



Implementation of Informed Consent on Hormonal Injection Contraceptive among Family Acceptors: A Phenomenology Study

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Abstract. Every medical treatment conducted by health professionals has to be based on consent from patients. This consent is obtained through informed consent. Informed consent is a communication process between health professionals and patients on approving the medical treatment. This study's objective was to explore the implementation of informed consent on the acceptor of the hormonal injection contraceptive family plan method. This study was a qualitative study using a phenomenology approach, in which the data analysis initialized by reducing interview results. Data were verified using data triangulation, and the research conclusion was developed. The participant of this study were three midwives and one primary midwife. The study identified three themes on implementing informed consent, including: 1) human resources, 2) the implementation of informed consent, and 3) the policy to implement informed consent on preferring the hormonal injection contraceptive. The acceptor adherence on signing the informed consent is considered low. Thus, the health education and approach of informed consent from health professionals are essential to increase public awareness, particularly the family plan contraceptive acceptor.

Keyword: *Puskesmas*, Hormonal Injection
Contraceptive; Family Plan Method, Informed Consent



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INTRODUCTION

Population issue arises in every country, particularly developing countries, including Indonesia, which is the vastly increasing number. The increasing population creates several

problems on education, economy, work productivity, and the growing unemployment. Thus, to reduce the rising population, the population growth has to be suppressed through the Family Plan program(1).

The law Number 52 the Year 2009 on citizen development and family establishment, Family Plan is formed to increase the awareness and community participation to manifest the small and wealthy family norm(2).

The family Plan program requires the infrastructure to support its' implementation. In this case, the needed infrastructure, namely the health professionals such as doctors and midwives, adequate medical equipment, and the cooperation with the users, the program acceptor. In order to carry out the family plan program, health professionals have to provide information or counseling on the contraceptive method, whether such as its' types, classifications, and usage methods. Counseling given have to be as clear and detail as possible (3).

Health services in the Family Plan program are regulated in Article 78 Law Number 36, the Year 2009 on health. The health service realizes that every health professionals obliged to provide informed consent to their patients. Providing informed consent is required because so often, the midwife would face emergency cases while providing family plan services (4).

Every medical treatment conducted by health professionals has to obtain permission from the patient. This permission is obtained through informed consent. Informed consent is a communication process between health professionals and patients related to the medical treatment agreement. It is aimed to provide complete information on the illness and medical treatment that will be conducted so the patient able to decide the therapy themselves (5).

In a study by Achmad Busro, it is stated that informed consent is a significant part of health services and an obligation by the law of health professionals to their patient(6).

Adriana Pakendek, in her study, stated that an informed consent form signed by the patient is liable for court evidence if there is prosecution in the future. The study also noted the imperative of conducting informed consent because approval of medical treatment by health professionals have to be documented (7).

The previous study by Friska Realita resulted that among 5 participants on implementing medical treatment (informed consent) activity, two respondents stated that health professionals sometimes explain. In contrast, three respondents did not conduct the medical treatment consent, whether oral or written consent. This unapplicable of medical treatment approval caused by the unclear explanation from health professionals, patient decline to be given a reason, and social, economic, and education factors (8).

Family Plan program initially oriented to achieve the target that in line with the program development now change to be more quality-oriented. The program's focus is on the quality of care of Family Plan program services and healthy reproductive health. The process of family plan service has to be initiated by providing complete and transparent information through counseling care(1).

One of the challenges in providing Family Plan care is not optimum availability, accessibility, and family plan care quality. Thus the guideline of providing good quality of care is needed (9).

Medical counseling care is needed considering that the client has to decide the proper contraceptive that fits their medical status and characteristics. Thus, the national family plan program currently focuses on increasing care quality and fulfilling the client's reproductive rights and partner. The Family Plan Management Guidelines stated that husband/wife have equal rights and obligation to decide on the managing birth.

Before contraceptive care, the client and partner must obtain complete, precise, and appropriate information from health professionals to decide on their preferences. The

contraceptive method's decision must be started by filling out the Informed Consent form to ensure that the husband and wife agree on the chosen birth control and strategy used.

Indonesian Ministry of Health Regulation Number 369/MENKES/SK/III/2007 on the midwife profession standard defines the second verdict as the guidelines for midwives in conducting their profession. The said regulation stated that providing information on patient/family, the presence of a witness is essential (10).

Based on the above policies, in deciding medical intervention to the patient, health professionals must obtain *informed consent* (an agreement of treatment based on the information or explanation provided).

A previous study from Rifatolistia in 2016 showed that informed consent in contraceptive method usage has already been conducted. However, It was not in line with the policy on population development and family establishment, which stated that deciding a contraceptive method is done by both legal husband and wife. The improper implementation of obtaining informed consent on family plan program by health workers poses a law consequence (11).

Puskesmas Kota (Kota Public Health Center) is a public health center in Manggarai Regency that leads 3 sub public health center (*pustu*) namely *Pustu* Kumba, *Pustu* Tenda and *Pustu* Karot. Based on the interview by this study researcher on midwife manager in *Puskesmas* Kota, it is found that *Puskesmas* Kota has already implemented the Family Plan Care based on the guidelines. However, obtaining informed consent has not been 100% done based on the guidelines mainly because almost all the Family Plan Program acceptor come to the health care by themselves without partner/husband's companion. Thus the informed consent form is signed by the acceptor only. Another challenge in implementing informed consent is that many acceptors were experiencing poor quality of care due to the acceptor's habit of buying contraceptive pills by themselves in the drugstore or pharmacy. Also, they met the health professionals by themselves to inject the contraceptive without consulting the health care services, in this case, *Puskesmas*.

The client's consent is significant to provide a more comprehensive, lasting use of contraceptive and client's comfort in deciding contraceptive method, considering that the current approach of care is providing good quality of care by qualified human resources and good quality product, based on a study by Ayu Windara (12).

Based on the above gap study and analysis, the researchers decided to conduct a phenomenology study on the Family Plan Program, particularly the hormonal injection contraceptive method acceptor, to evaluate the acceptor's implementation of informed consent.

OBJECTIVE

The study aimed to explore the implementation of informed consent on family planning of hormonal injection contraceptive program.

METHOD

This study was a descriptive qualitative study with a phenomenology approach, focusing on informed consent in contraceptive care. This study used a qualitative method to obtain a comprehensive description of implementing informed consent on the Family Plan Program acceptor. The study informant selection was based on the following criteria: midwives as the care delivered in each sub-public health center and midwife manager/coordinator in Kota Public Health Center. The sampling technique used Purposive Sampling with the requirements determined by inclusion and exclusion criteria. The inclusion criteria in this study including; 1) The midwife that carries out informed consent, 2) Education level Diploma III, 3) Willing to be study informant, and 4) Physically and mentally healthy

The exclusion criteria such as 1) ducation level Diploma II, and 2) The midwife that works outside Kota Public Health Center. This study recruited three informants with education qualification Diploma III of Midwifery and one midwife manager/coordinator that worked in Kota Public Health Center. The study aimed to evaluate the implementation of informed consent on the Hormonal Injection Contraceptive Family Plan Program acceptor. The sampling collection is the care provider/coordinator midwives that carry out the Mother and Child Health (*Kesehatan Ibu dan Anak/KIA*) and Family Plan Program (*Keluarga Berencana/KB*). Informants were assumed to have adequate knowledge and understand the issue related to informed consent and trusted data sources.

This study was conducted in Kota Public Health Center for one month. The data collection technique in this study was an in-depth interview on the Family Plan program. An in-depth interview was carried out for three weeks. The topics discussed during the interview are about the midwife's understanding of Family Plan counseling, place to conduct the counseling, the aim of the counseling, the counseling schedule, the pathway of counseling, the understanding of informed consent, policies related to informed consent, and the implementation of informed consent. To ensure data validity, this study used the triangulation method.

Triangulation used in this study was data source triangulation conducted by an in-depth interview with the informants. Data source triangulation was aimed to guide the researcher on data collection, so the researcher would use various data sources to explore the same data. Thus, one source's data can be tested by comparing the same data obtained from different sources. Data analysis was carried out from interview reduction, then verified through triangulation and followed by research conclusion.

RESULTS

This study presents interview result of each informant on the implementation og informed consent of contraceptive insertion by midwife in *Puskesmas* Kota.

Table 1 Informant's characteristics

No	Code	Age	Education Level	Position
1	B1	46 years old	D III	Midwife
2	B2	47 years old	D III	Midwife
3	B3	48 years old	D III	Midwife

Based on table 1, it is showed informant's criteria in this study are midwives with a longer working experience and education qualification is diiii of midwifery. informant's range of age is from 40 to 65 years old. the information obtained informants were validated by cross checking the data with 1 (one) midwife manager of family plan care in *puskesmas* kota.

Table 2 Triangulation characteristics

No	Age	Last Education Level	Position
1	49 years old	D III	Midwife manager in <i>Puskesmas</i> Kota

Midwife manager assigned as a midwife who manages and coordinates every mother and child health activities including family plan care in a *puskesmas*. Midwife manager is considered the more competent midwife to provide information on the implementation of informed consent in contraceptive insertion.

In-Depth Interview

This study result was obtained by processing the raw interview transcript collected, the data collected then being analyzed and given keywords to answer the study purpose. the keywords then being categorized and then each category was grouped as themes. categories and themes obtained and developed into a narration. the result of this study was exploring the midwives perception related to obtaining informed consent on contraceptive insertion care. from the in-depth interview, all of the informants define the informed consent as the agreement of the intervention given, eventhough they explain with different form of sentences.

The informant's statement related to informed consent are as follows:

" Informed Consent is a process of delivering information to the patients through a medical consent form before conducting medical intervention/treatment. " (B1)

"Informed consent is a letter of agreement signed before the medical intervention and have to be approved by the client and witness., in this case, the presence of witness is needed"(b2)

" Informed consent is an approval letter provided by the health professionals to the patients to be consent on the treatment (B3)

It can be conclude that the perception of three informants related to informed consent are the same in the sense that informed consent defined as the patient's approval before the medical treatment conducted. The implementation of informed consent done in *puskesmas* kota was not consistent to the procedure. it is due to the lack of human resources such as stated in the interview:

" B1: the actively working midwives is qualified enough by their educational background and quality of care. While from working quantity is still low, thus, the education and training on the guidelines of Family Plan Care to the acceptors is important to be given"

"B2: education qualification for midwives to fill the job is in line with the demands. the main challenge on implementing informed consent are the quantity of the unavailability of specific place for family plan care thus the information provision and implementing informed consent could not be done well"

"B3: the qualification of working midwives are in line with the regulation, but the quantity of the health professionals must be increased"

From the above statements it can be concluded that there is the demand for the continuous training and re-learning the materials related to the guidelines of obtaining informed consent in family plan care. The training and workshops could be able to increase the implementation of informed consent in *Puskesmas* Kota. The purpose of this activities are for the midwives tto emphasize the important of informed consent to the acceptor/client that using Family Plan Care.

B1: the implementation of informed consent conducted in a manner that responsible to the religions, cultural values, ethics, and health respectively. thus, in obtaining informed consent, the presence of witness is a must. the challenge happened so far is most of the acceptor come without witness. thus the signing of informed consent form does not comply with the regulation. the acceptor candidates often signed the form themselves"

" B2: obtaining informed consent is important because the contraceptive care is including contraceptive care movement, providing or inserting contraception and the management of contraceptions' side effects, complications, and failure, thus it is very important to sign the informed consent with the presence of witness. the challenge that we face so far is that the acceptors does not have witness. then they signed the form themselves. even in the puskesmas, the adequate data on informed consent is very poor due to the acceptor's bought the hormonal injection contraceptive by themselves in pharmacy and ask their known/relative whose health worker to inject the contraceptive at home.

" B3: the implementation of obtaining informed consent of medical treatment is usually conducted by husband/witness while on the family plan method counselling. the implementation of informed consent in puskesmas kota is conducted but not optimum yet. it is due to the acceptor who comes to the care usually come alone without accompanied by the husband/witness, so the informed consent form signing does not comply with the existed policy. the main challenge continually happen in puskesmas kota is that there were alot of Family Plan Program acceptor are not documented because they choose to buy the hormonal contraceptive injection by themselves in pharmacy and find the health worker on their own"

To achieve success in implementing informed consent, it can be concluded extra needed work from the health professionals, particularly midwives. Health professionals need to provide the continuum of care in the Family Plan Care, including reproductive health education to adolescents, counseling for brides and grooms/ women of childbearing age, counseling to the pregnant mothers, and Family Plan education on postpartum women and family. In the continuum of care, a witness's presence, mainly a husband, is essential in deciding the preferred contraceptive method. Thus, the regulation on implementing informed consent is needed.

" B1: the regulation related to the implementation of informed consent is running. It needed comprehensive care from midwives to do health education about filling the informed consent form.

" B2: the policy exists and running. It takes hard work from midwives to re-explain the importance of signing an informed consent form.

" B3: the regulation exists and running, but most of the patients did not understand the importance of it. Thus the incomplete data has happened in Puskesmas Kota.

The researcher concludes that to reduce the incomplete informed consent data, health professionals need to evaluate and socialize on the importance of Informed Consent. If the client offers the incomplete filled and signed by the witness in the informed consent form, the client must be sent home and unable to obtain the care.

DISCUSSION

Midwife perception on informed consent

Based on the study result, it can be analyzed that every informant has the same perception of the definition of informed consent, which is the approval of medical intervention. The same opinion was obtained, possibly due to the informants' same

educational background, which is Diploma III of Midwifery. Informed consent not only appertains the health professionals as a care provider but also the patient as care receiver.

According to PERMENKES (Minister of Health Regulation), Number 290 the Year 2009 on medical procedures approval, article 1 point 1 stated that approval of medical procedures is the approval given by the patient to physician after the patient obtain the complete explanation on the process that will be conducted on the patient (13). The study by David J Hilger, 2018 stated that informed consent is essential to provide information to the patient on medical risks and the ethics of contraception selection (14).

This study also in line with the study from Lestari et al., 2017, which resulted in all respondents on the study stated the same perception on the definition of Informed Consent, which is the approval of the emergency procedure. The participant in this study is the midwives with diploma III of Midwifery education qualification. In this study, the informant stated that they had been taught the theory of informed consent when they went through the midwifery education program's Diploma of III and further emphasized the Diploma of IV of the Midwifery program (15).

A study conducted in the US by Holly Goldberg (2009) obtained that every woman has to base their care decision upon accurate, updated, and understood information. The evidence of the effort to achieve these rights is through informed consent. The midwives acknowledge informed consent as the information that protects the patients and their rights on accepting or rejecting any medical procedures. The knowledgeable consent implementation has been long practiced in the US (16)

The implementation of Informed Consent

Informed consent's implementation is not following the standard procedure, mainly caused by the lack of human resources. Based on the informants' interview, most informants conclude that the performance is not following the existed procedure. The opinion was formed by their direct observation on education quality and qualification. A vital component to increase the documentation and report related to Informed Consent is the education and training on the manual of Family Plan intervention on the acceptor to fulfill the midwives' working quantity. The Manual of Family Plan Care needed to be trained, including: 1) The implementation of Family Plan care; 2) The pathway of Family Plan care in the health care facilities; 3) The path of documentation and report of Family Plan Care; 4) The monitoring and evaluation of Family Plan care

This study result is in line with the study from Haryani 2016, which resulted that the information provided in the health care settings is appropriate according to the standard. Still, the identity completeness and authentication in informed consent is in the poor category meaning it is incomplete/not adequate. This study suggests for the policymakers to consider the complete informed consent that has to be filled by physicians, nurses, or midwives (17)

The regulation related to implementing informed consent on selecting hormonal injection contraceptive

To achieve the success of implementing informed consent, it requires effort from health professionals to carry the comprehensive care on Family Plan program, including reproductive health education to adolescents, counseling to reproductive age women and partners. It has the complete care to emphasize the pathway of family plan care, including informed consent. The policy related to the importance of informed consent implementation has to be enforced by health professionals. The challenge faced while conducting this study is that the informed consent does not sign by the witness (husband or relatives). This is due to the client/Family Plan program acceptor attend the public health center by themselves without

witness accompanied. Thus, the informed consent signing is carried out by the acceptor themselves, without family/relatives' approval.

This is in line with a study by Wandarti conducted in Pipin Midwife Private Clinic (*Bidan Praktik Swasta/BPS*) (2011), where informed consent was obtained without the fixed procedure and regulation. So the acceptor unable to provide their informed consent appropriately that correspond to the system (18)

The Manual of Family Plan Care Management (*Pedoman Manajemen Pelayanan Keluarga Berencana*) (2014) has explained the pathway of Family Plan care for every healthcare facility. The pathway started with the client attend the care show their membership card. The midwife provides counseling in Mother and Child Health/Family Plan (*KIA/KB*) room to select their preferred family plan care. After the maintenance is approved, the physical examination is carried out. The informed consent is signed, followed by providing the family plan care and the medical monitoring and post-procedure health advice (3).

CONCLUSION

Based on the study result conducted in Kota Public Health Center of hormonal injection contraceptive family plan program acceptor, it obtains that the implementation of informed consent are as follows:

- a. Informants in this study midwives state the same perception on the definition of informed consent which is the approval
- b. the implementation of informed consent is not operating consistently with the regulation. thus the training and workshop on the manual of implementing family plan care is needed
- c. to achieve the adequate result on implementing informed consent, health professionals have to provide health education on the acceptor related to the importance of filling and signing the informed consent
- d. The regulation on informed consent is important component.

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