THE RELATION BETWEEN PATIENT EDUCATION AND DOCTORS’ COMPLIANCE ON INFORMED CONSENT IMPLEMENTATION

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ABSTRACT

Introduction: Informed consent is a patient's right and doctor's obligation to explain the patient's condition and disease to obtain medical approval. Doctors do not fully provide the information and explanation. Research conducted on informed consent patients showed 77.3% of respondents did not understand medical terms and explanations about the informed consent. The lack of knowledge from patients or families can lead to malpractice suits if there is a problem in administering medical treatment. Purpose: to determine patient education's impact on doctors' compliance in implementing informed consent.

Method: Quantitative research with pre-experimental research design (one group pre and post-test design). The research subjects were doctors who gave informed consent. The research object is patients or families who received informed consent. Researcher did the pre test by asking the patient or family about the content of informed consent whether they can answer or not and explained after all the questions had given that they had the right to know what they should know for the invasive procedure. Patient or family had the opportunity to ask the doctor some hours before invasive procedure. Then, researcher came back to evaluate the understanding of patient and family about the procedure by asking the same questions. The study was conducted for 3 (three) months, March - May 2020 on 30 patients or their families. The data analysis used Mann Whitney test to determine how significant the difference between two populations was taken from the same population. This research instrument used a structured interview checklist based on regulation of the Minister of Health of the Republic of Indonesia 290 / MENKES / PER / III / 2008 concerning Approval of Medical Actions and the Law on Medical Practice Article 45 of 2004.

Result: Pre-test showed that 83% of respondents know the doctor's name in charge, 63% of the diagnosis, 43% of the procedure's aim, and 3% of the prognosis. 50% of patients cited 2 points of informed consent, and 3.33% mentioned 4 points. In the post-test, 100% of respondents mentioned the doctor's name, the diagnosis, the purpose of the procedure, and when the patient's condition monitors, 73.33% of respondents mentioned 8 points of informed consent, 3.33% were able to mention 9 points. Mann Whitney test showed the following results (p = 0.000).

Conclusion: Education to patients or families improve doctors' compliance in implementing informed consent.

Keywords: informed consent, education, compliance

I. BACKGROUND

Medical action actually need an approval from the patient and explained by the doctor clearly to make patient and family understand what kind of procedure they will get. This kind of thing is called informed consent. After obtaining the doctor's information, consent is given by the patient (1). Informed consent is an ethical and legal obligation before performing any invasive procedure. Consent is a complex process involving the provision of information by a health professional and a dialogue between doctor and patient. Approval requires good communication and interpersonal skills to generate trust, explore understanding, patient or family feelings, and provide accurate information regarding planned procedures (2). Based on Regulation of the Minister of Health of
the Republic of Indonesia 290 / MENKES / PER / III / 2008 concerning Approval of Medical Actions and the
Law on Medical Practice Article 45 of 2004, the explanation of informed consent is considered sufficient by
submitting at least 6 (six) main points, namely: diagnosis and procedure, the purpose of the procedure being
carried out, other alternative procedures and their risks, the risks and complications that may occur, prognosis for
the procedure, and estimated financing.

In fact, Doctors do not fully provide the information and explanation. Yet, this juridical obligation must be
carried out by doctors to patients or the patient's family. Information and explanation are often provided by
nurses who are not legally authorized to convey and explain. This is related to the capacity of medical knowledge
that nurses have, which is much different from direct doctors who convey it (3).

In a study conducted on patients regarding informed consent, data obtained 77.3% of respondents did not
understand medical terms and explanations for informed consent, 27.4% were dissatisfied with the explanation
given before surgery, 5% did not fully know the diagnosis before surgery, and 38.2% did not know their right to
give informed consent before surgery (4).

The patient's lack of knowledge causes the majority of malpractice demands as a lay part of the world of
medicine. It can be said that if all patients or their families sue for malpractice, for this reason, there is an
injustice to the doctor's profession because a therapeutic agreement is an agreement that is inspirational. Where
the therapeutic agreement does not promise a definite result but a maximum effort to cure the patient (5).

The doctor's compliance with informed consent implementation is related to behavior and habits. Behavior is an
expected value in the form of social cognitive, highlighting the deliberate and reflective factors that focus on
predicting health, professionals' behavior, such as prescribing, examining, referring, and using clinical guidelines
widely. Habit is a phenomenon where internal and external cues trigger automatic reactions based on learned
stimulus-response associations. Habit develops when behavior is repeated (6). This is explained in the theory of
planned behavior (TPB). This theory has a foundation on the belief that can influence people to behave
specifically. The trust perspective is carried out through various characters, qualities, and complementary
information, which then forms a desire to behave. Intention or intention is a stimulus to take action, whether
consciously or not. This theory is suitable for describing all behaviors that require planning (7). Factors that
affect medical personnel's compliance consist of internal factors and external factors (8,9). Internal factors consist
of age, gender; years of service; knowledge; and attitude. External factors include Work environment, group
characteristics, and workload.

Several studies have been conducted to increase medical personnel's compliance, one of which is using multi-
pronged strategies to increase adherence among health workers. The combination of management support, secure
supply access, education, observation and training, workplace reminders, supervision, and performance feedback
has the potential to increase compliance by about 30% (10). Traditionally, strategies aimed at increasing
adherence were centered on the doctor himself and usually consisted of behavior modification or observation.
This strategy shows short term success. One study shows that involving patients in this effort can yield long-term
benefits. In addition, involving patients and families in an active role by asking will enable continuous
monitoring without the need for additional human resources (11,12).

Medical personnel have many responsibilities and obligations that must be carried out, especially for patients'
benefit. It is undeniable that fatigue is one of the problems that medical personnel cannot avoid because of the
many obligations and responsibilities they carry. Maslach and Jackson conceptualize fatigue as a 3 (three)
dimensional construct consisting of emotional exhaustion, depersonalization, and lack of personal achievement.
In several studies, the consequences of fatigue have shown detrimental outcomes on patient care, professionalism, health and safety of physicians themselves and the survival of the health care system as well as a
reduction in the professional work effort of physicians (13).

The current health system seeks to increase all lines' active role to achieve a better degree of health. One of them
involves the patient in planning and decisions about what to do with him. Patient-centered care is an innovative
approach to planning, delivering, and evaluating health services based on mutually beneficial partnerships
between health care providers, patients, and families. Patient-centered care can apply to patients of all age groups,
practiced in any form of health service (14). Patient-centered care focuses on four basic concepts: dignity and respect, sharing communication information, participation, and collaboration.
This is supported by the concept of patient empowerment, which enables patients to take an active role in the decision-making process about their health and quality of life. This concept is rooted in social action and is related to the community's interests and efforts to increase the autonomy, power, and influence of minority groups. The World Health Organization (WHO) has developed guidelines that emphasize that the patient's voice must be heard. First, one emphasis is placed on helping patients gain control over their health factors. Second, individual and collective empowerment is emphasized as critical to patients' ability to control their own lives. Patient experience and knowledge are considered a complement to the doctor's knowledge, which is essential for successful treatment and improving care quality (15). Therefore, to avoid malpractice suits due to a lack of knowledge and understanding of the patient as a layperson to the medical or medical world, the author wants to conduct a study involving patients, whether it affects doctors' compliance in implementing informed consent.

II. METHOD

This research is a quantitative research method using a pre-experimental research design (one group pre and post-test design). The purpose of pre-experimental research is to measure a causal relationship by using a group of subjects and measuring before and after treatment. Research ethics which are used in this research contains of three points. First, it is informed consent. Informed consent are given to respondents after the respondents receive an explanation from the researcher about the aims and objectives of this research. If the respondent has understood about the explanation from the researcher and agrees to be the respondent, the researcher asks the respondent's willingness to sign the consent form to become the respondent. If the candidate respondent is not willing, then the researcher must not impose his will and must respect the right of the respondent candidate. The second one is anonymity. Researcher will use the identity of the respondent only for this research and may only be disclosed if the respondent is involved in a legal problem (as evidence). The last is confidentiality. The principle of confidentiality must be upheld by researcher. Confidentiality referred to respondent's identity, respondent's answer or research results and respondent's address. All information obtained from respondents is used only for research purposes and will only be reported to those who are competent with the research. The interview checklist and the answers will be stored by the researcher in a safe place and will be destroyed within a predetermined time limit (5 years).

The subjects in this study were doctors who submitted informed consent. Doctors consist of surgeons, urologists, orthopedists, ear, nose, and throat specialists. The object of this research is patients or families who receive informed consent. The study was conducted for 3 (three) months, namely March-May 2020, on 30 patients or their families. The intervention, by giving an explanation content of informed consent hold in few hours before the invasive procedure is given by the doctor.

The sampling technique in this study used a simple random sampling technique, namely taking members of the sample from the population randomly without paying attention to the population's strata. The instrument used in this study was a checklist instrument based on the regulation of the Minister of Health of the Republic of Indonesia 290 / MENKES / PER / III / 2008 concerning Approval of Medical Actions and the Law on Medical Practice Article 45 of 2004. The checklist consists of the following ten statements. First, the patient or family names the doctor in charge. If the patient mentions other team members, but does not mention the name of the doctor in charge, it is considered that he does not understand the first point. Second, the patient or family mentions the patient's current diagnosis or condition and other possible conditions. This statement will be adjusted to the diagnosis written by the responsible doctor. Third, the patient or family states the purpose of the action or operation to be performed. Fourth, the patient or family mentions the treatment that the patient can choose according to his condition and the choice if not treated will make the patient's condition what kind of condition. Patients can also add preparations that must be done before, during, and after the procedure. Fifth, the patient or family mentions other treatment options and how risk they are to the patient's current condition. Sixth, the patient or family is able to describe the risks that may occur during and after the procedure as well as the complications from the procedure. Seventh, patients or families mention post-operative supervision carried out by the nurse or doctor in charge after the action is carried out. Eighth, patient or family states predictions regarding the progress of the patient's condition and what if no action is taken. Ninth, patients or families are given the opportunity to change their opinion whether they agree to the operation or not. Tenth, patients or families are allowed to consult with other doctors. If the patients or family could answer and explain each point from the questions, researcher would give check sign to the side column. In the end, researcher categorize the result based on how many patients or family understand about each point, which are the highest and which are the lowest. More patients or family answer certain point, it will be the most informed consent content that has been
understood by the patient or family delivered by doctor. And if there are few points which are not answered by them, it means they do not understand about the doctor’s explanation on that points.

Test the validity and reliability of this study using Internal Consistency Validity (CVI). The validity of the research instrument used the guidelines for the Regulation of the Minister of Health of the Republic of Indonesia Number 290 / MENKES / PER / III / 2008 concerning the Approval of Medical Action and the Law on Medical Practice Article 45 of 2004, which was discussed with the ethics committee lay experts at RSI Siti Aisyah Madiun. The reliability of the research instrument used Alpha Cronbach.

Before conducting data analysis, the researcher conducted a normality test to determine whether the research data were normally distributed or not. After obtaining the normality test results of abnormally distributed data, the researchers decided to use a non-parametric analytical test. Data was analysis using the Mann Whitney test. The level of significance used in this study is \( p < 0.05 \), which means that the researcher's decision to reject or support the null hypothesis has a probability of error of 5%.

### III. RESULTS

Table 2 showed that the majority of respondents were male with a percentage of 67%. Respondents aged 36-65 years rank the most, namely 60%. Surgery in the form of Transurethral Resection of the Prostate (TURP) is the most common action in this study, with a percentage of 20% and surgeons received the highest number of procedures at 53.3%.

The researcher conducted a pre-test on the respondents. The name of the doctor in charge of the patient (DPJP), diagnosis, the purpose of action, and prognosis can be mentioned again by the respondents, with the name DPJP as the highest percentage, 83%. As for the type of management, other alternative actions, risks, complications, under what conditions the patient will be monitored again, the opportunity to change his opinion, and asking another doctor's opinion was not mentioned by the respondent. After the intervention was carried out in the form of education about the informed consent contents, the researcher conducted a post-test. All of the respondents were able to mention the name of the DPJP, the diagnosis, the purpose of the action, and how the doctor would monitor the patient's condition. Meanwhile, regarding the patient's right to change their opinion regarding the action to be carried out and the opportunity to seek the opinion of another doctor, it occupies the lowest percentage.

In the pre-test, 15 (fifteen) research respondents, or 50% of the total, could mention 2 (two) points of informed consent, while only 1 (one) person or 3.33% of respondents could mention four points. After the intervention, 8 (eight) points of informed consent were mentioned by 22 (twenty-two) or 73.33% of respondents, and 1 (one) person mentioned 9 (nine) points of informed consent.

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Table 1 shows a significant difference between patients or their families after being given the intervention in the form of educational content of the points of informed consent compared to before. So, it is related to the compliance rate of doctors in implementing informed consent.

### IV. DISCUSSION

Comprehensive information is an ethical necessity before an invasive or surgery procedure and involving patient and family to decide the treatment is important. Patient and family have the right to receive the clear information from the doctor and may ask anything about the procedure. Patient who receive well information are more satisfied and minimize the law claim. Educational content of the points of informed consent is one from many ways to increase the understanding of patient and family about informed consent. Doctors need to spend more time build doctor-patient relationship and make sure if the patient and family understand about the procedure which will be given to them. By learning the characteristic of the patient and family such as ages and education, doctors implement the informed consent with the general language. Sometimes, doctors still use the medical term to explain, so that patient difficult to understand. Patient or family need to be encourage to make them brave asking the detail of the procedure. Sometimes, they were just afraid of the doctor, meanwhile they still confused and only follow what the doctors were suggested. Instead of them, doctors have to evaluate themselves supported

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by the hospital management about their quality on communication especially on how they deliver the informed consent and respond it to the patient and family and the problem from each doctors are actually different (16).

This difference may reflect the level of understanding among respondents and the process of informed consent, which places more emphasis on diagnosis than other points. This lower score was related to patient knowledge and understanding of informed consent and surgeons' poor practice (17).

Continuous medical education about the importance of the doctor-patient relationship. In addition to being a service provider where patient complaints can be handled, it is a complement to creating compliance with the implementation of informed consent (16). This is in accordance with what researchers did, which involved the participation of patients and families with how to provide intervention in the form of education on the content of informed consent to increase physician compliance in implementing informed consent. After the intervention was carried out in the form of education about the informed consent contents, the researcher conducted a post-test. 100% of research respondents can mention the name of the DPJP, diagnosis, purpose of action, and how the doctor will re-monitor the patient's condition, and 8 (eight) points of informed consent can be mentioned by 22 (twenty-two) or 73.33% of respondents and 1 (one) person mentioned 9 (nine) points of informed consent.

A study shows that remuneration strategies are used to improve physician compliance. The research results at 115 Muhammadiyah and Aisyah hospitals in Indonesia indicate that financial compensation influences the quality of health services and organizational performance (18).

Research that has been conducted at RSIA HST Trenggalek shows a strategy to increase patient or family understanding of informed consent using photonovel media. This study shows that the media has a big role in bridging the information that doctors convey to the recipient of information, thus becoming an important tool in improving patient-doctor communication (19).

Some of the obstacles in implementing informed consent can be divided into two factors: the doctor himself and the patient's factors. Factors from doctors include fatigue, age of the DPJP, work experience, and duration of training that has been attended (13,18).

One study reported that patients memorized little information during the informed consent process. Several factors such as patient age, education level, intelligence, cognitive function, occupation, and anxiety are related to patient understanding. Some patients decide to keep signing the informed consent form based on their instincts or other things such as the hospital's reputation and the reputation of the doctor in charge (20). Compliance behavior is not entirely rooted in the rules or policies made but also a combination of practice norms or values adopted, individual preferences, and a professional level (21).

From the other journal about the lack of informed consent implementation, most of them told about doctors’ communication skill problem. Therefore, it is necessary to carry out communication training for doctors as part of clinical skills to achieve doctor completeness and compliance in implementing informed consent. For example, a trained doctor can assist patients in defining what is the best option for the patient to improve their health status, according to their experience, and the values of trust and collaboration (joint decision) (22,23). Educated patients are aware of their rights and are more likely to understand the informed consent process's information than uneducated patients. Therefore, sufficient time should be given to less educated patients to gain good consent and understanding (24,25).

V. CONCLUSION

The provision of intervention in the form of content education from the points of informed consent showed a significant increase in doctors' compliance rate in implementing informed consent. Apart from patients' active role or families and doctors in this compliance, hospitals are advised to evaluate standard operating procedures (SOPs) and policies related to patients' rights and other doctor obligations.

VI. ACKNOWLEDGEMENTS

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REFERENCES


VII. TABLES AND FIGURES

Table 1. Non-Parametrik Analytic with Mann Whitney Test

| Mann Whitney (Education Intervention Impact on Improving Doctors’ Compliance) | .000 |
| Asymp. Sig. (2-tailed) | .000 |

Table 2. Data Distribution of Research Respondents
<table>
<thead>
<tr>
<th>Data</th>
<th>Total</th>
<th>Percentage</th>
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<tr>
<td>Gender</td>
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<tr>
<td>Men</td>
<td>20</td>
<td>67%</td>
</tr>
<tr>
<td>Women</td>
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</tr>
<tr>
<td>Age</td>
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<tr>
<td>18-35</td>
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<td>37%</td>
</tr>
<tr>
<td>36-65</td>
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<td>60%</td>
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<td>&gt;65</td>
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<td>3%</td>
</tr>
<tr>
<td>Procedure</td>
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<td></td>
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<tr>
<td>Partial Hip Replacement (PHR)</td>
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<td>3%</td>
</tr>
<tr>
<td>Open Reduction Internal Fixation (ORIF)</td>
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<td>6%</td>
</tr>
<tr>
<td>Laparotomy</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Excision and Biopsy</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Excision</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Tongue Tumor Biopsy</td>
<td>1</td>
<td>3%</td>
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<tr>
<td>Exirpation</td>
<td>1</td>
<td>3%</td>
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<tr>
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<tr>
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<td>3%</td>
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<tr>
<td>Hemorrhoidectomy</td>
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<td>6%</td>
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<tr>
<td>Hernioraphy</td>
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<td>6%</td>
</tr>
<tr>
<td>Hidroelektomny</td>
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<td>3%</td>
</tr>
<tr>
<td>Transurethral Resection of the Prostate (TURP)</td>
<td>6</td>
<td>20%</td>
</tr>
<tr>
<td>Litotripsy</td>
<td>2</td>
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<tr>
<td>Urologist</td>
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<tr>
<td>Otolaryngologist</td>
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<td>3.3%</td>
</tr>
</tbody>
</table>

**Fig 1. Comparison of Informed Consent Pre and Post Intervention**
Fig 2. Respondents Total Points of Pre and Post Intervention