REVIEW ARTICLE

Information Disclosure in Informed Consent

Lydia Aiseah Ariffin

Medical Ethics and Law Unit, Department of Psychiatry, Faculty of Medicine, Universiti Teknologi MARA, Sungai Buloh Campus, Jalan Hospital, 47000 Sungai Buloh, Selangor, Malaysia

ABSTRACT

Informed consent has been recognised as an essential part of clinical practice, giving ethical and legal legitimacy to medical intervention. There is no universal standard on the amount and type of information that a patient is entitled to and needs to be adequately disclosed. This article proposes nine information that will assist the doctor in providing adequate information for a patient to evaluate whether to authorise medical intervention. The recommended information are: (i) diagnosis, prognosis and its uncertainties; (ii) nature of proposed medical intervention; (iii) the expected benefit of proposed medical intervention; (iv) the potential risk of proposed medical intervention; (v) alternative to proposed medical intervention; (vi) progress of proposed medical intervention; (vii) opportunity for a second medical opinion and to seek further details; (viii) costs of proposed and alternative medical intervention; and (ix) the person responsible for implementing medical intervention.

Keywords: Informed consent, Information disclosure, Duty to inform, Material risk, Medical intervention

Corresponding Author:
Lydia Aiseah Ariffin, MMed Ethics & Med Juris
Email: drlydiaariffin@gmail.com/ lydia_aiseah@uitm.edu.my
Tel: +603 – 6126 5000

INTRODUCTION

Informed consent has been recognised to be an essential part of clinical practice as it gives ethical and legal legitimacy to all medical consultations, investigations, diagnosis, treatments and procedures (1). Before the introduction of informed consent, doctors were trained to believe that they were the best person to make medical decision for their patients (2,3). This placed doctors in an authoritative position that was caused by the patient's health information inadequacy and all the required health information is confined within the doctor's knowledge.

The rise in human rights movement (4-7), improvement in the education system and rapid evolution in the information technology has led to the demand for adequate information disclosure before obtaining informed consent (8). The demand for information is further supported by the courts' acknowledgement of doctor's duty to inform in the common law world with the emergence of legal cases that established the doctrine of informed consent (9-11).

Over the years, legal developments showed that increasing number of medical negligence proceedings between patients and doctors is founded on the matter of omission on the doctors' duty to disclose adequate information entailed in the suggested medical intervention to patients before committing their consent (9-17). Complications arise from court decisions involving informed consent cases and informed consent guidelines do not exactly specify what constitutes adequate information (18). Since there is no universal standard or quality in information disclosure (19), when a patient brings a claim against a doctor, the information that is supposed or required to be disclosed is subject to debate in court and the court will decide based on previous court precedence (20).

Prominent case laws established that informed consent needs to cover material risks (9-11) and alternatives (21) of the suggested medical intervention options and the legal position on the amount of information is that information disclosure should cover 'what a reasonable patient in the patient's equitable position would like to know' (22). Thus, it is impossible to set a standard on how much information to disclose and not every potential risk can be described in detail as there are limitations and differences in the ability of each patient to understand plenty of these details (23). It is exactly these grey areas in the requirements for informed consent that have opened doors for many of the cases reported failures of informed consent in clinical practice. Various efforts such as the development of informed consent guidelines and policies have been made to ensure information disclosure in medical intervention is adequate.

This article discusses the types of information to be disclosed to the patient before obtaining informed

consent by reviewing and analysing relevant international human right declaration (4-7), court decisions (9-15,21,22), consent guidelines (23-30) and articles dealing with the duty to advise. This information should be able to assist in guiding doctors towards obtaining adequate informed consent before proceeding with any medical intervention thus reducing the chance in failure in performing the duty to advise and future litigation.

RECOMMENDED INFORMATION

The objective of obtaining informed consent is to validate and subsequently legalise the proposed medical intervention. This article gathers nine types of information that can support the patient to decide whether to proceed with the proposed treatment or procedure. Based on the review and analysis, the nine recommended information for disclosure are: (i) diagnosis, prognosis and its uncertainties; (ii) nature of proposed medical intervention; (iii) the expected benefit of proposed medical intervention; (iv) the potential risk of proposed medical intervention; (v) alternative to proposed medical intervention; (vi) progress of proposed medical intervention; (vii) opportunity for a second medical opinion and to seek further details; (viii) costs of proposed and alternative medical intervention; and (ix) the person responsible for implementing medical intervention (Table I).

Table I: Nine (9) Recommended Information to Disclose before Obtaining Informed Consent

1	Diagnosis, prognosis and its uncertainties
2	Nature of proposed medical intervention
3	The expected benefit of proposed medical intervention
4	The potential risk of proposed medical intervention
5	Alternative to proposed medical intervention
6	Progress of proposed medical intervention
7	Opportunity for a second medical opinion and seek further details
8	Costs of proposed and alternative medical intervention
9	The person responsible for implementing medical intervention

Diagnosis, Prognosis and Its Uncertainties

The medical world is filled with uncertainties (31). When patients come to seek advice for a health problem, most will want to find out what is wrong or going on with their body. Unfortunately, not all of them will be able to be enlightened with their exact health problem and many patients have difficulties in understanding these uncertainties. The explanation on the main health issue will have to be explicit, whether it is a confirmed diagnosis, provisional diagnosis or whether a further investigational procedure is required to determine a diagnosis (23,32).

In some situations, before a doctor can come to diagnosis or no diagnosis at all, the doctor will have to perform an investigational procedure that may involve risks. A patient needs to be informed on these uncertainties to justify and consider the risks for determining whether to move forward with the proposed medical intervention to determine a diagnosis. When a diagnosis is confirmed, a doctor should then proceed with further explanation on the current state of the problem, the stage and progression of the disease, the effect of the disease to current and future health before proposing a medical intervention to resolve the problem or find the best outcome (14).

Nature of Proposed Medical Intervention

Once a patient has a satisfactory impression and idea of his/her medical problem, the doctor can then proceed to propose a medical intervention that may be investigational or treatment. For a majority of patients, especially those who are not accustomed to medical intervention, any kind of procedure is terrifying and peculiar where they have to place their physical well-being in the authority of an almost stranger. Thus, the disclosure of proposed medical intervention should clearly outline the purpose, why the proposed intervention is chosen and how it suits the patient's current situation (10,33). It will be a useful aid in the patient's evaluation to explain how the proposed intervention is going to treat the disease as well as the possible outcomes of the proposed treatment. Some patients also may have to be made aware that not all medical intervention is to cure a disease. Medical intervention can function to heal, control, investigate and/or help with other procedures.

The depth of the explanation of the nature of the proposed intervention should involve basic technical aspects of the planned procedure or the role of medication in the patient's body depending on the patients' comprehension level and amount of information that can be absorbed (33). When informing patients of the plan for medical intervention, explanation on the nature proposed should also include consequences which are unavoidable if the proposed treatment is carried out. Doctors are also recommended to advise patients on the likely outcomes of postponing or not opting to have the proposed treatment (25,27,29). Patients might also require information whether the offered medical intervention is unconventional, experimental or part of a research program in deciding whether to proceed (23,25,27,30,34).

The Expected Benefit of Proposed Medical Intervention

For a patient to decide whether to proceed with medical intervention, adequate information disclosure on the aim of the medical intervention and its benefits is required. The patient needs to be informed on the extent

of the realistic potential good that can transpire after undergoing medical intervention to justify the necessity to proceed with it (33). Some patients may have unrealistic expectations of the potential value of medical intervention. Those misconceptions can influence their capability to make informed health care decisions. These patients have to be adequately counselled on the extend of the proposed medical intervention that could be minimal, major or non-beneficial at all.

Patients also need to be fully aware of the benefit to evaluate whether the risks that come with the medical intervention is worth to take. If the medical intervention is an investigational procedure which may not have a clear health benefit to the patient, expected result and subsequent intervention plan that depending on the expected result should also be revealed.

The Potential Risk of Proposed Medical Intervention

Risks of the proposed medical intervention are the most widely discussed issue in the common law world. There were numerous legal actions taken worldwide alleging failure of doctors to disclose material risks before medical intervention. The current common law imposes doctors to practice appropriate caution in ensuring that the patient is well informed of any material risks relevant to the proposed medical intervention. Material risk is defined as "a risk to which a reasonable person in the patient's situation would be likely to attach significance, or a risk that a doctor is aware would potentially be considered of significance by this specific patient" (5). Doctors should be well aware that a material risk to a single individual patient may not be material to another different patient.

Risks can take place in various manifestations, but will usually be in the form of undesirable effects, complications or failure of medical intervention to reach the required objective (36). Risks may also diversify from generally common but negligible side effects to unusually rare but extremely grievous detrimental consequences with the potential to cause permanent impairment or loss of life (11). For effective risks discussion with the patient, prominent court decisions and consent guidelines recommend doctors to identify the adverse effects that may be the consequence of the specific proposed medical intervention (12,30,37).

The discussion on risk with patients should be based and concentrated on each patients' circumstances and the outcome of risk to them. In evaluating the risk to an individual patient, the doctor should take into consideration the basic details of the patient's current and past health conditions as well as other circumstances as discussed in the patient's background and history. These variable elements may influence the likelihood of adverse outcomes happening and the final decision.

The numerical data on the potential of very low risk is not an adequate ground for omission to inform. The importance of risk is related with the basic elements of the risk, the risk outcome to the life of a particular patient, the value of expected benefits of the proposed medical intervention to the patient, the available alternatives and their associated risks. Thus, the amount and complexity of information about risk that is required to be disclosed to patients will rely on each patient's set of circumstances, their requirement of medical intervention and their capability as well as desire to know (14,15). While some patients may have high expectation for potential benefits, others may have a lower expectation of risk occurring for proposed medical intervention. Doctors may have to correct this misconception to ensure that they do not misjudge and able to properly evaluate the information before agreeing or refusing intervention.

The risk for a proposed medical intervention may occasionally require emergency or contingency intervention upon initial findings (26,33). For example, Caesarean section or dilatation and curettage that subsequently requiring an emergency hysterectomy or appendicectomy later on requiring open laparotomy and resection. If these complications are expected for certain patients, it has to be adequately disclosed and explained before the procedure. If patients are not going to be able to engage in decision making at the time of initial findings, advance consent for such further anticipated procedures must be secured. This will also set a clear limitation to the extent of medical intervention that a doctor can proceed as agreed by the patient (26).

Along with this, the doctor also must never make any assumption regarding a patient's comprehension of the disclosed risk or the significance they attach to the various consequences. Doctors need to adequately talk about any arising problem with risks with the patient. For example, for a patient who works in a health care setting, a doctor must never assume that the patient already has good knowledge of the proposed procedure. In a few circumstances, there is also a possibility that medical condition may deteriorate after medical intervention. To prepare a patient for this future eventuality, this risk is also needed to be appropriately disclosed (29).

Alternative to Proposed Medical Intervention

For every medical problem, there could be more than one method of investigation or medical intervention. Apart from the proposed intervention, other available and accessible alternative intervention and comparative risk between alternative treatment is a mandatory disclosure. The common law has decided that failure to discuss this alternative issue is regarded as a violation of the doctor's duty of disclosure (21).

The explanation on nature, benefits and risks for each of the alternatives are similar to the information disclosure required for proposed medical intervention. The additional information is to include why this alternative

is not recommended and the possible outcomes of not opting for the proposed intervention (29). Doctors are also required to disclose if the alternative is not available in the current facility and only available outside current healthcare facility or research (23).

Progress of Proposed Medical Intervention

When patients come to solicit advise on their health issue, most are unaware that health problems might take a huge chunk of their time and commitment. If possible, at the earliest stage, the doctor is advised to clarify to the patient the period that will be involved in the follow-up, consultation, investigation and proposed medical intervention. Once a patient has opted for medical intervention, further explanation will be required to counsel on the recovery period, reasonable time that the patient will be unable to carry on with their routine activities and plausible period that the patient's function will be restricted and may require medical leave (30).

It is also practical to advise patients if they might require additional follow-up treatment or further special intervention and supervision. This is to engage the patient's agreement and cooperation in making sure that the post-intervention treatment plan is underway and to lower the possibility for further complications to occur. By exploring the patient's background and history, this problem may be foreseeable in which complications may arise from the inability to attend a follow-up appointment and defaulting further treatment plan. For this group of patients, sufficient information needed to be further enforced to gain full commitment to participate in completing the course of medical intervention.

Opportunity for Second Medical Opinion and Seek Further Details

The majority of reviewed guidelines recommended doctors to provide the opportunity for second medical opinion or seek further details (23,24,26,29,30). These measures may benefit by gaining a great deal of patient's trust and confidence in which to demonstrate that the doctor has taken an appropriate and reasonable step in helping to resolve a patient's medical issue. This opportunity should be offered in the informed consent process especially when the patient refuses the proposed or all medical intervention or unable to decide whether to proceed with proposed or any medical intervention.

It will also be very beneficial to refer the patient for a second medical opinion when they exhibit unusual concern regarding the risks that are going to be undertaken and when or if the patient request for it. Recommending a second medical opinion and other sources of information are also another way doctors can transfer the focus away from themselves and toward the patient especially in a difficult situation.

As both patient and doctor are now easily accessible to many information avenues, the doctor can take the advantage to guide the patient to the right source to look for additional input. The patient may use this opportunity to take their time to learn further details regarding their health problems, process the complexity of the disease and involved medical intervention as well to digest the huge amount of unfamiliar information. Accordingly, patients may even come out with a lot more questions to ask their doctor which will improve communication and the exchange of information between both parties.

Costs of Proposed and Alternative Medical Intervention

Even though accessibility to health intervention is a basic human right, doctors and patients have to accept the fact that health intervention incurs resources such as time, material, manpower and facility that will demand financial expenditure. Accordingly, a few medical interventions were also being chosen for its economic benefits and cheaper cost (37). Thus, when medical intervention is proposed, someone or authority will have to bear the cost for its implementation. If the cost will have to eventually be supported by the patients and their family, then patients are entitled to be aware of the exact or the estimated amount that they will have to get ready. If the patient is not going to be able to afford the cost, the doctor may advise the need for obtaining funding and offer a more affordable solution within the doctor's capability or refer to another centre that can offer the medical intervention at the cost that the patient can manage. The downside of informing all the cost is that the patient may feel forced by their financial capability to opt for less effective medical care or might even refuse the required medical intervention.

Person Responsible for Implementing Medical Intervention

Several guidelines recommend doctors to provide information on the person who will be responsible for executing the medical care (24,26,38). Providing information on the doctors who are going to perform the proposed medical intervention may authorise patients to achieve the desired commitment whether to proceed with the intervention and from whom the medical intervention is going to be received. It may also be better and more practical to tailor the amount of information about the responsible person according to whether the intervention bears high risk or invasive. Intervention that carries higher risk or more invasive will require a more explicit detail on the person performing the procedure (38).

Informing the qualification and performance rates of the individual doctor in informed consent may help to improve patient's autonomy in making a decision and enhance medical care quality (38). Further information on a doctor's experience in conducting a certain procedure, comparing risk statistics with other doctors conducting same procedure and the availability of other doctors and health care institution that able to execute the procedure better would also have provided patient's

with all of the viable alternatives and thereby enhanced the patient's right to informed consent. Additionally, this type of disclosure may encourage frankness and accountability which subsequently can contribute to the development of doctor-patient trust relationship.

CONCLUSION

For informed consent to be valid, adequate information need to be provided to the patient before decision can be made. The type and amount of information disclosure need to be tailored according to the patient's background and history, wishes and need for information. It is not recommended to swamp patient with all available information at the same time. Besides, it is better to impart the information throughout a few sessions especially when there is a lot of complex information. Some patient may also require a time to conduct own study to help in digesting and understanding provided information to make a decision. The important point to note is that obtaining informed consent is not a one-off situation but a continuous process. All consultation sessions that include disclosing vital information need to be properly documented and not necessarily just on the one-page sheet of the form where the patient put their signature on. Next, with a proposed procedure getting more complicated, further study needs to be done on how to accurately capture all these into complete documentation to prove that it all has been done correctly.

In conclusion, there is no universal standard in the required type and amount of information to be provided before obtaining informed consent. The combination of the available court decision and practice guidelines may assist in guiding doctors concerning defining the legal duty to provide adequate information and the details of required information for the patient to make a decision. Doctors will subsequently require continuous training to update themselves on the ethically and legally accepted practice in obtaining valid informed consent.

REFERENCES

1. Coggon J, Miola J. Autonomy, Liberty, and Medical Decision-Making. The Cambridge Law Journal. 2011;70(3):523-47.
2. Svoboda JS. Tortured Bodies, Tortured Doctrines: Informed Consent as a Legal Fiction Inapplicable to Neonatal Male Circumcision. In: Denniston G, Hodges F, Milos M, editors. Genital Cutting: Protecting Children from Medical, Cultural, and Religious Infringements. Dordrecht: Springer; 2013.
3. Jones KB. Surgeons' Silence: A History of Informed Consent in Orthopaedics. The Iowa Orthopaedic Journal. 2007; 27:115-20.
4. European Consultation on the Rights of Patients. A Declaration on the Promotion of Patients' Rights in Europe. Amsterdam: World Health Organisation; 1994.
5. Office of the United Nations High Commissioner for Human Rights. Human Rights Fact Sheet No. 31: The Right to Health. Geneva: United Nations Office; 2008.
6. United Nations Educational, Scientific and Cultural Organisation. Universal Declaration on Bioethics and Human Rights; 2005.
7. United Nations. Universal Declaration of Human Rights; 2015.
8. Demiris G, Afrin LB, Speedie S, Courtney KL, Sondhi M, Vimarlund V, et al. Patient-centered applications: use of information technology to promote disease management and wellness. A white paper by the AMIA knowledge in motion working group. Journal of the American Medical Informatics Association. 2008;15(1):8-13.
9. Salgo v Leland Stanford Jr University Board of Trustees, 154 Cal. App. 2d 560, 317 P. 2d 170 (1957).
10. Canterbury v Spence, 464 F 2d 786 (DC Cir 1972).
11. Rogers v Whitaker [1992] 175 CLR 479.
12. Foo Fio Na v Dr Soo Fook Mun and Assunta Hospital [2007] 1 MLJ 593.
13. Zulhasnimar Hasan Basri & Anor v Dr Kuppu Velumani P & Ors [2017] 1 LNS 1057.
14. Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 1.
15. Hii Chii Kok v Ooi Peng London Lucien and Another [2016] SGHC 21.
16. Oyebode F. Clinical errors and medical negligence. Medical Principles and Practice. 2013;22(4):323-33.
17. Pienaar L. Investigating the reasons behind the increase in Medical Negligence Claims. Potchefstroom Electronic Law Journal/ Potchefstroomse Elektroniese Regsblad. 2016(19).
18. Murray B. Informed Consent: What Must a Physician Disclose to a Patient? American Medical Association Journal of Ethics. 2012;14(7):563-6.
19. Chima SC. Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study. BMC Medical Ethics. 2013;14 (Suppl 1):S3.
20. Raab EL. The Parameters of Informed Consent. Transactions of the American Opthalmological Society. 2004;102.
21. Janet Birch v University College London Hospital NHS Foundation Trust [2008] All ER (D) 113 (Sep).
22. Pearce v United Bristol Healthcare NHS trust [1998]. 48 BMLR 118 (CA).
23. General Medical Council. Consent: patients and doctors making decisions together; 2008.
24. Malaysian Medical Council. Consent for Treatment of Patients by Registered Medical Practitioner; 2017.
25. Australian Government National Health and Medical Research Council. General Guidelines for

Medical Practitioners on Providing Information to Patients; 2004.
26. Singapore Medical Council. SMC Ethical Code and Ethical Guidelines (2016 Edition); 2016.
27. New South Wales Health. Consent to Medical Treatment - Patient Information; 2005.
28. Victoria Department of Health. Informed Consent; 2014.
29. Western Australia Health. Consent to Treatment Policy (2016); 2016.
30. Queensland Health. Guide to Informed Decision-making in Health Care; 2017.
31. Nijhawan LP, Janodia MD, Muddukrishna BS, Bhat KM, Bairy KL, Udupa N, et al. Informed consent: Issues and challenges. Journal of Advanced Pharmaceutical Technology and Research. 2013;4(3):134-40.
32. Politi MC, Han PK, Col NF. Communicating the uncertainty of harms and benefits of medical interventions. Medical Decision Making. 2007;27(5):681-95.
33. Jamjoom A, White S, Walton S, Hardman J, Moppett I. Anaesthetists' and surgeons' attitudes towards informed consent in the UK: an observational study. BMC Medical Ethics. 2010;11(2).
34. Vickers AJ, Young-Afat DA, Ehdaie B, Kim SYH. Just-in-time consent: The ethical case for an alternative to traditional informed consent in randomized trials comparing an experimental intervention with usual care. Clinical Trials. 2017;15(1):3-8.
35. Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine. Overview of Diagnostic Error in Health Care In: Balogh EP, Miller BT, Ball JR, editors. Improving Diagnosis in Health Care. Washington: National Academic Press; 2015.
36. Pietra LL, Calligaris L, Molendini L, Quattrin R, Brusaferro S. Medical errors and clinical risk management: state of the art. Acta Otorhinolaryngologica Italica. 2005;25:339-46.
37. Rosenbaum L. The Less-Is-More Crusade - Are We Overmedicalizing or Oversimplifying? The New England Journal of Medicine. 2017;377(24):2392-7.
38. Burger I, Schill K, Goodman S. Disclosure of Individual Surgeon's Performance Rates During Informed Consent. Annals of Surgery. 2007;245(4):507-13.