The Analysis Causes of Informed Consent in Supporting the Quality of Medical Record In Graha Hospital Medika Banyuwangi

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Abstract:

Backgrounds: Informed consent is an agreement given by the patient or family after receiving a clear explanation of the patient's medical or dental action to be carried out. The standard of completeness of the Informed Consent is based on the Hospital Minimum Service Standard No. 290 of 2008 and the hospital quality standard is 100%. The number of incomplete informed consent at Graha Medika Hospital in the third quarter of 2020 was 11.14%, 26.90%, and 41%, which means that the standard for completeness of informed consent has not been achieved. The purpose of the study was to analyze the factors causing incomplete informed consent.

Methods: The research design used a quantitative approach with a cross-sectional research design. The population and sample were 258 informed consent forms. The unit of analysis was 30 medical doctors who filled out the informed consent. Data analysis used univariate, bivariate with Spearman Rank, and multivariate with Partial Least Square.

Results: The bivariate analysis results showed that the resource indicator had a relationship with the completeness of Informed Consent with a value of 0.005. A multivariate analysis that organizational factors had a relationship with the completeness of Informed Consent with a value of 0.001.

Conclusion: Strengthening the resource sector with a solid organizational commitment will increase the completeness of informed consent, which is inseparable from the quality of the organization's management function. A good management function will run in harmony with the level of compliance of good service personnel.

Keywords: Informed consent, Gibson Theory, quality completeness.

I. INTRODUCTION

The hospital is one of the health care facilities needed to support health care with complex characteristics and organizations with various scientific and medical technologies that are useful in providing standard quality services that make the complexity of problems in hospitals (Kemenkes, 2008b). One of the problems is related to the delivery of information, such as delivery that is not clear, poorly understood, which can affect patient and family decisions. Giving a complete and clear explanation is a patient's right that must be fulfilled by the hospital in improving the quality of health services so that an agreement such as Informed Consent is needed (Wulandari et al., 2019).
incomplete Informed Consents that continues to rise from July to September means that the completeness of filling out Informed Consents has not been achieved according to Minimum Service Standards (SPM) and hospital quality is 100% (Oktavia et al., 2020). Minimum Service standards are performance benchmarks in determining the type and quality of basic service achievements (Government Regulation No. 58, 2005).

The observation results are that doctors will fill out medical records if given by nurses, and some doctors do not fill out medical records due to limited time. This is in line with Kencana et al. (2019) research that doctors know that filling informed consent is their responsibility. However, some doctors do not fill in because they are in a hurry with other practice schedules, and many patients result in the delayed filling. The results of an interview with one of the doctor's assistants that the doctor will fill it out if given the form to fill out. Although some doctors do not fill it completely, the assistant will complete it. Obstacles experienced by doctors directly related to time and filling of equipment can be a burden if there are many patients so that filling is delayed after service. Not all doctors want to fill in the completeness immediately after the service, some have piled up, and some can be completed after the service. This reflects that the doctor in charge still has responsibility for the completeness of the patient's medical record file, even though the doctor's performance in filling out Informed Consent after being given information is still not up to standard and needs to be improved.

It is known that three factors that can affect the completeness of filling informed consent are organizational, technical, and behavioral factors that have a positive effect on performance (Paulus et al., 2019). Gibson et al. (2012) in Putri (2020) that job performance is the result of work-related to organizational goals in the form of quality, efficiency, and effectiveness. Gibson et al. (2005) in Fitria et al. (2018) performance theory models that affect individual behavior and performance include individual, organizational and psychological factors. Individual factors consist of abilities and skills, background, and demographics. Psychological factors consist of perception, attitude, personality, learning and motivation. While organizational factors are classified into resources, leadership, rewards, structure, and job design (Putri, 2020).

The impact of incomplete filling informed consent is on the quality and quality of medical records and guarantees of legal certainty for patients, health workers, and hospitals (Oktavia et al., 2020). In negligence on medical action in accordance with Article 359 of the Criminal Code. So with this Informed Consent, errors that are suspected of being malpractice can be minimized (Syafruddin & Rohman, 2019). However, the approval of medical action does not abolish legal liability if it is proven that there is negligence in medical action that results in patient losses (Ministry of Health, 2008a).

Based on the description above, incomplete informed consent can be called errors and omissions according to law. The researchers are interested in analyzing the factors that cause incomplete informed consent in supporting hospitals' quality of medical records. The theory that will be used is the Performance theory by Gibson, which includes individual, psychological and organizational factors.

II. METHODS

The research design used a quantitative approach with an analytic observational research type and a cross-sectional research design. The research location is at Graha Medika Banyuwangi Hospital for 6 months. The population in this study is the informed consent form for the Fourth Quarter of 2020 with a total of 722 forms with a sample of 258 Informed Consent forms and sampling using simple random sampling with a lottery system.

The unit of analysis used 30 doctors. Data sources are primary data in the form of a questionnaire filled out by the doctor and secondary data obtained from the checklist for the completeness of the Informed Consent form. The independent variables are individual factors (ability, family background, experience, age, gender), psychological factors (perception, attitude, personality, learning, motivation), organizational factors (resources and leadership), and the dependent variable is the completeness of informed consent. Data analysis using univariate, bivariate using Spearman Rank test with SPSS software and multivariate using Partial Least Square with SmartPLS 3.0 software.

III. RESULTS AND DISCUSSION

Respondents in this study were 30 doctors who worked at Graha Medika Hospital with a distribution of 25 specialists and 5 general practitioners and divided into 14 permanent doctors and 16 contract doctors. 30 doctors were asked to be the unit of analysis to measure the factors that could affect the completeness of the Informed Consent. There were 258 Informed Consent forms in the analysis of the completeness of the fillings, which are spread over 30 doctors.

Based on the results of univariate data analysis, 83% of the Informed Consent forms filled out by doctors at Graha Medika Hospital were at a completeness level of 81-100%. The perception of doctors who filled out the informed consent at Graha Medika Hospital were very good at 90.3%. 71.3% of doctors who filled out Informed Consent at Graha Medika Hospital were good. 50.8% of doctors who filled Informed Consent at Graha Medika Hospital were very good. 66.7% of doctors who filled out Informed Consent at Graha Medika Hospital were very good. 80.2% motivation of doctors who filled out the Informed Consent at Graha Medika Hospital was very good. The resources at Graha Medika Hospital are very supportive of the completeness of the Informed Consent of 51.2%. By 80.

The bivariate test in this study used the Spearman Rank correlation test with the help of SPSS to answer the hypothesis between the independent variables (individual factors, psychological factors, and organizational factors) and the dependent factor (incomplete informed consent). This bivariate test aims to determine the level of closeness of the relationship between variables X and Y. The results of the bivariate analysis are described in Table 1.
The table can be explained that individual and psychological factors have a p-value > 0.05, which means that there is no relationship between individual and psychological factors on the incompleteness of Informed Consent. Meanwhile, organizational factors have a p-value <0.05 (p-value 0.001), which means a relationship between organizational factors and the incompleteness of Informed Consent.

A. Completeness Informed Consent

The results showed that 83% of the Informed Consent forms at Graha Medika Hospital were at a completeness level of 81-100%, which means that the completeness was very good. The results of the observation on the form that out of 258 forms, as many as 216 were written complete and the rest were written incomplete. The most incomplete fillings at the 0-20% level are 17 forms which are contained in the contents and signatures. This incomplete Informed Consent form will be returned to the unit or DPJP in charge of the patient to be completed. This Informed Consent form must be filled out completely because it involves the responsibility and accountability of a health professional so that if the informed consent is incomplete, it will be returned to the responsible unit.

This is in accordance with the results of the Wicaksana research (2019), which explains that informed consent is a therapeutic contract between a doctor and a patient. Informed consent will guarantee a legal relationship between doctors and patients based on fulfilling rights and obligations that can be fully accounted for. Before approval, informed consent is made between doctors, and patients must go through an explanation phase. Patients must understand the procedures that will be received later so that there is no element of coercion. Any action given to the patient without informed consent is confirmed to be invalid and can be legally challenged.

An Informed Consent is given after the client has received complete information, including the purpose of the procedure, the risks and benefits of the procedure, as well as all information related to the procedure that the patient will receive. Completeness of informed consent is an absolute thing in implementing health services. Therefore, the essence of implementing Informed Consent is in a detailed explanation so that the patient understands the actions or services received by him while in the health facility (Falvo, 2011 in Sharma, 2017).

B. The Analysis of Relationship of Individual Factors to Completeness Informed Consent

This study indicates that all indicators on individual factors have no relationship with incomplete informed consent (p-value > 0.05). Based on the p-value, the highest is on the gender indicator, and the lowest is on the age indicator. This means that the age indicator is more likely to be associated with incomplete informed consent than other indicators. The gender indicator is the indicator least associated with incomplete informed consent. Whether or not an Informed Consent document is complete manifests individual compliance with an applicable standard procedure. The incompleteness of the Informed Consent is a reference for the
doctor's non-compliance with the legal aspects that have been determined.

The ability of doctors to understand Informed Consent accompanied by implementation according to standard procedures reflects that the doctor individually can fulfill medical service standards so that the ability of doctors has a relevant relationship with the completeness of the Informed Consent form (Riyadi, 2018). Informed consent's theoretical ability and experience will be higher if it is based on good motivation to fulfill Informed Consent documents according to standard procedures. Motivation becomes a psychological driving force when doctors provide medical services. This is in accordance with the results of Meyyulinar's research (2019).

The facts from the research mention things that are different from the theory and relevant research above. The results of this study indicate that all indicators of individual factors (ability, background, experience, age, and gender) do not have a relationship with incomplete Informed Consent due to other factors that have a stronger influence on individual doctors in completing Informed Consent. Individual factors that can affect the completeness of the Informed Consent are the high routine of doctors' activities in providing services in several places so that it can reduce attention to the completeness of the Informed Consent document. Most of the doctors at Graha Medika Hospital (53.3%) are contract doctors. The phenomenon of the high busyness of doctors to provide medical services in several health facilities can reduce the awareness of doctors themselves in completing medical record documents, one of which is Informed Consent. This is in accordance with Ramadani's research (2017), which explains that not all doctors fill out the Informed Consent sheet according to their responsibilities. This is due to the high level of doctor's busyness, resulting in a lack of awareness that Informed Consent is essential medical record documentation to be completed. It was explained that not all doctors filled out the Informed Consent sheet in accordance with their responsibilities. This is due to the high level of doctor's busyness, resulting in a lack of awareness that Informed Consent is vital medical record documentation to be completed. It was explained that not all doctors filled out the Informed Consent sheet in accordance with their responsibilities. This is due to the high level of doctor's busyness, resulting in a lack of awareness that Informed Consent is a very important medical record documentation to be completed.

C. The Analysis of Relationship of Psychological Factors to Completeness Informed Consent

This study indicates no relationship between psychological factors from indicators of perception, attitude, personality, learning, and motivation with incomplete informed consent (p-value > 0.05). Table 4.5 shows that the highest p-value is on the motivation indicator, and the lowest is on the perception indicator. It means that perception has a greater chance of being associated with incomplete Informed Consent than other indicators on psychological variables, and motivation has the highest level of omission relationship with incomplete Informed Consent than other indicators on psychological variables.

This is in accordance with the results of Haniefia's research (2014) that there is no relationship between the doctor's education phase and perceptions related to Informed Consent. The difference in the level of medical education is only in terms of expertise, not in the depth of insight of Informed Consent so that all levels of medical education will treat the interests of Informed Consent equally. This study shows no relationship between attitudes as one indicator with incomplete Informed Consent has the same relevance as the perception indicator. The absence of a relationship between perceptions and incomplete informed consent also affects attitudes and incomplete informed consent. In theory, it is stated that a good attitude will result in a good performance.

Similarly, Aisyiah's research (2015) explains a relationship between attitude and motivation with performance. A person's work behavior is strongly influenced by the person's attitude at work because there is a will in a person's attitude to do / not do the job well. Czerw's research (2015) also confirms a strong relationship between work attitude and performance. Psychological factors in the form of attitudes significantly affect performance because attitudes will directly encourage individual behavior to work according to procedures. Czerw's research (2015) also confirms a strong relationship between work attitude and performance.

The results of this study indicate that most of the doctors' personalities at Graha Medika Hospital are very good (50.8%), but the study's conclusion states that there is no relationship between personality and incomplete informed consent (p-value 0.222). Some doctors' behavior is good, and the completeness of the informed consent is good (81-100%), but the results of the analysis shows there is no relationship (Sari & Chalidyanto, 2016).

This is contrary to the results of the research conducted by Kosegeran (2019), which explains a relationship between personality type and performance. The study explains that personality affects performance because personality will impact work motivation. The last psychological factor is motivation. The results showed that most doctors at Graha Medika Hospital had very good motivation (80.2%). However, the conclusion of the research analysis stated that there was no relationship between motivation and incomplete Informed Consent (p-value 0.571). Motivation is self-motivation to try to make changes in behavior to meet their needs better. Self-motivation in the world of work emphasizes producing good performance according to workplace regulations. Self-motivation is needed for a worker to keep work psychologically stable so that the quality of work will be maintained simultaneously (Sadijn, 2008).

The results of this study contradict the research of Sudarmono (2017). It is explained that there is a relationship between motivation and a doctor's performance, and motivation has an effect of 8,155 times better than compensation and job satisfaction in influencing performance. Motivation is an internal driver of behavior that can defeat other influencing factors.

A study of all indicators of psychological factors, including perception, attitude, personality, learning, and
motivation, can be concluded that perception, self-personality, and learning are the main elements of a doctor's psychological factors in viewing and responding to the importance of Informed Consent. Motivation is the main thing that affects self-attitude in processing object stimulation in the form of Informed Consent, whether it is important or not important to be completed every time provide health services to patients. Informed consent, which is one of the benchmarks for doctors' performance in providing services, becomes a correction of how many psychological factors influence doctors' performance in the form of completing the Informed Consent form.

D. The Analysis of Relationship of Organizational Factors to Completeness Informed Consent

There are two indicators of organizational factors, namely resources and leadership. The results showed that only resource indicators had a relationship with incomplete informed consent (p-value 0.005). The results of the tabulation study stated that most doctors (51.2%) stated that the resources at Graha Medika Hospital strongly supported the availability of complete Informed Consent documents. The results of the analysis stated that there was a relationship between resources and incomplete Informed Consent (p-value 0.005). Resources are valuable and have benefits for their use for survival and the achievement of certain goals. Completeness of the Informed Consent form will not be realized if there are no adequate resources to support it. Resources summarized in man,

The results of this study are relevant to the theory proposed by Purnaya (2016) that resources have a solid contribution to the quality of the completeness of the Informed Consent document. Adequate resources in each institution will support the completeness of documents for each performance, for example, adequate resources in hospitals will certainly support completeness of documents, including Informed Consent. This is because the resources owned by the hospital are the principal capital for the progress of the hospital and the provision of services in accordance with regulations and ethics. The resource problem that appears in this study lies in the human aspect, namely the high number of contract doctors (53.3%) at Graha Medika Hospital.

The relationship between resources and incomplete informed consent can also be influenced by the doctor's tenure at Graha Medika Hospital. Most of the work experience of doctors at Graha Medika Hospital is between 0-5 years (73.3%). Doctors who are still relatively new can be an obstacle in understanding the completeness of Informed Consent because it is related to their insight about Informed Consent. This is in line with Vyas' research (2019), which explains that Informed Consent's knowledge, attitude, and practice to doctors who have just graduated are adequate. However, conducting an in-depth study through workshops or seminars is necessary to increase in-depth understanding of Informed Consent. Relatively new Doctors already have an understanding of Informed Consent. It is just that in practice, it is often not appropriate. Therefore, recommendations for increasing insight through socialization are the right steps.

The next indicator of organizational factors is leadership. The results showed that most of the leadership at Graha Medika Hospital was very good (80.2%) to support the completeness of the Informed Consent. The hospital management has demanded and encouraged the completeness of the Informed Consent document as a legal, medical record document. The analysis results concluded that there was no relationship between leadership and incomplete informed consent (p-value 0.104). This means that other factors in the organizational factor have a stronger influence on the completeness of the Informed Consent.

Leadership in a service facility is closely related to resources. This is related to the leader as a policymaker in the workplace. Policymaking certainly goes through various stages of study, and one of them considers the available resources so that there is a strong correlation between leadership patterns and resources. The pattern of leadership cannot be the same in all organizations because the dynamics of each organization are different. Therefore, the right leadership pattern will significantly affect organizational commitment and employee performance. This is in line with Titioka's research (2019) that leadership style has a positive and significant effect on organizational commitment and employee performance. Leaders as role models must be precise in making a policy. The right policy will be an organizational commitment in its implementation, so that employee performance will increase following the organizational commitment made. The absence of a relationship between leadership and incomplete Informed Consent is still related to the limited resources available at Graha Medika Hospital so that the commitments formed in each hospital are less binding. This has become a classic phenomenon when there are limited doctors. A service that is not primary often becomes neglected and, in this case, is the completeness of the Informed Consent document.

E. The Analysis of Relationship of Individual, Psychological and Organizational Factors to Completeness Informed Consent

The results of the PLS test of this study stated that only organizational factors had an influence on the incompleteness of Informed Consent (p-value 0.001). The influence of organizational factors on the incompleteness of Informed Consent is inseparable from the indicators of available resources at Graha Medika Hospital. Table 4.5 shows that the p-value of the resource indicator is 0.005 (p-value <0.05), so it can be concluded that resources have a relationship with incomplete informed consent. The frequency distribution table of the research results shows that the resource indicator on the organizational factor variable has a unique variant compared to other indicators. The variance of the data on the resource indicator is directly proportional to the incompleteness of the Informed Consent.

The relationship between resources and incomplete informed consent cannot be separated from the high number of contract doctors at Graha Medika Hospital. The high number of contract doctors at Graha Medika Hospital directly affects the quality of service professionalism, especially in the field of completeness of ethical documents. This condition has its own psychological and organizational effects. In some places, the practice cycle of doctors makes the workload high and even beyond the limits of ability. This high workload indirectly
creates a priority mindset, so doctors will rule out less considered primary. Changes in work attitudes that tend to decrease are triggered by fatigue due to excessive workload. In line with the results of Ma's research (2014), explained that excessive workload can cause fatigue both psychologically and physiologically. Excessive workload will result in excessive energy loss and high emotional stress, coupled with strong stressor power conditions. The condition is the same as experienced by contract doctors. Practices carried out in several places make physical activity increase and psychological stress in itself. Of course, this condition causes a disorientation effect on several aspects that are considered not urgent, such as the completeness of the Informed Consent.

Strengthening an organization's resources cannot be separated from the quality of its management function itself. The results of Ritonga's research (2019) explain a relationship between the management function and compliance with a positive direction of the relationship. A good management function will run in harmony with the level of compliance of good service personnel as well. According to standardization, the availability of good resources will certainly affect the quality of services, one of which is the fulfillment of ethical documents. A good and proportionate doctor’s resources will certainly focus attention on the completeness of the Informed Consent. Doctors will view that Informed Consent is one of the principles of patient safety that is sought, not an additional task. Therefore,

The absence of a relationship from individual factors and psychological factors to the incompleteness of Informed Consent is strongly influenced by aspects of the resources owned by Graha Medika Hospital. One of the primary resources in the hospital is human resources. Human resources will be optimal if they are supported by other main resources, such as finance (money) and facilities (materials) (Misbahuddin, 2020; Setyawan, 2020).

A service must have good quality resources to realize a professional service. The quality of reliable human resources has a positive relevance to employee performance because it directly increases the professionalism of the employee's work. Research by Gasim (2019) explained that the quality of human resources is an absolute must to realize work professionalism that is measurable in the performance of employees of a company. The quality of resources is realized when the number of employees is balanced with the workload received, and the competencies possessed by employees are in accordance with the work qualifications carried out.

The limited number of doctor resources owned by Graha Medika Hospital in the form of a large number of contract doctors has become a special concern to fix the regulations for the provision of permanent doctors. Although the description of individual factors and psychological factors on average are in the positive category in supporting the completeness of the informed consent, organizational factors are more dominant in influencing the completeness of the informed consent. The facts and scientific review of this research conclude that resources have a strong contribution to supporting the Informed Consent's completeness. Therefore, there is a need for an increase in resources in building services that meet ethical aspects to improve patient safety, one of which is fulfilling the completeness of Informed Consent according to applicable standards.

IV. CONCLUSIONS AND RECOMMENDATIONS

The Informed Consent forms at Graha Medika Hospital are very good, reflecting one of the health services' professionalism. There was no relationship between individual factors and incomplete Informed Consent. The results showed that ability, family background, experience, age and gender have no relationship with doctors' performance in the completeness of Informed Consent. There was no relationship between psychological factors and incomplete Informed Consent, and perceptions, attitudes, personality, learning, and motivation have no relationship with doctors' performance in the completeness of Informed Consent. There was a relationship between resources and incomplete Informed Consent on organizational factors. Only organizational factors had a relationship with Informed Consent incompleteness at Graha Medika Hospital. The effect of organizational factors on Informed Consent incompleteness is inseparable from the indicators of available resources at the hospital.

The hospital should conduct an in-depth study of their resources to support forming a service system that meets legal requirements with high ethical compliance for all workers and supports maximum use of resources. Hospital leaders can give warnings to doctors who do not comply with filling out the completeness of medical records and socializing about filling out to doctors regarding filling out Informed Consent and the importance of this Informed Consent. Further studies are necessary to measure the workload factor on work commitment to doctors who practice in several health-cares to determine doctors' performance. A qualitative approach can be carried out to deeply explore the factors related to doctors' performance, especially the completeness of filling out informed Consent/medical records.

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