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

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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**	0.256	−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	0.266	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	0.966	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	0.328	−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	0.966	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	0.133	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.

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