



ANALYSIS OF FACTORS FOR NON-DISCLOSURE OF INFORMATION BY DOCTOR-INVESTIGATORS IN CLINICAL TRIALS IN MALAYSIA

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Abstract

In clinical trials, the need to obtain patient's consent by way of informed consent has been mandatorily imposed as a way to protect the patient as subject. Unfortunately, many studies have shown that the doctor-investigators had failed to disclose full information to patients. Hence, the aim of this paper is to examine the factors for non-disclosure of information by doctor-investigator and provide potential solutions to the problem. This study 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 12 patients recruited to participate in a trial to investigate drug for chemotherapy and schizophrenia. This study reveals that doctor-investigators fail to disclose information due to the absence of monitoring by the ethics committees and that the Good Clinical Practice Training Curriculum (GCPTC) is too basic and almost introductory and the attitude of the patient that put high hopes on doctor-investigators. Hence, random monitoring by the ethics committees and monitoring using video tape during the informed consent process are recommended. In addition, GCPTC needs to be improvised and further enhanced by inserting topic on the differences of objective between medical treatment and clinical trials and topic on infamous conduct according to Code of Professional Conduct 1987 (CPC). In addition, a framework model in respect of information disclosure is also proposed by incorporating several new clauses in the CPC equivalent to the requirements of internationally recognized rights of patient as subject.

Keywords: Informed Consent, Clinical Trials, Doctor-investigators, Patients, Information Disclosure.

1. Introduction

Clinical trials or medical research using human as subject has proven to improve the welfare of mankind by solving medical problems by finding better ways to prevent, diagnose or treat diseases and disorders, test new medicines or devices or to discover about health problems. In order to safeguard the subject, the need to obtain patient's consent by way of informed consent has been made compulsory to justify the patient's recruitment. This is because the risks to the patient 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 in clinical trials (Yuhanif et al., 2015).

Informed consent in clinical trials has been declined 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/she wanted without jeopardizing his/her current or future treatment (Levine, 1986).

Unfortunately, many studies have shown that doctors failed to disclose full information to patients which includes the risks (Liao, Sheehan & Clarke, 2009; Rathor et al., 2011). A study involved 17 patients recruited 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 by Yuhanif, Anisah and Zaki Morad (2014) also has 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. Hence, the aim of this paper is to examine the reasons for non-disclosure of information by doctor-investigator during the process of obtaining informed consent in clinical trials. This paper also aim to propose solutions to the problem. A qualitative methodology and analysis were used in an open-ended, face-to-face interviews with 12 patients recruited to participate in a trial to investigate drug for chemotherapy and schizophrenia.

2. Reasons for Non-Disclosure

There are two reasons for non-disclosure of information by doctor-investigators which are process and attitude. As to process, there are two reasons which have led the doctor-investigator not to disclose full information about the trials to the patient since there are the absence of monitoring by ethics committees and the Good Clinical Practice Training Curriculum by the Ministry of Health is too basic and almost introductory. Regarding the attitude of a patient, he/she has high expectations on the 'doctor' which indirectly has enabled doctor-investigators to practice the principle of therapeutic privilege, an act of paternalism that has been brought into the process of consent taking in clinical trials causing doctor-investigators to restrain from disclosing full information to patients.

Monitoring is generally not done by the ethics committee. However, at the Ministry of Health for example, monitoring cannot be done on the ground that since all the members of the ethics committee are full-time staff who are bound by their official duties as doctors (personal communication with Dr. Zaki Morad Mohamad Zaher, former Chairman of Malaysian Research Ethics Committee, October 10, 2015). Meanwhile, at the National Heart Institute as another example, the monitoring is only done based on the complaints made to the ethics committees either by the patients themselves or other individuals who were involved in the trials (personal communication with Dr. Suhaini Kadiman, Chairman of National Heart Institute Ethics Committees, June 24, 2015).

Conversely, the current practise is that the ethics committee will give approval to the doctor-investigator after conducting the reviewing process of the proposed research protocol based on

the documentation i.e. Patient Information Sheet & Informed Consent Form.¹ Interview session with doctor-investigator will only be carried out if the ethics committee feels that there is a need for further explanation or doubt arises. Unfortunately, nothing has been done by the ethics committee to ensure that the implementation is based on procedures. For example, by conduct monitoring during the informed consent process to make sure the doctor-investigator disclose full information to patient as what is provided in the Patient Information Sheet & Informed Consent Form. Indeed, the problem of the absence of monitoring by the ethics committee is not an exception in other countries that conduct clinical trials. As Fleischman put it, local IRBS have been criticised for excessive focus on the informed consent form, rather than the process, and for neglecting other equally important aspects of ethical review such as conflict of interest and confidentiality (Fleischman, 2005).

It is important to note that the Good Clinical Practice Training Curriculum is so basic and almost introductory. Important topics such as the difference objective between medical treatment and clinical trials and topic related to infamous conduct under the Code of Professional Conduct 1987 are not included. To elaborate, in medical treatment, doctors could decide not to disclose information for the best interest of the patients. Known as the doctor's 'therapeutic privilege', this was accepted by Lord Scarman in the leading case of *Siddaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* ([1985] A.C. 871; [1985] 1 All E.R. 643; B.M.L.R. 15 (H.L.)). This principle exempts doctors from disclosing risky information at his/her discretion, especially if by doing so will cause harm or trauma to patients. However, this principle is not recognised in clinical trials as Kennedy and Grubb (2000) have argued, "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 clinical trial and what that entails." 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 (Morreim, 2005). Previous experience too has demonstrated that patient-subjects cannot rely on the beneficence of doctors in the clinical trials arena (Lenrow, 2006). 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. In fact, a doctor-investigator is put on a high standard of duty to disclose information (*Moore v. Regents of the University of California*, 1990). Unfortunately, the difference objective between medical treatment and clinical trials is not included as one of the topic in the Good Clinical Practice Training Curriculum.

This study showed that patients in general placed high hopes on 'doctor'. This attitude has indirectly encouraged the doctor-investigator not to disclose information by adopting the principle of therapeutic privilege, a practice seen in normal doctor-patient relationship. In other words, in medical treatment the doctors are excluded from disclosing information for the best interest of the patients by adopting this principle. This act of paternalism has been brought into the process of consent taking in clinical trials. The special relationship that exist between

¹ Since every research protocol for clinical trials must be reviewed and approved by the ethics committee, doctor-investigators must show how a trial participation's consent will be obtained. Legally, the Patient Information Sheet (PIS) & Informed Consent Form are very important legal documents in relation to patient as subject. Failure to adhere to the legal requirements of obtaining a valid and proper informed consent in clinical trials may potentially lead to a civil negligence action by patient, as it constitutes a breach of the medical duty of care. The patient may even claim legal remedies by alleging that there had been fraudulent misrepresentation, and a criminal offence under Penal Code and/or civil negligence actions in that there was a failure to obtain informed consent resulting in injury.

'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 has also caused patient-subjects to rely on them to make decision (Yuhanif, Anisah & Rejab, 2015). However, the paternalism of doctor needs to be balanced with the autonomy of the patient since the the patient's right to be informed and give consent have been recognized as patients' rights and it is already enshrined in the Patients Charter 1995 (Anisah, 2008). Therefore, if the doctor does not disclose full information as prescribed in the Malaysian Guidelines for Good Clinical Practice² it directly imputes the doctor-investigator has neglected or ignored his/her professional responsibilities which have been set by the Code of Professional Conduct 1987.³ As a result, a doctor-investigator may be disciplined because of abusing privileges and professional skills that is known as infamous conduct.

3. Recommendations for Non-Disclosure of Information

By taking into account the importance of monitoring carried out during the process of informed consent with the view to safeguard the patient as well as to put the seal on recognition of patients' rights globally, the authors suggested that it should be done in two methods, namely : -

3. 1 Recommendations Relating to the Standard Operating Procedures

- (a) Monitoring through the usage of video footage during the process of conducting informed consent.

Two copies must be submitted to the body which inter alia is a copy to the ethics committee and another to the archives to be stored for seven years. Should, for example complaints arise regarding any doctor-investigator who failed to disclose information about the study to the patient, then the video recording will be analyzed to verify the authenticity of that allegations or complains. This is because the procedurally procured patient signatures on Patient Information Sheet and Consent Form is sine qua non and as a sign of approval for patients to participate in clinical trials exemplified the facts that there were aspects of compliance within procedural rigidity that must be observed and steadfastly cannot be foresaken at whatever instances, as the case may be. However, there are ways that doctor-investigators elude the same way as they could indiscreetly shield their wayward actions hiding behind the guise of documentation stating otherwise the full and frank disclosure had been administered. Thus, to prove that the doctor-investigator does not submit complete information on compliance to Malaysian Guidelines for Good Clinical Practice is by way of analyzing video recordings during the process of informed consent.

- (b) Random monitoring by ethics committee.
This monitoring can be done by selecting a few patient-subjects involved in a study to be interviewed to ensure that every one of them had run through the rigour of the acid rain test of the interview processes and that informed consent had been procured. If it is found that the doctor-investigator does not conduct the process of informed consent,

² Malaysian Guidelines for Good Clinical Practice is the only existing guidelines related to clinical trials in Malaysia at <https://www.mrc.ac.uk/documents/pdf/malaysian-guidelines-for-good-clinical-practice/>

³ Code of Professional Conduct 1987 is a code governing the practice of medical practitioners including doctor-investigators who are registered under the Medical Act 1971 so as not to act contrary to the norms of professional conduct of a medical practitioner. Any misconduct from any profession according to the Code can be subject to disciplinary action by the Malaysian Medical Council.

then action may be taken against him/her by terminating the study and subsequently call the doctor- investigator involved for questioning. If it is proven that the doctor-investigators have neglected the process of informed consent, then sterned action will be taken against them. The insignificant numbers of experts who form the composition of the ethics committees too need to be addressed. The present number of vis-a-vis the national trashhold numbers of doctor-investigators warrant a review of the said composition in the ethics committee. As such, the authors suggested to form a large secretariat of 30 to 50 experts to assist the independent body monitoring the ethical duties. However, members of the secretariat should be among those who have regular duties related to ethics independent body. For example, in the Ministry of Health, the secretariat of the Institute of Health Management is responsible for the Malaysian Research Ethics Committee (MREC) and the duties associated with clinical trials. Thus, the authors have suggested that the secretariat includes expertise to assist MREC monitoring duties. MREC members consist of doctors who are unable to perform the task of monitoring because they are tied to their official duties. Members of the existing secretariat features are not authorized to perform monitoring and they per se do the administrative work related to clinical trials only. Thus, the authors have also suggested that the secretariat should authorize representative from MREC to perform the task of monitoring and MREC should only focus on the process of reviewing the protocol. Hence, the members should be enlarged so that the monitoring process can be implemented effectively. The authors believe that this proposal is not dauntingly impossible to be implemented since the structure and training is already emplaced and intact.

3. 2 Recommendations to strengthen Good Clinical Practice Training Curriculum

For a doctor to be qualified as a doctor-investigator, he/she must run the guntlet and be certified to have passed the certificate for Good Clinical Practice Training Curriculum. In this training, they are given exposure to ethics and the law on the procedure for good clinical trials practices and governance. However, the Good Clinical Practice Training Curriculum should be further enhanced to make it relevant and in accordance with the requirements of the current and good practice. Here are some suggestions for improvement to the Good Clinical Practice Training Curriculum: -

- (a) To include topics related to the difference objective between standard medical treatment and 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/her discretion especially if by doing so will cause harm or trauma to patients (Yuhanif et al., 2015). However, this principle is not recognised in clinical trials. The objective of clinical trials being conducted is to offer benefits to future patients at the 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 (Morrein, 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 (McCance, 1951). Conversely, the need to obtain patient's consent by way of informed consent has been made

obligatory to safeguard the patients. Article 1 of Nuremberg Code⁴ in 1974 provides that: “The voluntary consent of the human subject is absolutely essential” (US Government Printing Office: The Nuremberg Code, 1949). The doctor-investigator must fully disclose information about the trial to the patient.

- (b) To include topics related to infamous conduct in accordance to the Code of Professional Practice 1987

Generally, patients place high hopes on the doctor. However, the paternalism of doctors needs to be balanced with the autonomy of the patient because the concept of patient’s rights has been recognized internationally and locally (Yuhanif, Anisah & Latifah, 2011). Therefore, if the doctor does not disclose full information as required by the Malaysian Guidelines for Good Clinical Practice, then invariably it means that the doctor-investigators have neglected or ignored their professional responsibilities as set out in the Code of Professional Conduct 1987. As a result, doctor-investigators can be disciplined for his or her abusing privileges and professional skills that are nomenclaturely referred to in the Code of Professional Conduct 1987 as infamous conduct.

3. 3 Proposed Framework Model in Aspects of Information Disclosure

The Code of Professional Conduct 1987 was never amended till to date. With the exponential development in medical sciences and the progressive pace therein occasioned in clinical trials the once blished code of 1987 is no longer able to address the fouling ethical problems and standards from the current clinical trials activities which have a major impact on the patient as subject. In addition, there is only one provision which discusses aspects of the information disclosure. Clause 1.5.1 of the Code has underlined 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.*” Therefore, the authors have incorporated several new clauses as proposed to fine-tune some aspects of the information disclosure equivalent to the requirements of internationally recognized rights of patients as subjects as follows: -

1.5 Duty to give full and reasonable explanation and information

- (1) Before a clinical trial is carried out or conducted, the doctor investigator shall give the subject and any person giving consent on behalf of the subject, a full and reasonable explanation of the following:
- (a) that the clinical trial involves research;
 - (b) the purpose of the clinical trial;
 - (c) the treatments to be administered in the clinical trial and the probability for random assignment of each treatment;
 - (d) the procedures to be followed in the clinical trial, including all invasive procedures;
 - (e) the responsibilities of the subject;
 - (f) the aspects of the clinical trial which are experimental;
 - (g) the reasonably foreseeable risks or inconveniences to the subject;
 - (h) the reasonably expected benefits, including whether there is any intended clinical benefit to the subject;

⁴ Although it did not carry the force of law, the Nuremberg Code was the first international document which advocated voluntary participation and informed consent.

- (i) any alternative procedures or treatments available to the subject, and their potential benefits and risks;
- (j) any compensation and treatment available to the subject in the event of injury arising from participation in the clinical trial;
- (k) any pro-rated payment to the subject for participating in the clinical trial;
- (l) any anticipated expenses to the subject from participating in the clinical trial;
- (m) that the subject's participation in the clinical trial is voluntary and that he may refuse to participate in or may withdraw from the clinical trial at any time without penalty or loss of benefits which the subject would otherwise be entitled;
- (n) the persons who will be granted access to the subject's medical records and the extent of such access, including the possibility that the licensing authority may inspect the records;
- (o) the extent to which records identifying the subject will be kept confidential;
- (p) that the subject or his legal representative will be informed in a timely manner of any information becoming available which may be relevant to the subject's willingness to continue participating in the clinical trial;
- (q) the persons to contact for further information relating to the clinical trial and the rights of subjects and in the event of injury arising from participation in the clinical trial;
- (r) any foreseeable circumstances under or reasons for which the subject's participation may be terminated;
- (s) the expected duration of the subject's participation in the clinical trial;
- (t) the approximate number of subjects involved in the clinical trial; and
- (u) any other information which the licensing authority may require to be given.

(2) If any information becomes available which may be relevant to a subject's willingness to continue participating in a clinical trial, the doctor-investigator shall, at the earliest feasible opportunity, give to the subject or his legal representative a full and reasonable explanation of that information.

1.6 Compelling person to participate in research

- (1) Any doctor-investigator who –
 - (a) by means of coercion or intimidation, compels another person against that person's will to participate or continue to participate as a research subject in any clinical trial;
 - (b) by means of coercion or intimidation, compels another person (A) against A's will to give A's consent or to refrain from withdrawing A's consent for the participation of another person (B) as a research subject in any clinical trial;
 - (c) by means of deception or misrepresentation, causes another person to participate or continue to participate as a research subject in any clinical trial; or
 - (d) by means of deception or misrepresentation, causes another person (A) to give A's consent or to refrain from withdrawing A's consent for the participation of another person (B) as a research subject in any clinical trial.

1.1 Person qualified to procure informed consent

Doctor-investigator or any person assisting him in clinical trial shall not conduct the informed consent process with the exception of a non participating third party doctor who himself is not a doctor-investigator in that particular clinical trial.

1.2 Conflict of interest in clinical trial

Doctor-investigator or any person assisting him in clinical trial or any subject in a clinical trial shall not, directly or indirectly, have any conflict of interest in the trial.

1.9 Monitoring procedure in informed consent process

Any doctor-investigator shall –

- (a) video tape the process of informed consent during clinical trial
- (b) submit a copy of the informed consent process to the ethics committee
- (c) submit a copy to the archives section for a duration of seven (7) years for the purpose of auditing

2.0 Penalty

Any doctor-investigator who fails to comply with the above provisions shall be considered as being guilty of infamous conduct in any professional respect according to section 29 (2) (b) Medical Act 1971. As such the Malaysian Medical Council may impose disciplinary punishment under section 30 Medical Act 1971.

The above clauses are proposed to be included in the Code of Professional Conduct 1987 to ensure that doctor-investigators disclose information to the patient, so that the safety aspect of the patient as subject is guaranteed. The word "shall" is used to ensure that doctor-investigators are not practicing doctor paternalism in disclosing information during the process of informed consent. The authors opined that the doctor-investigators are mandatorily required to disclose information to the patient-subject as the directive word "shall" had been transcribed in the proposed amendment to the 1987 code. In other words, the doctor-investigators mandatorily need to disclose information in accordance with the provisions of the Code of Professional Conduct. Even with the existence of the Code of Professional Conduct, patients can still take legal action against the doctor-investigators either through Tort or Royal Prerogative through Judicial Review under Rule 53 of the Rules of Court 2012. Both methods of legislative action is also known as Grievance Procedures.

3. 4 Others Proposals

- (i) Awareness programs to doctor-investigators on the responsibility to disclose information to patients

Informed consent has been recognized globally in clinical trials aimed at protecting the patient-subject from being exploited by doctor-investigators. Therefore, it is the responsibility of the doctor-investigators to disclose full information so that a rational decision can be made by the patient to accept or decline the invitation to participate in the trials. Hence, the information to be communicated is proposed within the framework of the proposed model in terms of information disclosure above (provision 1.5 - 2.0 Code of Professional Conduct 1987). Despite the views of experts who surmised that this is difficult to be realized because of the different level of comprehension amongst some patients or there is a knowledge gap between patient-doctors, thus hindering the patient to understand the information conveyed which with all decorum are not subscribed by the authors. In other words, the authors believe that doctor-investigators cannot assume that the patient-subject is not able to know or understand the information presented to him/her. As professionals, they should endeavour their level best and try to find a way to ensure that all information presented can be understood by the patient-subject. For example, 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" (Brannigan & Boss, 2001). The underlying rationale is simple and straight forward

that doctor-investigator cannot deny the rights of patient-subjects to get information which is their right.

(ii) To remove the Perception "A doctor knows best" among doctor-investigators.

The off-cited rationale of the differential in the level of education and knowledge of the patient-subject and the doctor-investigator could not be a basis and excuse to deny patients of their rights to make their own decisions even to the extent that it is contrary to the views or intentions of doctor-investigators. How well intentioned be of a doctor-investigator to assist the patients, but the penultimate decision to so decide on the available and comprehensively advised by the said doctor shall, in all propensity lie with the patient himself/herself without more. In other words, good intentions cannot legalize patient rights to decide to participate in clinical trials or not. Furthermore, the trials itself mean that something is in trial and not definite only then subsequent to that will if be known to be of benefit or otherwise. Therefore, the doctor-investigators need to have a mind shift and change his/her perception that they know best than the patients.

(iii) Awareness programs to patients/public to seize the opportunity to gain a better treatment by participating in clinical trials

Basically, clinical trials in Malaysia is still new compared to countries that are more advanced in clinical research such as Singapore and the United States. The advantages or benefits that can be gained from participation is relatively unknown to patients in particular and the Malaysian society in general. Therefore, due to this disinformation, clinical trial is seen as something negative. People in the past thought that the purpose of doctor-investigators conducting clinical trials is to 'dabble' and be harmful to patients who are akin to guinea pigs in scientific land. Unlike in the West, where everyone wants to participate in clinical trials hoping to get better treatment. For example, patients with pediatric cancer who still has no curative treatment, but when told that there are new drugs that will be tested eventhough not confirmed as to its effectiveness as only 60% survival rate did not prevent patients from taking part to have the opportunity to get something better (personal communication with an expert from UKM Medical Centre, October 27, 2015). Therefore, campaign or awareness programs to patients/communities such as Clinical Trials Day or Lets Participate in Clinical Trials for the chance to get a better treatment should be carried out.

In addition to awareness programs, the use of electronic print and electronic media can also be used to provide education opportunities to obtain a better treatment by participating in clinical trials. Hence, a way forward to educate the public and make them better exposed to the wholesome benefit of clinical trials are varied and amongst others is through issuing flyers, booklets, pamphlets and other parapermalias which are catchy and could attract attentions. The task is not have to be shouldred alone by Ministry of Health, but all other institutions that conduct research and clinical trials have to bring home the good and benefit of the trials and to dispel apathy amongst the public. A testimony worth sharing by the authors themselves that a lackadaisical sense of urgency in so doing was evident when there was absence of literatures/books/pamphlets and the like on the display at the shelves or counters in hospitals or institutions that conduct the clinical trials for public readings either advertisement or inadvertantly reflect the situation and the proporal indeed is a mooted one for one to ponder or think about.

4. Conclusion

In conclusion, the enforcement of the obligation to disclose information about the trials by doctor-investigators to patients is significant to protect patients in terms of recognizing their rights. This is because without the law enforcement, doctor-investigators would not follow the Malaysian Guidelines for Good Clinical Practice to disclose information to the patients. With the enforcement of the law in terms of the disclosure of information through the Code of Professional Practice 1987, the autonomy of the patient and doctor paternalism can be balanced.

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