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Original Research Paper

Overview of the application of informed consent in family planning services

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Abstract
The results of the study of the patient safety management team in Indonesia for health services revealed that the provision of informed consent in various healthcare institutions needs to be optimal. Most health workers only ask patients and families to sign informed consent without providing a detailed explanation. This condition certainly affects the knowledge of patients and families. Knowledge of patients and families can cause problems if desirable things happen. This study aimed to describe the application of informed consent in family planning services at Anisa Yogyakarta Independent Midwife Practice (PMB). This study used descriptive qualitative methods. The sampling technique using snowball sampling technique amounted to 4 midwife informants and four acceptor informants. The results of in-depth interviews conducted with four midwife informants said that the implementation of informed consent in family planning services at the Independent Midwife Practice (PMB) had gone well. The midwife had carried out the obligation to ask for consent and provide information while for the completeness of filling out informed consent, 14 informed consent filled in, as many as eight informed consent and six incomplete informed consent and from in-depth interviews, the acceptor was able to explain the contents of the informed consent. Acceptor informants said they signed the action consent sheet after the midwife explained about family planning (KB) that acceptors would use. The informed consent application in family planning services at the Independent Midwife Practice (PMB) has generally been done well. Still, the completeness of filling out informed consent has yet to be maximized, and acceptors generally understand informed consent in family planning services.

Keywords: family planning services; informed consent; qualitative

1. Introduction

The Indonesian government has launched various programs to address population issues. One is the National Family Planning program (Nurhidayati & Setyoningsih, 2021). The National Family Planning Program, which was originally oriented towards achieving targets, in line with the development of the current program, has changed to be oriented towards the quality aspects of great concern in the service of the Family Planning (KB) program and healthy reproductive health. In the process of family planning services, it must begin with providing complete and clear information through counseling services (Wandira, 2020).

Based on PMK Number 28 of 2017 concerning Licensing and Implementation of Midwife Practice in Article 28 letter d, midwives are obliged to seek approval for actions to be taken in carrying out midwifery practice. Asking for approval of action is the same as asking for approval of medical action (informed consent) to the patient. The provision of informed consent is only part of the many existing KB acceptors, proving the need for more implementation of informed consent in KB acceptors. Sofar, evaluating the use of the required forms is rare, including implementing informed consent forms. (Kristiana, 2021). The informed consent form must be written in language that is easy to understand, minimize the possibility of coercion or undue influence, and be given sufficient time to consider.

Informed consent is not just a signed form but a process where the patient understands the actions to be taken and the risks that can occur, clearly explainedin the code of ethics and laws and regulations (Manti & Licari, 2018).

Internationally, standards of informed consent practice continue to evolve. The explicit protection of medical treatments and procedures has long been upheld by international law, although actual informed consent practices vary by country and can be influenced by cultural factors. Overall, there is a trend towards more patient-centered informed consent standards. A good informed consent standard generally consists of a discussion between the patient and the doctor or health worker where the health worker provides an explanation or information about the treatment, followed by signing an informed consent form (Feinstein et al., 2021).

The results of the study of the patient safety management team in Indonesia for health services revealed that the provision of informed consent in various healthcare institutions could have been more optimal. Most health workers only ask patients and families to sign informed consent without providing a detailed explanation. This condition certainly greatly affects the knowledge of patients and families. Poor knowledge of patients and families can cause problems if undesirable things happen (Ministry of Health, 2016). Good knowledge can provide an understanding of the benefits of informed consent given to patients, both good and bad, and the impact of actions taken later (Feinstein et al., 2021).

Informed consent in family planning services is very important. This aligns with the International Code of Ethics for Midwives that midwives must respect women's rights after receiving an explanation and encourage women to accept responsibility for the results of their choices (Lestari & Innaka T, 2021). There is often debate about how much information should be given to patients for informed consent. Inadequate information, especially about serious risks, is unsatisfactory. However, too much information can also be a problem, as patients may be overwhelmed with information leading to indecision and unnecessary procedures (Hilger et al., 2018). The impacts that will occur if informed consent in family planning services is not implemented properly include a lack of information about how contraceptive methods work, causing acceptors to change often ways of using contraceptive methods, which can cause boredom and ultimately stop using contraceptives, which has an impact on increasing drop out of contraceptive use (Donsu et al., 2013).

The results of Pratiwi's research (2018) state that midwives have carried out the obligation to seek approval for actions according to the obligations of midwives, but the implementation of informed consent in the labor process carried out by midwives has not been carried out optimally because there is no information provision sheet that the patient should sign after the midwife provides an explanation and the completeness of the contents of the informed consent form by midwives is considered very lacking compared to the informed consent form by doctors and dentists (Pratiwi, 2018). Meanwhile, based on the results of research conducted by Puji Astuti and Kristiana in 2020 at one of the Yogyakarta PMBs. The implementation of informed consent for midwifery services at PMB has gone well, and information has been provided. Meanwhile, based on the results of a documentation study at PMB on 7 KB medical records and ten labor medical records, it was found thatfor filling out the KB action approval sheet from 7 medical records/approval sheets, 2 of them were invalid because there was no signature on the action approval sheet while on the delivery approval sheet from 10 medical records, 4 of them did not have a midwife's signature. One witness must still sign the approval sheet (Pujiastuti & Kristiana, 2020). The results of previous studies state that the application of informed consent in PMB and other health facilities still needs to be implemented. The causes include the absence of the signature of the midwife or patient on the informed consent sheet, the unavailability of informed consent which the patient should sign after the midwife explains, and the completeness of the contentsof the medical action consent form.

Based on this description, the researcher is interested in researching the description of the

application of informed consent in family planning services at Anisa Yogyakarta Independent Midwife Practice (PMB). The purpose of this study was to determine the description of the application of informed consent in family planning services at Anisa Yogyakarta Independent Midwife Practice (PMB), the completeness of filling out informed consent in family planning services, and understandingof family planning acceptors related to informed consent in family planning services at Anisa Yogyakarta Independent Midwife Practice (PMB).

2. Research Methods

The research design used in this study is descriptive qualitative. The informants in this study were four midwives at PMB Anisa and four family planning acceptors who performed family planning services at PMB Anisa, with the criteria of new family planning acceptors and family planning acceptors changing methods. The sampling technique used in this study was snowball sampling. Snowball sampling is a data source sampling technique that initially amounts to a small amount, gradually becoming large (Sugiyono, 2020).

The instruments used in this study were interview guidelines, tape recorders, cameras, and notebooks. Interview guidelines were used as a reference in conducting interviews with informants. Interview guidelines are designed to facilitate researchers in obtaining information from midwives and couples of childbearing age who perform family planning services (Sugiyono, 2018). The questions asked to the informants were semi-structured, among others, about how informed consent was implemented at PMB and what explanations midwives gave to KB acceptors and acceptors'.

Understanding of the consent form or informed consent, the interview was conducted for ± 10-15 minutes. Data collection techniques in this study were interviews, observations, and document studies. Document studies were conducted on informed consent forms filled out by midwives during the study time, as many as 14 informed consent forms.

The data collection stage in this study begins with conveying the research objectives to midwives and couples of childbearing age who perform family planning services, then asking for consent to become informants by giving informant consent sheets to be signed. The data source collection technique is that the researcher's informants were initially midwife informant one and family planning acceptor 1 (Inf B.1 and Inf A.1), whom the researcher interviewed, then the researcher conducted interviews with midwife informant two and family planning acceptor 2 (Inf B.2 and Inf A.2). From 1 and2 informants, they have not obtained complete data, so the researchers conducted interviews with midwife informant three and family planning acceptor 3 (Inf B.3 and Inf A.3). From midwife informant three and family planning acceptor 3, the researcher has not obtained accurate data, so the researcher continues to midwife informant four and family planning acceptor 4 (Inf B.4 and Inf A.4), until the midwife informant four and family planning acceptor four the data is saturated, so the data source sample is sufficient,so there is no need to add new samples anymore. The data that has been collected is then examined several times and searched for keywords that are by the research objectives. The keywords that have been obtained are summarized into categories and themes. After that, researchers grouped keywords containing categories and themes into research results in the form of narratives.

The process of analyzing themes in this study was carried out manually, starting with interviews with informants. If the interviewee's answer after being analyzed feels unsatisfactory, the researcher will continue the question again until a certain stage obtains data that is considered credible. Data validation tests are carried out by triangulating techniques and time triangulation, where data obtained by interview is then checked by observation, documentation, or other techniques at different times or situations. The data that has been obtained is then analyzed through data reduction. After the data is reduced, the next step is to display the data (presentation of data), and the final step is to conclude.

This research was conducted after obtaining a research ethics eligibility letter from the Ethics Commission of 'Aisyiyah University Yogyakarta issued with No.2467/KEP-UNISA/XII/2022.

3. Results and Discussion

3.1.Results

Based on the results of the study, three themes that describe the application of informed consent in family planning services at PMB are:

3.1.1. Implementation of Informed Consent in Family Planning Services at PMB

Based on interviews with four informants. All informants said that the implementation of informed consent at PMB Anisa had gone well, where the midwife explained before taking action. This is by the informant's statement as follows:

> "**What is certain is that as usual, every patient comes, we explain, after being understood, then give a consent sheet or informed consent to be signed if the mother has agreed**" (Inf B.1).
>
> "So far, it is usually smooth, and usually IUDs and implants do **use informed consent after beingexplained**, but if the new injectable carb is like that, just explain it" (Inf B.2).
>
> "Usually, those who use informed consent are long-term ones here, and there is an informed consentitself informed consent kb, **there is a patient's signature if the patient has agreed after being explained about the contraception,** then if the patient uses bpjs there is a photocopy of the bpjs
> / kis, if the patient is okay, initially, if the first time is checked for urine first, if it is negative, install it, or the previous week has not had contact, **so far, the provision of informed consent here is still done** "(Inf B.3).
>
> "**If the new birth control gets approval first**, it is **clear**, then if the injection model is not yet written, but we convey the side effects, then check the urine first, then take action" (Inf B.4).

3.1.2. Completeness of Informed Consent in Family Planning Services at PMB

Based on observations and documentation studies, the completeness of filling out informed consent in childbirth services at pmb Anisa has not been maximized. Incomplete filling, such as the service provider's identity, the type of action provided, and the service provider's signature, was found.

Table 1. Completeness of informed consent form

No.	Indicator	Informed Consent Form				N
		Complete		Incomplete		
		n	%	n	%	
1	Service provider identity	9	64.28	5	35.71	14
2	Identity of patient and husband	14	100	0	0	14
3	The type of action provided	13	92.85	1	7.14	14
4	signature of the service provider	10	71.42	4	28.57	14
5	signature of the patient or family planning acceptor.	14	100	0	0	14
6	Date of Service	14	100	0	0	14
7	Date of Revisit/Withdrawal	14	100	0	0	14

Source: primary data, 2022

Of the 14 informed consent forms in family planning services, it was found that to complete the service provider's identity, 14 forms were filled in. 9 (64.28%) and 5 (35.71%) were not filled in. The identity of the patient and husband has been filledin the name and Population Identification Number (NIK) completely on 14 forms (100%). The type ofaction given was filled in 13 forms (92.85%), and 1 form (7.14%) was not filled in. Four forms (28.57%)did not contain the service provider's signature, and the service provider signed ten forms (71.42%). Fourteen forms (100%) contained the signature of the patient or family planning acceptor, the date of service, and the date of re-visit / revocation completed 14 forms (100%).

3.1.3. Understanding of Family Planning Acceptors Related to Informed Consent in Family Planning Services at the PMB

Mothers' understanding of informed consent or consent to action before family planning services differs. Mothers or acceptors who use long-term family planning explain that informedconsent is given in writing and signed by the patient. In contrast, for mothers or injectable family planning, acceptors explain that only informed consent is given orally, according to the results of the interview below:

> "The consent sheet was signed before the midwife inserted the IUD if. Earlier, before the IUD was inserted, the midwife asked my name and husband, then what kind of birth control I wanted and weighed the tension asked when the last menstruation was then explained that this IUD is long-term and does not affect breast milk and a few side effects after that I was told to sign the consentsheet" (Inf A.1).

> "Mostly, I was asked by the midwife if I was sure I wanted to use injectable birth control, but the midwife explained the effects of injectable birth control first, and because I was determined to inject it, the midwife immediately injected it, but I was told to check my pee first." (Inf A.2)

> "I was asked questions first and then explained. He said that if you are sure and have agreed, youcan sign the consent sheet so that action is taken. The midwife gave the consent sheetbefore installing the IUD, but the midwife explained first about the IUD" (Inf A.3).

> "Yes, I was asked again by the midwife if you are sure you want to use injectable birth control after everything was explained earlier. I said yes, I want to use injectable birth control first" (InfA.4).

Based on the interview results above, birth control acceptors already understand that the consent form is given or signed after the acceptor gets an explanation from the midwife about the contraception to be used.

3.2.Discussion

3.2.1. Implementation of Informed Consent in Family Planning Services at PMB

It has been well implemented based on in-depth interviews conducted with four midwife informants about the application of informed consent in family planning services at PMB Anisa. Midwives have carried out their obligations, namely conveying information and providing action consent letters to patients before taking action.

As the research of Wahyuni and Sugiarti (2017) explained, in general, the necessity of informed consent in writing is signed by the patient before certain medical actions are carried out in health

facilities, namely hospitals or clinics, because it is closely related to documentation in medical records (Wahyuni & Sugiarti, 2017).

This is by PMK Number 28 of 2017 concerning Licensing and Implementation of Midwife Practice in Article 28 letter d, which explains that in carrying out midwifery practice, midwives are obliged to seek approval for actions to be taken. Asking for approval of action is the same as asking for informed consent from patients. All family planning services are given an explanation of the contraceptives used first and then the approval of the action before the action is taken, either orally or in writing (PerMenKes, 2017). After being sufficiently informed, the patient has the right to give or withhold their consent. To make a decision, the patient must get clear information (Mulyanti et al., 2017). The informed consent procedure requires the patient to be healthy in understanding the information presented so that the patient can make the right decision after receiving an explanation or information about the action to be taken (Nijhawan & Janodia, 2013).

3.2.2. Completeness of Informed Consent in Family Planning Services

Completeness of informed consent is very important because it reflects that the rights of patients and families have been fulfilled. They have received the information needed for medical action to be carried out. They can be used as a reason for a lawsuit against a doctor if there is a deviation in medical practice from the intention of approving medical action (Razi F, 2018).

The form analysis results on the service provider's identity found that five forms (35.71%) were not filled in completely. There are 14 forms (100%) that contain the complete identity of the patient and husband. A total of 1 form (7.14%) was not filled in the type of action given. Fourteen forms(100%) contained the patient's signature. The service provider had not signed four forms (28.57%). Fourteen forms (100%) had the date of service and date of revisit or revocation filled in.

The research above is by the research which explains that the approval of medical actions is a form that is considered important as evidence/basis in legal cases so that in filling out the informed consent form must be filled in completely and accurately (Marsum et al., 2018). Completeness of the informed consent sheet can be used for various purposes. These purposes include evidentiary material in legal cases, research, and educational materials. They can be used to analyze and evaluate the quality of services provided by health service agencies. This informed consent protects patients legally and protects health workers/doctors from disproportionate patient demands (Dewi Oktavia et al., 2020).

3.2.3. Family Planning Acceptors' Understanding of Informed Consent in Family Planning Services at PMBs

Based on in-depth interviews conducted with family planning acceptor informants related to the understanding of family planning acceptors about informed consent where informants were able to explain the flow of family planning services at PMB and informants said they signed the action consent sheet after being asked several questions by the midwife such as the identity of the patient and husband, address, contraceptives to be used. The midwife explained the family planning that acceptors would use. The explanation was about side effects, advantages, disadvantages, the period of use of KB, the time for re-visiting, and the schedule for revocation or removal of contraceptives.

Based on research by Menendez (2013), it is stated that to maximize understanding, information must be provided carefully to increase the patient's understanding of what is being explained. Information is provided in simple and clear language and adapted to the patient's educational and intellectual level so that the patient can understand clearly (Menendez, 2013).

A simple understanding of informed consent is that before being asked to consent, the patient has been given information about the action to be taken, its side effects, alternatives, and success rates. In detail, the information that must be conveyed is a description of the recommended action, side

effects, advantages and disadvantages, alternative actions that can be taken, and the period of use. (Gizela, 2017). Suppose the patient does not understand the explanation or information provided by the doctor before taking medical action. In that case, the doctor must explain it again to the patient to avoid future problems (Octaria & Trisna, 2016).

4. Conclusion

The informed consent application in family planning services at PMB Anisa has generally been carried out well. Midwives have carried out the obligation to ask for consent according to the obligations of midwives, and providing information has been carried out, midwives are obliged to ask for approval for actions to be taken. Asking for approval of action is the same as asking for approval of medical action (informed consent) to the patient. All family planning services are given an explanation of the contraceptives used first, then the approval of the action before the action is taken, either orally or in writing. This is by PMK Number 28 of 2017 concerning Licenses and Implementationof Midwife Practice in Article 28.

Completeness of filling out informed consent in family planning services has not been maximized. Family planning acceptors generally understand the informed consent or consent form in family planning services, where the results of in-depth interviews acceptors can explain the contents of informed consent and can explain if the informed consent/consent form is given or signed afterthe acceptor gets an explanation from the midwife about the contraception to be used.

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