KORESPONDENSI

JUDUL ARTIKEL: Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region

eISSN: 1857-9655

Publish: Open Access Macedonian Journal of Medical Sciences. 2022 Aug 01; 10(E):1630-1634.

Publisher:
https://www.scimagojr.com/journalsearch.php?q=Open+Access+Macedonian+Journal+of+Medical+Sciences

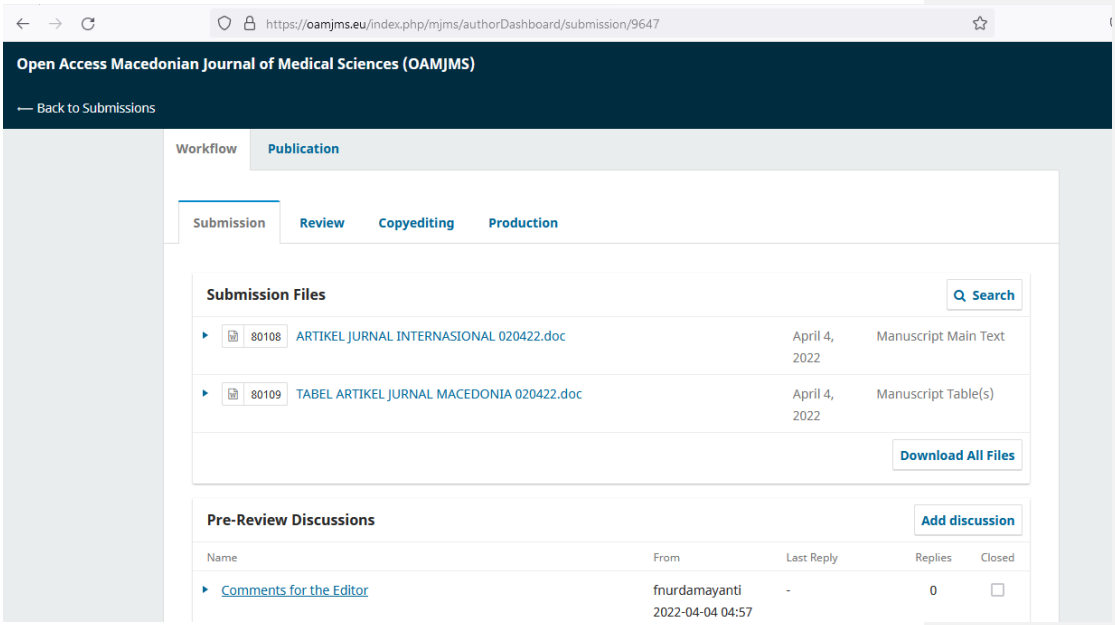
URL: https://oamjms.eu/index.php/mjms/article/view/9647/8054

Tanggal Publisher: 1 Agustus 2022

Urutan file ini sebagai berikut:

1. Riwayat Submit
2. Manuskrip yang disubmit
3. Riwayat Review/review substatansi
4. Manuskrip setelah revisi
5. In Press
6. Artikel sudah publish

1. RIWAYAT SUBMIT



2. MANUSKRIP YANG DISUBMIT

Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region

Fitriani Nur Damayanti[1], Novita Nining Anggraini[1]

Abstract

Background : In the data analysis report it was found that in more than 80 countries the number of deaths due to COVID-19. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. The use of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete

informed consent in every medical action. The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

Materials and Methods: The carried out by means of a *sampling non-probability sampling technique* wasusing purposive sampling, namely a sampling technique with certain considerations made by the researchers themselves, based on characteristics, namely that they had already done a second dose of vaccine and also with the characteristics of the population that had been previously known. The sample is 100 people.

Results: *Informed consent* was explained to the patient, not all were informed, because there were still things that had not been explained, such as procedures for action, previous medical history. *Informed consent of* the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. The explanation to the patient is enough to explain what is important and more orally.

Conclusion: The implementation of COVID-19 vaccination can be carried out on men and women aged 18-60 years, the implementation of informed consent for COVID-19 vaccination is not in accordance with the applicable laws and regulations, namely the place is not in the right place. give *informed consent for* the COVID-19 vaccination, the information in the informed consent is still incomplete, so it has not been fully informed to patients. It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

Keywords: Informed Consent, COVID-19 Vaccination

Introduction

The COVID-19 pandemic has become one of the most important threats to world health [1]. Health systems around the world are improving because they are exacerbated by fear, stigma, misinformation and limited health care delivery [2].

In the data analysis report, it was found that in more than 80 countries the number of deaths due to COVID-19. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. The use of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action. There is a need for informed consent in the implementation of the COVID-19 vaccine [3]. The use of *informed consent* for the COVID-19 vaccine in health workers is still very low [4].

The flow in the implementation of vaccine administration is table 1: registration, table 2: screening, table 3: vaccination, table 4: recording and observation. There is no legality in the use of informed consent in the COVID-19 vaccine [5].

With this background, it is necessary to have legal informed consent for the implementation of the COVID-19 vaccine program in the Semarang City Region.

Materials And Methods

1. Sample

This research was conducted in the city of Semarang. Thecarried out by means of a *samplingnon-probability sampling technique* wasusing *purposive sampling,sampling* which is atechnique with certain considerations made by the researcher himself, based on characteristics, namely that he had already done a second dose of vaccine and also with the characteristics of the population that had been previously known. The sample is 100 people.

2. Instruments

By using a questionnaire that will be used as an instrument in the research process, the validity and reliability are first tested. The data will be analyzed using a statistical test, namely SPSS and will then be described quantitatively and qualitatively.

Results

1. Characteristics of Respondents

Based on research conducted on 100 respondents who vaccinated against COVID-19, it can be seen that:

Table 1 Distribution of Respondents

Characteristics Characteristics	f	%
Gender		
Male	40	40
Female	60	60
Age		
19-25	21	21
26-35	33	33
36-45	25	25
≥ ≥ 46	21	21

Source: Primary Data Processed in 2021

Based on the table above shows the majority of respondents are female by 60% and aged between 26-35 years by 33%. The implementation of the COVID-19 vaccination can be carried out on men and women over the age of 18 years.

2. Places to Provide Information on COVID-19 Vaccinations

Based on research conducted on 100 respondents who vaccinated against COVID-19, it can be seen that:

Table 2 Distribution of places to provide information on COVID-19 vaccinations

Places	f	%
Vaccines Places		
Hospital	17	17
Puskesmas	8	8
Kelurahan	11	11
Subdistrict	4	4
Others	60	60
Place of information giving		
Place of Observation	1	1
Place of Action	1	1
Place of Registration	15	15
Place of history taking	83	83

Source: Primary Data Processed in 2021

Based on the table above, it shows that the majority of respondents took vaccines in places other than hospitals, health centers, urban villages, and sub-districts by 60% and the majority of places where information is provided by 83% are done in anamnesis. Places for giving COVID-19 vaccinations can be done in hospitals, health centers, sub-districts and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

3. Implementation of *Informed Consent* Vaccinations COVID-19

Based on research conducted on 100 respondents were vaccinated COVID-19, it can be seen that:

Table 3 Distribution of the implementation of *the informed consent* of vaccination COVID-19

Statement	Very informed		informed		Quite informed		Slightly informed		Not informed	
		f%		f%	f	%	f	%	f	%
Obtaining general information about COVID-19	25	25	39	39	25	25	8	8	3	3
Obtaining information about the use of the COVID-19 vaccine	22	22	36	36	22	22	12	12	8	8
Obtaining information about the brand of COVID-19 vaccine used	24	24	37	37	25	25	9	9	5	5
Getting information about vaccine doses COVID 19	26	26	30	30	28	28	10	10	6	6
Obtain information about the vaccine's effectiveness COVID 19	16	16	34	34	34	34	9	9	7	7
Getting information about the effects of side effects after the COVID-19 vaccine	24	24	31	31	28	28	11	11	6	6
Getting information about the screening process for the COVID-19 vaccine	13	13	37	37	31	31	14	14	5	5
Doing the COVID-19 vaccine without coercion	28	28	33	33	25	25	10	10	4	4
Get information about the benefits of participating in the COVID-19 vaccination	21	21	32	32	28	28	13	13	6	6
The COVID-19 vaccine approval sheet is given at the first and second doses	23	23	21	21	35	35	16	16	5	5
Information in the consent form submitted verbally and in writing	19	19	37	37	21	21	17	17	6	6

Source: Primary Data Processed in 2021

Based on the table above shows the majority of respondents answered "Informed" on each question item. In item 1, 39% of respondents stated that they were informed about COVID-19 in general. In question item 2, as many as 36% of respondents stated that they were informed about the usefulness of the COVID-19 vaccine. In question item 3, 37% of respondents stated that they were informed about the brand of COVID-19 vaccine used. In question item 4, as many as 30% of respondents stated that they were informed about the dose of the COVID-19 vaccine given. In question item 5, as many as 34% of respondents stated that they were informed about the effectiveness of the COVID-19 vaccine. In question item 6, as many as 31% of respondents stated that they were informed about side effects after the COVID-19 vaccine was administered. In question item 7, as many as 37% of respondents stated that they were informed that they

had followed the screening process in the COVID-19 vaccine. In question item 8, as many as 33% of respondents stated that they were informed of carrying out the COVID-19 vaccine without coercion. In question item 9, as many as 32% of respondents stated that they were informed that participating in the COVID-19 vaccination would prevent contracting COVID-19. In question item 10, as many as 35% of respondents stated that they were sufficiently informed about the approval sheet regarding the COVID-19 vaccine at the first and second doses. In question item 11, as many as 37% of respondents stated that they were informed of the consent form which was delivered verbally and in writing.

Discussion

1. Characteristics of Respondents

The priority group for vaccine recipients is residents who are domiciled in Indonesia aged 18 years. Population groups under 18 years of age can be vaccinated if adequate vaccine safety data are available and approval for use in an emergency period *(emergency use authorization)* or issuance of a distribution permit number (NIE) from the Food and Drug Administration [6].

There are vaccine candidates that can be given to people aged 18-60 years who are the most exposed to COVID-19. In addition, because the majority of vaccine categories in the world have only been tested on healthy adults aged 18-60 years, and it will take additional time to identify the suitability of COVID-19 vaccines for other age ranges [7]. Phase 3 clinical trials of the vaccine in Indonesia, which have been conducted since last August, involve the 18-59 year age group. This age group is the most infected with COVID-19 in Indonesia, accounting for almost 80% of positive cases, and is also considered to be more mobile than the older age group. By providing immunity at that age, it is hoped that other citizens who have not received the vaccine can also be protected [8].

2. Places for Giving COVID-19 Vaccination Information Places for giving COVID-19

vaccinations can be done in hospitals, health centers, sub-districts and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely in

government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination. The COVID-19 vaccination flow has 4 tables, namely table 1 for registration of vaccination targets and recording or verifying data by mobile officers. Table 2 is for screening, history taking, education where it aims to ensure the vaccination target is in good health because one of the vaccination requirements is being in good health. Table 3 is carried out by medical personnel to provide vaccinations according to the provisions of the dose and method of administration. The last table is table 4 where the officer records the target that has been vaccinated and invites the target to sit down to wait 30 minutes which aims to anticipate the presence of AEFI [9].

In the Regulation of the Minister of Health Number 10 of 2021 article 21 states that the vaccination program service is carried out at health service facilities owned by the central government, regional government, or the public/private sector, which meet the requirements [10]. The place for providing information about COVID-19 vaccination. The results of the study have not fully complied with the provisions of Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999. In the regulation, it is emphasized that medical information is provided in a conducive room, meaning that it is not disturbed by other parties, so that medical information can be well received by patients/families. Given that the place for providing medical information in various places, must provide a special place/room for its implementation [11].

This is supported by Permenkes No. 290/2008, article 17 paragraph (2) it is emphasized that health service facilities are responsible for implementing the approval for medical (medical) actions. The provisions of article 17 are supported by article 18 paragraph (2) that in order to improve the quality of health services, the health office needs to supervise the implementation of these services [12]. The availability of this room provides a sense of comfort for patients to convey very personal matters, as well as health workers will provide in-depth explanations, including if there are things that are patient confidentiality, thus confidentiality can be guaranteed.

3. Implementation of *Informed Consent for* COVID-19 Vaccination

The results of the above research will be in line with the policies of the ministry of health. Based on Permenkes 290/Menkes/Per/III/2008 and Kep.Dir.Yanmedis HK.00.06.3.5. 1866/1999, the method of delivering an explanation by the responsible health worker is distinguished by, (a) an explanation that is delivered orally, (b) an explanation that is delivered in writing. This provision provides an opportunity for health workers to choose whether to only convey verbally or both. According to the results of the study, there were no health workers who provided written and verbal explanations.

However, these results conclude that the informants agree that if the information is explained, it should be written first and then explained orally. Written information and explained orally will be easier to understand and can be read again. Written information will provide information certainty and legal certainty, because it can be authentically proven. Oral information has various weaknesses, firstly the lack of clarity of medical information, and weak as evidence, so that written information and verbally explained will reduce this [13].

It is implied that written information is better than oral, to improve understanding of patients/families health workers can use assistive devices, such as leaflets or other forms of publication if they can help provide detailed information [14]. Based on this explanation, it can be concluded that the explanation with the aids is expected to be more effective, especially if the information in writing is certainly easier to understand, because it can be re-read. Written information can be a good document, so that it can be used as strong evidence, can protect interested parties, therefore it is necessary to review various policies which state that medical information is submitted orally, and in writing only as a complement [15]. Information should be submitted in writing and explained orally, not the other way around [16].

Thus, when viewed from the contents of the *informed consent* explained to the patient, it turns out that all of them have not been informed, because there are still things that have not been explained, such as procedures for action, previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. Every medical action must provide a consent form to the patient as proof of approval for medical action. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. There isof

informed consent still a lack, so the explanation given to the patient is still limited. This needs to be improved in the form of an *informed consent* form with more complete fields so that all information related to information that has not been submitted can be written in full on theform *informed consent*.

Conclusion

Implementation of COVID-19 vaccination can be carried out on men and women aged 18-60 years, the implementation of informed consent for COVID-19 vaccination is not in accordance with applicable laws and regulations, namely the place is not in accordance with the place that should be given *informed consent for* the COVID-19 vaccination, the information contained in the informed consent is still incomplete so that all of it has not been informed to patients. It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

REFERENCES

[1] Royal College of Obstetricians and Gynaecologists UK. Coronavirus (COVID-19) infection in pregnancy: Information for health care professionals. [Online].; 2020. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/2020-03-21-cov.

[2] Strategies and plans: strategic preparedness and response plan [website]. [Online].; 2020 [cited 16 October 2020]. Available from: (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/strategies-and-plans

[3] Vivilaki V. G., Asimaki E.. Respectful midwifery care during the COVID-19 pandemic. European Journal of Midwifery. 2020 April; 4. doi:10.18332/ejm/120070

[4] Hanahoe, M. Midwifery-ied care can lower caesarean section rates according to the robson teh group classification system. Eur J Midwifery. 2020 March; 4: p. 1-5. doi:10.18332/ejm/119164

[5] Astuti, N. P., Nugroho, E. G. Z., Lattu, J. C., Potempu, I. R., & Swandana, D. A. (2021). Persepsi Masyarakat terhadap Penerimaan Vaksinasi COVID-19: Literature Review. Jurnal Keperawatan, 13(3), 569-580.

[6] Global surveillance for human infection with coronavirus disease (COVID-19) [website]. [Online].; 2020 [cited 2020 October 20]. Available from: https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov)

[7] International Confederation of Midwives. Women's right in childbirth must be upheld during the coronavirus pandemic. [Online].; 2020 [cited 2020 October 18]. Available from: https://www/internationalmidwife.co.id.

[8] Hanahoe, M. Midwifery-ied care can lower caesarean section rates according to the robson teh group classification system. Eur J Midwifery. 2020 March; 4: p. 1-5. doi:10.18332/ejm/119164

[9] Kemenkes RI Tahun 2020 tentang Novel Coronavirus (NCOV). Diakses dari : https://www.kemkes.go.id/resources/COVID-19.pdf

[10] Permenkes No. 10 Tahun 2021 tentang Pelaksanaan Vaksinasi Dalam Rangka Penanggulangan Pandemi Corona Virus Disease 2019 (COVID-19)

[11] Surat Keputusan Direktur Jenderal Pelayanan Medik Nomor HK.00.06.3.5.1866/1999 tentang Pedoman Persetujuan Tindakan Medik

[12] Permenkes 290/Menkes/Per/ III/2008 tentang Persetujuan Tindakan Kedokteran

[13] K. Kelland, S. Nebehay. WHO officials rethink epidemic messaging amid pandemic debate. [Online].; 2020,313 [cited 2020 October 19]. Available from: https://www.reuters.com/article/us-health-coronavirus-who-messaging-insi/who-officials-rethink-epidemic-messaging-amid-pandemic-debate-idUSKBN2101AY

[14]UNFPA and COVID 19. Website . [Online].; 2020. Available from: https://www/unfpa.org/covid19

[15] Damayanti, FA, etc. A Literature Review on the Vaccination of COVID-19 in Pregnant and Breastfeeding Women: Effectiveness and Safety. Macedonian Journal of Medical Sciences. 2021 Aug 21; 9(F):234-237.

[16] Paul E, Brown GW, Kalk A, Ridde V. Playing vaccine roulette: Why the current strategy of staking everything on COVID-19 vaccines is a high-stakes wager.

Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region

Tables

Table 1 Distribution of Respondents

Characteristics Characteristics	f	%
Gender		
Male	40	40
Female	60	60
Age		
19-25	21	21
26-35	33	33
36-45	25	25
≥ ≥ 46	21	21

Source: Primary Data Processed in 2021

Table 2 Distribution of places to provide information on COVID-19 vaccinations

Places	f	%
Vaccines Places		
Hospital	17	17
Puskesmas	8	8
Kelurahan	11	11
Subdistrict	4	4
Others	60	60
Place of information giving		
Place of Observation	1	1
Place of Action	1	1
Place of Registration	15	15
Place of history taking	83	83

Source: Primary Data Processed in 2021

Table 3 Distribution of the implementation of *the informed consent* of vaccination COVID-19

Statement	Very informed		informed		Quite informed		Slightly informed		Not informed	
		f%		f%	f	%	f	%	f	%
Obtaining general information about COVID-19	25	25	39	39	25	25	8	8	3	3
Obtaining information about the use of the COVID-19 vaccine	22	22	36	36	22	22	12	12	8	8
Obtaining information about the brand of COVID-19 vaccine used	24	24	37	37	25	25	9	9	5	5
Getting information about vaccine doses COVID 19	26	26	30	30	28	28	10	10	6	6
Obtain information about the vaccine's effectiveness COVID 19	16	16	34	34	34	34	9	9	7	7
Getting information about the effects of side effects after the COVID-19 vaccine	24	24	31	31	28	28	11	11	6	6
Getting information about the screening process for the COVID-19 vaccine	13	13	37	37	31	31	14	14	5	5
Doing the COVID-19 vaccine without coercion	28	28	33	33	25	25	10	10	4	4
Get information about the benefits of participating in the COVID-19 vaccination	21	21	32	32	28	28	13	13	6	6
The COVID-19 vaccine approval sheet is given at the first and second doses	23	23	21	21	35	35	16	16	5	5
Information in the consent form submitted verbally and in writing	19	19	37	37	21	21	17	17	6	6

Source: Primary Data Processed in 2021

3. RIWAYAT REVIEW/REVIEW SUBSTATANSI

ANALYSIS OF THE IMPLEMENTATION OF INFORMED CONSENT COVID-19 VACCINATION IN THE SEMARANG CITY REGION

Fitriani Nur Damayanti
Universitas Muhammadiyah Semarang, Indonesia
Email:
Phone:

Edited by:
Citation:
Keywords:
***Correspondence:**
Fitriani Nur Damayanti
Universitas Muhammadiyah Semarang, Indonesia
Email:
Received:
Revised: **Accepted:**

Funding:
Competing Interests:
The authors have declared that no competing interests exist

Abstract

Introduction: Informed consent is a process of communication between patient and your health care provider that often leads to agreement or permission for COVID-19 vaccination procedure. Every patient has the right to get information and ask questions before COVID-19 vaccination procedures. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1.216.650 people who have received the first and second doses of the COVID-19 vaccine. Implementation of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action.

AIM: The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

Methods: Observational study, with descriptive approach. 100 sample taken as purposive sample, with random sampling technique, namely a sampling technique with certain considerations by the researchers themselves. Instrument research used is questionnaire. Data collected has process with descriptive analysis.

Result: Informed consent of COVID-19 vaccination was explained to the patient, but not all informed well, because there were still things that had not been explained, such as procedures for action, previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. The explanation to the patient is enough to explain what is important and more orally.

Discussion: COVID-19 vaccination is eligible given to men and women aged 18-60 years as long as there is no contra indication. Before COVID-19 vaccine given, must be deliver all information about COVID-19 vaccine, according with the laws and regulations.

Conclusion: Informed consent COVID-19 vaccination is important role during massive of COVID-19 vaccination program. Within informed consent, patient will get full the information of the indication, contra indication, dose and side effect of COVID-19 vaccine. With all information get, patient will be decide accepted or rejected to this procedure. If informed consent is still incomplete, so it has not been fully informed to patients and will make patient confused.

Recommendation: It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

Keywords: Informed Consent, COVID-19 Vaccination

Introduction

The COVID-19 pandemic has become one of the most important threats to world health [1]. Health systems around the world are improving because they are exacerbated by fear, stigma, misinformation and limited health care delivery [2].

In the data analysis report, it was found that in more than 80 countries the number of deaths due to COVID-19. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. The use of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action. There is a need for informed consent in the implementation of the COVID-19 vaccine [3]. The use of informed consent for the COVID-19 vaccine in health workers is still very low [4].

The flow in the implementation of vaccine administration is table 1: registration, table 2: screening, table 3: vaccination, table 4: recording and observation. There is no legality in the use of informed consent in the COVID-19 vaccine [5].

With this background, it is necessary to have legal informed consent for the implementation of the COVID-19 vaccine program in the Semarang City Region.

Objective of study

The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

Materials And Methods

1. Type of research

Descriptive study with Survey approach. This research was conducted in the city of Semarang. This research will describe of determinant of implementation informed consent COVID-19 Vaccine.

2. Sample

The size sample is 100 people. The carried out by means of a sampling non-probability sampling technique was using purposive sampling, sampling which is a technique with certain considerations made by the researcher himself, based on characteristics, namely that he had already done a second dose of vaccine and also with the characteristics of the population that had been previously known.

Commented [s1]: Why only 100 sample, any explanation.

3. Instruments

The research instrument used is a questionnaire. Questionnaire was developed to determine of implementation informed consent COVID-19 Vaccination. Questionnaire was tested for validity and reliability.

4. Data analysis

The data will be analyzed using statistical tests, then will be described quantitatively and qualitatively.

Results

1. Characteristics of Respondents

Bas Based on the table 1 above shows the majority of respondents are female by 60% and aged between 26-35 years by 33%. The implementation of the COVID-19 vaccination can be carried out on men and women over the age of 18 years.

Table 1
Distribution of Respondents

Characteristics	f	%
Gender		
Male	40	40
Female	60	60
Age		
19-25	21	21
26-35	33	33
36-45	25	25
≥ ≥ 46	21	21

Source: Primary Data Processed in 2021

2. Places to Provide Information on COVID-19 Vaccinations

Table 2 showed the research conducted on 100 respondents who vaccinated against COVID-19.

Table 2

Distribution of places to provide information on COVID-19 vaccinations

Vaccines Setting Places	**F**	**%**
Hospital	17	17
PHC	8	8
Village Office	11	11
Subdistrict Office	4	4
Others	60	60
Place of information giving	**F**	**%**
Table 1: Registration	15	15
Table 2: Screening and history taking	83	83
Table 3: Vaccination.	1	1
Table 4: Observation post Vaccination.	1	1

Source: Primary Data Processed in 2021

Table 2, showed that the majority of respondents took vaccines in places other than hospitals, health centers, urban villages, and sub-districts by 60% and the majority of places where information is provided by 83% are done at the station history taking.

Places for giving COVID-19 vaccinations can be done in hospitals, health centers, sub-districts and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

3. Result of Validity and Reliability Questionnaire

Commented [s2]: Please support with result test of validity and reliability Questionnaire.

For a questionnaire to be regarded as acceptable, it must possess two very important qualities which are reliability and validity. The former measures the consistency of the questionnaire while the latter measures the degree to which the results from the questionnaire agrees with the real world.

Table 3

Distribution of the implementation of *the informed consent* of vaccination COVID-19

Statement	Very informed		informed		Quite informed		Slightly informed		Not informed	
	f	%	f	%	f	%	f	%	f	%
Obtaining general information about COVID-19	25	25	39	39	25	25	8	8	3	3
Obtaining information about the use of the COVID-19 vaccine	22	22	36	36	22	22	12	12	8	8
Obtaining information about the brand of COVID-19 vaccine used	24	24	37	37	25	25	9	9	5	5
Getting information about vaccine doses COVID 19	26	26	30	30	28	28	10	10	6	6
Obtain information about the vaccine's effectiveness COVID 19	16	16	34	34	34	34	9	9	7	7
Getting information about the effects of side effects after the COVID-19 vaccine	24	24	31	31	28	28	11	11	6	6
Getting information about the screening process for the COVID-19 vaccine	13	13	37	37	31	31	14	14	5	5
Doing the COVID-19 vaccine without coercion	28	28	33	33	25	25	10	10	4	4
Get information about the benefits of participating in the COVID-19 vaccination	21	21	32	32	28	28	13	13	6	6
The COVID-19 vaccine approval sheet is given at the first and second doses	23	23	21	21	35	35	16	16	5	5
Information in the consent form submitted verbally and in writing	19	19	37	37	21	21	17	17	6	6

Source: Primary Data Processed in 2021

Discussion

Implementation of Informed Consent Vaccinations COVID-19

Based on research conducted on 100 respondents were vaccinated COVID-19, it can be seen that:

1. **Places for Giving COVID-19 Vaccination Information Places for giving COVID-19**

   Vaccinations can be done in hospitals, health centers, sub-districts and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

   The COVID-19 vaccination flow services divided into 4 station:

   - Table 1 for registration of vaccination targets and recording or verifying data by mobile officers.
   - Table 2 is for screening, history taking, education where it aims to ensure the vaccination target is in good health because one of the vaccination requirements is being in good health.
   - Table 3 is carried out by medical personnel to provide vaccinations according to the provisions of the dose and method of administration.
   - Table 4 where the officer records the target that has been vaccinated and invites the target to sit down to wait 30 minutes which aims to anticipate the presence of AEFI [9].

   In the Regulation of the Minister of Health Number 10 of 2021 article 21 states that the vaccination program service is carried out at health service facilities owned by the central government, regional government, or the public/private sector, which meet the requirements [10]. The place for providing information about COVID-19 vaccination.

   The results of the study have not fully compliance with the provisions of Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999. In the regulation, it is emphasized that medical information is provided in a conducive room, meaning that it is not disturbed by other parties, so that medical information can be well received by patients/families. Given that the place for providing medical information in various places, must provide a special place/room for its implementation [11].

   This is supported by Health Minister Regulation No. 290/2008, article 17 paragraph (2) it is emphasized that health service facilities are responsible for implementing the approval for medical (medical) actions. The provisions of article 17 are supported by article 18 paragraph (2) that in order to improve the quality of health services, the health office needs to supervise the implementation of these services [12]. The availability of this room provides a sense of comfort for patients to convey very personal matters, as well as health workers will provide in-depth explanations, including if there are things that are patient confidentiality, thus confidentiality can be guaranteed.

2. **Implementation of Informed Consent for COVID-19 Vaccination**

   The results of the above research will be in line with the policies of the ministry of health. Based on Health Minister Regulation no 290/Menkes/Per/III/2008 and Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999, the method of delivering an explanation by the responsible health worker is distinguished by, (a) an explanation that is delivered orally, (b) an explanation that is delivered in writing. This provision provides an opportunity for health workers to choose whether to only convey verbally or both. According to the results of the study, there were no health workers who provided written and verbal explanations.

However, these results conclude that the informants agree that if the information is explained, it should be written first and then explained orally. Written information and explained orally will be easier to understand and can be read again. Written information will provide information certainty and legal certainty, because it can be authentically proven. Oral information has various weaknesses, firstly the lack of clarity of medical information, and weak as evidence, so that written information and verbally explained will reduce this [13].

It is implied that written information is better than oral, to improve understanding of patients/families health workers can use assistive devices, such as leaflets or other forms of publication if they can help provide detailed information [14]. Based on this explanation, it can be concluded that the explanation with the aids is expected to be more effective, especially if the information in writing is certainly easier to understand, because it can be re-read. Written information can be a good document, so that it can be used as strong evidence, can protect interested parties, therefore it is necessary to review various policies which state that medical information is submitted orally, and in writing only as a complement [15]. Information should be submitted in writing and explained orally, not the other way around [16].

Thus, when viewed from the contents of the informed consent explained to the patient, it turns out that all of them have not been informed, because there are still things that have not been explained, such as procedures for action, previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. Every medical action must provide a consent form to the patient as proof of approval for medical action. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. There is of informed consent still a lack, so the explanation given to the patient is still limited. This needs to be improved in the form of an informed consent form with more complete fields so that all information related to information that has not been submitted can be written in full on the form of informed consent.

Acknowledgements

Implementation of COVID-19 vaccination can be carried out on men and women aged 18-60 years, the implementation of informed consent for COVID-19 vaccination is not in accordance with applicable laws and regulations, namely the place is not in accordance with the place that should be given informed consent for the COVID-19 vaccination, the information contained in the informed consent is still incomplete so that all of it has not been informed to patients. It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

References

1. Royal College of Obstetricians and Gynecologists UK. (2020). Coronavirus (COVID-19) infection in pregnancy: Information for health care professionals. [Online].; 2020. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/2020-03-21-cov.
2. Strategies and plans. (2020). strategic preparedness and response plan [website]. [Online].; 2020 [cited 16 October 2020]. Available from: (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/strategies-and-plans
3. Vivilaki V. G., Asimaki E. (2020). Respectful midwifery care during the COVID-19 pandemic. European Journal of Midwifery. 2020 April; 4. http://doi:10.18332/ejm/120070
4. Hanahoe, M. (2020). Midwifery-ied care can lower caesarean section rates according to the

robson teh group classification system. Eur J Midwifery. 2020 March; 4: p. 1-5. http://doi:10.18332/ejm/119164
5. Astuti, N. P., Nugroho, E. G. Z., Lattu, J. C., Potempu, I. R., & Swandana, D. A. (2021). Community perception of accepted COVID-19: Literature Review. Jurnal Keperawatan, 13(3), 569-580.
6. Global surveillance for human infection with coronavirus disease (COVID-19) [website]. [Online].; 2020 [cited 2020 October 20]. Available from: https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov)
7. International Confederation of Midwives. (2020). Women's right in childbirth must be upheld during the coronavirus pandemic. [Online].; 2020 [cited 2020 October 18]. Available from: https://www/internationalmidwife.co.id.
8. Hanahoe, M. (2020). Midwifery-ied care can lower caesarean section rates according to the robson teh group classification system. Eur J Midwifery. 2020 March; 4: p. 1-5. doi:10.18332/ejm/119164
9. Health Minister regulation (2020). About Novel Coronavirus (NCOV). Diakses dari : https://www.kemkes.go.id/resources/COVID-19.pdf
10. Health Minister regulation (2021). No. 10, 2021, Implementation Vaccine program for managing Corona Virus Disease 2019 (COVID-19).
11. Decision Director Medical Services (1999). No. HK.00.06.3.5.1866/1999 Guideline Informed Consent Medical Intervention.
12. Health Minister regulation (2008). No. 290/Menkes/Per/III/2008. Informed Consent Medical Intervention.
13. K. Kelland, and S. Nebehay. (2020). WHO officials rethink epidemic messaging amid pandemic debate. [Online].; 2020,313 [cited 2020 October 19]. Available from: https://www.reuters.com/article/us-health-coronavirus-who-messaging-insi/who-officials-rethink-epidemic-messaging-amid-pandemic-debate-idUSKBN2101AY
14. UNFPA and COVID 19. Website . [Online].; 2020. Available from: https://www/unfpa.org/covid19
15. Damayanti FN, Riafisari AA, Ngestiningrum AH. (2022). A Literature Review on the Vaccination of COVID-19 in Pregnant and Breastfeeding Women: Effectiveness and Safety. Open Access Maced J Med Sci [Internet]. 2021 Aug. 21 [cited 2022 Apr. 29];9(F):234-7. https://oamjms.eu/index.php/mjms/article/view/6651
16. Paul, E., Brown, G. W., Kalk, A., & Ridde, V. (2021). Playing vaccine roulette: Why the current strategy of staking everything on Covid-19 vaccines is a high-stakes wager. Vaccine, 39(35), 4921–4924. https://doi.org/10.1016/j.vaccine.2021.07.045

Scientific Foundation SPIROSKI, Skopje, Republic of Macedonia
Open Access Macedonian Journal of Medical Sciences. 2022 Feb 05; 10(E):1-5.
https://doi.org/10.3889/oamjms.2022.9647
eISSN: 1857-9655
Category: E - Public Health
Section: Public Health Legislation

Since 2002

open access

Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region

Fitriani Nur Damayanti*

AQ2 *Department of ???, Universitas Muhammadiyah Semarang, Semarang, Indonesia*

Edited by: https://publons.com/researcher/3919671/miko-iqbal-ali/
Citation: Damayanti FN. Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region. Open Access Maced J Med Sci. 2022 Feb 05; 10(E):1-5. https://doi.org/10.3889/oamjms.2022.9647
AQ3 **Keywords:** Informed consent; COVID-19 vaccination
***Correspondence:** Fitriani Nur Damayanti, Universitas Muhammadiyah Semarang, Semarang, Indonesia.
AQ4 **E-mail:** ???
AQ5 **Received:** ???
Revised: ???
Accepted: ???

Funding: This research did not receive any financial support
Competing Interests: The authors have declared that no competing interests exist

Abstract

INTRODUCTION: Informed consent is a process of communication between patient and your health-care provider that often leads to agreement or permission for COVID-19 vaccination procedure. Every patient has the right to get information and ask questions before COVID-19 vaccination procedures. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. Implementation of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action.

AIM: The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

METHODS: This study was observational study, with descriptive approach. One hundred sample taken as purposive sample, with random sampling technique, namely, a sampling technique with certain considerations by the researchers themselves. Instrument research used is questionnaire. Data collected have process with descriptive analysis.

RESULTS: Informed consent of COVID-19 vaccination was explained to the patient, but not all informed well, because there were still things that had not been explained, such as procedures for action and previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. The explanation to the patient is enough to explain what is important and more orally.

DISCUSSION: COVID-19 vaccination is eligible given to men and women aged 18–60 years as long as there is no contra indication. Before COVID-19 vaccine given must be deliver all information about COVID-19 vaccine, according with the laws and regulations.

CONCLUSION: Informed consent COVID-19 vaccination is important role during massive of COVID-19 vaccination program. Within informed consent, the patient will get full the information of the indication, contra indication, dose, and side effect of COVID-19 vaccine. With all information get, the patient will be decide accepted or rejected to this procedure. If informed consent is still incomplete, so it has not been fully informed to patients and will make patient confused.

RECOMMENDATION: It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

Introduction

The COVID-19 pandemic has become one of the most important threats to world health [1]. Health systems around the world are improving, because they are exacerbated by fear, stigma, misinformation, and limited health-care delivery [2].

In the data analysis report, it was found that in more than 80 countries the number of deaths due to COVID-19. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. The use of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action. There is a need for informed consent in the implementation of the COVID-19 vaccine [3]. The use of informed consent for the COVID-19 vaccine in health workers is still very low [4].

The flow in the implementation of vaccine administration is Table 1: registration, Table 2: screening, Table 3: vaccination, and Table 4: recording and observation. There is no legality in the use of informed consent in the COVID-19 vaccine [5].

With this background, it is necessary to have legal informed consent for the implementation of the COVID-19 vaccine program in the Semarang City Region.

Objective of study

The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

30

Materials and Methods

Type of research

This study was descriptive study with survey approach. This research was conducted in the city of Semarang. This research will describe of determinant of implementation informed consent COVID-19 Vaccine.

Sample

The size sample is 100 people who have met the inclusion and exclusion criteria. The carried out by means of a sampling non-probability sampling technique was using purposive sampling, sampling which is a technique with certain considerations made by the researcher himself, based on characteristics, namely, that he had already done a second dose of vaccine and also with the characteristics of the population that had been previously known.

Instruments

The research instrument used is a questionnaire. Questionnaire was developed to determine of implementation informed consent COVID-19 vaccination. Questionnaire was tested for validity and reliability.

Data analysis

The data will be analyzed using statistical tests, then will be described quantitatively and qualitatively.

Results

Characteristics of respondents

Bas based on Table 1 shows that the majority of respondents are female by 60% and aged between 26 and 35 years by 33%. The implementation of the COVID-19 vaccination can be carried out on men and women over the age of 18 years.

AQ10 **Table 1: Distribution of respondents**

Characteristics	f	%
Gender		
Male	40	40
Female	60	60
Age		
19–25	21	21
26–35	33	33
36–45	25	25
≥46	21	21

Source: Primary Data Processed in 2021

Places to Provide Information on COVID-19 Vaccinations

Table 2 showed the research conducted on 100 respondents who vaccinated against COVID-19.

Table 2: Distribution of places to provide information on COVID-19 vaccinations

Vaccines setting places	F	%
Hospital	17	17
PHC	8	8
Village Office	11	11
Subdistrict Office	4	4
Others	60	60
Place of information giving	F	%
Table 1: Registration	15	15
Table 2: Screening and history taking	83	83
Table 3: Vaccination,	1	1
Table 4: Observation post-vaccination	1	1

Source: Primary Data Processed in 2021

Table 2 showed that the majority of respondents took vaccines in places other than hospitals, health centers, urban villages, and subdistricts by 60% and the majority of places, where information is provided by 83% that are done at the station history taking.

Places for giving COVID-19 vaccinations can be done in hospitals, health centers, and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely, in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

Result of validity and reliability questionnaire

The answers to each group of respondents were tested for validity and reliability tests for. The validity test uses the Pearson Correlation test to obtain an average value of r calculated which is then the average value of r calculated is compared with the value of r table to determine that the questionnaire questions are valid (valid). While the reliability test (reliability) of the instrument used the Cronbach's alpha test to obtain the results of the Cronbach's alpha average value which was used to determine that the survey instrument was reliable (reliable).

The following is the results of the validity and reliability tests:

Validity questionnaire

From the existing data, the output of the correlation value between the question items and the total is obtained. This value will then be compared with the value of r_{table}. r_{table} is sought at a significance of 0.05 with (n) 30. Then, we get an r_{table} of 0.361. From the output of the correlation value between the question items and the total, it can be seen in the "Total" line, namely, the Pearson correlation value. The Pearson correlation value in each variable is more than the r_{table}

31

value. Hence, it can be concluded that all question items can be declared valid.

Reliability questionnaire

Reliability Statistics		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	Number of Items
0.719	0.718	12

The basis for making decisions on reliability tests usually uses the 0.6 limit. according to now (1992), reliability less than 0.6 is not good, while 0.7 is acceptable and above 0.8 is good. Based on the reliability statistics table, Cronbach's alpha value is 0.719, so it can be said to be reliable, because Cronbach's alpha value is > 0.07. Hence, it can be concluded that the data from the questionnaire can be trusted.

Discussion

Implementation of informed consent vaccinations COVID-19

Based on research conducted on 100 respondents which were vaccinated COVID-19, it can be seen that:

Places for giving COVID-19 vaccination information places for giving COVID-19

Vaccinations can be done in hospitals, health centers, sub-districts, and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely, in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

The COVID-19 vaccination flow services divided into four stations:

- Table 1 for registration of vaccination targets and recording or verifying data by mobile officers.
- Table 2 is for screening, history taking, education where it aims to ensure the vaccination target is in good health, because one of the vaccination requirements is being in good health.
- AQ12 Table 3 is carried out by medical personnel to provide vaccinations according to the provisions of the dose and method of administration.
- AQ12 Table 4 where the officer records the target that has been vaccinated and invites the target to sit down to wait 30 min which aims to anticipate the presence of AEFI [9].

In the Regulation of the Minister of Health Number 10 of 2021, article 21 states that the vaccination program service is carried out at health service facilities owned by the central government, regional government, or the public/private sector, which meet the requirements [10]. The place for providing information about COVID-19 vaccination. AQ6

The results of the study have not fully compliance with the provisions of Kep. Dir. Yanmedis HK.00.06.3.5.1866/1999. In the regulation, it is emphasized that medical information is provided in a conducive room, meaning that it is not disturbed by other parties so that medical information can be well received by patients/families. Given that, the place for providing medical information in various places, must provide a special place/room for its implementation [11].

This is supported by Health Minister Regulation No. 290/2008, article 17 paragraph (2), it is emphasized that health service facilities are responsible for implementing the approval for medical (medical) actions. The provisions of article 17 are supported by article 18 paragraph (2) that to improve the quality of health services, the health office needs to supervise the implementation of these services [12]. The availability of this room provides a sense of comfort for patients to convey very personal matters, as well as health workers will provide in-depth explanations, including if there are things that are patient confidentiality, thus confidentiality can be guaranteed.

Implementation of informed consent for COVID-19 vaccination

The results of the above research will be in line with the policies of the ministry of health. Based on Health Minister Regulation no 290/Menkes/Per/III/2008 and Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999, the method of delivering an explanation by the responsible health worker is distinguished by, (a) an explanation that is delivered orally and (b) an explanation that is delivered in writing. This provision provides an opportunity for health workers to choose whether to only convey verbally or both. According to the results of the study, there were no health workers who provided written and verbal explanations.

However, these results conclude that the informants agree that if the information is explained, it should be written first and then explained orally. Written information and explained orally will be easier to understand and can be read again. Written information will provide information certainty and legal certainty, because it can be authentically proven. Oral information has various weaknesses, firstly the lack of clarity of medical information, and weak as evidence, so that written information and verbally explained will reduce this [13].

It is implied that written information is better than oral, to improve understanding of patients/families health workers can use assistive devices, such as

AQ11 **Table 3.1: Correlation**

	Questions 1	Questions 2	Questions 3	Questions 4	Questions 5	Questions 6	Questions 7	Questions 8	Questions 9	Questions 10	Questions 11	Questions 12	Total
Questions 1													
Pearson Correlation	1	0.099	0.156	0.070	0.457*	0.440*	0.253	0.149	−0.087	0.087	−0.062	0.048	0.419*
Sig. (2-tailed)		0.604	0.410	0.712	0.011	0.015	0.177	0.433	0.646	0.647	0.744	0.799	0.021
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 2													
Pearson Correlation	0.099	1	0.153	0.147	−0.019	0.233	0.118	0.326	0.471**	0.155	0.191	0.321	0.559**
Sig. (two-tailed)	0.604		0.419	0.438	0.922	0.214	0.536	0.077	0.009	0.415	0.312	0.084	0.001
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 3													
Pearson Correlation	0.156	0.153	1	0.208	0.705**	0.485**	0.256	−0.072	−0.124	−0.016	0.409*	0.258	0.581**
Sig. (two-tailed)	0.410	0.419		0.269	0.000	0.007	0.173	0.707	0.513	0.931	0.025	0.168	0.001
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 4													
Pearson Correlation	0.070	0.147	0.208	1	0.255	0.254	0.218	0.268	0.097	0.568**	0.008	0.090	0.526**
Sig. (2-tailed)	0.712	0.438	0.269		0.173	0.176	0.247	0.156	0.608	0.001	0.966	0.636	0.003
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 5													
Pearson Correlation	0.457*	−0.019	0.705**	0.255	1	0.280	0.300	−0.135	−0.182	0.176	0.371*	0.030	0.499**
Sig. (two-tailed)	0.011	0.922	0.000	0.173		0.133	0.108	0.478	0.336	0.352	0.043	0.874	0.005
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 6													
Pearson Correlation	0.440*	0.233	0.485**	0.254	0.280	1	0.235	0.060	0.000	0.034	−0.191	0.143	0.502**
Sig. (two-tailed)	0.015	0.214	0.007	0.176	0.133		0.211	0.753	1.000	0.859	0.312	0.452	0.005
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 7													
Pearson Correlation	0.253	0.118	0.256	0.218	0.300	0.235	1	0.618**	0.305	−0.022	−0.059	0.211	0.546**
Sig. (two-tailed)	0.177	0.536	0.173	0.247	0.108	0.211		0.000	0.101	0.907	0.757	0.262	0.002
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 8													
Pearson Correlation	0.149	0.326	−0.072	0.268	−0.135	0.060	0.618**	1	0.481**	0.098	−0.142	0.162	0.494**
Sig. (two-tailed)	0.433	0.077	0.707	0.156	0.478	0.753	0.000		0.007	0.608	0.453	0.393	0.005
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 9													
Pearson Correlation	−0.087	0.471**	−0.124	0.097	−0.182	0.000	0.305	0.481**	1	0.440*	0.000	0.277	0.428*
Sig. (2-tailed)	0.646	0.009	0.513	0.608	0.336	1.000	0.101	0.007		0.015	1.000	0.138	0.018
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 10													
Pearson Correlation	0.087	0.155	−0.016	0.568**	0.176	0.034	−0.022	0.098	0.440*	1	0.104	0.71	0.405*
Sig. (two-tailed)	0.647	0.415	0.931	0.001	0.352	0.859	0.907	0.608	0.015		0.583	0.708	0.026
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 11													
Pearson Correlation	−0.062	0.191	0.409*	0.008	0.371*	−0.104	−0.059	−0.142	0.000	0.104	1	0.332	0.384*
Sig. (two-tailed)	0.744	0.312	0.025	0.966	0.043	0.312	0.757	0.453	1.000	0.583		0.73	0.036
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 12													
Pearson Correlation	0.048	0.321	0.258	0.090	0.030	0.143	0.211	0.162	0.277	0.071	0.332	1	0.520**
Sig. (two-tailed)	0.799	0.084	0.168	0.636	0.874	0.452	0.262	0.393	0.138	0.708	0.073		0.003
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Total													
Pearson Correlation	0.419*	0.559**	0.581**	0.526**	0.499**	0.502**	0.546**	0.494**	0.428*	0.405*	0.384*	0.520**	1
Sig. (two-tailed)	0.021	0.001	0.001	0.003	0.005	0.005	0.002	0.005	0.018	0.026	0.036	0.003	
N	30	30	30	30	30	30	30	30	30	30	30	30	30

*Correlation is significant at the 0.05 level (two-tailed). **Correlation is significant at the 0.01 level (two-tailed).

AQ11 **Table 3.2: Distribution of the implementation of the informed consent of vaccination COVID-19**

Statement	Very informed		informed		Quite informed		Slightly informed		Not informed	
	f	%	f	%	f	%	f	%	f	%
Obtaining general information about COVID-19	25	25	39	39	25	25	8	8	3	3
Obtaining information about the use of the COVID-19 vaccine	22	22	36	36	22	22	12	12	8	8
Obtaining information about the brand of COVID-19 vaccine used	24	24	37	37	25	25	9	9	5	5
Getting information about vaccine doses COVID-19	26	26	30	30	28	28	10	10	6	6
Obtain information about the vaccine's effectiveness COVID-19	16	16	34	34	34	34	9	9	7	7
Getting information about the effects of side effects after the COVID-19 vaccine	24	24	31	31	28	28	11	11	6	6
Getting information about the screening process for the COVID-19 vaccine	13	13	37	37	31	31	14	14	5	5
Doing the COVID-19 vaccine without coercion	28	28	33	33	25	25	10	10	4	4
Get information about the benefits of participating in the COVID-19 vaccination	21	21	32	32	28	28	13	13	6	6
The COVID-19 vaccine approval sheet is given at the first and second doses	23	23	21	21	35	35	16	16	5	5
Information in the consent form submitted verbally and in writing	19	19	37	37	21	21	17	17	6	6

Source: Primary Data Processed in 2021

leaflets or other forms of publication if they can help provide detailed information [14]. Based on this explanation, it can be concluded that the explanation with the aids is expected to be more effective, especially if the information in writing is certainly easier to understand, because it can be re-read. Written information can be a good document so that it can be used as strong evidence, can protect interested parties; therefore, it is necessary to review various policies which state that medical information is submitted orally, and in writing only as a complement [15]. Information should be submitted in writing and explained orally, not the other way around [16].

Thus, when viewed from the contents of the informed consent explained to the patient, it turns out that all of them have not been informed, because there are still things that have not been explained, such as procedures for action and previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. Every medical action must provide a consent form to the patient as proof of approval for medical action. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. There is of informed consent still a lack, so the explanation

given to the patient is still limited. This needs to be improved in the form of an informed consent form with more complete fields so that all information related to information that has not been submitted can be written in full on the form of informed consent.

Conclusion

AQ7 ???

Acknowledgment

Implementation of COVID-19 vaccination can be carried out on men and women aged 18–60 years, the implementation of informed consent for COVID-19 vaccination is not in accordance with applicable laws and regulations, namely, the place is not in accordance with the place that should be given informed consent for the COVID-19 vaccination, the information contained in the informed consent is still incomplete so that all of it has not been informed to patients. It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

AQ8 **References**

1. Royal College of Obstetricians and Gynecologists UK. (2020). Coronavirus (COVID-19) Infection in Pregnancy: Information for Health Care Professionals; 2020. Available AQ9 from: https://www.rcog.org.uk/globalassets/documents/guidelines/2020-03-21-cov
2. Strategies and Plans. Strategic Preparedness and Response Plan; 2020. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/strategies-and-plans [Last accessed on 2020 Oct 16].
3. Vivilaki VG, Asimaki E. Respectful midwifery care during the COVID-19 pandemic. Eur J Midwifery. 2020;4:8. http://doi.org/10.18332/ejm/120070
PMid:33537610
4. Hanahoe M. Midwifery-led care can lower caesarean section rates according to the Robson Teh group classification system. Eur J Midwifery. 2020;4:1-5. http://doi.org/10.18332/ejm/119164
5. Astuti NP, Nugroho EG, Lattu JC, Potempu IR, Swandana DA. Community perception of accepted COVID-19: Literature review. J Keperawatan. 2021;13(3):569-80.
6. Global Surveillance for Human Infection with Coronavirus Disease (COVID-19); 2020. Available from: https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov) [Last accessed on 2020 Oct 20].
7. International Confederation of Midwives. Women's Right in Childbirth Must be Upheld during the Coronavirus Pandemic; 2020. Available from: https://www/internationalmidwife.co.id [Last accessed on 2020 Oct 18].
8. Hanahoe M. Midwifery-led care can lower caesarean section rates according to the robson teh group classification system. Eur J Midwifery. 2020;4:7. http://doi.org/10.18332/ejm/119164
PMid:33537609
9. Health Minister Regulation. About Novel Coronavirus (NCOV). Diakses Dari; 2020. Available from: https://www.kemkes.go.id/ AQ9 resources/COVID-19.pdf
10. Health Minister Regulation. No. 10, 2021, Implementation Vaccine Program for Managing Corona Virus Disease 2019 (COVID-19). India: Health Minister Regulation; 2021.
11. Decision Director Medical Services. No. HK.00.06.3.5.1866/1999 Guideline Informed Consent Medical Intervention. India: Decision Director Medical Services; 1999.
12. Health Minister Regulation. No. 290/Menkes/Per/III/2008. Informed Consent Medical Intervention. Health Minister Regulation; 2008.
13. Kelland K, Nebehay S. WHO Officials Rethink Epidemic Messaging Amid Pandemic Debate; 2020. Available from: https://www.reuters.com/article/us-health-coronavirus-who-messaging-insi/who-officials-rethink-epidemic-messaging-amid-pandemic-debate-idUSKBN2101AY [Last accessed on 2020 Oct 19].
14. UNFPA and COVID 19; 2020. Available from: https://www/ AQ9 unfpa.org/covid19
15. Damayanti FN, Riafisari AA, Ngestiningrum AH. A literature review on the vaccination of COVID-19 in pregnant and breastfeeding women: Effectiveness and safety. Open Access Maced J Med Sci. 2022;9:234-7.
16. Paul E, Brown GW, Kalk A, Ridde V. Playing vaccine roulette: Why the current strategy of staking everything on Covid-19 vaccines is a high-stakes wager. Vaccine. 2021;39(35):4921-4. https://doi.org/10.1016/j.vaccine.2021.07.045
PMid:34315610

Author Queries???
AQ1: Kindly provide running title
AQ2: Kindly provide department
AQ3: Kindly provide minimum three keywords
AQ4: Kindly provide corresponding author email id
AQ5: Kindly provide history details
AQ6: Kindly review the sentence as it seems to be incomplete.
AQ7: Kindly provide conclusion text part
AQ8: Kindly cite reference citation 6-8 in the text part
AQ9: Kindly provide last accessed details
AQ10: Kindly check the tables and its numbering
AQ11: Kindly cite table 3.1 and 3.2 in the main text part
AQ12: Kindly check and provide physical table 3 and 4 in the text part

4. MANUSKRIP SETELAH REVISI

ANALYSIS OF THE IMPLEMENTATION OF INFORMED CONSENT COVID-19 VACCINATION IN THE SEMARANG CITY REGION

Fitriani Nur Damayanti
Universitas Muhammadiyah Semarang, Indonesia
Email:
Phone:

Edited by:
Citation:
Keywords:
***Correspondence:**
Fitriani Nur Damayanti
Universitas Muhammadiyah Semarang, Indonesia
Email:
Received:
Revised: **Accepted:**

Funding:
Competing Interests:
The authors have declared that no competing interests exist

Abstract

Introduction: Informed consent is a process of communication between patient and your health care provider that often leads to agreement or permission for COVID-19 vaccination procedure. Every patient has the right to get information and ask questions before COVID-19 vaccination procedures. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1.216.650 people who have received the first and second doses of the COVID-19 vaccine. Implementation of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action.

AIM: The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

Methods: Observational study, with descriptive approach. 100 sample taken as purposive sample, with random sampling technique, namely a sampling technique with certain considerations by the researchers themselves. Instrument research used is questionnaire. Data collected has process with descriptive analysis.

Result: Informed consent of COVID-19 vaccination was explained to the patient, but not all informed well, because there were still things that had not been explained, such as procedures for action, previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. The explanation to the patient is enough to explain what is important and more orally.

Discussion: COVID-19 vaccination is eligible given to men and women aged 18-60 years as long as there is no contra indication. Before COVID-19 vaccine given, must be deliver all information about COVID-19 vaccine, according with the laws and regulations.

Conclusion: Informed consent COVID-19 vaccination is important role during massive of COVID-19 vaccination program. Within informed consent, patient will get full the information of the indication, contra indication, dose and side effect of COVID-19 vaccine. With all information get, patient will be decide accepted or rejected to this procedure. If informed consent is still incomplete, so it has not been fully informed to patients and will make patient confused.

Recommendation: It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

Keywords: Informed Consent, COVID-19 Vaccination

Introduction

The COVID-19 pandemic has become one of the most important threats to world health [1]. Health systems around the world are improving because they are exacerbated by fear, stigma, misinformation and limited health care delivery [2].

In the data analysis report, it was found that in more than 80 countries the number of deaths due to COVID-19. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. The use of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action. There is a need for informed consent in the implementation of the COVID-19 vaccine [3]. The use of informed consent for the COVID-19 vaccine in health workers is still very low [4].

The flow in the implementation of vaccine administration is table 1: registration, table 2: screening, table 3: vaccination, table 4: recording and observation. There is no legality in the use of informed consent in the COVID-19 vaccine [5].

With this background, it is necessary to have legal informed consent for the implementation of the COVID-19 vaccine program in the Semarang City Region.

Objective of study

The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

Materials And Methods

1. Type of research

Descriptive study with Survey approach. This research was conducted in the city of Semarang. This research will describe of determinant of implementation informed consent COVID-19 Vaccine.

2. Sample

The size sample is 100 people who have met the inclusion and exclusion criteria. The carried out by means of a sampling non-probability sampling technique was using purposive sampling, sampling which is a technique with certain considerations made by the researcher himself, based on characteristics, namely that he had already done a second dose of vaccine and also with the characteristics of the population that had been previously known.

3. Instruments

The research instrument used is a questionnaire. Questionnaire was developed to determine of implementation informed consent COVID-19 Vaccination. Questionnaire was tested for validity and reliability.

4. Data analysis

The data will be analyzed using statistical tests, then will be described quantitatively and qualitatively.

Results

1. Characteristics of Respondents

Bas Based on the table 1 above shows the majority of respondents are female by 60% and aged between 26-35 years by 33%. The implementation of the COVID-19 vaccination can be carried out on men and women over the age of 18 years.

Table 1
Distribution of Respondents

Characteristics	f	%
Gender		
Male	40	40
Female	60	60
Age		
19-25	21	21
26-35	33	33
36-45	25	25
≥ ≥ 46	21	21

Source: Primary Data Processed in 2021

2. Places to Provide Information on COVID-19 Vaccinations

Table 2 showed the research conducted on 100 respondents who vaccinated against COVID-19.

Table 2

Distribution of places to provide information on COVID-19 vaccinations

Vaccines Setting Places	**F**	**%**
Hospital	17	17
PHC	8	8
Village Office	11	11
Subdistrict Office	4	4
Others	60	60
Place of information giving	**F**	**%**
Table 1: Registration	15	15
Table 2: Screening and history taking	83	83
Table 3: Vaccination.	1	1
Table 4: Observation post Vaccination.	1	1

Source: Primary Data Processed in 2021

Table 2, showed that the majority of respondents took vaccines in places other than hospitals, health centers, urban villages, and sub-districts by 60% and the majority of places where information is provided by 83% are done at the station history taking.

Places for giving COVID-19 vaccinations can be done in hospitals, health centers, sub-districts and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

3. Result of Validity and Reliability Questionnaire

The answers to each group of respondents were tested for validity and reliability tests for. The validity test uses the Pearson Correlation test to obtain an average value of r calculated which is then the average value of r calculated is compared with the value of r table to determine that the questionnaire questions are valid (valid). While the reliability test (reliability) of the instrument used the Cronbach's Alpha test to obtain the results of the Cronbach's Alpha average value which was used to determine that the survey instrument was reliable (reliable).

The following are the results of the validity and reliability tests:

Validity Questionnaire

Table 3.1 Correlation

		Questions 1	Questions 2	Questions 3	Questions 4	Questions 5	Questions 6	Questions 7	Questions 8	Questions 9	Questions 10	Questions 11	Questions 12	Total
Questions 1	Pearson Correlation	1	.099	.156	.070	.457*	.440*	.253	.149	-.087	.087	-.062	.048	.419*
	Sig. (2-tailed)		.604	.410	.712	.011	.015	.177	.433	.646	.647	.744	.799	.021
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 2	Pearson Correlation	.099	1	.153	.147	-.019	.233	.118	.328	.471**	.155	.191	.321	.559**
	Sig. (2-tailed)	.604		.419	.438	.922	.214	.536	.077	.009	.415	.312	.084	.001
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 3	Pearson Correlation	.156	.153	1	.208	.705**	.485**	.256	-.072	-.124	-.016	.409*	.258	.581**
	Sig. (2-tailed)	.410	.419		.269	.000	.007	.173	.707	.513	.931	.025	.168	.001
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 4	Pearson Correlation	.070	.147	.208	1	.255	.254	.218	.266	.097	.568**	.008	.090	.526**
	Sig. (2-tailed)	.712	.438	.269		.173	.176	.247	.156	.608	.001	.966	.636	.003
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 5	Pearson Correlation	.457*	-.019	.705**	.255	1	.280	.300	-.135	-.182	.176	.371*	.030	.499**
	Sig. (2-tailed)	.011	.922	.000	.173		.133	.108	.478	.336	.352	.043	.874	.005
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 6	Pearson Correlation	.440*	.233	.485**	.254	.280	1	.235	.060	.000	.034	-.191	.143	.502**
	Sig. (2-tailed)	.015	.214	.007	.176	.133		.211	.753	1.000	.859	.312	.452	.005
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 7	Pearson Correlation	.253	.118	.256	.218	.300	.235	1	.618**	.305	-.022	-.059	.211	.546**
	Sig. (2-tailed)	.177	.536	.173	.247	.108	.211		.000	.101	.907	.757	.262	.002
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 8	Pearson Correlation	.149	.328	-.072	.266	-.135	.060	.618**	1	.481**	.098	-.142	.162	.494**
	Sig. (2-tailed)	.433	.077	.707	.156	.478	.753	.000		.007	.608	.453	.393	.005
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 9	Pearson Correlation	-.087	.471**	-.124	.097	-.182	.000	.305	.481**	1	.440*	.000	.277	.428*
	Sig. (2-tailed)	.646	.009	.513	.608	.336	1.000	.101	.007		.015	1.000	.138	.018
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 10	Pearson Correlation	.087	.155	-.016	.568**	.176	.034	-.022	.098	.440*	1	.104	.071	.405*
	Sig. (2-tailed)	.647	.415	.931	.001	.352	.859	.907	.608	.015		.583	.708	.026
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 11	Pearson Correlation	-.062	.191	.409*	.008	.371*	-.191	-.059	-.142	.000	.104	1	.332	.384*
	Sig. (2-tailed)	.744	.312	.025	.966	.043	.312	.757	.453	1.000	.583		.073	.036
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 12	Pearson Correlation	.048	.321	.258	.090	.030	.143	.211	.162	.277	.071	.332	1	.520**
	Sig. (2-tailed)	.799	.084	.168	.636	.874	.452	.262	.393	.138	.708	.073		.003
	N	30	30	30	30	30	30	30	30	30	30	30	30	30
Total	Pearson Correlation	.419*	.559**	.581**	.526**	.499**	.502**	.546**	.494**	.428*	.405*	.384*	.520**	1
	Sig. (2-tailed)	.021	.001	.001	.003	.005	.005	.002	.005	.018	.026	.036	.003	
	N	30	30	30	30	30	30	30	30	30	30	30	30	30

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

From the existing data, the output of the correlation value between the question items and the total is obtained. This value will then be compared with the value of r_{table} , r_{table} is sought at a significance of 0.05 with (n) 30. Then we get an r_{table} of 0.361. From the output of the correlation value between the question items and the total, it can be seen in the 'Total' line, namely the Pearson correlation value. The Pearson correlation value in each variable is more than the r_{table} value. So, it can be concluded that all question items can be declared valid.

Reability Questionnaire

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.719	.718	12

The basis for making decisions on reliability tests usually uses the 0.6 limit. according to now (1992), reliability less than 0.6 is not good, while 0.7 is acceptable and above 0.8 is good. Based on the reliability statistics table, Cronbach's alpha value is 0.719, so it can be said to be reliable because Cronbach's alpha value is > 0.07. so it can be concluded that the data from the questionnaire can be trusted.

Table 3.2

Distribution of the implementation of *the informed consent* of vaccination COVID-19

Statement	Very informed		informed		Quite informed		Slightly informed		Not informed	
	f	%	f	%	f	%	f	%	f	%
Obtaining general information about COVID-19	25	25	39	39	25	25	8	8	3	3
Obtaining information about the use of the COVID-19 vaccine	22	22	36	36	22	22	12	12	8	8
Obtaining information about the brand of COVID-19 vaccine used	24	24	37	37	25	25	9	9	5	5
Getting information about vaccine doses COVID 19	26	26	30	30	28	28	10	10	6	6
Obtain information about the vaccine's effectiveness COVID 19	16	16	34	34	34	34	9	9	7	7
Getting information about the effects of side effects after the COVID-19 vaccine	24	24	31	31	28	28	11	11	6	6
Getting information about the screening process for the COVID-19 vaccine	13	13	37	37	31	31	14	14	5	5
Doing the COVID-19 vaccine without coercion	28	28	33	33	25	25	10	10	4	4
Get information about the benefits of participating in the COVID-19 vaccination	21	21	32	32	28	28	13	13	6	6
The COVID-19 vaccine approval sheet is given at the first and second doses	23	23	21	21	35	35	16	16	5	5
Information in the consent form submitted verbally and in writing	19	19	37	37	21	21	17	17	6	6

Source: Primary Data Processed in 2021

Discussion

Implementation of Informed Consent Vaccinations COVID-19

Based on research conducted on 100 respondents were vaccinated COVID-19, it can be seen that:

1. **Places for Giving COVID-19 Vaccination Information Places for giving COVID-19**

Vaccinations can be done in hospitals, health centers, sub-districts and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

The COVID-19 vaccination flow services divided into 4 station:

- Table 1 for registration of vaccination targets and recording or verifying data by mobile officers.
- Table 2 is for screening, history taking, education where it aims to ensure the vaccination target is in good health because one of the vaccination requirements is being in good health.
- Table 3 is carried out by medical personnel to provide vaccinations according to the provisions of the dose and method of administration.
- Table 4 where the officer records the target that has been vaccinated and invites the target to sit down to wait 30 minutes which aims to anticipate the presence of AEFI [9].

In the Regulation of the Minister of Health Number 10 of 2021 article 21 states that the vaccination program service is carried out at health service facilities owned by the central government, regional government, or the public/private sector, which meet the requirements [10]. The place for providing information about COVID-19 vaccination.

The results of the study have not fully compliance with the provisions of Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999. In the regulation, it is emphasized that medical information is provided in a conducive room, meaning that it is not disturbed by other parties, so that medical information can be well received by patients/families. Given that the place for providing medical information in various places, must provide a special place/room for its implementation [11].

This is supported by Health Minister Regulation No. 290/2008, article 17 paragraph (2) it is emphasized that health service facilities are responsible for implementing the approval for medical (medical) actions. The provisions of article 17 are supported by article 18 paragraph (2) that in order to improve the quality of health services, the health office needs to supervise the implementation of these services [12]. The availability of this room provides a sense of comfort for patients to convey very personal matters, as well as health workers will provide in-depth explanations, including if there are things that are patient confidentiality, thus confidentiality can be guaranteed.

2. **Implementation of Informed Consent for COVID-19 Vaccination**

The results of the above research will be in line with the policies of the ministry of health. Based on Health Minister Regulation no 290/Menkes/Per/III/2008 and Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999, the method of delivering an explanation by the responsible health worker is distinguished by, (a) an explanation that is delivered orally, (b) an explanation that is delivered in writing. This provision provides an opportunity for health workers to choose whether to only convey verbally or both. According to the results of the study, there were no health workers who provided written and verbal explanations.

However, these results conclude that the informants agree that if the information is explained, it should be written first and then explained orally. Written information and explained orally will be easier to understand and can be read again. Written information will provide information certainty and legal certainty, because it can be authentically proven. Oral information has various weaknesses, firstly the lack of clarity of medical information, and weak as evidence, so that written information and verbally explained will reduce this [13].

It is implied that written information is better than oral, to improve understanding of patients/families health workers can use assistive devices, such as leaflets or other forms of publication if they can help provide detailed information [14]. Based on this explanation, it can be concluded that the explanation with the aids is expected to be more effective, especially if the information in writing is certainly easier to understand, because it can be re-read. Written information can be a good document, so that it can be used as strong evidence, can protect interested parties, therefore it is necessary to review various policies which state that medical information is submitted orally, and in writing only as a complement [15]. Information should be submitted in writing and explained orally, not the other way around [16].

Thus, when viewed from the contents of the informed consent explained to the patient, it turns out that all of them have not been informed, because there are still things that have not been explained, such as procedures for action, previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. Every medical action must provide a consent form to the patient as proof of approval for medical action. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. There is of informed consent still a lack, so the explanation given to the patient is still limited. This needs to be improved in the form of an informed consent form with more complete fields so that all information related to information that has not been submitted can be written in full on the form of informed consent.

Acknowledgements

Implementation of COVID-19 vaccination can be carried out on men and women aged 18-60 years, the implementation of informed consent for COVID-19 vaccination is not in accordance with applicable laws and regulations, namely the place is not in accordance with the place that should be given informed consent for the COVID-19 vaccination, the information contained in the informed consent is still incomplete so that all of it has not been informed to patients. It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

References

1. Royal College of Obstetricians and Gynecologists UK. (2020). Coronavirus (COVID-19) infection in pregnancy: Information for health care professionals. [Online].; 2020. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/2020-03-21-cov.
2. Strategies and plans. (2020). strategic preparedness and response plan [website]. [Online].; 2020 [cited 16 October 2020]. Available from: (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/strategies-and-plans
3. Vivilaki V. G., Asimaki E. (2020). Respectful midwifery care during the COVID-19 pandemic. European Journal of Midwifery. 2020 April; 4. http://doi:10.18332/ejm/120070

4. Hanahoe, M. (2020). Midwifery-ied care can lower caesarean section rates according to the robson teh group classification system. Eur J Midwifery. 2020 March; 4: p. 1-5. http://doi:10.18332/ejm/119164
5. Astuti, N. P., Nugroho, E. G. Z., Lattu, J. C., Potempu, I. R., & Swandana, D. A. (2021). Community perception of accepted COVID-19: Literature Review. Jurnal Keperawatan, 13(3), 569-580.
6. Global surveillance for human infection with coronavirus disease (COVID-19) [website]. [Online].; 2020 [cited 2020 October 20]. Available from: https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov)
7. International Confederation of Midwives. (2020). Women's right in childbirth must be upheld during the coronavirus pandemic. [Online].; 2020 [cited 2020 October 18]. Available from: https://www/internationalmidwife.co.id.
8. Hanahoe, M. (2020). Midwifery-ied care can lower caesarean section rates according to the robson teh group classification system. Eur J Midwifery. 2020 March; 4: p. 1-5. doi:10.18332/ejm/119164
9. Health Minister regulation (2020). About Novel Coronavirus (NCOV). Diakses dari : https://www.kemkes.go.id/resources/COVID-19.pdf
10. Health Minister regulation (2021). No. 10, 2021, Implementation Vaccine program for managing Corona Virus Disease 2019 (COVID-19).
11. Decision Director Medical Services (1999). No. HK.00.06.3.5.1866/1999 Guideline Informed Consent Medical Intervention.
12. Health Minister regulation (2008). No. 290/Menkes/Per/III/2008. Informed Consent Medical Intervention.
13. K. Kelland, and S. Nebehay. (2020). WHO officials rethink epidemic messaging amid pandemic debate. [Online].; 2020,313 [cited 2020 October 19]. Available from: https://www.reuters.com/article/us-health-coronavirus-who-messaging-insi/who-officials-rethink-epidemic-messaging-amid-pandemic-debate-idUSKBN2101AY
14. UNFPA and COVID 19. Website . [Online].; 2020. Available from: https://www/unfpa.org/covid19
15. Damayanti FN, Riafisari AA, Ngestiningrum AH. (2022). A Literature Review on the Vaccination of COVID-19 in Pregnant and Breastfeeding Women: Effectiveness and Safety. Open Access Maced J Med Sci [Internet]. 2021 Aug. 21 [cited 2022 Apr. 29];9(F):234-7. https://oamjms.eu/index.php/mjms/article/view/6651
16. Paul, E., Brown, G. W., Kalk, A., & Ridde, V. (2021). Playing vaccine roulette: Why the current strategy of staking everything on Covid-19 vaccines is a high-stakes wager. Vaccine, 39(35), 4921–4924. https://doi.org/10.1016/j.vaccine.2021.07.045

ANALYSIS OF THE IMPLEMENTATION OF INFORMED CONSENT COVID-19 VACCINATION IN THE SEMARANG CITY REGION

Fitriani Nur Damayanti
Universitas Muhammadiyah Semarang, Indonesia
Email:
Phone:

Edited by:
Citation:
Keywords: Informed Consent, COVID-19 Vaccination
***Correspondence:**
Fitriani Nur Damayanti, Universitas Muhammadiyah Semarang, Indonesia
Email:
Received:
Revised:
Accepted:

Funding:
Competing Interests: The authors have declared that no competing interests exist

Abstract

Introduction: Informed consent is a process of communication between patient and your health care provider that often leads to agreement or permission for COVID-19 vaccination procedure. Every patient has the right to get information and ask questions before COVID-19 vaccination procedures. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1.216.650 people who have received the first and second doses of the COVID-19 vaccine. Implementation of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action.

AIM: The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

Methods: Observational study, with descriptive approach. 100 sample taken as purposive sample, with random sampling technique, namely a sampling technique with certain considerations by the researchers themselves. Instrument research used is questionnaire. Data collected has process with descriptive analysis.

Result: Informed consent of COVID-19 vaccination was explained to the patient, but not all informed well, because there were still things that had not been explained, such as procedures for action, previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. The explanation to the patient is enough to explain what is important and more orally.

Discussion: COVID-19 vaccination is eligible given to men and women aged 18-60 years as long as there is no contra indication. Before COVID-19 vaccine given, must be deliver all information about COVID-19 vaccine, according with the laws and regulations.

Conclusion: Informed consent COVID-19 vaccination is important role during massive of COVID-19 vaccination program. Within informed consent, patient will get full the information of the indication, contra indication, dose and side effect of COVID-19 vaccine. With all information get, patient will be decide accepted or rejected to this procedure. If informed consent is still incomplete, so it has not been fully informed to patients and will make patient confused.

Recommendation: It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

Introduction

The COVID-19 pandemic has become one of the most important threats to world health [1]. Health systems around the world are improving because they are exacerbated by fear, stigma, misinformation and limited health care delivery [2].

In the data analysis report, it was found that in more than 80 countries the number of deaths due to COVID-19. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. The use of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action. There is a need for informed consent in the implementation of the COVID-19 vaccine [3]. The use of informed consent for the COVID-19 vaccine in health workers is still very low [4].

The flow in the implementation of vaccine administration is table 1: registration, table 2: screening, table 3: vaccination, table 4: recording and observation. There is no legality in the use of informed consent in the COVID-19 vaccine [5].

With this background, it is necessary to have legal informed consent for the implementation of the COVID-19 vaccine program in the Semarang City Region.

Objective of study

The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

Materials And Methods

5. Type of research

Descriptive study with Survey approach. This research was conducted in the city of Semarang. This research will describe of determinant of implementation informed consent COVID-19 Vaccine.

6. Sample

The size sample is 100 people who have met the inclusion and exclusion criteria.

The carried out by means of a sampling non-probability sampling technique was using purposive sampling, sampling which is a technique with certain considerations made by the researcher himself, based on characteristics, namely that he had already done a second dose of vaccine and also with the characteristics of the population that had been previously known.

7. Instruments

The research instrument used is a questionnaire. Questionnaire was developed to determine of implementation informed consent COVID-19 Vaccination. Questionnaire was tested for validity and reliability.

8. Data analysis

The data will be analyzed using statistical tests, then will be described quantitatively and qualitatively.

Results

2. Characteristics of Respondents

Bas Based on the table 1 above shows the majority of respondents are female by 60% and aged between 26-35 years by 33%. The implementation of the COVID-19 vaccination can be carried out on men and women over the age of 18 years.

Table 1
Distribution of Respondents

Characteristics	f	%
Gender		
Male	40	40
Female	60	60
Age		
19-25	21	21
26-35	33	33
36-45	25	25
≥ ≥ 46	21	21

Source: Primary Data Processed in 2021

4. Places to Provide Information on COVID-19 Vaccinations

Table 2 showed the research conducted on 100 respondents who vaccinated against COVID-19.

Table 2

Distribution of places to provide information on COVID-19 vaccinations

Vaccines Setting Places	**F**	**%**
Hospital	17	17
PHC	8	8
Village Office	11	11
Subdistrict Office	4	4
Others	60	60
Place of information giving	**F**	**%**
Table 1: Registration	15	15
Table 2: Screening and history taking	83	83
Table 3: Vaccination.	1	1
Table 4: Observation post Vaccination.	1	1

Source: Primary Data Processed in 2021

Table 2, showed that the majority of respondents took vaccines in places other than hospitals, health centers, urban villages, and sub-districts by 60% and the majority of places where information is provided by 83% are done at the station history taking.

Places for giving COVID-19 vaccinations can be done in hospitals, health centers, sub-districts and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

5. Result of Validity and Reliability Questionnaire

The answers to each group of respondents were tested for validity and reliability tests for. The validity test uses the Pearson Correlation test to obtain an average value of r calculated which is then the average value of r calculated is compared with the value of r table to determine that the questionnaire questions are valid (valid).

While the reliability test (reliability) of the instrument used the Cronbach's Alpha test to obtain the results of the Cronbach's Alpha average value which was used to determine that the survey instrument was reliable (reliable).

From the existing data, the output of the correlation value between the question items and the total is obtained. This value will then be compared with

the value of r table, r table is sought at a significance of 0.05 with (n) 30. Then we get an r table of 0.361. From the output of the correlation value between the question items and the total, it can be seen in the 'Total' line, namely the Pearson correlation value. The Pearson correlation value in each variable is more than the r table value. So, it can be concluded that all question items can be declared valid.

The basis for making decisions on reliability tests usually uses the 0.6 limit. according to now (1992), reliability less than 0.6 is not good, while 0.7 is acceptable and above 0.8 is good. Based on the reliability statistics table, Cronbach's alpha value is 0.719, so it can be said to be reliable because Cronbach's alpha value is > 0.07. so it can be concluded that the data from the questionnaire can be trusted.

The basis for making decisions on reliability tests usually uses the 0.6 limit. according to now (1992), reliability less than 0.6 is not good, while 0.7 is acceptable and above 0.8 is good. Based on the reliability statistics table, Cronbach's alpha value is 0.719, so it can be said to be reliable because Cronbach's alpha value is > 0.07. so it can be concluded that the data from the questionnaire can be trusted.

The following are the results of the validity and reliability tests:

Table 3.1 Correlation and Reliability Test

	Validity Test			Reliability test	
	Pearson Correlation to total Question	Sig (2 tail)	N	Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items
Question 1	0.419	0.021	30		
Question 2	0.559	0.001	30		
Question 3	0.581	0.001	30		
Question 4	0.526	0.003	30		
Question 5	0.499	0.005	30		
Question 6	0.502	0.005	30	0.719	0.718
Question 7	0.546	0.002	30		
Question 8	0.494	0.005	30		
Question 9	0.428	0.018	30		
Question 10	0.405	0.026	30		
Question 11	0.384	0.036	30		

Question 12	0.52	0.003	30

Source: Primary Data Processed in 2021

Table 3.2

Distribution of the implementation of *the informed consent* of vaccination COVID-19

Statement	Very informed		informed		Quite informed		Slightly informed		Not informed	
	f	%	f	%	f	%	f	%	f	%
Obtaining general information about COVID-19	25	25	39	39	25	25	8	8	3	3
Obtaining information about the use of the COVID-19 vaccine	22	22	36	36	22	22	12	12	8	8
Obtaining information about the brand of COVID-19 vaccine used	24	24	37	37	25	25	9	9	5	5
Getting information about vaccine doses COVID 19	26	26	30	30	28	28	10	10	6	6
Obtain information about the vaccine's effectiveness COVID 19	16	16	34	34	34	34	9	9	7	7
Getting information about the effects of side effects after the COVID-19 vaccine	24	24	31	31	28	28	11	11	6	6
Getting information about the screening process for the COVID-19 vaccine	13	13	37	37	31	31	14	14	5	5
Doing the COVID-19 vaccine without coercion	28	28	33	33	25	25	10	10	4	4
Get information about the benefits of participating in the COVID-19 vaccination	21	21	32	32	28	28	13	13	6	6
The COVID-19 vaccine approval sheet is given at the first and second doses	23	23	21	21	35	35	16	16	5	5
Information in the consent form submitted verbally and in writing	19	19	37	37	21	21	17	17	6	6

Source: Primary Data Processed in 2021

Discussion

Implementation of Informed Consent Vaccinations COVID-19

Based on research conducted on 100 respondents were vaccinated COVID-19, it can be seen that:

3. Places for Giving COVID-19 Vaccination Information Places for giving COVID-19

Vaccinations can be done in hospitals, health centers, sub-districts and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

The COVID-19 vaccination flow services divided into 4 station:

- Table 1 for registration of vaccination targets and recording or verifying data by mobile officers.
- Table 2 is for screening, history taking, education where it aims to ensure the vaccination target is in good health because one of the vaccination requirements is being in good health.
- Table 3 is carried out by medical personnel to provide vaccinations according to the provisions of the dose and method of administration.
- Table 4 where the officer records the target that has been vaccinated and invites the target to sit down to wait 30 minutes which aims to anticipate the presence of AEFI [9].

In the Regulation of the Minister of Health Number 10 of 2021 article 21 states that the vaccination program service is carried out at health service facilities owned by the central government, regional government, or the public/private sector, which meet the requirements [10]. The place for providing information about COVID-19 vaccination.

The results of the study have not fully compliance with the provisions of Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999. In the regulation, it is emphasized that medical information is provided in a conducive room, meaning that it is not disturbed by other parties, so that medical information can be well received by patients/families. Given that the place for providing medical information in various places, must provide a special place/room for its implementation [11].

This is supported by Health Minister Regulation No. 290/2008, article 17 paragraph (2) it is emphasized that health service facilities are responsible for implementing the approval for medical (medical) actions. The provisions of article 17 are supported by article 18 paragraph (2) that in order to improve the quality of health services, the health office needs to supervise the implementation of these services [12]. The availability of this room provides a sense of comfort for patients to convey very personal matters, as well as health workers will provide in-depth explanations, including if there are things that are

patient confidentiality, thus confidentiality can be guaranteed.

4. Implementation of Informed Consent for COVID-19 Vaccination

The results of the above research will be in line with the policies of the ministry of health. Based on Health Minister Regulation no 290/Menkes/Per/III/2008 and Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999, the method of delivering an explanation by the responsible health worker is distinguished by, (a) an explanation that is delivered orally, (b) an explanation that is delivered in writing. This provision provides an opportunity for health workers to choose whether to only convey verbally or both. According to the results of the study, there were no health workers who provided written and verbal explanations.

However, these results conclude that the informants agree that if the information is explained, it should be written first and then explained orally. Written information and explained orally will be easier to understand and can be read again. Written information will provide information certainty and legal certainty, because it can be authentically proven. Oral information has various weaknesses, firstly the lack of clarity of medical information, and weak as evidence, so that written information and verbally explained will reduce this [13].

It is implied that written information is better than oral, to improve understanding of patients/family's health workers can use assistive devices, such as leaflets or other forms of publication if they can help provide detailed information [14]. Based on this explanation, it can be concluded that the explanation with the aids is expected to be more effective, especially if the information in writing is certainly easier to understand, because it can be re-read. Written information can be a good document, so that it can be used as strong evidence, can protect interested parties, therefore it is necessary to review various policies which state that medical information is submitted orally, and in writing only as a complement [15]. Information should be submitted in writing and explained orally, not the other way around [16].

Thus, when viewed from the contents of the informed consent explained to the patient, it turns out that all of them have not been informed, because there are still things that have not been explained, such as procedures for action, previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. Every medical action must provide a consent form to the patient as proof of approval for medical action. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. There is of informed consent still a lack, so the explanation given to the patient is still limited. This needs to be improved in the form of an informed consent form with more complete

fields so that all information related to information that has not been submitted can be written in full on the form of informed consent [17],[18],[19].

Conclusion

Implementation of COVID-19 vaccination can be carried out on men and women aged 18-60 years, the implementation of informed consent for COVID-19 vaccination is not in accordance with applicable laws and regulations, namely the place is not in accordance with the place that should be given informed consent for the COVID-19 vaccination, the information contained in the informed consent is still incomplete so that all of it has not been informed to patients. It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

References

17. Royal College of Obstetricians and Gynecologists UK. (2020). Coronavirus (COVID-19) infection in pregnancy: Information for health care professionals. [Online].; 2020. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/2020-03-21-cov.
18. Strategies and plans. (2020). strategic preparedness and response plan [website]. [Online].; 2020 [cited 16 October 2020]. Available from: (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/strategies-and-plans
19. Vivilaki V. G., Asimaki E. (2020). Respectful midwifery care during the COVID-19 pandemic. European Journal of Midwifery. 2020 April; 4. http://doi:10.18332/ejm/120070
20. Hanahoe, M. (2020). Midwifery-ied care can lower caesarean section rates according to the robson teh group classification system. Eur J Midwifery. 2020 March; 4: p. 1-5. http://doi:10.18332/ejm/119164
21. Astuti, N. P., Nugroho, E. G. Z., Lattu, J. C., Potempu, I. R., & Swandana, D. A. (2021). Community perception of accepted COVID-19: Literature Review. Jurnal Keperawatan, 13(3), 569-580.
22. Global surveillance for human infection with coronavirus disease (COVID-19) [website]. [Online].; 2020 [cited 2020 October 20]. Available from: https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov)
23. International Confederation of Midwives. (2020). Women's right in childbirth must be upheld during the coronavirus pandemic. [Online].; 2020 [cited 2020 October 18]. Available from: https://www/internationalmidwife.co.id.
24. Patwary, M.M.; Alam, M.A.; Bardhan, M.; Disha, A.S.; Haque, M.Z.; Billah, S.M.; Kabir, M.P.; Browning, M.H.E.M.; Rahman, M.M.; Parsa, A.D.; et al. (2022). COVID-19 Vaccine Acceptance among Low- and Lower-Middle-Income Countries: A Rapid Systematic Review and Meta-Analysis. Vaccines 2022, 10, 427. https://doi.org/10.3390/vaccines10030427
25. Health Minister regulation (2020). About Novel Coronavirus (NCOV). Diakses dari : https://www.kemkes.go.id/resources/COVID-19.pdf
26. Health Minister regulation (2021). No. 10, 2021, Implementation

Vaccine program for managing Corona Virus Disease 2019 (COVID-19).
27. Decision Director Medical Services (1999). No. HK.00.06.3.5.1866/1999 Guideline Informed Consent Medical Intervention.
28. Health Minister regulation (2008). No. 290/Menkes/Per/III/2008. Informed Consent Medical Intervention.
29. K. Kelland, and S. Nebehay. (2020). WHO officials rethink epidemic messaging amid pandemic debate. [Online].; 2020,313 [cited 2020 October 19]. Available from: https://www.reuters.com/article/us-health-coronavirus-who-messaging-insi/who-officials-rethink-epidemic-messaging-amid-pandemic-debate-idUSKBN2101AY
30. UNFPA and COVID 19. Website . [Online].; 2020. Available from: https://www/unfpa.org/covid19
31. Damayanti FN, Riafisari AA, Ngestiningrum AH. (2022). A Literature Review on the Vaccination of COVID-19 in Pregnant and Breastfeeding Women: Effectiveness and Safety. Open Access Maced J Med Sci [Internet]. 2021 Aug. 21 [cited 2022 Apr. 29];9(F):234-7. https://oamjms.eu/index.php/mjms/article/view/6651
32. Paul, E., Brown, G. W., Kalk, A., & Ridde, V. (2021). Playing vaccine roulette: Why the current strategy of staking everything on Covid-19 vaccines is a high-stakes wager. Vaccine, 39(35), 4921–4924. https://doi.org/10.1016/j.vaccine.2021.07.045
33. Amelia R, Harahap J, Wahyuni AS, Fujiati II, Yunanda Y, Eyanoer PC, Wijaya H, Ariga RA. Analysis of Community Behavior in Coronavirus Disease-19 Prevention in Medan. Open Access Maced J Med Sci [Internet]. 2020 Sep. 15 [cited 2022 May 11];8(T1):382-6. Available from: https://oamjms.eu/index.php/mjms/article/view/5302
34. Zafar M. Association of Coronavirus Disease-19 Infected Mothers with Newborn Infants Health – A Review. Open Access Maced J Med Sci [Internet]. 2020 Sep. 10 [cited 2022 May 11];8(T1):175-8. Available from: https://oamjms.eu/index.php/mjms/article/view/5142
35. Sahar J, Kiik SM, Wiarsih W, Rachmawati U. Coronavirus Disease-19: Public Health Nurses' Knowledge, Attitude, Practices, and Perceived Barriers in Indonesia. Open Access Maced J Med Sci [Internet]. 2020 Oct. 23 [cited 2022 May 11];8(T1):422-8. Available from: https://oamjms.eu/index.php/mjms/article/view/544

5. IN PRESS

wise

Transfer confirmation

Funded
May 13, 2022

Paid out
May 13, 2022

Transfer
#414856184

Membership
P38350608

Your details

Name
khairatun nasyiatul aisyiyah

Address
JL Ketileng Indah Blok N/66
Semarang, 50272
Indonesia

Transfer overview

Amount paid by khairatun nasyiatul aisyiyah
6,197,632.00 IDR

Fee
Conversion 125,387.00 IDR

Amount converted
6,072,245.00 IDR

Exchange rate
1 EUR = 15181.417944 IDR

Converted and sent to Scientific Foundation SPIROSKI
400.00 EUR

wise

Taxes

VAT
12,426.00 IDR

Sent to

Name
Scientific Foundation SPIROSKI

Reference
9647 Fitriani Nur Damayanti

Account details
NLB BANKA AD SKOPJE
MK07210722000034890
TUTNMK22XXX

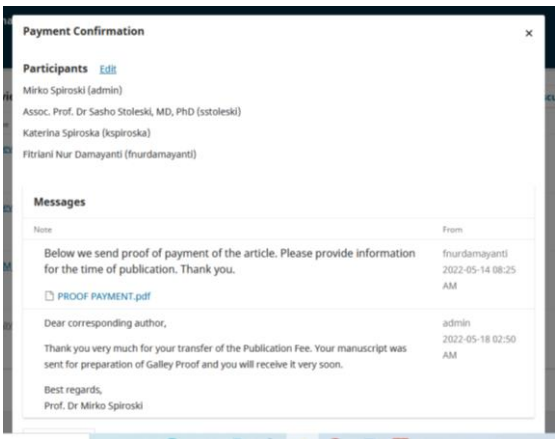
Paid out from

Name
PT. Wise Payments Indonesia on behalf of khairatun nasyiatul aisyiyah

Delivered via
SWIFT transfer

Banking partner
JPM Global EUR payout TW Ltd (EUR)

Banking partner reference
6336018



Payment Confirmation

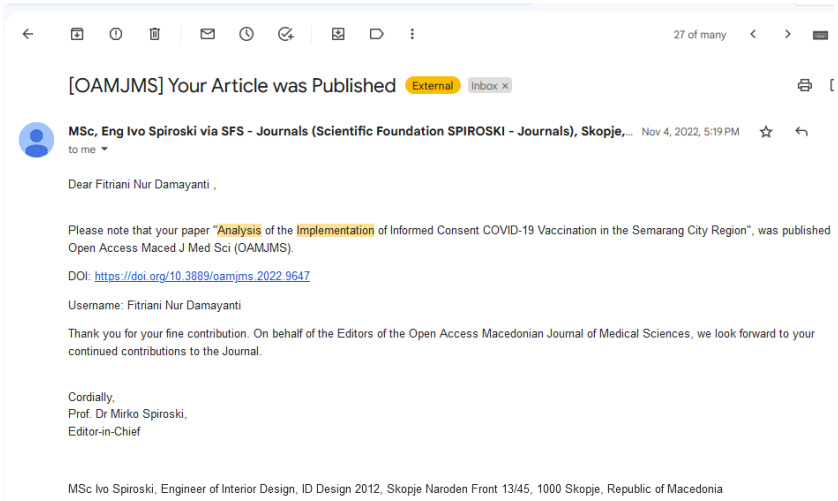
Participants Edit

Mirko Spiroski (admin)
Assoc. Prof. Dr Sasho Stoleski, MD, PhD (sstoleski)
Katerina Spiroska (kspiroska)
Fitriani Nur Damayanti (fnurdamayanti)

Messages

None	From
Below we send proof of payment of the article. Please provide information for the time of publication. Thank you. PROOF PAYMENT.pdf	fnurdamayanti 2022-05-14 08:25 AM
Dear corresponding author, Thank you very much for your transfer of the Publication Fee. Your manuscript was sent for preparation of Galley Proof and you will receive it very soon. Best regards, Prof. Dr Mirko Spiroski	admin 2022-05-18 02:50 AM

6. ARTIKEL SUDAH PUBLISH



27 of many

[OAMJMS] Your Article was Published External Inbox ×

MSc, Eng Ivo Spiroski via SFS - Journals (Scientific Foundation SPIROSKI - Journals), Skopje,... Nov 4, 2022, 5:19 PM

to me

Dear Fitriani Nur Damayanti ,

Please note that your paper "Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region", was published Open Access Maced J Med Sci (OAMJMS).

DOI: https://doi.org/10.3889/oamjms.2022.9647

Username: Fitriani Nur Damayanti

Thank you for your fine contribution. On behalf of the Editors of the Open Access Macedonian Journal of Medical Sciences, we look forward to your continued contributions to the Journal.

Cordially,
Prof. Dr Mirko Spiroski,
Editor-in-Chief

MSc Ivo Spiroski, Engineer of Interior Design, ID Design 2012, Skopje Naroden Front 13/45, 1000 Skopje, Republic of Macedonia

https://oamjms.eu/index.php/mjms/article/view/9647

fnurdamayanti

Open Access Macedonian Journal of Medical Sciences (OAMJMS)

About Announcements Metrics Current Archives EU Scopus NCBI CABI Indexation Search

Membership

Home / Archives / Vol. 10 No. E (2022): E - Public Health / Public Health Legislation

Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region

Fitriani Nur Damayanti
Departement of Midwifery, Faculty of Nursing and Health Science, Universitas Muhammadiyah Semarang, Semarang, Indonesia

Novita Nining Anggraini
Departement of Midwifery, Faculty of Nursing and Health Science, Universitas Muhammadiyah Semarang, Semarang, Indonesia

DOI: https://doi.org/10.3889/oamjms.2022.9647

Keywords: Informed consent, COVID-19, Vaccination

PDF

Information
For Readers
For Authors
For Librarians

Make a Submission

Browse
Categories
A - Basic Sciences
B - Clinical Sciences

Scientific Foundation SPIROSKI, Skopje, Republic of Macedonia
Open Access Macedonian Journal of Medical Sciences. 2022 Aug 01; 10(E):1630-1634.
https://doi.org/10.3889/oamjms.2022.9647
eISSN: 1857-9655
Category: E - Public Health
Section: Public Health Legislation

Since 2002

open access

Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region

Fitriani Nur Damayanti*, Novita Nining Anggraini

Departement of Midwifery, Faculty of Nursing and Health Science, Universitas Muhammadiyah Semarang, Semarang, Indonesia

Edited by: Sasho Stoleski
Citation: Damayanti FN, Anggraini NN. Analysis of the Implementation of Informed Consent COVID-19 Vaccination in the Semarang City Region. Open Access Maced J Med Sci. 2022 Aug 01; 10(E):1630-1634. https://doi.org/10.3889/oamjms.2022.9647
Keywords: Informed consent; COVID-19; Vaccination
***Correspondence:** Fitriani Nur Damayanti, Universitas Muhammadiyah Semarang, Semarang, Indonesia. E-mail: fitriani@unimus.ac.id
Received: 04-Apr-2022
Revised: 16-Jul-2022
Accepted: 21-Jul-2022

Funding: This research did not receive any financial support
Competing Interests: The authors have declared that no competing interests exist

Abstract

BACKGROUND: Informed consent is a process of communication between patient and your health-care provider that often leads to agreement or permission for COVID-19 vaccination procedure. Every patient has the right to get information and ask questions before COVID-19 vaccination procedures. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. Implementation of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action.

AIM: The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

METHODS: This study was observational study, with descriptive approach. One hundred sample taken as purposive sample, with random sampling technique, namely, a sampling technique with certain considerations by the researchers themselves. Instrument research used is questionnaire. Data collected have process with descriptive analysis.

RESULTS: Informed consent of COVID-19 vaccination was explained to the patient, but not all informed well, because there were still things that had not been explained, such as procedures for action and previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. The explanation to the patient is enough to explain what is important and more orally.

DISCUSSION: COVID-19 vaccination is eligible given to men and women aged 18–60 years as long as there is no contra indication. Before COVID-19 vaccine given must be deliver all information about COVID-19 vaccine, according with the laws and regulations.

CONCLUSION: Informed consent COVID-19 vaccination is important role during massive of COVID-19 vaccination program. Within informed consent, the patient will get full the information of the indication, contra indication, dose, and side effect of COVID-19 vaccine. With all information get, the patient will be decide accepted or rejected to this procedure. If informed consent is still incomplete, so it has not been fully informed to patients and will make patient confused.

RECOMMENDATION: It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

Introduction

The COVID-19 pandemic has become one of the most important threats to world health [1]. Health systems around the world are improving, because they are exacerbated by fear, stigma, misinformation, and limited health-care delivery [2].

In the data analysis report, it was found that in more than 80 countries the number of deaths due to COVID-19. The vaccine in Semarang City has been carried out, the Semarang City Health Service noted, there are 1,216,650 people who have received the first and second doses of the COVID-19 vaccine. The use of informed consent in the COVID-19 vaccine is still very low. It was found that 80% of COVID-19 vaccines used incomplete informed consent in every medical action. There is a need for informed consent in the implementation of the COVID-19 vaccine [3]. The use of informed consent for the COVID-19 vaccine in health workers is still very low [4].

The flow in the implementation of vaccine administration is Table 1: registration, Table 2: screening, Table 3: vaccination, and Table 4: recording and observation. There is no legality in the use of informed consent in the COVID-19 vaccine [5].

With this background, it is necessary to have legal informed consent for the implementation of the COVID-19 vaccine program in the Semarang City Region.

Objective of study

The purpose of this study was to determine the implementation of informed consent for COVID-19 vaccination in the Semarang City Region.

Materials and Methods

Type of research

This study was descriptive study with survey approach. This research was conducted in the city of Semarang. This research will describe of determinant of implementation informed consent COVID-19 Vaccine.

Sample

The size sample is 100 people who have met the inclusion and exclusion criteria. The carried out by means of a sampling non-probability sampling technique was using purposive sampling, sampling which is a technique with certain considerations made by the researcher himself, based on characteristics, namely, that he had already done a second dose of vaccine and also with the characteristics of the population that had been previously known.

Instruments

The research instrument used is a questionnaire. Questionnaire was developed to determine of implementation informed consent COVID-19 vaccination. Questionnaire was tested for validity and reliability.

Data analysis

The data will be analyzed using statistical tests, then will be described quantitatively and qualitatively.

Results

Characteristics of respondents

Bas based on Table 1 shows that the majority of respondents are female by 60% and aged between 26 and 35 years by 33%. The implementation of the COVID-19 vaccination can be carried out on men and women over the age of 18 years.

Table 1: Distribution of respondents

Characteristics	f	%
Gender		
Male	40	40
Female	60	60
Age		
19–25	21	21
26–35	33	33
36–45	25	25
≥46	21	21

Source: Primary Data Processed in 2021

Places to Provide Information on COVID-19 Vaccinations

Table 2 showed the research conducted on 100 respondents who vaccinated against COVID-19.

Table 2: Distribution of places to provide information on COVID-19 vaccinations

Vaccines setting places	F	%
Hospital	17	17
PHC	8	8
Village Office	11	11
Subdistrict Office	4	4
Others	60	60
Place of information giving	F	%
Table 1: Registration	15	15
Table 2: Screening and history taking	83	83
Table 3: Vaccination.	1	1
Table 4: Observation post-vaccination.	1	1

Source: Primary Data Processed in 2021

Table 2 showed that the majority of respondents took vaccines in places other than hospitals, health centers, urban villages, and subdistricts by 60% and the majority of places, where information is provided by 83% that are done at the station history taking.

Places for giving COVID-19 vaccinations can be done in hospitals, health centers, and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely, in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

Result of validity and reliability questionnaire

The answers to each group of respondents were tested for validity and reliability tests for. The validity test uses the Pearson Correlation test to obtain an average value of r calculated which is then the average value of r calculated is compared with the value of r table to determine that the questionnaire questions are valid (valid). While the reliability test (reliability) of the instrument used the Cronbach's alpha test to obtain the results of the Cronbach's alpha average value which was used to determine that the survey instrument was reliable (reliable).

The following is the results of the validity and reliability tests:

Validity questionnaire

From the existing data, the output of the correlation value between the question items and the total is obtained. This value will then be compared with the value of r_{table}. r_{table} is sought at a significance of 0.05 with (n) 30. Then, we get an r_{table} of 0.361. From the output of the correlation value between the question items and the total, it can be seen in the "Total" line, namely, the Pearson correlation value. The Pearson correlation value in each variable is more than the r_{table}

value. Hence, it can be concluded that all question items can be declared valid.

Table 3: Reliability questionnaire

Reliability Statistics		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	Number of Items
0.719	0.718	12

The basis for making decisions on reliability tests usually uses the 0.6 limit. according to now (1992), reliability less than 0.6 is not good, while 0.7 is acceptable and above 0.8 is good. Based on the reliability statistics table, Cronbach's alpha value is 0.719, so it can be said to be reliable, because Cronbach's alpha value is > 0.07 (Table 3). Hence, it can be concluded that the data from the questionnaire can be trusted.

Discussion

Implementation of informed consent vaccinations COVID-19

Based on research conducted on 100 respondents which were vaccinated COVID-19, it can be seen that:

Places for giving COVID-19 vaccination information places for giving COVID-19

Vaccinations can be done in hospitals, health centers, sub-districts, and sub-districts. However, according to the results of the study, most of them carried out vaccinations in other places, namely, in government and private institutions that had collaborated with the Health Office and had met the requirements for the acceleration of COVID-19 vaccination.

The COVID-19 vaccination flow services divided into four stations:

- Table 1 for registration of vaccination targets and recording or verifying data by mobile officers.
- Table 2 is for screening, history taking, education where it aims to ensure the vaccination target is in good health, because one of the vaccination requirements is being in good health.
- Table 4 is carried out by medical personnel to provide vaccinations according to the provisions of the dose and method of administration.
- Table 5 where the officer records the target that has been vaccinated and invites the target to sit down to wait 30 min which aims to anticipate the presence of AEFI [9].

In the Regulation of the Minister of Health Number 10 of 2021, article 21 states that the vaccination program service is carried out at health service facilities owned by the central government, regional government, or the public/private sector, which meet the requirements [10]. The place is also used for providing information about COVID-19 vaccination.

The results of the study have not fully compliance with the provisions of Kep. Dir. Yanmedis HK.00.06.3.5.1866/1999. In the regulation, it is emphasized that medical information is provided in a conducive room, meaning that it is not disturbed by other parties so that medical information can be well received by patients/families. Given that, the place for providing medical information in various places, must provide a special place/room for its implementation [11].

This is supported by Health Minister Regulation No. 290/2008, article 17 paragraph (2), it is emphasized that health service facilities are responsible for implementing the approval for medical (medical) actions. The provisions of article 17 are supported by article 18 paragraph (2) that to improve the quality of health services, the health office needs to supervise the implementation of these services [12]. The availability of this room provides a sense of comfort for patients to convey very personal matters, as well as health workers will provide in-depth explanations, including if there are things that are patient confidentiality, thus confidentiality can be guaranteed.

Implementation of informed consent for COVID-19 vaccination

The results of the above research will be in line with the policies of the ministry of health. Based on Health Minister Regulation no 290/Menkes/Per/III/2008 and Kep.Dir.Yanmedis HK.00.06.3.5.1866/1999, the method of delivering an explanation by the responsible health worker is distinguished by, (a) an explanation that is delivered orally and (b) an explanation that is delivered in writing. This provision provides an opportunity for health workers to choose whether to only convey verbally or both. According to the results of the study, there were no health workers who provided written and verbal explanations.

However, these results conclude that the informants agree that if the information is explained, it should be written first and then explained orally. Written information and explained orally will be easier to understand and can be read again. Written information will provide information certainty and legal certainty, because it can be authentically proven. Oral information has various weaknesses, firstly the lack of clarity of medical information, and weak as evidence, so that written information and verbally explained will reduce this [13].

It is implied that written information is better than oral, to improve understanding of patients/families health workers can use assistive devices, such as leaflets or other forms of publication if they can help

Table 4: Correlation

	Questions 1	Questions 2	Questions 3	Questions 4	Questions 5	Questions 6	Questions 7	Questions 8	Questions 9	Questions 10	Questions 11	Questions 12	Total
Questions 1													
Pearson Correlation	1	0.099	0.156	0.070	0.457*	0.440*	0.253	0.149	−0.087	0.087	−0.062	0.048	0.419*
Sig. (2-tailed)		0.604	0.410	0.712	0.011	0.015	0.177	0.433	0.646	0.647	0.744	0.799	0.021
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 2													
Pearson Correlation	0.099	1	0.153	0.147	−0.019	0.233	0.118	0.328	0.471**	0.155	0.191	0.321	0.559**
Sig. (two-tailed)	0.604		0.419	0.438	0.922	0.214	0.536	0.077	0.009	0.415	0.312	0.084	0.001
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 3													
Pearson Correlation	0.156	0.153	1	0.208	0.705**	0.485**	0.296	−0.072	−0.124	−0.016	0.409*	0.258	0.581**
Sig. (two-tailed)	0.410	0.419		0.269	0.000	0.007	0.173	0.707	0.513	0.931	0.025	0.168	0.001
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 4													
Pearson Correlation	0.070	0.147	0.208	1	0.259	0.254	0.218	0.266	0.097	0.568**	0.008	0.090	0.526**
Sig. (2-tailed)	0.712	0.438	0.269		0.173	0.176	0.247	0.156	0.608	0.001	0.968	0.636	0.003
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 5													
Pearson Correlation	0.457*	−0.019	0.705**	0.255	1	0.280	0.300	−0.135	−0.182	0.176	0.371*	0.030	0.499**
Sig. (two-tailed)	0.011	0.922	0.000	0.173		0.133	0.108	0.478	0.336	0.352	0.043	0.874	0.005
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 6													
Pearson Correlation	0.440*	0.233	0.485**	0.254	0.280	1	0.235	0.060	0.000	0.034	−0.191	0.143	0.502**
Sig. (two-tailed)	0.015	0.214	0.007	0.176	0.133		0.211	0.753	1.000	0.859	0.312	0.452	0.005
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 7													
Pearson Correlation	0.253	0.118	0.296	0.218	0.300	0.235	1	0.618**	0.305	−0.022	−0.059	0.211	0.546**
Sig. (two-tailed)	0.177	0.536	0.173	0.247	0.108	0.211		0.000	0.101	0.907	0.757	0.262	0.002
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 8													
Pearson Correlation	0.149	0.328	−0.072	0.266	−0.135	0.060	0.618**	1	0.481**	0.098	−0.142	0.162	0.494**
Sig. (two-tailed)	0.433	0.077	0.707	0.156	0.478	0.753	0.000		0.007	0.608	0.453	0.393	0.005
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 9													
Pearson Correlation	−0.087	0.471**	−0.124	0.097	−0.182	0.000	0.305	0.481**	1	0.440*	0.000	0.277	0.428*
Sig. (2-tailed)	0.646	0.009	0.513	0.608	0.336	1.000	0.101	0.007		0.015	1.000	0.138	0.018
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 10													
Pearson Correlation	0.087	0.155	−0.016	0.568**	0.176	0.034	−0.022	0.098	0.440*	1	0.104	0.71	0.405*
Sig. (two-tailed)	0.647	0.415	0.931	0.001	0.352	0.859	0.907	0.608	0.015		0.583	0.708	0.026
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 11													
Pearson Correlation	−0.062	0.191	0.409*	0.008	0.371*	−0.191	−0.059	−0.142	0.000	0.104	1	0.332	0.384*
Sig. (two-tailed)	0.744	0.312	0.025	0.968	0.043	0.312	0.757	0.453	1.000	0.583		0.73	0.036
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Questions 12													
Pearson Correlation	0.048	0.321	0.258	0.090	0.030	0.143	0.211	0.162	0.277	0.071	0.332	1	0.520**
Sig. (two-tailed)	0.799	0.084	0.168	0.636	0.874	0.452	0.262	0.393	0.133	0.708	0.073		0.003
N	30	30	30	30	30	30	30	30	30	30	30	30	30
Total													
Pearson Correlation	0.419*	0.559**	0.581**	0.526**	0.499**	0.502*	0.546**	0.494*	0.428*	0.405*	0.384*	0.520**	1
Sig. (two-tailed)	0.021	0.001	0.001	0.003	0.005	0.005	0.002	0.005	0.018	0.026	0.036	0.003	
N	30	30	30	30	30	30	30	30	30	30	30	30	30

*Correlation is significant at the 0.05 level (two-tailed). **Correlation is significant at the 0.01 level (two-tailed).

provide detailed information [14]. Based on this explanation, it can be concluded that the explanation with the aids is expected to be more effective, especially if the information in writing is certainly easier to understand, because it can be re-read. Written information can be a good document so that it can be used as strong evidence, can protect interested parties; therefore, it is necessary to review various policies which state that medical information is submitted orally, and in writing only as a complement [15]. Information should be submitted in writing and explained orally, not the other way around [16].

Thus, when viewed from the contents of the informed consent explained to the patient, it turns out that all of them have not been informed, because there are still things that have not been explained, such as procedures for action and previous medical history. Informed consent of the COVID-19 vaccine was not given in the first and second doses. However, the majority are given in the first dose. Every medical action must provide a consent form to the patient as proof of approval for medical action. The information provided by health workers at the time of vaccinating COVID-19 did not provide a complete explanation. There is of informed consent still a lack, so the explanation

Table 5: Distribution of the Implementation of the Informed consent of vaccination COVID-19

Statement	Very informed		informed		Quite informed		Slightly informed		Not informed	
	f	%	f	%	f	%	f	%	f	%
Obtaining general information about COVID-19	25	25	39	39	25	25	8	8	3	3
Obtaining information about the use of the COVID-19 vaccine	22	22	36	36	22	22	12	12	8	8
Obtaining information about the brand of COVID-19 vaccine used	24	24	37	37	25	25	9	9	5	5
Getting information about vaccine doses COVID-19	26	26	30	30	28	28	10	10	6	6
Obtain information about the vaccine's effectiveness COVID-19	16	16	34	34	34	34	9	9	7	7
Getting information about the effects of side effects after the COVID-19 vaccine	24	24	31	31	28	28	11	11	6	6
Getting information about the screening process for the COVID-19 vaccine	13	13	37	37	31	31	14	14	5	5
Doing the COVID-19 vaccine without coercion	28	28	33	33	25	25	10	10	4	4
Get information about the benefits of participating in the COVID-19 vaccination	21	21	32	32	28	28	13	13	6	6
The COVID-19 vaccine approval sheet is given at the first and second doses	23	23	21	21	35	35	16	16	5	5
Information in the consent form submitted verbally and in writing	19	19	37	37	21	21	17	17	6	6

Source: Primary Data Processed in 2021

given to the patient is still limited. This needs to be improved in the form of an informed consent form with more complete fields so that all information related to information that has not been submitted can be written in full on the form of informed consent.

Conclusion

Implementation of COVID-19 vaccination can be carried out on men and women aged 18–60 years, the implementation of informed consent for COVID-19 vaccination is not in accordance with applicable laws and regulations, namely, the place is not in accordance with the place that should be given informed consent for the COVID-19 vaccination, the information contained in the informed consent is still incomplete so that all of it has not been informed to patients. It is recommended to evaluate the implementation of informed consent to see the suitability of its implementation with the laws and regulations.

References

1. Royal College of Obstetricians and Gynecologists UK. (2020). Coronavirus (COVID-19) Infection in Pregnancy: Information for Health Care Professionals; 2020. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/2020-03-21-cov [Last accessed on 2021 May 25].
2. Strategies and Plans. Strategic Preparedness and Response Plan; 2020. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/strategies-and-plans [Last accessed on 2020 Oct 16].
3. Vivilaki VG, Asimaki E. Respectful midwifery care during the COVID-19 pandemic. Eur J Midwifery. 2020;4:8. http://doi.org/10.18332/ejm/120070
   PMid:33537610
4. Begum T, Nababan H, Rahman A, Islam MR, Adams A, Anwar I. Monitoring caesarean births using the Robson ten group classification system: a cross-sectional survey of private for-profit facilities in urban Bangladesh. PloS one. 2019;14(8):e0220693.
5. Astuti NP, Nugroho EG, Lattu JC, Potempu IR, Swandana DA. Community perception of accepted COVID-19: Literature review. J Keperawatan. 2021;13(3):569-80.
6. Global Surveillance for Human Infection with Coronavirus Disease (COVID-19); 2020. Available from: https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov) [Last accessed on 2020 Oct 20].
7. International Confederation of Midwives. Women's Right in Childbirth Must be Upheld during the Coronavirus Pandemic; 2020. Available from: https://www/internationalmidwife.co.id [Last accessed on 2020 Oct 18].
8. Hanahoe M. Midwifery-led care can lower caesarean section rates according to the robson teh group classification system. Eur J Midwifery. 2020;4:7. http://doi.org/10.18332/ejm/119164
   PMid:33537609
9. Health Minister Regulation. About Novel Coronavirus (NCOV). Diakses Dari; 2020. Available from: https://www.kemkes.go.id/resources/COVID-19.pdf [Last accessed on 2021 May 25].
10. Health Minister Regulation. No. 10, 2021, Implementation Vaccine Program for Managing Corona Virus Disease 2019 (COVID-19). India: Health Minister Regulation; 2021.
11. Decision Director Medical Services. No. HK.00.06.3.5.1866/1999 Guideline Informed Consent Medical Intervention. India: Decision Director Medical Services; 1999.
12. Health Minister Regulation. No. 290/Menkes/Per/III/2008. Informed Consent Medical Intervention. Health Minister Regulation; 2008.
13. Kelland K, Nebehay S. WHO Officials Rethink Epidemic Messaging Amid Pandemic Debate; 2020. Available from: https://www.reuters.com/article/us-health-coronavirus-who-messaging-insi/who-officials-rethink-epidemic-messaging-amid-pandemic-debate-idUSKBN2101AY [Last accessed on 2020 Oct 19].
14. UNFPA and COVID 19; 2020. Available from: https://www/unfpa.org/covid19 [Last accessed on 2021 May 25].
15. Damayanti FN, Riafisari AA, Ngestiningrum AH. A literature review on the vaccination of COVID-19 in pregnant and breastfeeding women: Effectiveness and safety. Open Access Maced J Med Sci. 2022;9:234-7.
16. Paul E, Brown GW, Kalk A, Ridde V. Playing vaccine roulette: Why the current strategy of staking everything on Covid-19 vaccines is a high-stakes wager. Vaccine. 2021;39(35):4921-4. https://doi.org/10.1016/j.vaccine.2021.07.045
    PMid:34315610