

## **The Non-Admissibility of the Principle of Therapeutic Privilege in Clinical Trials**

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### **ABSTRACT**

The objective of this paper is to examine the issue of non-admissibility of the principle of therapeutic privilege in clinical trials. In medical treatment, doctors could decide not to disclose information for the best interest of the patients by adopting the principle of therapeutic privilege. This principle exempts doctors from disclosing risky information at his discretion especially if by doing so will cause harm or trauma to patients. However, this principle is not recognised in clinical trials. Instead, the need to obtain patient's consent by way of informed consent has been mandatorily imposed as a way to protect the patients. The doctor-investigator must disclose full information pertaining to the trial to the patient. This paper is a library based collating literature review data. Qualitative methodology and analysis were used in this paper. This paper revealed that despite the fact that the principle of therapeutic privilege has not been recognised in clinical trials, the attitude of patients that placed high hopes on doctor-investigator has indirectly encouraged the latter not to disclose information by adopting this principle. This paper implies that the doctor-investigator practices the principle of therapeutic privilege, an act of paternalism that has been brought into the process of consent taking in clinical trials. In conclusion, the Good Clinical Practice Training Curriculum by the Ministry of Health Malaysia is suggested to be improvised and further enhanced.

*Keywords:* Clinical trials, doctor-investigator, informed consent, the principle of therapeutic privilege, patient-subject

### **ARTICLE INFO**

*Article history:*

Received: 24 February 2015

Accepted: 21 August 2015

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### **INTRODUCTION**

Clinical trials or medical research using human as subject is a patient-orientated research. It is a method by doctor-

investigator to find panacea for all ailments by finding better ways to prevent, diagnose or treat diseases and disorders, test new medicines or devices or to learn about health problem by using human subject (Jackson, 2006). Using human subject in clinical research cannot be avoided as not all medical problems could be overcome using animal as subject (Jackson, 2006).

In clinical trials, the pre-requisite need to obtain patient's consent by way of informed consent has been made compulsory to justify the patient's recruitment (Vollman & Winau, 1996). The doctor-investigator must disclose full information about the trial to the patient. In fact, a doctor-investigator is put on a high standard of duty to disclose information to patient (*Moore v. Regents of the University of California*, 1990). Invariably, this would mean that the doctor-investigator cannot hide behind the guise of the principle of therapeutic privilege, a practice seen in normal doctor-patient relationship, into the process of consent taking in clinical trials.

It has been exemplified that many studies have shown that the doctor-investigators had failed to disclose full information to patient-subjects. As mentioned by Rathor *et al.*, (2011) "*Participants [research—subjects] were not told the aim of the trial, its methodology, potential hazards or anticipated benefits of treatment*". Meanwhile, a study by Yuhanif *et al.*, (2014) who studied informed consent in clinical trials with reference to information disclosure to patient-subjects revealed that doctor-investigators in

Malaysia adopt the principle of therapeutic privilege which is not recognised in clinical trials. The doctor-investigators fail to disclose full information to patient-subjects. Instead, doctor-investigators only disclosed information which they thought were necessary for the patient-subjects to know. The study also showed that there were doctor-investigators who did not disclose information at all to the patient-subjects (Yuhanif *et al.*, 2014). Hence, the objective of this paper is to examine the non-admissibility of the principle of therapeutic privilege in clinical trials which are frequently being employed by doctors to dilute the exigency of procuring the patient consent which must be an informed one.

#### **THE REASONS FOR NON-ADMISSIBILITY OF THE PRINCIPLE OF THERAPEUTIC PRIVILEGE IN CLINICAL TRIALS**

The principle of therapeutic privilege is an exception to the general requirement of informed consent. If a doctor feels that disclosure of certain information will lead to the harm or suffering of the patient, she or he is said to be free to withhold this information (Etchells *et al.*, 1996). In medical treatment, the doctors are excluded from disclosing information for the best interest of the patients by adopting this principle.

The principle of therapeutic privilege is in fact in conflict with the most fundamental portion of the Hippocratic Oath: "do no harm". According to the

oath, doctor is required to use his or her knowledge and skills for the patient's best interest. However, the fact that patients are vulnerable and doctors have greater medical knowledge indirectly causes the latter to decide what is the best for patient even though their actions supersede the capable patients' wishes. This is where the concept or doctor's paternalistic approach through the principle of therapeutic privilege applied for the patient best interest. For instance, the patient is too sick that it affects his ability to make decisions or is not capable of understanding the important information about the treatment so the doctor's paternalism has to take over (Thomasma, 2008). Doctors recommend treatment options based on the evaluation of benefits and risks but the patient may only assess from the point of sheer emotion. Therefore, sometimes the doctor will need to use the power of paternalism in order to over-rule the patient's autonomy for the patients' sake - just to protect them. This is where the concept or the approach of paternalism applies using the principles of therapeutic privilege, which is introduced in the interest of the patient. This principle exempts doctors from conveying risky information at his discretion especially if by doing so will cause any harm or unnecessary trauma to the patients. This means that any information to be communicated to the patient is at the discretion of the doctor.

The application of the principle of therapeutic privilege can be seen in the case of *Siddaway v Bethlem Royal Hospital Governors* ([1984] 1 ALL ER 1018).

Lord Scarman held that, "*This exception [therapeutic privilege] enables a doctor to withhold from his patient information as to risk if it can be shown that a reasonable medical assessment of the patient would have indicated to the doctor that disclosure would have posed a serious threat ...of physiological detriment to the patient*".

The judgment in *Siddaway's* case has been applied in Malaysia. The recognition to the principle of therapeutic privilege in medical treatment can be seen in the case of *Liew Sin Kiong v Dr Sharon M Pauraj* ([1996] 2 AMR 1403). Justice Ian Chin held that if a doctor was of the view that a patient was in need of an operation, then such benefit outweighs a remote risk as the doctor should be allowed the "therapeutic privilege" in deciding whether or not to disclose the risk.

Another case worth referring to is *Dr Ismail Abdullah v Poh Hui Lin (administrator for the estate of Tan Amoi @ Ong Ah Mauy, deceased)* ([2009] 2 MLJ 599). In this case, the respondent/plaintiff is the administrator of the deceased's estate. She brought a claim against the first and second appellants/defendants for medical negligence in, inter alia, failing to advise the deceased of the risks of acute pancreatitis and acute respiratory distress syndrome ('ARDS') prior to the operation by the first appellant on the deceased to remove kidney stones that were causing biliary obstruction. The first appellant stated, inter alia, that the deceased had been advised on and consented to the operation. The Sessions Court did not

hold the applicants liable for negligence when treating the deceased but held that they were liable for failing to advise the deceased of the risks.

In allowing the appeal with costs, Justice Azahar Mohamed held that the appellants were not liable as only material risks of injury needed to be disclosed, not minimal risks. On the effect of therapeutic privilege on non-disclosure of a material risk, the learned Judge went on to say:

*If there was in fact a material risk as a result of the operation, the first defendant's therapeutic privilege justified the non-disclosure of it because of her severe medical problems. This privilege says that such information can be withheld if the disclosure would cause serious harm to the patient's health. The deceased needed the operation to save her life. The first defendant's therapeutic privilege outweighed any duty to warn her of any material risk which would result in her refusing the life saving operation.*

Even though the two cases above did not specifically deal with the application of therapeutic privilege by doctor, the cases did show the recognition of this principle in medical treatment. The importance of the judgment is that the Court recognises medical paternalism vis-à-vis therapeutic privilege especially in cases of life and death significance. Here, the doctors are exercising their experts' opinion or clinical diagnosis in order to save the patient's life. If it is justifiable on the basis of clinical

judgment, the doctor is indeed privilege to proceed with the treatment without informing the patient. An analogy can be made in cases of emergency where informed consent is disregarded because of the need to save a patient's life (*Re F* [1990] 2 AC 1 HL).

In contrast, the application of the principle of therapeutic privilege is not recognised in clinical trials. In support of this view, a reference could be made to the points put forward by Kennedy and Grubb in their book entitled, *Medical Law* (Kennedy & Grubb, 2000). They stated that "Lord Scarman's recourse [in the case of *Siddaway*] to the 'therapeutic privilege' as justifying non-disclosure of information does not apply to information relating to the fact that the patient is in a clinical trial and what that entails." A similar view is shared by Redmon (1986) who stated that "The physician has some latitude (how much is a matter of great debate) in informing his patient of the risks and other factors in a therapeutic procedure, the researcher has none. One reason is that the physician is working on behalf of his patient and the researcher need not be. This, the type of paternalistic behavior we might allow in the physician is not permissible in the researcher ...." The objective of clinical trials being conducted is to offer benefits to future patients at the sacrificial expense of the patients themselves. This is because clinical trials focus on creating an overall knowledge for the benefits of future patients, a process requiring the doctor-investigator to conduct trial according to

a protocol and not according to what is individually best for the patient-subjects (Morreim, 2005). Moreover, the risks inherent in a trial cannot be discounted and averted by the patient. It may be a small one, but it is always there (Edelson *et al.*, 2001).

Instead, the need to obtain patient's consent by way of informed consent has been made obligatory to safeguard the patients. The doctor-investigator must fully disclose information about the trial to the patient. For example, the objective of the trial, purpose of the trial, procedures of the trial, alternative methods available, probable benefits and risks, the possibility of being randomised and that the patient's involvement is voluntary. Thus, it is equally vital to inform the patient that he can withdraw from the study whenever he wanted without jeopardising his current or future treatment. In support of this view, reference can also be made to Article 1 of the Nuremberg Code 1947 which states that:

*The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.*

The carnage and ravages of World War II had lent us a benign lesson in history. The wanton human subject experimentation and the aftermath atrocity perpetrated had rudely awakened world communities. The exposure of the research atrocities performed on prisoners of war by German doctors and scientists discovered after World War II were morbid and inhumane. The prisoners were forced to serve as subjects without their consent. The exposure to this dark episode had made the world community felt unease and being apprehensive on the aspect of subject's protection particularly to ensure the rights of subject are to be respected (McNeill & Pfeffer, 2001). The sequel to this incident had necessitated that informed consent be made as a condition to justify subject's participation in clinical trials (McNeill & Pfeffer, 2001). Hence, informed consent is introduced to protect patient from being abused as subject in order to accomplish the strong desire of doctor-investigator to acquire new scientific discovery. Nevertheless, the special doctor-patient relationship exists as a barrier that incapacitated the patient from making a free choice.

#### **THE DOCTOR-PATIENT RELATIONSHIP**

The word 'special relationship' is a tortuous concept used to determine when an individual is casted with a duty to protect the other person from risks that are not consequent act of that particular person himself. However, in the context of medical

treatment, a duty of care arises from this special relationship between doctor and patient when the patient sought a medical treatment from the doctor.

Generally, patients believe that doctors will always perform their duty with full commitment and dedication as it involves life and death of their patients. Furthermore, the fact that doctors having had greater medical knowledge also causes patients to rely on them to make decision. In fact, throughout history, doctors have put up a clarion advised that patients' needs are best served by following doctors' orders. As stated by Talcott Parsons, "[The physician's] competence and specific judgments and measure cannot be judged by layman. The latter must ... take these judgments and measures on 'authority.' The doctor-patient relationship has to be one involving an element of authority – we speak of 'doctor's orders'" (Kantz, 2003). The doctors have the knowledge that can relieve suffering or save patients' life. As such, it is better for the patient to accept the doctor's suggestion as one of gospel truth without question. Further, doctors are assumed to act for the best interest of their patients and have no reason whatsoever to have any spite and ill intentions towards them. They always try their level best to assist the patients. This kind of attitude is an altruist that is based on trust and confident that arises from the special relationship between the doctors and the patients.

The special relationship between patient and doctor-investigator is different to the normal doctor-patient relationship.

The reason is because the scope of disclosure required for informed consent for clinical trials is different compared to the informed consent for ordinary medical treatment (Agati, 2006). Consequently, the standard of disclosure put on the doctor-investigator is higher compared to the typical doctor. The patient is eligible to be informed of all risks, no matter how remote of an actual occurrence the risk is (*Whitlock v. Duke* (637 F. Supp. 1463 [(M.D.N.C. 1986), aff'd, 829 F.2d 1340 (4th Cir. 1987)]). In Malaysia, the lack of case law does not mean a higher standard of disclosure is not imposed on the doctor-investigators. Clause 1.5 of the Code of Professional Conduct 1987 provides that:

In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entails. He or she should be informed that he or she is at liberty to abstain.

This special doctor-patient relationship is established between the 'doctor' and the patient based on the fact that most of the patients are originally a patient to the 'doctor' before the latter involved in clinical trials. The existence of this relationship was the reason that strengthened patient-subjects' trust and confidence that 'doctors' will act in their interests and hence they accepted the doctors' invitation to participate in the trial (Corfield *et al.*, 2008; Pik Pin Goh, 2011). Hence, the existence of this relationship has indirectly hindered the patient to make a decision voluntarily.

A patient will mistakenly assume that he or she will be getting a treatment which the doctor trusts to be in the best interest by tolerant the doctors' offer to join in the trial. Furthermore, when a person is suffering from a disease, he would then agree to do whatever he thinks can provide relief or cure. In other words, the illness borne by the patient makes him vulnerable - who would have to rely on the doctor - thus leaving him exposed of exploitation by the doctor.

Nevertheless, the authors are of the view that the attitude of the patient that sets high expectations on doctor-investigator has indirectly encouraged the latter not to disclose information by subscribing to the principle of therapeutic privilege. The special relationship that exists between 'doctor' and patient has led the patient to believe and feel confident that the 'doctor' will act in their best interest. This comforting trust has muffled the patient from asking the 'doctor' for further information.

## CONCLUSION

The existence of doctor-patient relationship is real and clinical trial is something that cannot be avoided. Most of the patient-subjects are patients to the 'doctor' before the doctor 'change cap' and turn into a 'doctor-investigator' who immerses himself in clinical trials by recruiting them as patient-subjects. Nevertheless, they must always be vigilant and aware that they are no longer allowed to withhold information from the patients on the

pretext of therapeutic privilege even though this practice seems to be normal in ordinary doctor-patient relationship. They are responsible to disclose full information pertaining to the trials and particularly the risks to patient-subjects. Furthermore, the objective of clinical trials is to benefit future patients and not the patient-subjects who are the "experimentation objects" for the advancement of the medical sciences. As such, we suggest that the *Good Clinical Practice Training Curriculum*<sup>1</sup> by the Ministry of Health Malaysia is to be improvised by introducing a sub-topical subject additional to the same on the topic of doctor-patient relationship in clinical trials.

## REFERENCES

- Agati, A. (2006). Clinical research trials in the courtroom. In J. E. Steiner (Ed.), *Clinical Research Law and Compliance Handbook* (pp. 411-436). Sudbury, MA: Jones and Bartlett Publishers.
- Corfield, L., Granne, I., & Latimer-Sayer, W. (2008). *ABC of Medical Law*. UK: Wiley-Blackwell.
- Dr. Ismail Abdullah v Poh Hui Lin (administrator for the estate of Tan Amoi @ Ong Ah Maury, deceased)* [2009] 2 MLJ 599.

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<sup>1</sup>Doctors have to undergo a Good Clinical Practice Training to obtain a certificate in order to be qualified as doctor-investigators. The approval by the *National Committee for Clinical Research* (NCCR) is required to conduct the training and the content must adhere with the co-curriculum provides by the NCCR. See *Malaysian Guidelines for Good Clinical Practice* at <http://www.nccr.gov.my>.

- Edelson, J. (2001). Informed consent in human experimentation and the physicians' response. In L. Doyal & J. S. Tobias (Eds.), *Informed consent in Medical Research*. London: BMJ Publishing.
- Etchells, E., Sharpe, G., & Burgess, M. M. (1996). Bioethics for clinicians: 2 disclosure. *Canadian Medical Association Journal*, 155(4), 387–391.
- Jackson, E. (2006). *Medical law: Text, cases & materials*. Oxford University Press.
- Kantz, J. (2003). Human experimentation and human rights. *Saints Louis University Law Journal*, 38, 7-54.
- Kennedy, I., & Grubb, A. (2000). *Medical law* (3<sup>rd</sup> Ed). London, Edinburgh, Dublin: Butterworths.
- Liew Sin Kiong v Dr Sharon M Pauraj* [1996] 2 AMR 1403. Sweet and Maxwell Asia, Malaysia.
- McNeill, P., & Pfeffer, N. (2001). Learning from the unethical research. In L. Doyal & J. S. Tobias (Eds.), *Informed consent in medical research*. London: BMJ Publishing.
- Moore v. Regents of the University of California* (793. P.2d 479, 483-85 (Cal.1990).
- Morrein, E. H. (2005). The clinical investigator as fiduciary: Discarding a misguided idea. *Journal of Law, Medicine & Ethics*, 33(3), 586–598.
- Rathor, M. Y., Rani, M. F., Shah, A. M., & Akter, S. F. (2011). Informed consent: A socio-legal study. *Medical Journal Malaysia*, 66(5), 423–422
- Redmon, R. B. (1986). How children can be respected as “ends” yet still be used as subjects in non-therapeutic research. *Journal of medical ethics*, 12(2), 77-82.
- Re F (Mental patient sterilisation)* [1990] 2 AC 1 HL.
- Siddaway v Bethlem Royal Hospital Governors* [1984] 1 All ER 1018
- Thomasma, D. C. (2008). Telling the truth to patients: A clinical ethics exploration. In T. L. Beauchamp (Ed), *Contemporary issues in bioethics*. USA: Thomson Wadsworth.
- Vollman, J., & Winau, R. (1996). Informed consent in human experimentation before the Nuremberg Code. *British Medical Journal*, 313(7070), 1445–1447.
- Whitlock v. Duke* 637 F.Supp. 1463 (M.D.N.C. 1986), aff'd, 829 F.2d 1340 (4th Cir. 1987)
- Yusof, Y., Ngah, A. C., & Zaher, Z. M. M. (2014). Informed consent in clinical trials with reference to information disclosure to patient-subjects. *International Journal of Public Health Research*, 4(1), 384–390.