



The Doctor's Dilemma Against the Patient's Right to Information in Clinical Trial

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Abstract

In clinical trials, the right to information has been recognised as a right of the patients. This is because the risks to the patients as subjects are inevitable. Therefore, the information about risks is important to disclose so that the patient can decide voluntarily whether to accept or reject the doctor's invitation to participate. However, the doctors' good intention to help the patients by inviting them to participate is questionable as risks are something uncertain until the trials are completed. Hence, the objective of this paper is to discuss on doctors' dilemma to disclose information on risks and the patients' right to get information. A qualitative methodology is used in writing this conceptual paper. The findings reveal that doctors must disclose information on risks to patients as risks can be evaluated. However, detail information on how the risks will occur need not be disclosed. The doctors' should not recruit patients as subjects if unable to bear responsibility to disclose information during the informed consent process. The usage of audio visual player on how the trial will be conducted is to recorded and aired to the patients to help them decide in participating in the trials is also proposed.

INTRODUCTION

In clinical trials, the right to information has been recognised as a right of the patients. This right is translated through the Nuremberg Code by introducing the doctrine of informed consent as a condition to justify the patients' participation as subjects.¹ Informed consent generally means a process of negotiation or communication between doctor and patient to obtain the consent of patient to participate in clinical trials. In other words, the informed consent recognised the right of patients to obtain information to enable them to decide voluntarily to participate in the research as subjects. This doctrine has existed in the legal system based on the principle that every individual has the power of autonomy to make decisions that will impact their lives. For

¹ Article 1 of Nuremberg Code provides that: "The voluntary consent of the human subject is absolutely essential". Although it did not carry the force of law, the Nuremberg Code was the first international document which advocated voluntary participation and informed consent.

example, in *Schloendorff v Society of New York Hospital* 105 N.E. 92, 93 (N.Y. 1914), Judge Cardozo stated that: “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages”.

Hence, doctors must disclose all information on the trial to the patient during the informed consent process including the risks. This is because in clinical trials, the risks to the patients as subjects are inevitable. In an off-cited remark by the former President of the Royal Society of Medicine (Edelson, 2001), he was quoted to say, “All experiments involve some risks. It may be an infinitesimally small one, but it is always there. If the experiment involves special techniques, then the risk is considerably enhanced”. According to Levine (1981), “risks” means the forecast of a danger that is likely to occur. Meanwhile Portney & Watkins (2000) have refined the meaning of “risks” as referring to physical harm, psychological or social contingencies that occur in human life. Therefore, the information on risks is important that should be disclosed to the patient during the informed consent process. In other words, the patients have the right not to be placed at risk of harm without their informed consent.

Unfortunately, many studies have shown that doctors failed to disclose full information to patients which includes the risks. Liao, Sheehan & Clarke (2009) states that: “Participants in some clinical trials are at risk of being harmed and sometimes are seriously harmed as a result of not being provided with available, relevant risk information”. According to Rathor MY, Mohammad Fauzi Abdul Rani, Azarisman Mohammad Shah & Sheikh Fariuddin Akter (2011), patients were not told the aim of the trial, its methodology, potential risks or anticipated benefits of treatment. A study by Yuharif, Anisah & Zaki Morad (2014) also has revealed that doctor-investigators fail to disclose full informations 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.

In fact, most of the litigation against the doctor is caused by the failure to disclose full information particularly the risks to enable the patients to consent (Mello, Studdert & Brennan, 2003; Jansson, 2003). For example, in *Doherty v. Merck*, Case Number 2005M00638, Court of New Jersey, Atlantic County Civil Division, Merck’s former chief scientist attested that in 2001, some key people in Merck already knew from the results of two studies that Alzheimer’s patients taking Vioxx had higher death rates than those who took a placebo. Another case worth looking to is Jesse Gelsinger’s case. In 1999 at the University of Pennsylvania, Jesse Gelsinger died during an experiment after being injected with viruses designed to carry healthy copies of gene into his body. The Food and Drug Administration and the National Institutes of Health found afterwards that Gelsinger was not informed that two other patients had experienced serious side effects from the same procedure; and that monkeys had died when given a similar treatment (Walters, 2000). The more recent TGN1412 trial at Northwick Park is another, more complex and controversial case of non-disclosure (Kenter and Cohen, 2006).

However, the dilemma arises between how doctors to communicate the risks to patients because the risks are something which can not be ascertained until the clinical trials are completed and the doctors’ goodwill to help restore the patient (in the interest or welfare of the patients) by inviting them to join the in clinical trials. In fact, the term “trial” itself means that it is something you are unsure of which were executed and subsequently thereafter only the benefits or risks could be determined. It is not something that could be pre-determined until the trials had been executed on the patients (Easterbrook & Houghton, 2003). In other words, only when after the trial was conducted, it can be known whether the drugs were better than existing treatments. There is always a possibility that the new drug being studied will be ineffective or cause more harm than good. Hence, the objective of this paper is to discuss on doctors’ dilemma to disclose information on risks as it is something which is uncertain and the patients’ right to get information.

THE PRINCIPLE OF BENEFICENCE

The principle of beneficence generally is a principle to do good. This principle which derives from the Hippocratic tenets can be seen from the pledge which unequivocally stated, “I will prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone”. The Declaration of Geneva in 1948 also recognises the same by saying that, “The health of my patient will be my first consideration”. This means that the principle of beneficence requires that doctor to use his or her knowledge and expertise for the benefit of the individual patients “the patient’s best interest”.

However, the principle of beneficence in clinical trials is different from the medical treatments. This is because in clinical trials, patients “voluntarily” accept the risks inherent in trials for the benefit of future patients and not for themselves. This is because clinical trials focus on creating an overall knowledge for the benefit of future

patients, a process requiring doctor to conduct trial according to a protocol and not according to what is individually best for the patient (Morreim, 2005; Lenrow, 2006). As such, the principle of beneficence in clinical trials is translated through “a risk versus benefit analysis for the subject”. This indirectly gives a sense that the term “beneficence” go beyond its general meaning that is to do good. On the other hand, “beneficence” of a doctor involves two obligations; first, to do no harm, and second, to maximise benefits and minimise risks (Finn, 1999).

It also indirectly implies that the philosophical application of the principle of beneficence that centered on the principle of “do no harm” does not mean that the doctor will never bring harm or risk to the patient but instead seeks to generate benefit outweighs the risk and maximise the benefits that can be expected and minimise the risk can be expected (Beauchamp, 2008; Grady, 2002). In fact, this is also recognised by the Nuremberg Code by stating, “the degree of risk to be taken should never be exceed that determined by the humanitarian importance of the problem to be solved by the experiment”. In other words, doctors may conduct high risk research in an effort to cure dangerous diseases like cancer and not merely for treating ordinary flu.

The evaluation of the benefits and risks are not impossible because although the risks in clinical trials cannot be avoided but it can be a ‘calculated risks’. Levine (1981) opines that, “The harm or injury [risk] itself may be evaluated quantitatively; e.g., it may be described as either a large or small harm”. A similar view was shared by the Chairman of the Malaysian Research Ethics Committee, Ministry of Health Dato' Dr. Chang Kia Meng (personal communication, June 1, 2010) when he said, “Most of the time we [doctors] are able to look at the benefit and the risk in sort of calculate. So that there is no such thing that ‘tak tau risiko’ (sic: colloqually in Malay to mean do not know the risks) ... I would say 99.9% of the time we are able to calculate what is the risk and benefit”. This in turn means that the principle of beneficence using the concept of paternalism which is a normal practice seen in the context of ordinary medical treatment is not recognised in clinical trials. As such, the principle of therapeutic privilege exempting doctors from disclosing the information on the grounds of real risks particularly for the benefit of patients, does not apply.

The next question is, whether disclosure should be made in full detail of the likely risks? In the case of *R v Mental Health Act Commission ex parte X (orse W)* (1988) 9 BMLR 77, Mr Justice Stuart Smith states that, “no doubt consent has to be ‘informed consent’ in that [the patient] knows the nature and likely effects of the treatment”. In this case, when the anti-cancer drug (goserelin) has been used to restrain sexual desire, the learned judge decided that it was significant for the patient to know about this. However, he rejected the proposition that, “a patient must understand the precise physiological process involved before he can be said to be capable of understanding the nature and likely effects of the treatment or can consent to it”. According to him, the patient does not need to know in detail all the processes involved.

Hence, based on the above decision, the researchers submitted that a full disclosure of information in clinical trials means that the doctors must disclose all information particularly the risks. However, a detail information on how the risks will occur need not to be disclosed to patient-subjects. For example, in stent procedure, patient needs to go through an angiogram, where doctor-investigator will place a small thin tube in the patient’s arm or leg to inject an x-ray dye into his blood vessel so the narrowing of the blood vessel can be easily seen under special x-rays. Patient may feel a warm sensation during the angiogram, which is caused by the x-ray dye. This warm sensation usually passes after a short time. All this information needs to be disclosed to the patient but the detail information on how the warm sensation process occurs need not to be disclosed.

CONCLUSION

The present study explores on doctors’ dilemma to disclose information and the patients’ right to get information. The doctors’ good intention to help the patients, i.e., for the patients’ best interest by inviting them to participate in the clinical trials as subjects is questionable as risks in clinical trials are something which are uncertain. The results of this study reveal that doctors must disclose information on risks to patients as risks in clinical trials can be evaluated qualitatively; e.g., it may be described as either a large or small harm.

However, a detail information on how the risks will occur need not to be disclosed to patient-subjects. As such there is no exception for doctors to deny the rights of the patient to get information on the ground of uncertainty.

It is noteworthy that the main purpose of the patients go to the doctors is to get treatment to cure ailments incurred and not to offer themselves as subjects. In addition, although the clinical trials needs to be done but the law does not allow patients to be placed at risk of harm without their informed consent because of a legal

obligation to uphold human rights as enshrined in the Declaration of Human Rights of 1948.² This in turn meant that human lives cannot be 'gambled' in the interest of the public, private or science. In short, the importance of the patients overrides the interests of others. By right, the doctors must let the patients to decide voluntarily to participate in clinical trials by giving full information. The rights of patient to get information especially the risks inherent in clinical trials is important in order to give opportunity to the patient to decide whether or not to accept the doctor's invitation to participate. It is not denying the fact that there is a patient who wants to recover from illness suffered, there is patient with a heart of gold to help future patients, but not all patients are willing to face the risks and harm inherent in the trials. Based on the findings, the authors propose that the doctors' should not recruit the patients as subjects if unable to abide responsibility to disclose information thus acknowledge patients' rights to information about risks during the informed consent process, i.e., too busy and do not communicate well with the patients. In addition, the usage of audio visual player on how the trial will be conducted is to recorded and aired to the patients during the informed consent process to help them in making decision to participate in the trials is also proposed.

² Article 1 of the Declaration of Human Rights of 1948 provides that: "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood. Whereas recognition of inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world".

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