UNIVERSITI TEKNOLOGI MARA

A COMPARATIVE STUDY ON THE EVALUATION OF PATIENT'S SATISFACTION ON ENDOSCOPIC PROCEDURE BETWEEN PRE-FILLED AND STANDARD HAND-WRITTEN CONSENT FORM IN HOSPITAL KUALA LIPIS

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ABSTRACT

Informed consent is the patient's self-determination authorization of a choice made by themself before any intervention is performed by the health care provider. It should be a structured process that includes the disclosure of relevant procedural information, benefit, risk and other treatment option. it is also an ethical and legal requirement in respecting patients' autonomy and the right of patients to receive adequate information. The standard hand-written consent form produced by the Ministry of Health is an empty form that the health care provider must fill up before obtaining the informed consent. There are possibilities that the information may be inadequately explained, information retention by the doctors and depends on the person's experience in explaining and obtaining the consent. The pre-filled consent form was created to improve the informed consent process, standardize the information and avoid missing important material risks. This research aims to evaluate the patient's satisfaction in this pre-filled consent form compared to the standard hand-written consent form. Gastrointestinal Endoscopy Satisfaction Questionnaire version 2 has been used to evaluate the patient's satisfaction. This research concluded that there is a significant difference in patient's satisfaction using the pre-filled consent form compared to the standard handwritten consent form. The factors associated with the difference score was the years of doctor’s experience who taking the consent and gender of the patients. Otherwise, other factors such as age, race, level of education and occupation of the patients were not significant in this research.

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1.1.1 Informed Consent

Informed consent has evolved over the past decades from an ethical concept to a legal principle. It is constructed on the ethical principles of respecting patients' autonomy and self-determination to empower them in making their own decisions. Taking consent for any procedure is not just about taking signature from patients on the consent form, but it is a decision-making process involving a competent person who fully understands the procedure and the possible complication that may occur and makes a decision without coercion (Sil & Das, 2017). It also has a mutual connection and trusts in-between clinician and patient with patient's autonomy being the main concern. Furthermore, it is a legal duty of healthcare professionals to obtain valid consent from patients as required by the Malaysian Medical Council (MMC, 2016b). Material risks relevant to the patient should be informed for the patient to make an informed decision. The more risk of the procedure, the more disclosure of information must be done (Cocanour, 2017). A valid and complete consent form must include the detail of the process of the procedure, associated risks, how the procedure will be performed, post-procedure management, and other alternative options. The information must also include any benefit, risk and procedure limitation, any tissue sampling, image recording and presence of a supervisor for the trainee to perform any invasive procedure (Everett et al., 2016). The informed consent also must include estimated overall cost of treatment to avoid "surprise medical bill" which cause unsatisfactory and unpleasant experience to the patients (Bernstaein J, 2020).