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## PUBLIC HEALTH RESEARCH

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### Informed Consent in Clinical Trials with Reference to Information Disclosure to Patient-Subjects

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#### ABSTRACT

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<b>Received</b>	23 September 2013
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<b>Introduction</b>	The aim of this study was to examine the aspect of information disclosure by doctor-investigator during the process of obtaining informed consent in clinical trials.
<b>Methods</b>	This research employed a mixed-method data collection that is library research and interview. A qualitative methodology and analysis were used in an open-ended, face-to-face interviews with 17 patient-subjects. The interview questions were based on information that needed to be disclosed to patient-subjects during the process of obtaining informed consent. Each interview took place in Kajang Hospital and National Heart Institute and lasted 25-30 minutes. Interviews were conducted in Bahasa Melayu and English. The interviews were tape-recorded, and the main points from the interviews were jotted down to ensure that all information was adequately gathered. Interviewed occurred in Kajang Hospital and National Heart Institute. The participants were patients who had been referred to the Kajang Hospital and National Heart Institute. They were recruited (8 from Kajang Hospital and 9 from National Heart Institute) by their own doctors to participate in a study to evaluate the safety and effectiveness of the investigational stent after been diagnosed with coronary artery disease and also in a study to investigate drug for antidepressant. respectively.
<b>Results</b>	The study revealed that 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.
<b>Conclusions</b>	This study implies that the aspect of information disclosure in the process of obtaining informed consent in clinical trials is rather poor and did not fulfill the criterion of good medical practice. A random monitoring task to be conducted by the research ethics committees during the informed consent process is suggested.
<b>Keywords</b>	Informed consent - Clinical trials - Patient-subjects - Doctor-investigators - Process - Information.

## INTRODUCTION

In clinical trials, patient-subjects 'voluntarily' accept the risks inherent in a trial for the benefit of future patients and not themselves. This is because clinical trials focus on creating an overall knowledge for the benefit 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-subject<sup>1</sup>. Previous experience too has demonstrated that patient-subjects cannot rely on the beneficence of doctors in the clinical trials arena<sup>2</sup>. In fact, a breach of duty that leads to negligence in clinical trials often occur due to failure of doctor-investigators to disclose full information to enable patient-subjects to give consent to participate in the clinical trials<sup>3</sup>. Therefore, the need to obtain patient-subjects' consent by way of informed consent has been made compulsory to justify the patient-subjects' recruitment in clinical trials<sup>4</sup>. Informed consent in clinical trials has been demarcated in general as a negotiation or communication process between the doctor-investigator and the patient for the purpose of obtaining the patient's consent to participate in the trial. The doctor-investigator must disclose full information about the trial during this process, among them are 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 whereby the patient can withdraw from the study whenever he wanted without jeopardizing his current or future treatment<sup>5</sup>.

Informed consent implies that participation is voluntarily. As such, doctor-investigator must ensure that the patient-subject knows the implications of participation. Even if a patient-subject has signed an informed consent form, the patient-subject does not necessarily understand what the participation will entail, and consent thus may not be informed<sup>6</sup>. The question is, to what extent the patient-subject needs to know in order to be 'informed'? According to Roth *et al.*,<sup>7</sup> the 'knowing' prong needs the doctor-investigator to make full disclosure of the purpose, procedure, and risk and benefits of the study. Morin<sup>8</sup> shared a similar view when she said that, "[o]nly a distinct and strict rule on full disclosure can protect the principle of autonomy of human research subjects." Thus, this leads to another question to ponder as to what is meant by 'full disclosure of information'?

In the case of *R v Mental Health Act Commission ex parte X (or se W)* (1988) 9 BMLR 77, Judge 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 doctor-investigator 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 a feel 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 patient but the detail information on how the warm sensation process occurs need not to be disclosed.

Unfortunately, many studies have shown that doctor-investigators failed to disclose full information to patient-subjects. Patient-subjects were not told the aim of the trial, its methodology, potential risks or anticipated benefits of treatment<sup>9</sup>. A study by Titus dan Keane as cited by Hall<sup>10</sup> who studied 167 principal investigators applying to Midwestern review boards for approval for a range of research studies, including clinical trials, drug and device studies indicated that only one-third of the investigators gave a detailed description of the purpose and procedure of their study, but meaningful discussion of all other areas, including risks, benefits and alternatives were almost non-existent; eighty percent demonstrated that they relied wholly on asking close-ended questions, precluding any form of dialogue with the patient; few of the researchers appeared to have any appreciation of the need to assess potential subject's understanding of what they had been told. Meanwhile, in a study investigating the effects of different drugs in 43 women with acute salpingitis, five were not aware that a second laparoscopy was performed only for research purposes. Seven women stated that they had not been aware of the meaning of participating in the study and 17 women did not know that they could withdraw from the study whenever they wanted<sup>11</sup>.

In Malaysia, until today there is no study conducted on the aspect of information disclosure by doctor-investigator. However, this does not mean doctor-investigators in Malaysia do not practice disclosing full information. This is mainly

due to the fact that Malaysian society, specifically the patients, place great trust on their doctors. As such, doctors do not disclose full information to them. In support of this view, reference can be made to the points put forward by Puteri Nemie Jahn Kasim & Mohamad Akram Shair Mohammad in the book titled *Issues in Medical Law and Ethics*. The authors stated that, “*The main problem for patients in Malaysian hospital is that their consent has rarely been ‘informed’ in nature. They are usually asked to sign consent forms before any operation but in reality, they do not really understand what they are signing. They are rarely informed about the risks inherent in any proposed treatment.*”<sup>12</sup> For instance, in the case of *Tan Ah Kau v Government of Malaysia* (1997) 2 AMR 1382, the court held that no consent was actually given by the plaintiff, as the nature of such operation had not fully and comprehensively explained to the plaintiff. Unfortunately, there is no literature or case to support that patient-subjects also put high hope on ‘doctor’ in clinical trial as in medical treatment. However, the researchers were of the opinion that a similar attitude occurs. This opinion can be supported by quoting the words of Dr. Suhaini Kadiman: “*Based on our experience if the consent is taken by the ‘doctor’ the chances of recruitment is higher because of trust and confident to ‘doctor’ compared to consent taken by a third party for example a health care personnel*”<sup>13</sup>. Hence, the aim of this study is to examine the aspect of information disclosure by doctor-investigator during the process of obtaining informed consent in clinical trials.

**METHODS**

This research applies a mixed-method data collection that is library research and interview. Qualitative methodology and analysis were used in open-ended, face-to-face interviews with 17 patient-subjects. Fourteen semi-structured questionnaires were administered to the patient-subjects during the interview. The interview questions were based on information that needed to be disclosed to patient-subjects during the process of obtaining informed consent. Only 17 patient-subjects interviewed due to doctor-investigators’ refusal in allowing their patient-

subjects to participate. The participants were patients who had been referred to the Kajang Hospital and National Heart Institute. They were recruited (eight from Kajang Hospital and nine from National Heart Institute) by their own doctors to participate in a study to evaluate the safety and effectiveness of the investigational stent after been diagnosed with coronary artery disease and are scheduled to undergo coronary stent placement and in a study to investigate drug for antidepressant. respectively. Patient-subjects involved 10 males and seven females from the ages of 20 to 60. They were government servants as well as private employees, pensioners and a college student. Since the researchers were not the doctor-investigators who must obtain signed informed consent from the patient-subjects in order to be enrolled in the trial, the patient-subjects’ consent were only taken orally after being informed that the data collected were for academic purposes. Upon the advice from the National Institutes of Health, online registration was made with the National Medical Research Register in seeking permission to conduct interview pursuant to the Director of Health Circular No. 9/2007. The registration involved the submission of the proposal of the study and the questionnaires of the interview to be considered for approval. A letter in seeking permission to conduct interview was also send to the Medical Director of National Heart Institute. Each interview took place in Kajang Hospital and National Heart Institute and lasted 25-30 minutes. Interviews were conducted in Bahasa Melayu and English. The interviews were tape-recorded, and the main points from the interviews were jotted down to ensure that all information was adequately gathered. It was also important to capture the verbal and non-verbal reaction of the officers during the interview.

**RESULTS**

Out of the 17 patient-subjects interviewed on whether doctor-investigators performed informed consent process, 12 answered ‘Yes’ and five answered ‘No’. Answers given by patient-subjects saying that no informed consent process was held by doctor-investigators were described below and illustrated with verbatim quotes from patient-subjects.

**Table 1** Lists of answers given by patient-subjects saying that no informed consent process was held by doctor-investigators

No.	Answers
1.	<i>“The research nurse said that there will be a study to try a new drug only. I read the form ... but there was not much explanation given ... if I agree I can participate. During the process of obtaining the consent no explanation was given as she was in a hurry. She said that if I agree to participate I can sign but if not I need not to sign.”</i>
2.	<i>“He [doctor-investigator] took for granted because we have read through already ... Doctor should try to explain as much as possible.”</i>

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3. *“Doctor said, after undergoing the angiogram procedure, there will be a stent procedure because my blood vein was 90% blocked ... cannot insert balloon [balloon catheter process] anymore. I thought it was a normal procedure for my treatment and not a study”.*
  4. *“There was no explanation session pertaining to the study [informed consent process]. The doctor only told me about trying a new drug in the OT room before undergoing the angiogram procedure. I ask for postponement but the doctor objected the postponement. He said that this study [the stent procedure] is good. This is a study to investigate whether it will work better or as good as the current one, it will not be lesser than the current one but it will be better.”*
  5. *“The doctor only told me to sign the release form for survey purpose.”*
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When the researchers asked about information dissemination, all 12 patient-subjects confirmed that the doctor-investigators have conducted the informed consent process. They added that the doctor-investigators have informed them of the background of the study, the purpose of the study and the fact that there is nothing wrong with the current treatment. They also confirmed that the doctor-investigator had informed them that he wanted to try a new drug. However, when researcher asked whether doctor-investigator had disclosed on the probable benefits and risks of the study, only nine answered ‘Yes’ while eight answered ‘No’.

All of the 12 patient-subjects answered ‘No’ to the question of whether they were informed about the possibility of being randomized. The researchers also found out that all of them did not even understand the meaning of randomization in clinical trials.

When asked whether the doctor-investigators disclosed to them that their participation were voluntary and that the patient-subjects can participate or withdraw from the trial at any time without jeopardizing their current and future treatment, all of the 12 patient-subjects answered ‘Yes’. However, one patient-subject said that even though the doctor-investigators informed him that his participation is voluntary, he failed to explain in detail that he (the patient-subject) was free to accept or withdraw from the trial at any time without jeopardizing his current or future treatment. The patient-subject said, *“Only informed that you [the patient-subject] has been chosen ... not everybody can get this opportunity ... this is why motivate me to participate.”*

Relating to the question of whether patient-subjects were given the chance to ask questions about the trial, 10 patient-subjects answered ‘Yes’ while two answered ‘No’. However, when the researchers asked whether doctor-investigators gave adequate time to give consent, all of the 12 patient-subjects answered ‘Yes’. Nevertheless, according to one patient-subject, he signed the consent form in a hurry as he was about to be discharged from the hospital and the distance from his house to the hospital was far. In addition, according to another patient-subject,

the doctor-investigator invited him to participate in the trial when he was in pain in the ‘Coronary Care Unit’ (CCU) and since the doctor-investigator was in a hurry so he only read the information which he thought was important.

When they were asked whether their own doctor had conducted informed consent process, all of the 12 patient-subjects answered ‘Yes’. Next, when asked whether they felt obliged to participate as their own doctors have invited them, all of the 12 patient-subjects answered ‘No’. However, the patient-subjects gave the following answers:

- i) *“I always felt exhausted, doctor said I can try the drug [study drug] can get rid of my exhaustion ... so I try”*
- ii) *“I am sick ... doctor suggested we have to accept it ... we cannot reject his invitation. As a doctor of course he will suggest only the best for his patient. Although we do not know but he is a doctor. A doctor will not give poison ... I am not being forced to participate in the study but since the doctor wanted to make a study we have to follow ... we want to get well”.*
- iii) *“He [doctor] said that the study drug can help me ... the medicine I have been taken before is quite expensive so he offered me to take the new medicine ... to participate in the study and to help me financially”*
- iv) *“I had a heart attack when he invited me to join the trial.”*
- v) *“The doctor informed me that if I want the drug, I have to join the trial.*
- vi) *“Doctor said that the previous medication had many side effects, the new ones have lesser side effects so that’s why I join ... to be cured.”*
- vii) *“Doctor said can get well if I join”*

When the researchers asked whether they understood all the information disclosed by the doctor-investigators, all of the 12 patient-subjects answered ‘Yes’. However, a few of them said that the form was too long and that they only read the information that they felt important. Other comments included, the doctor-investigators were in a hurry, informed consent process were

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conducted while they were in the CCU ward and while they were about to be discharged from the hospital.

When asked whether their relatives were present during the informed consent process being

held, 10 patient-subjects answered 'Yes' while two answered 'No'. One of the patient-subject answered 'No' as he was in CCU ward during that time. Table 2 below shows the results of informed consent process.

**Table 2** Questions and results of patient-subjects regarding the informed consent process

	Yes	No
Was information on the trial given to you before you signed the consent form?	12	5
If yes, did you understand the information given?	12	0
Did your doctor conducts informed consent process?	12	0
If yes, did you feel oblige to accept his invitation?	0	12
Were your relatives present during the informed consent process being held?	10	2
Were you informed about the background of the study?	12	0
Were you informed about purpose of the study?	12	0
Were you informed that currently you are receiving the 'best current proven treatment', meaning that there is no problem with it but it is just that the doctor wants to try a new drug?	12	0
Were you informed about the procedure(s) of the study?	12	0
Were you informed about the probable benefits and risks of the study?	9	8
Were you informed about the possibility of being randomized?	12	12
Were you given the chance to aks questions pertaining to the trial?	11	1
Were you given enough time to make decision?	12	0
Did you voluntarily participate in the trial?	12	0

## DISCUSSION

The present study explored the process of obtaining informed consent in clinical trials in Malaysia. The results of this study revealed that the doctor-investigators fail to disclose full information to patient-subjects. Instead, the 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 other words, no informed consent process were conducted. The results of this study were not suprising as similar results was revealed by previous studies as mentioned earlier.

The results demonstrated that doctor-investigators in Malaysia practiced medical paternalism similar to doctor-investigators around the world. The strong desire to obtain a new scientific knowledge '*ethos of science*' has led

some doctor-investigators to deliberately ignore the patient-subjects' protection through informed consent. In a study at the National Women's Hospital in Auckland, New Zealand a researcher, Associate Professor Herbert Green, believed that 'carcinoma in situ' [CIS] left untreated, would not lead to invasive cancer of the cervix. To test his proposition (which was against the international opinion at the time) conventional treatment was withheld from some of the women diagnosed with CIS, who were then observed for signs of progression of their disease. Those in the treatment group received normal treatment (essentially removal of suspect tissue). However, many more women in the 'non-treatment' group advanced to the invasive stage. An official inquiry headed by Judge Silvia Cartwright found that at least 27 on the non-treatment group had died unnecessarily and many suffered the consequences of their disease for years without ever being informed of their initial diagnosis. Green maintained that, it was not in the

women's interests to tell them about what he was doing. Patients he said, "*were unnecessarily frightened if they heard the word cancer, and should be protected from doctors' uncertainties*"<sup>14</sup>. In 1997, a research involving HIV testing of all patients' admitted to intensive care units in Durban for diseases unrelated to HIV, this was done without the patients' prior knowledge or consent. Part of the researchers' rationale was that it was essential not to inform the patients since, "*patients who were likely to be at risk for HIV infection would also be inclined to refuse the study, which would seriously limit its value.*" Also in 1997, a cervical cancer study in India, commissioned by the Indian Council of Medical Research, excluded any requirement for informing the participants of their risk of developing cancer. The researchers argued that the women participating in the study were illiterate and obtaining informed consent would be impossible<sup>15</sup>.

Nevertheless, the researchers were of the opinion that the attitude of the patients-subjects that placed high hopes on doctor-investigators has indirectly encouraged the latter not to disclose information by adopting *the principle of therapeutic privilege*, a practice seen in the normal doctor-patient relationship. This act of paternalism has been brought into the process of consent taking in clinical trials. The special relationship that exist between 'doctor' and patient has led patients to believe and feel confident that the 'doctor' will act in their best interest. Hence, in general the patient does not ask the 'doctor' for information. In addition, the fact that 'doctors' have greater medical knowledge also caused patient-subjects to rely on them to make decision. This opinion can be supported by quoting one of the patient-subjects answer: "*I am sick ... doctor suggested we have to accept it ... we cannot reject his invitation. As a doctor of course he will suggest only the best for his patient. Although we do not know but he is a doctor. A doctor will not give poison ... I am not being forced to participate in the study but since the doctor wanted to make a study we have to follow ... we want to get well*". This kind of attitude is generally higher among patients with illness. As said by the Director of Clinical Research Centre, Dr. Goh Pik Pin, "*... when patients have good trustworthy doctors and are in need of new therapies they are more willing to subject themselves to trials*"<sup>16</sup>.

However, the researchers were of the opinion that doctor-investigators cannot use the reason that the patients placed high hopes on them for them not to disclose information. Rightfully, the special relationship that exist requires doctor-investigators to disclose full information to patient-subjects. This is because the doctor-patient relationship impedes the ability of the patient to make a free choice. A patient usually will wrongly

assume that they will be receiving a treatment which their doctor believes to be in their best interest by accepting the doctors' invitation to participate in the trial. In actual fact they are actually been invited to take part in a trial which is designed to yield knowledge for the benefit of the future patients and not to meet their individual health needs. Thus, the doctor has the responsibility to disclose full information to the patient. Applying the principle of therapeutic privilege is not appropriate in taking informed consent in clinical trials; it can cause harm to the patient. The privilege will not apply when the patient rejects an intervention suggested by physician. Henceforth the informed consent in clinical trial must be fully informed, a stricter standard than required in medical treatment.

The researchers were also of the opinion that doctor-investigators cannot make an assumption that patient-subjects do not have the ability to understand the information disclosed to them. In a 1998 study, schizophrenic patients participating in randomized clinical trials of different antipsychotic medications were first given informed consent forms to read and sign. The study found that the patients were able to understand the material in the forms. Even one week later, the patients were able to answer most of the questions asked about "*the study's procedures and goals, patients' available choices as participants, their doctors' responsibilities to the study, and potential ill effects of antipsychotic drugs that were to be given in the trial*"<sup>17</sup>. This will be more so if it involves a competent patient as a patient-subject. That is why doctor-investigator cannot deny the rights of patient-subjects to get information.

## CONCLUSIONS

The aspect of information disclosure in the process of obtaining informed consent in clinical trials is rather poor and did not fulfill the criterion of good medical practice. The doctor-investigators failed to disclose full information to patient-subjects. This indicated that doctor-investigators failed to acknowledge patient-subjects' protection through informed consent. Considering that informed consent process is important to ensure protection of patient-subject in clinical trials, doctor-investigators must understand their duty in disclosing information better. They must always bring to mind that they are no longer allowed to withhold information from patients by practising the principle of therapeutic privilege once they are involved in clinical trials. In other words, once the 'doctor' puts on the hat of a 'doctor-investigator' by conducting a trial he is responsible to disclose full information about the trials particularly the risks to the patient-subjects. This study focussed on competent patient-subjects; a study on the process of taking informed consent in incompetent patient-

subjects (vulnerable subjects) may be more revealing on the frailties of the process and thus should be a logical extension of this research. We suggest that random monitoring be conducted by the research ethics committees on the process of taking informed consent.

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