health education Website for the public.⁷² However, the development process of these educational materials is not clear and only limited health topics are covered (obesity, physical activity, smoking, diabetes, heart disease, and mental health). The Website provides an interactive risk calculator and helps users discuss their results further with doctors. However, SDM is mentioned neither implicitly nor explicitly. Moreover, the usability, the usefulness, and the comprehensiveness of the health information of this Website have not been evaluated.

⁶⁶ Anne M Stiggelbout, Maarten P.T. De Wit et al. (2012) ‘*Shared Decision Making: Really Putting Patients At The Centre Of Healthcare*’ 344 :e256 BML. <10 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1313854/pdf/114187>>accessed 27 Jun 2019.pg.3

⁶⁷ Salzburg Global Seminar. Salzburg statement on shared decision making. (2011), 342:1745 BMJ < <https://www.salzburgglobal.org/>> accessed on 3 July 2019

⁶⁸ France Legare et al, (2012), “*Inter-professionalism and Shared Decision-Making In Primary Care: A Stepwise Approach Towards A New Model*,” Journal of Interprofessional Care 25-1 < <https://www.tandfonline.com/doi/full/10.3109/13561820.2010.490502?scroll=top&needAccess=true> > accessed on 27.6.2019

⁶⁹ Sarjeet Singh Sidhu, (2014) *Spousal Consent and Medical Negligence: A Bridge Too Far?* Malayan Law Journal Articles, 4 MLJ cix. pg.11

⁷⁰ Loh S, Packer TL, Yip CH, Passmore A: Targeting health disparity in breast cancer: insights into women's knowledge of their cancer profile in Malaysia. *Asian Pac J Cancer Prev* 2009, 10:631–636

⁷¹ Health Education Division Ministry of Health Malaysia. <http://www.infosihat.gov.my/infosihat/artikelHP/bahanrujukan/HEam/Health%20Education%20Division.pdf>.

⁷² My health. <http://www.myhealth.gov.my/myhealth/index.php>.

4. Conclusion

It is undeniable that an establishment of patient centred care in Malaysia with shared decision-making component would be really helpful in improving medical service itself. The principle advocate by shared decision-making if execute diligently will result in better management of patient' care which will eventually increase patient's satisfaction and quality of life. All the situations of inadequate disclosure of information also can be overcome if shared decision is practiced as it encourages active involvement of patient and diligent guidance by doctors in a fairly conducted discussion.

For a higher quality of service care for the citizens, it would be great to convert National Health Institute or National Cancer Institute from a disease centre care to a patient centre care. Both approach will theoretically improve the performance of the service as both centre deal with elusive disease which will affect the patient's life and require major intervention by medical practitioners. It would be good too for shared decision making process to be implemented in fertility treatments in Malaysia as it involves detailed careful long medical plan and costly treatment. But it is also an undeniable facts that, the whole medical system need to be revamped to properly employ share decision making in Malaysia health care service. In other words, currently Malaysia is not ready for an establishment of patient-centred care neither for the enforcement of shared decision-making process.

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