

PRESCRIBING GENERIC DRUGS: PERCEPTION, OBEDIENCE, AND SUPERVISION AT KALISAT DISTRICT HOSPITAL

*Pereseapan Obat Generik: Persepsi, Kepatuhan, dan Pengawasan
di Rumah Sakit Daerah Kalisat*

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ABSTRACT

Background: The average of generic drugs prescription at Kalisat District Hospital, Jember, in 2009-2011, reached 57.50%, while patent medicine prescription amounted to 42.50%. It showed that the use of generic drugs at Kalisat District Hospital was higher than the use of patent medicine. However, the prescription has not obeyed the service standard with the supposed minimum standard of 90%.

Aim: This study aims to determine the doctors' obedience and their perception toward the supervision of prescribing generic drugs as well as the correlation between doctors' supervision and obedience in prescribing generic drugs.

Methods: This study is a descriptive and observational study by employing a cross-sectional design. This study was conducted starting from April to July 2013 at Kalisat District Hospital, Jember. The samples were 50 prescription documents taken randomly in April 2013. Besides, questionnaires were distributed to 12 doctors in July 2013.

Results: The supervision on prescribing generic drugs at Kalisat District Hospital was considered insufficient by the doctors with the percentage of 58.3%. The level of doctors' obedience in prescribing generic drugs at Kalisat District Hospital reached 68%, while the national standard in April 2013 amounted to 90%. It means that they had not reached the standard of prescribing generic drugs.

Conclusion: Based on the cross-tabulation analysis used to investigate the correlation between doctors' supervision and obedience in prescribing generic drugs at Kalisat District Hospital in July 2013, the results suggested that generic drug supervision correlates with the doctors' obedience in prescribing generic drugs. The correlation between these two factors is considered moderate. The hospital should increase the supervision of prescribing generic drugs. Thus, doctors should prescribe generic drugs optimally. The hospital management should also perform continuous socialization on the use of generic drugs.

Keywords: generic drugs, supervision, obedience, perception.

ABSTRAK

Latar Belakang: Rata-rata resep obat yang menggunakan obat generik di RSD Kalisat Jember 2009-2011 sebesar 57.50% sedangkan resep obat yang menggunakan obat paten sebesar 42.50%. Artinya, pemakaian obat generik di RSD Kalisat Jember lebih tinggi daripada obat paten namun peresepannya masih di bawah standar dan belum mematuhi standar pelayanan minimal yang seharusnya, yakni 90%.

Tujuan: Penelitian ini menganalisis kepatuhan dan persepsi dokter terhadap pengawasan pereseapan obat generik, serta hubungan antara pengawasan dan kepatuhan dokter dalam pereseapan obat generik.

Metode: Penelitian ini adalah penelitian deskriptif dan penelitian observasional yang menggunakan studi cross sectional. Penelitian dilakukan pada bulan April – Juli 2013. Sampel penelitian adalah 50 dokumen resep yang diambil secara acak pada bulan April dan 12 dokter yang diberi kuisioner pada bulan Juli.

Hasil: Pengawasan penggunaan obat di RSD Kalisat Jember dinilai kurang oleh dokter dengan persentase 58.3%. Tingkat kepatuhan dokter dalam menulis resep menggunakan obat generik dengan standar penulisan resep 90% pada April 2013 di RSD Kalisat Jember 68%, artinya belum mencapai standar penulisan resep.

Kesimpulan: Berdasarkan uji tabulasi silang yang digunakan untuk menilai hubungan antara pengawasan penggunaan obat dengan kepatuhan penulisan resep obat generik di RSD Kalisat Jember bulan Juli 2013 menunjukkan bahwa ada hubungan antara pengawasan penggunaan obat dengan kepatuhan penulisan resep obat generik dan kekuatan hubungannya adalah sedang. Upaya yang dapat dilakukan oleh rumah sakit adalah meningkatkan pengawasan penggunaan obat generik sehingga penggunaannya dapat optimal dan harus ada sosialisasi yang terus-menerus dari manajemen rumah sakit tentang penggunaan obat generik.

Kata kunci: obat generik, pengawasan, kepatuhan, persepsi.

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INTRODUCTION

Hospitals are essential in the health sector. The Law of the Republic of Indonesia Number 44 of 2009 about hospital states that hospital is a service-based health institution for the community which is influenced by the development of health science, technological advancement, and the people's socio-economic life. Hospitals need to be improved continuously to provide better service quality but affordable for the community to achieve the highest possible health standard. Hospital is also a health service institution that carries out a complete individual health service which provides inpatient, outpatient, and emergency services. Meanwhile, excellent health service is a health service that includes promotive, preventive, curative and rehabilitative efforts.

According to excellent health services, medicine becomes one of the most needed elements, especially in curative efforts. If someone is on the clinical disease stage, the first intervention provided by the doctor is through medicine prescription. There are two kinds of medicine in the pharmaceutical world; generic drugs and patent medicines. Patent medicines are medicines that have a patent right, while generic drugs are medicines that their patent right has expired. The official name of those medicines is listed in International Nonproprietary Names (INN), which are specified in the Indonesian Pharmacopoeia or other standard books for efficacious substances (Yusuf, 2016)

According to the European Medicines Agency (EMA) in Yu (2017), generic drugs are the medicine developed to be identical with the authorized medicines or reference medicines. Generic drugs contain the same active substance quantitatively and qualitatively as the referenced medicines and they are used at the same time and dose to treat diseases as referenced medicines. Bioequivalence demonstrations between generic drugs and reference medicines have been used worldwide as the basic criteria for generic drug approval. Generic drugs can only be distributed after the patent period of the referenced medicines has expired.

Syafris (2016) stated that the cost of medicines is the highest cost of the total treatment cost, which is around 60-70%. In order to provide alternative medicines for the community with guaranteed quality and affordable prices and adequate drug availability, since 1989 the government issued an inexpensive drug program called Labeled Generic Drugs or *Obat Generik Berlogo* (OGB). Reviewing its development, the use of Labeled Generic drugs in Indonesia in 2001 was only around 12%, and in 2007 it decreased to 7.8% even though the national medicines market was high.

To intensify the use of generic drugs and to ensure access to medicines for the entire community, one of the government's effort is to keep hospitals' capability in providing qualified services that are accessible to all levels of society. It is re-enforced in the Regulation of Indonesian Ministry of Health Number HK.02.02/MENKES/068/I/2010 concerning the obligation to use generic drugs in all government healthcare facilities at the district or municipality level. The Decree of the Indonesian Ministry of

Health Number 1457/MENKES/SK/X/2003 concerned the rules of using generic drugs, explaining the minimum service standard in district healthcare services. The article 2 Paragraph 2 Point X, stated that the standard prescribing generic drugs are 90% of all given prescriptions. The obligation to use generic drugs is based on the recommendation of the generic drug to be used throughout the countries and it has become an international agreement to prescribe generic drugs for health services, including Indonesia. However, in reality, the use of generic drugs in government healthcare services is not optimal yet. The pharmaceutical industries mostly produce patent medicine prescriptions.

In accordance with the regulation, Kalisat District Hospital is obliged to provide basic healthcare services and affordable pharmaceutical services for all society. It means that the generic drugs used in the hospital should meet the government standard of 90%. However, according to the prescription data received from the Pharmacy Unit of Kalisat District Hospital in 2009-2011, it was found that the average of generic drugs prescription was only 57.50%, while patent medicines prescription was 42.50%. From the data, it could be interpreted that the generic drug prescription at Kalisat District Hospital was higher than patent medicine, but it is still below the minimum standard of 90%.

Various factors may affect individual obedience, such as individual characteristics, the existence of powers (authorities), and social situations. The factors that affect obedience according to Mahfudhoh and Rohmah (2015) are including the perception of location status, personal responsibilities, peer supports, legitimacy of authority figures, the status of authority figures, and adjacency of authority figures.

Disobedience in using generic drugs can cause various impacts. The impact could be a discrepancy between drug stock and use. If the doctor prescribes patent medicine, then there will be an excessive amount of generic drugs left. If the stock of patent medicines is poor, the drug purchasing cost will increase. If those who receive patent medicine prescriptions are middle to lower economic class and/or not an insurance participant, it might become a hindrance for them to the accessible medicines. Based on the national data, the use of generic drugs in Indonesia is still relatively low, even though the price is much lower and has the same benefits as branded medicine (Yusuf, 2016).

The Hospital Pharmacy Unit (HPU) is a hospital unit that provides, manages, and distributes information and evaluation about medicines as stated in the Regulation of Indonesian Ministry of Health Number HK.02.02/MENKES/068/I/2010. It mentions that there are authorized parties supervising the Pharmacy and Therapeutics (P&T) Committee who assist the pharmacy unit in developing a review on regional and national policies and regulations. Regaletha (2009) stated that there are four obligations for the for Pharmacy and Therapeutics (P&T) Committee; first, to provide a recommendation to the head of hospital to achieve culturally rational medicine management and use;

second, to coordinate the process of diagnosis and therapy guidelines, hospital formularies, guidelines for antibiotics, and so forth; third, to provide education on management and medicine use to related parties; fourth, to provide studies on management and medicine use, also to provide feedback for the assessment results. As stated before, the fourth obligation of the Pharmacy and Therapy Department is to assess medicine use and provide feedback. To implement that obligation, the Pharmacy and Therapy Department needs to supervise medicine prescriptions in the hospital regularly.

The problem found at Kalisat District Hospital is the utilization of the generic drug that has not achieved the standard. It was only reached 57.50% out of 90% as the minimum service standard for generic drugs prescription. This study aims to determine the doctors' obedience and their perception of prescribing generic drugs as well as the correlation between supervision and doctors' obedience in prescribing generic drugs.

METHOD

This study is an observational study using a cross-sectional design. This study is also a descriptive study because it examines other variables related to the problem. This study was conducted at Kalisat District Hospital, Jember during April-July, 2013. The data were collected in April 2013 from prescription forms. Meanwhile, in July 2013, the researchers distributed a questionnaire to the doctors as respondents. The samples of the study were all functional doctors as well as prescription documents at Kalisat District Hospital. The hospital has 12 doctors which consist of 6 general practitioners, 2 dentists, 4 specialists (neurologist, gynaecologist, anaesthesiologist, and orthopaedic). Meanwhile, the obtained document samples were 50 prescription documents taken randomly from the data on prescription medical

records by using computer application in the Pharmacy Unit of Kalisat District Hospital for 2 weeks starting from April 15-April 27, 2013.

The independent variable of this study was the doctors' perception of supervision on medicines. The doctors' perception was assessed through a questionnaire about the monitoring and evaluation of medicine prescriptions over the past few years by the Pharmacy and Therapeutics (P&T) Committee. Meanwhile, the dependent variable was the doctors' obedience in prescribing generic drugs.

RESULTS AND DISCUSSION

Doctors' Perception of Supervision on the Medicines Prescription

The doctors' perception of supervision on medicines prescription is the doctors' assessment of the activities of the Pharmacy and Therapeutics (P&T) Committee which include supervision on medicine prescription and formulary evaluation on both generic formulary and generic complementary for the past year. The indication used to assess doctors' perception is by monitoring and evaluating activities carried out by the Pharmacy and Therapeutics (P&T) Committee within one year. The Pharmacy and Therapeutics (P&T) Committee monitors and evaluates the use of generic formularies and generic complementaries (patent medicine) as well as their side effects. The result of the study on the variable of doctors' perception of supervision on medicine prescription could be seen in Table 1. Based on Table 1, it showed that 33.3% out of 12 doctors answered good medicines supervision, those who answered adequately were only 8.3%, and those who answered poorly were 58.3%. From the data above, it could be concluded that the supervision on medicines prescription at Kalisat District Hospital is poor, based on the doctors' perception with the highest percentage of 58.3%.

Table 1. Doctors' Perception of Medicine Prescription Supervision at Kalisat District Hospital Based on Score Criteria in July 2013.

Supervision of Medicine Usage	General Practitioner		Dentist		Specialist		Total	
	n	%	n	%	n	%	n	%
Good	2	33.3	2	100	0	0	4	33.3
Adequate	0	0	0	0	1	25	1	8.3
Poor	4	66.7	0	0	3	75	7	58.3
Total	6	100	2	100	4	100	12	100

To complete the data, the researchers also assessed the doctors' perception of drug formulary supervision and evaluation at Kalisat District Hospital in July 2013 based on the doctors' specifications, such as general practitioner, dentist, and specialist. The result showed that the dentists assessed that the supervision and evaluation of the formulary at Kalisat District Hospital were good. Meanwhile, the general practitioners and specialist doctors assessed that the supervision and evaluation of formulary were poor.

The study results regarding the doctors' perception of supervision about medicines

prescription indicated that the doctors felt unattended when prescribing medicine. The Kalisat District Hospital evaluated the formulary, but there were no supervisions on medicine prescription. Based on the information from the Pharmacy Unit, supervision on medicines prescription and formulary evaluation at Kalisat District Hospital was carried out by the pharmacy, and only recorded the use of medicines that were often used to increase its amount at each formulary evaluation. Based on this matter, after the registration process of the frequently used medicines, the pharmacist should report to the

Pharmacy and Therapeutics (P&T) Committee for cross-checking the use of generic drugs, checking whether the use of generic drugs was in accordance with the standard or not. Besides, the Kalisat District Hospital should make a system on reward and punishment in terms of prescribing. The doctors who often prescribe generic drugs would be rewarded, and those who often prescribe patent medicines were given a penalty. It is necessary to motivate the doctors to increase the prescription of generic drugs at Kalisat District Hospital. Through this system, doctors will think carefully before they use prescription of patent medicines, thus they are expected to prescribe generic drugs.

Supervision is defined as an activity of seeing and paying attention to people's behavior by observing, maintaining, and controlling. The term of supervision is not distinctive from monitoring. WHO (2011) defined monitoring as an activity of tracking and reporting regularly about information regarding the development of a program, the output, and the desired result. Supervision is also meant to collect data from all relevant sources to analyze what is happening, where, and by whom. Monitoring uses a set of core indicators and targets to provide timely and accurate information for partners to inform about performance progress. Evaluation is built based on monitoring, but the analysis goes more in-depth, considering the factors that affect the situation. Monitoring and evaluation are crucial to be conducted to a policy or program that is being implemented. As a result, if an unexpected event happens, it can be early solved.

Aprilia and Ayuningtyas (2013) stated that supervision is a method used to evaluate the doctors' prescription. Supervision and evaluation of medicine prescriptions are needed to be conducted in order to reduce the incidence of medication errors. The lack of attention is one of the factors that can cause medication errors (Luz et al., 2016). The lack of attention can also be interpreted as a lack of supervision on medicine prescriptions. Lack of supervision will also affect someone's responsibilities, especially doctors, in prescribing medicines. A study conducted by Luz et al (2016) stated that the other cause of medication errors is the high workload caused by a small number of workers.

A medication error is a severe problem in the world and one of the most common medicinal errors that threaten patient safety and even causes death (Gorgich et al. 2015). The other study was also conducted by Gorgich et al. (2015) on Khatam-al-Anbia Hospital's nursing staff and Iran's Zahedan midwifery nursing internship student. The result showed that the most common cause of medication error in nursing was fatigue because of high workloads (97.8%). For nursing students, the error was regarding medicines calculation (77.4%). According to the nurse's point of view, other factors that affect medication errors were the heavy workloads, a large number of patients who were in critical conditions, doctors' unreadable order, unequal ratios between nurses and patients as well as environmental conditions that may cause interference has the highest impact on medication errors in nursing. From the study, it was found that

the doctors' unreadable command might cause the most significant impact on medication errors in nursing. The doctors' unreadable command could also come from prescription writing that was difficult for nurses to understand. In connection with the cause of medication error and the importance of preventing medication error as the measurement of the healthcare quality, reducing workload must be done by increasing personnel. The number of workers should be proportional to the number and condition of patients, and managers must resolve problems related to human resources. An adequate system innovation such as electronic medicine cards to supervise doctors' written prescription is a must, as it will help the nurses and pharmacists to understand the prescription written by the doctors. Also, it can reduce medication errors due to unreadable doctors' handwriting. The supervision is not only referred to the frequently used medicines but also including supervision on doctors' obedience in using generic drugs according to the established standard.

Doctors' Obedience

Measurement of doctors' obedience level was performed through prescription document analysis. A total of 50 prescription documents were taken randomly using the computer application from the data of prescription medical records of the Pharmacy Unit at Kalisat District Hospital for 2 weeks in April 2013. Prescription documents were taken from April 15-April 27, 2013.

Table 2. Doctors' Obedience Level in Prescribing Generic drugs out of 90% Prescription Standards in April 2013 at Kalisat District Hospital.

Obedience Level	Number of Prescription (n)	Percentage %
Obey	34	68
Disobey	16	32
Total	50	100

The results of the secondary data shown in Table 2 showed that 34 or 68% of total prescription documents had obeyed the standard in using generic drugs, while 16 or 32% of total prescription documents had not used generic drugs. Based on the data, the conclusion was the level of doctors' obedience in prescribing generic drugs at Kalisat District Hospital in April 2013 was 68%, far below the standard of 90%.

Hassali *et al* (2014) stated that the quality of generic drugs and successful implementation on generic substitution and generic prescription required communication and cooperation of all parties involved in the process. According to the statement, as a recommendation to increase the use of generic drugs, there should be cooperation among healthcare professionals such as pharmacists, doctors, and other prescribers and providers. The doctor, as someone who is directly related to the patient, should be able to cooperate. The

cooperation that could be performed was by obediently prescribing generic drugs.

Obedient is a behavior that shows adherence to orders, rules, and so forth. Meanwhile, according to Mcleod (2007), obedient is one type of social behavior where a person tends to obey and keep the command given by authority figures. From this definition, it can be interpreted that people will do particular behaviour in the presence of supervision and element of the commands given by the authorities. The low number of prescription that uses generic drugs can be caused by the lack of obedience regarding the regulation about an obligation to use generic drugs.

Mahfudhoh and Rohmah (2015) stated that if someone believes that the institutions which organize the programs are the institution that has the status of validity, prestige, and honor, then those institutions will be obeyed by the members of the organization. Related to this statement, the Pharmacy and Therapeutics (P&T) Committee has a role as the program organizing committee. If the Pharmacy and Therapeutics (P&T) Committees properly supervise the generic drugs prescription, the members of the organization will obey the regulation, especially when they prescribe generic drugs. Leaders also hold an important role. A study conducted by Aprilia and Ayuningtyas (2013) explained that leaders who were less assertive and lacked in socialization regarding the use of medicine in accordance with the formulary influenced the doctors in prescribing medicine.

Another supporting study was from Mahfudhoh and Rohmah (2015). The research focused on the factors that influence prescribing obedience according to the formulary. In their research, the obtained results showed that factors which hold significant correlation to prescribing obedience according to formulary at the Outpatient Unit of Jemursari Islamic Hospital Surabaya are personal responsibilities, peer supports, and adjacency with authority figures. The study results were in accordance with the Milgram experiment regarding the personal relationship with the authority figures (Mcleod, 2007). When the doctors were personally close to the authority figures, they were more likely to obey the medicine prescription policies. It greatly determined the obedience of formulary based prescriptions. If between the doctors and the authority figures are not personally close, which in this study is the Pharmacy and Therapeutics (P&T) Committee of the Hospital as the party who should supervise generic drugs prescription, it will be challenging to support the doctors' obedience behavior.

Based on the study conducted by Flood *et al.* (2017) about the perception and utilization of generic drugs in Guatemala, the research targets were doctors and pharmacists. There were 12 doctors and 30 pharmacy staff from three locations in Central Guatemala. The results showed that 41% of the pharmacy staff believed that generic drugs were not as safe as medicines with commercial brand names, while 33% of them believed that generic drugs were not effective. Meanwhile, 55% of doctors believed that generic drugs were not as safe as medicines with

commercial brand names, and 55% of them also said that they were not effective. Nine respondents also said that they objected to using generic drugs, they argued that generic drugs did not have good quality and did not offer the same results on patients. The doctors who became the respondents admitted that the quality of generic drugs depended on the capability of companies which produced the generic drugs, and the low price of generic drugs showed their inadequate quality. From the research conducted by Flood *et al.* (2017), it could be concluded that doctors' perception of generic drugs influenced their willingness to use generic drugs for patients, therefore it also influenced their adherence in medicines prescription by using generic drugs. Whereas basically, generic drugs are one of the pharmaceutical preparations that have fulfilled the pharmacopeia requirements and passed the manufacturing process according to the article about how to produce proper medicinal drugs (Yusuf, 2016).

The doctors' perception of generic drugs that would support their obedience in using generic drugs was also influenced by information factors. The study results of Tsaprantzi *et al.* (2016) showed that information played a significant role in generic drugs. Information provision altered misconceptions about the safety and efficacy of generics and increased doctors' and patients' confidence in adhering to generic substitution policies. Hence, more given information about generic drugs is expected to change doctors' attitudes toward the use of generic drugs.

Table 3. Correlation Between Perception of Supervision and Obedience on Generic Drug Prescription at Kalisat District Hospital in July 2013.

Medicine Prescription Supervision	Prescription Obedience				Total	
	Obey		Disobey		n	%
	N	%	N	%		
Good	4	100	0	0	4	100
Poor	4	50	4	50	8	100
					12	100

The Correlation between Doctors' Perception of Supervision on Medicine Prescription and Obedience

The doctors' perception of supervision on medicine prescription is the doctors' assessment on the activities of the Pharmacy and Therapeutics (P&T) Committee which include supervision on medicine prescription and formulary evaluation both on generic formulary and generic companion formulary for a year. Table 3 showed the doctors at Kalisat District Hospital who adhered to the policies of prescribing generic drugs. It reached 100% of them believed that there was supervision on medicine prescription carried out by the Pharmacy and Therapeutics (P&T) Committee. Based on the test conducted, the result showed that the value of X^2 was 1.172 with a significance of 0.041 and r 0.500, which meant there was a correlation between the supervision on medicine prescription with the

obedience on prescribing generic drugs. The strength of the relations was considered moderate.

It was noticed that there was a correlation between medicine supervision and prescription obedience. The obedient doctors tended to have a good perception of supervision, and disobeyed doctors tended to ignore the supervision. This statement was in accordance with the study by Mahfudhoh and Rohmah (2015) which stated that obedience is one type of social behavior where someone obeys the requests of others to do something because of authority. The person who has legal authority in this study was the Pharmacy and Therapeutics (P&T) Committee and Director. Doctors' who perceived that their ways of prescribing would be monitored and evaluated by the Pharmacy and Therapeutics (P&T) Committee tended to obey the regulation of medical prescription.

CONCLUSION

Based on the results, it can be concluded that the doctors' perceptions towards supervision on generic drugs prescription are poor, considered from the doctors' perception percentage with the highest percentage of 58.3%. The standard level of doctors' obedience in prescribing generic drugs is 90% from the total of given prescription, while it only reached 68% in April 2013 at Kalisat District Hospital. It means that they have not reached the standard for generic drugs prescription. Based on the tests conducted, it shows that there is a correlation between supervision on medicine prescription and doctors' obedience to generic drugs prescription. The obedient doctors tend to have a good perception of supervision, and those who do not adhere to the prescription standard are less generic. The supervision of medicine prescription and obedience of generic drugs prescription have a moderate correlation.

The Kalisat District Hospital should increase the supervision of medicine prescriptions to optimize the use of generic drugs. The socialization must also be carried out continuously by the management of Kalisat District Hospital together with the Pharmacy Unit regarding the importance of prescribing generic drugs. The system of reward and punishment in terms of prescribing can also be implemented. As for doctors who often write generic prescriptions will be rewarded and those who often prescribe patent medicine will be given a penalty. It aims to motivate doctors to increasing generic drugs prescription at Kalisat District Hospital. This system will make doctors think carefully before they prescribe patent medicine, thus it is expected that they will prescribe more generic drugs.

CONFLICT OF INTEREST

The authors state that there is no conflict of interest for this article.

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