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PROBLEMATIC OF AUTONOMY REVIEW OF THE COVID-19 VACCINATION INFORMED CONSENT

Problematika Tinjauan Otonomi dari Persetujuan Vaksinasi COVID-19

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Abstract

Background: Not all approvals to receive COVID-19 vaccination are based on understanding the right information, and it can be seen from some inappropriate motivations related to inadequate government policies.
Aims: This study aims to identify the implementation of informed consent in COVID-19 vaccination, in terms of the autonomy of the vaccine recipients, so that the necessary policy could be recommended.
Methods: The research took place in Surabaya in June-December 2021 using descriptive qualitative methods through in-depth interviews with five vaccinators and five vaccine recipients by purposive sampling. Data were analyzed from interview transcripts using coding and categorization, and thematic analysis, then compared to relevant references.
Results: The results showed some of the COVID-19 vaccination's informed consents were inadequate, lacking complete information disclosure and the signature of consent. These findings suggest that the autonomy of the COVID-19 vaccine recipients has not been respected.
Conclusion: Inadequate respect for the autonomy of the vaccine recipients has the risks of causing a medical conflict in the future if there are unexpected effects. Thus, the government needs to make standard informed consent procedures for COVID-19 vaccination and collaborate with the local government.

Keywords: COVID-19 vaccination, informed consent, information disclosure, respect for autonomy

Abstrak

Latar Belakang: *Belum semua persetujuan untuk menerima vaksinasi COVID-19 didasari oleh pengertian akan informasi yang benar, terlihat dari motivasi yang belum sepenuhnya tepat, yang berkaitan dengan kurang memadainya kebijakan pemerintah.*
Tujuan: *Penelitian ini untuk mengidentifikasi pelaksanaan informed consent dalam vaksinasi COVID-19, terkait otonomi penerima vaksin, sehingga dapat direkomendasikan kebijakan yang diperlukan.*
Metode: *Lokasi penelitian di kota Surabaya pada bulan Juni-Desember 2021 dengan metode kualitatif deskriptif melalui wawancara mendalam kepada lima orang vaksinator dan lima orang penerima vaksin, secara* purposive sampling*. Data dianalisis dari transkrip wawancara, dengan membuat koding, kategori, dan tema, lalu dibandingkan dengan referensi yang sesuai.*
Hasil: *Hasil penelitian menunjukkan bahwa sebagian informed consent terkait vaksinasi COVID-19 tidak memadai dengan pemberian informasi tidak lengkap dan tanpa tanda tangan persetujuan. Temuan ini menunjukkan bahwa penghormatan terhadap otonomi penerima vaksin COVID-19 belum dilakukan.*
Kesimpulan: *Penghormatan otonomi penerima vaksin yang tidak memadai berisiko menimbulkan sengketa medis di kemudian hari jika terdapat efek yang tidak diharapkan. Dengan demikian, pemerintah perlu membuat standar prosedur informed consent dalam vaksinasi COVID-19 yang memadai.*

Kata kunci*: Vaksinasi COVID-19, informed consent, pemberian informasi medis, penghormatan terhadap otonomi*

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Introduction

The COVID-19 pandemic has hit the whole world since early 2020, impacting various sectors of life. Many people have experienced losses in the fields of economy, health, tourism, trade, industry, etc (Atalan, 2020; Gilardino, 2020). Various efforts have been made by the Indonesian government to suppress the transmission of COVID-19. In addition to carrying out health protocols, the government also tried to build immunity in the wider community against the SARS COV-2 virus, through vaccination (Indonesia, 2021). COVID-19 vaccination is no longer an option to be carried out or not. In the context of a country experiencing an outbreak as written in Law No. 4 of 1984 concerning Infectious Diseases Outbreak, citizens are obliged to support efforts to control the outbreak, including receiving COVID-19 vaccinations. The Indonesian government has made COVID-19 vaccination one of the conditions for using public facilities to travel, shop, attend school, or obtain government facilities (*BPJS, BLT*, etc.). This method is quite effective in motivating people to be willing to receive the COVID-19 vaccine although it cannot be denied that the motivation of the citizens to receive the vaccination varies, and some are based on incorrect understanding.

In November 2020, a survey was conducted by the Indonesian Ministry of Health, WHO, and UNICEF on the opinion of the Indonesian people regarding their willingness to receive the COVID-19 vaccination, with more than 112.000 respondents (Satgas COVID-19, 2020). The survey results showed that more than 60% of respondents were willing to be vaccinated, more than 7% refused, and the rest said they did not know. Most of the respondents said they did not have complete information about vaccines. Thirty percent of respondents were unsure about the safety of vaccines, 22% of respondents were not sure about the effectiveness of vaccines, and the rest were worried about negative side effects after vaccination. It appears that in the initial stages of vaccination, not all people had the complete and correct information about vaccination. Another research conducted in January 2021 found that 48.1% of respondents were worried about the COVID-19 vaccine, especially regarding the safety and *'halal'* of the vaccine (Putri *et al.*, 2021). In this study, it was found that some respondents who were willing to be vaccinated experienced anxiety about the vaccine they received. After the vaccination program was carried out, another survey was conducted by the "Indikator" survey agency in January-February 2022 (Indikator, 2022) with the result that 61.5% of respondents agreed to the 3rd COVID-19 vaccination (booster). The rest did not agree and did not know. This problem is also faced by various countries as reported by Lazarus *et al.* in 2021 and 2022 (Lazarus *et al.*, 2021, 2023). These studies found that public knowledge based on the information obtained influenced confidence in the COVID-19 vaccination. Even though people are willing to be vaccinated, they do not always trust the vaccine they receive. Some people consider the COVID-19 vaccination as only necessary for formality, fulfillment of obligations, and requirement to use public facilities.

From the various data that have been mentioned before, the most common cause of a lack of understanding was inadequate information or much misinformation that confused the public in determining which information was reliable. One of the ways of providing information about the COVID-19 vaccination was the informed consent process before administering the vaccine. Therefore, it is necessary to study whether the informed consent process for COVID-19 is adequate or not. Sun and Paul also conducted research which showed that the public's willingness to accept the COVID-19 vaccine accompanied by the correct understanding was closely related to information about the vaccine previously received (Paul, Steptoe and Fancourt, 2021; Sun, Lin and Operario, 2021). According to Faden and Beauchamp, being forced to accept a medical action (in this context, including the COVID-19 vaccination) can be caused by incomplete information. This condition will still result in consent although involuntarily, and this

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does not respect the autonomy of the vaccine recipient (Faden and Beauchamp, 1986). Data found from the research showed the percentage of people who were not willing to receive the COVID-19 vaccine and the reasons for it. However, the research did not examine this unwillingness from an ethical point of view, specifically in terms of autonomy and the completeness of vaccine information. Therefore, this study was conducted to identify the information disclosure in the informed consent of COVID-19 as a principle of medical ethics respect for autonomy, so that recommendations for appropriate solutions could be given.

Method

The study was conducted using a descriptive qualitative method through in-depth interviews with five COVID-19 vaccine recipients and five COVID-19 vaccinators. This method was used to explore the experience of the respondents regarding informed consent in COVID-19 vaccination (Martha and Kresno, 2016). The selection of research subjects/respondents was carried out through purposive sampling, targeting vaccine recipients who were at least 18 years old, had received the first or second dose of COVID-19 vaccination, and were willing to participate in this study. The snowball method was also used in this study where participants recommended other participants until data saturation was reached. There were a lot of people in the population who could become respondents, but the results of the interviews reached saturation with ten respondents. As a result, the researcher determined the optimal number of respondents in this study was ten people. This decision was aligned with the principle of saturation in qualitative research (Green and Thorogood, 2018).

To ensure triangulation, different informants (vaccinators) were included. The method of triangulation was conducted through references in legislation, bioethics, and articles in other relevant journals. The research location was chosen *purposively* in Surabaya. Surabaya is a city that is a priority for vaccination because of the high mobility of the people. With a substantial number of vaccination participants and the snowball sampling method for subject selection, the data collected was rich, representing respondents from various regions in Surabaya. The study was conducted from June to December 2021.

Respondents were interviewed for about 30-45 minutes, addressing several questions related to the implementation of the COVID-19 vaccination approval they received, and the information received by vaccine recipients during the COVID-19 vaccination process. The questions for respondents covered topics such as whether there was information disclosure before receiving the COVID-19 vaccination, the information to be filled in, motivation for receiving the vaccine, understanding of the benefits of the COVID-19 vaccine, and the adequacy of information provided by the government about COVID-19. A semi-structured interview was employed, allowing the respondents to answer questions directionally while also providing the freedom to share stories as long as the response was relevant to the topic of the question. The interviews were held by appointment with the respondents and were recorded using a recording device. The interviewer was the researcher in qualitative research, holding credentials as a medical doctor, a bioethicist, and a lecturer in the medical faculty. This background equipped her with competency in medical ethics, qualitative research, and medical science, particularly related to this topic. The results of the interviews were then transcribed and coded, then classified into categories and themes. Subsequently, the data were analyzed and compared with reference sources, including articles of the relevant journal, bioethics, medical law, and legal references. The findings were presented through a descriptive narrative and supported by tables or diagrams.

Result and Discussion

Respondents were classified into two groups as source validation, namely vaccinator staff and vaccine recipients of

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the COVID-19 vaccine, described in the table 1.

Table 1. The demographic data from research respondents

Data	Vaccinator staff	Vaccine recipients
Gender		
Man	-	2 (20%)
Woman	5 (50%)	3 (30%)
Age (years)		
<30	1 (10%)	-
30-40	3 (30%)	2 (20%)
>40-50	1 (10%)	2 (20%)
>50	-	1 (10%)
Last education		
Senior High School	-	3 (30%)
Diploma of Nursing	4 (40%)	-
Bachelor	-	2 (20%)
Doctor	1 (10%)	-
Occupation		
Health worker	5 (50%)	-
Private employee	-	3 (30%)
Housewife	-	1 (10%)
Entrepreneur	-	1 (10%)
Ever refused a COVID-19 vaccination	-	1 (10%)

The research was not analyzed based on demographic data. However, the demographic data in the table showed that the interviews were conducted with respondents from various backgrounds which enriched the data.

Overview of the Implementation of the Informed Consent of COVID-19 Vaccination

From the interview results, it was found that three vaccinator respondents and three vaccine recipient respondents said that informed consent before COVID-19 vaccination was given, while the other four respondents said that vaccination was carried out without informed consent even though the screening was done by health professionals.

Two vaccinator respondents stated that the implementation of informed consent for COVID-19 vaccination depends on the policy of each health facility. The approval of the vaccine recipient was not required in some health facilities, while screening and observation during post-vaccination were still carried out to monitor the occurrence of post-vaccine side effects. Mrs. Vi, the vaccinator, 41 years old, said that it was not the patient who signed the consent but the doctors who screened and injected the vaccines did. It was considered that the patient must have agreed since he/she had filled out the screening form. Several reasons and obstacles in the response to the lack of informed consent for COVID-19 vaccination were too many vaccine recipients (4 participants), limited resources of vaccinators (3 participants), limited time (2 participants), and online registration being considered as a vaccination approval (1 participant). Another vaccinator, Mrs. De, 37 years old, mentioned that there was no explanation given in a mass vaccination because there were too many vaccine recipients. The vaccine recipients filled out the form by themselves without any detailed explanation as in the previous vaccination.

Completeness of Medical Information Disclosure Before The Informed Consent of COVID-19 Vaccination

From the results of the interview, despite three vaccine recipient respondents who signed the consent before the vaccination, only one vaccine recipient received an explanation about the benefits of the vaccine and the side effects that can occur after receiving the COVID-19 vaccination. Other respondents said that there was no explanation before signing the vaccination consent, and they even said they signed the form without knowing the content of the form. Mr. D, a vaccine recipient, 33 years old, said he signed twice on two pages but did not know what he signed.

Furthermore, based on the respondents' statements, the consent form was not standardized by the government resulting in different information included in the forms. In general, the consent only contains information related to the initial screening criteria before receiving the COVID-19 vaccination and an explanation of what must be done after the vaccination

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or if side effects occur. Explanations about the benefits, effectiveness, risks and side effects of vaccination are often not conveyed by vaccinators. In this research, there was even certain information that vaccinators deliberately withhold because of the potential for debate, as stated below by Ms. E, one of the vaccinators. The 39 years old vaccinator mentioned that there were pros and cons about the Astra Zeneca vaccination at that time, and there was fear from both the medical personnel and the vaccinators. Therefore, to avoid making the vaccine recipients worried, they did not inform the vaccine recipients.

The mapping of the information contained in the COVID-19 vaccination is explained in table 2.

Table 2. Types of Information in the COVID-19 Vaccination Informed Consent

Type of information	Frequencies (from 10 respondents)
What to do in case of Post Vaccine Side Effect	5
Who can and can't be vaccinated	4
Explanation to rest	3
Type of the vaccine given	3
Goal of vaccination	3
Vaccine side effects and risks	2
No information	4

In this research, most of the information explained by the vaccinator was the actions to be taken in case of post-vaccine side effects and the requirements of vaccine recipients. The effectiveness of the vaccine given, the benefits of the vaccine/the vaccine goals, and vaccine risks were rarely informed although they were important. This could cause vaccine recipients not to receive complete information that may affect their decision to receive the vaccine. They were vaccinated without knowing about the vaccine.

The reasons for receiving the COVID-19 vaccine from the vaccine recipients

It is interesting that despite the inadequate information regarding the COVID-19 vaccination, respondents were still willing to receive the vaccination. There are several motivations from vaccine recipients to receive COVID-19 vaccination as expressed by vaccine recipients and vaccinator respondents. Mr. D, a vaccine recipient, 33 years old, said that he would be safe since he learned from the news that the vaccine would only be a problem for old men with illnesses. Another vaccine recipient, Mrs. E., who was 60 years old, said that she was a social worker who was directly in contact with other people, so she was willing to be vaccinated to avoid getting infected.

From the results of the interview, the motivation for receiving the COVID-19 vaccine was not only the concern of health, but also fulfillments of requirements for using public facilities, receiving government assistance, or having previous bad experiences with families exposed to COVID-19. Not all respondents were aware of the true benefits of receiving the COVID-19 vaccine. A vaccinator said that the initial motivation of the vaccine recipients he served was mostly because of getting a vaccine certificate and fear of not being able to access government facilities anymore. This diagram shows the mapping of the reasons for receiving the vaccine from the vaccine recipients. The percentage meant the biggest reason for receiving the vaccine (Figure 1).

The true meaning of informed consent and respect for patient's autonomy

Respect for the patient's autonomy is a part of the principles of medical ethics. Autonomy is a person's right to make his own choices without any coercion or pressure from outsiders (Beauchamp and Childress, 2019). Kusmaryanto explained, which was rewritten by Dewi, that respect for autonomy is based on respect for human dignity and, that the owner of the body has the right to determine what will happen to his body (Dewi, 2021).

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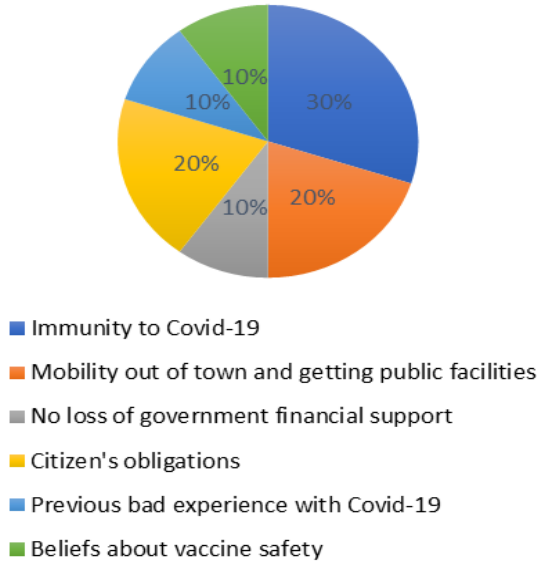

Figure 1. The mapping of the reasons for receiving the vaccine

Informed consent is carried out with respect to the autonomy of the patient, so that the medical therapy that will be given by the doctor/medical professional is legal (Beauchamp and Childress, 2019). The existence of informed consent before medical therapy is carried out indicates that without the consent of the patient, the doctor/medical staff will not be able to perform any medical therapy on the patient.

Informed consent means the consent after an explanation. This means that before a person approves medical therapy, he must first receive an explanation of the medical therapy he will receive ('Minister of Health regulations No. 290/Menkes/ PER/III/2008 concerning Informed Consent'). The decision to approve or reject a medical therapy must be based on the right understanding of the right information. Thus, informed consent is not only a formal consent signature but also an agreement based on an understanding of correct information about medical therapy and all its benefits and side effects.

As said by Kadam, for the implementation of quality (autonomous) informed consent, four criteria must be met, namely: competence (competence of the recipient of information), information disclosure (providing information before approval of action), comprehension (understanding of the information provided), and voluntariness (volunteering in giving consent) (Kadam, 2017). The information submitted in the informed consent must also be in a good manner, complete in content, and true about the things conveyed (Dewi, 2021). At least several components must be conveyed in the medical information, namely indications of action, benefits/ importance of the action, side effects/ complications that can be caused by the action, other alternative actions along with benefits and side effects, and estimated costs.

Approval of action can be in the form of verbal or written. Low-risk medical procedures usually require verbal approval, but moderate or high-risk medical procedures must be approved in writing. Respecting the patient's autonomy means giving the patient the freedom to accept or to refuse a medical treatment. Thus, it should also be understood that to help patients make autonomous decisions, health professionals must provide adequate information to patients about these actions. A medical therapy that was carried out without the consent of the patient/ recipient of the action, or even though there was consent without an understanding of adequate information, would be very prone to causing doctor-patient conflict (Sinaga, 2021).

The results of this study indicated that health workers were not fully aware of the need to respect the autonomy of vaccine recipients by providing adequate information. Being registered to receive the COVID-19 vaccination was already considered as the patient's consent. Health experts considered that there was no longer the need for informed consent and signed approval. The research results showed that not all respondents who wanted to receive the COVID-19 vaccination understood the importance of vaccination, and this could be seen from the motivation of vaccine recipients. When someone received a vaccine without receiving the correct information, or because of compulsion, then the consent to vaccination was not autonomous (Disemadi and Pardede, 2021).

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Informed consent of COVID-19 vaccination in a pandemic context

Giving the COVID-19 vaccination is considered as a medical therapy. Vaccine recipients who do not know the benefits, risks, side effects, etc. of the vaccinations they receive can potentially sue if side effects occur after the vaccination. The provision of correct information along with public understanding is needed so that vaccination is carried out with awareness, not coercion. A study was conducted in China in March-April 2020 regarding the willingness of respondents to take part in a clinical trial of COVID-19 vaccination with the result showing 35.99% disagreed to the COVID-19 vaccination (Sun, Lin and Operario, 2021). This research was supported by Paul who found the factors that cause a person to refuse the COVID-19 vaccination (Paul, Steptoe and Fancourt, 2021). These studies stated that many factors influenced a person's consent to receive the COVID-19 vaccine, and one of the most crucial factors was the provision of correct information.

Seen from the coverage of the first dose of vaccination, 85.26% of the target was achieved and 58.09% of the target for the second dose was achieved. It means vaccination in Indonesia can be said to be quite successful (COVID-19, 2022). However, what needs to be analyzed in terms of medical ethics is whether the vaccination approval is based on an autonomous decision or not, especially in terms of the implementation of providing medical information before vaccination.

Law No. 36 of 2009 concerning Health Article 152 paragraph (1a) states that "Government, local government, and society are responsible for carrying out preventive measures, control and eradication of infectious diseases and the consequences it causes." Because the COVID-19 pandemic was included in these criteria, the public must support the government's efforts to prevent the spread of COVID-19 by vaccinating and limiting social contact (Law No. 6 of 2018 concerning Health Quarantine). Although approval of COVID-19 vaccination is not needed since it is a citizen's obligation, it is still better if approval is obtained in respect of the autonomy of citizens (Dewi, 2022). Vaccination is still a medical action that has side effects, so citizens need to know the right and complete information regarding the vaccination. Law No. 4 of 1984 concerning Infectious Diseases Outbreak stated that the community must play an active role in efforts to control the epidemic. Thus, the public must support the implementation of the COVID-19 vaccination with the awareness of the importance of this vaccination, not merely out of obligation.

The government has provided information about vaccination through the website (for example Covid19.go.id) and social media with the hope that each member of the Community as an individual will know and agree independently, but that does not mean it has been accepted by the whole community. The number of hoax news on social media can reduce the public's trust in the COVID-19 vaccine, and it was proven in the study that stated respondents who had received hoax news think twice before receiving the COVID-19 vaccine (Marbella *et al.*, 2021). The incessant demands of company leaders who require their employees to be vaccinated as a condition for entering work can cause people's motivation to be vaccinated just so they can still work. Regulations in the transportation sector that require people to get vaccinated before going out of town can also create compulsion to receive vaccines. Vaccination was finally considered a necessity due to a lack of understanding about the importance of the COVID-19 vaccine, which was caused by a lack of proper information regarding the purpose of COVID-19 vaccination. Information in quantity may be sufficient, and social media has also reported a lot, but not all people have received it, because not everyone has access to social media and there is a high number of hoax news. Thus, providing information about the COVID-19 vaccine before vaccination is still needed to accommodate this deficiency. Even though COVID-19 vaccination is a citizen's

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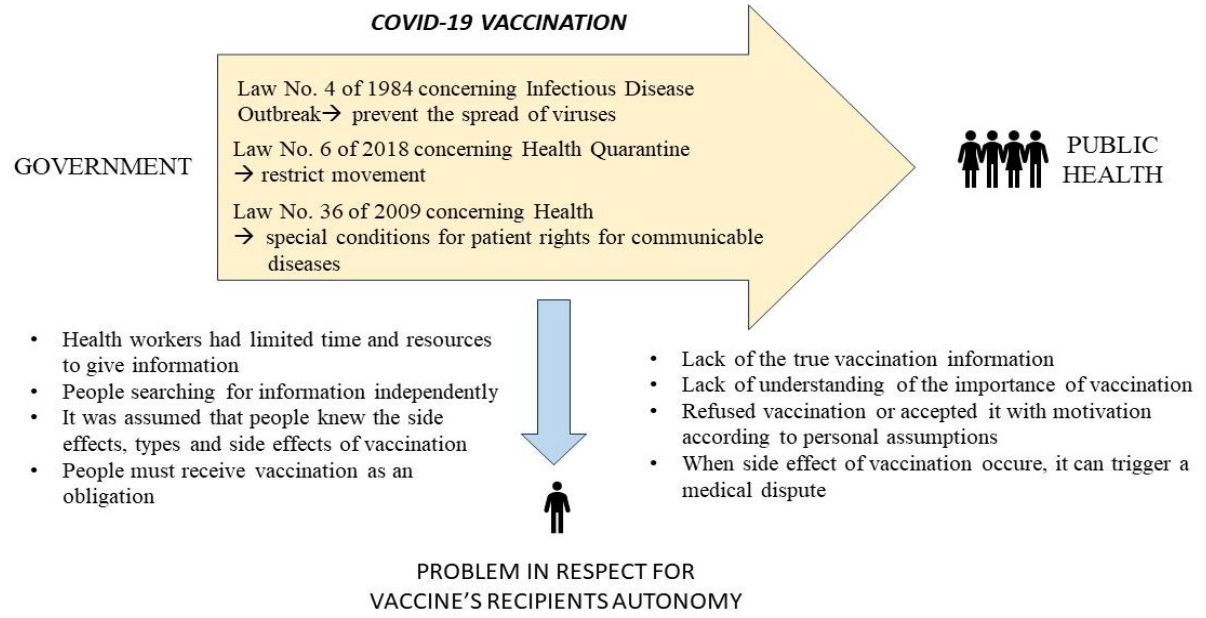

Figure 2. The Problematic of Informed Consent for COVID-19 Vaccination

obligation as written in Law No. 4 of 1984 concerning Infectious Diseases Outbreak and Law No. 6 of 2018 concerning Health Quarantine, citizens still have the right to know the benefits, side effects and effectiveness of vaccines, because vaccination is also a medical procedure. The problems in informed consent for COVID-19 vaccination discussed in this article are depicted in Figure 2.

Completeness and correctness of information in informed consent for COVID-19 vaccination

With adequate explanation in the informed consent process, the approval of medical therapy can be an autonomous and responsible decision, not out of compulsion. Adequate information must not only be complete but also correct in its content. It has been mentioned that the completeness of medical information includes several things, namely indications, benefits of the procedure, risks/side effects and complications of the procedure, other alternative actions along with their benefits and risks ('Minister of Health regulations No. 290/Menkes/PER/III/2008 concerning Informed Consent').

Another study found that the patient's understanding of medical information was influenced by the completeness of the information received by the patient (Dewi, 2021; Susanto, Pratama and Hariyanto, 2017). Based on Faden and Beauchamp's statement, incomplete information can be in the form of reducing or adding information content (Faden and Beauchamp, 1986). Information that is usually reduced or not mentioned is the risks or complications that can occur. If this information is clearly stated, health professionals are worried that patients are afraid and refuse medical therapy, so treatment efforts cannot be carried out. In addition to this fear, health professionals also think that information about the risks or complications of the procedure does not need to be fully known to the patient. However, if the risk occurs without the patient's knowledge, medical conflict can occur between health professionals and patients (Siregar and Ahmad, 2019).

From the results of this study, it was found that vaccinators did not inform the risk of vaccination before the COVID-19 vaccination was administered. Some even did not inform the type of vaccine given, for fear of causing conflict. This would be very risky if these uninformed side effects occurred. The addition of information material was often done, especially on the benefits of action. Health professionals exaggerated the benefits of the procedure

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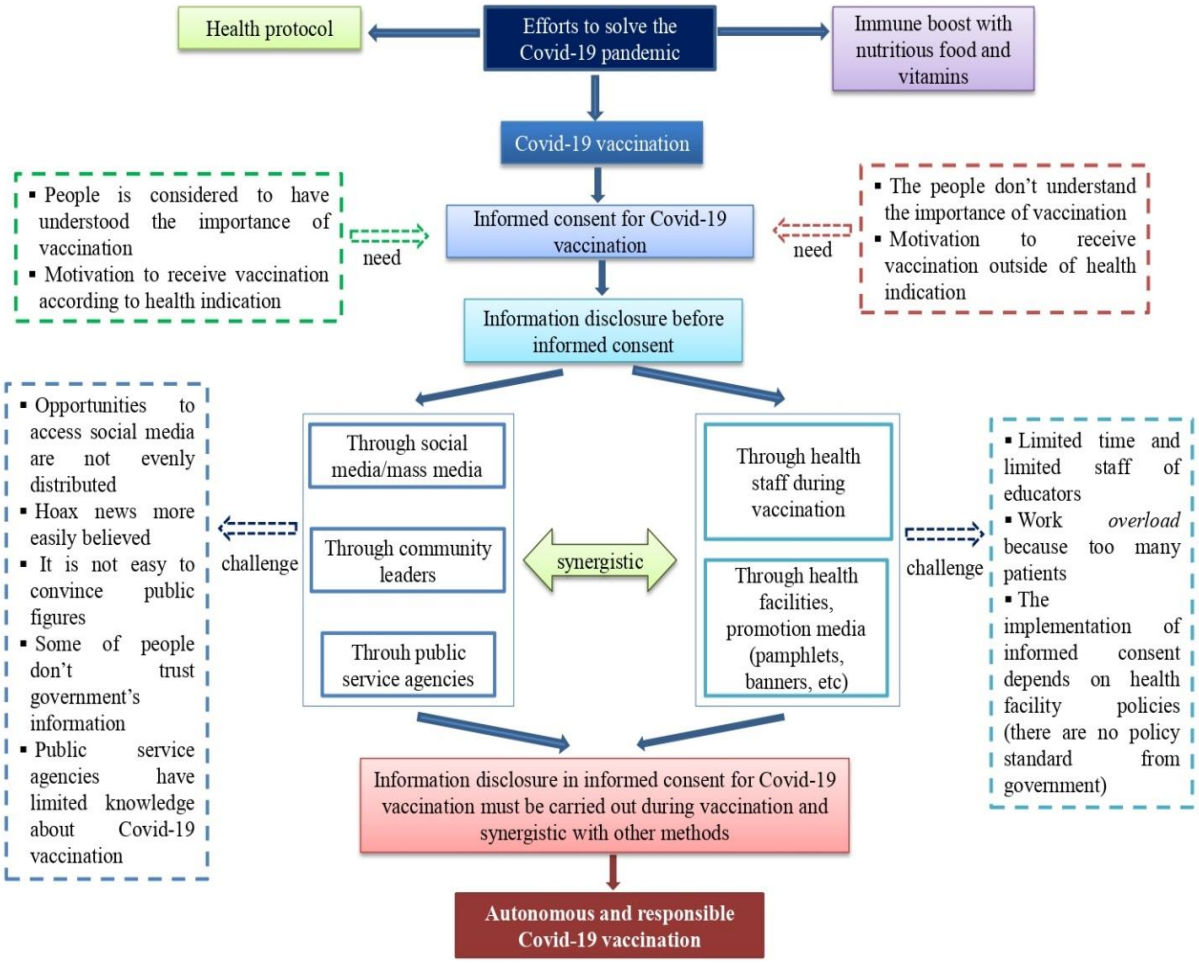

Figure 3. The Importance of Providing Information in COVID-19 Vaccination Implemented Synergistically

so that the patient agreed to the procedure. This was risky if the benefits or results of the action did not happen. The patient would be disappointed and medical conflicts can occur in the future.

Furthermore, according to Faden and Beauchamp, information can be incorrect if manipulated or associated with changing the patient's perception of the medical action so that the patient agrees to receive it (Faden and Beauchamp, 1986). In the case of the COVID-19 vaccination, the actual benefits of the vaccine from a medical point of view were sometimes obscured by information that COVID-19 vaccine certificate was a requirement to access public facilities.

This research showed that there was a lot of incompleteness of information. Health professionals were given a target for vaccination coverage, and they were doing everything to achieve it. There was a target but there was limited time and resources, health professionals decided to ignore the consent to vaccination. From the research conducted by Hanif *et al*., Wake, and Osuji, a cultural approach could help vaccination implementation because the obstacle in conveying information was the inappropriate approach to the community. In addition, an approach by earning the public trust model could also help the effectiveness of delivering medical information, especially in this COVID-19 vaccination. This effort was to explore and emphasize the public's understanding of the severity of COVID-19 so that prevention efforts were needed, one of which is vaccination (Hanif *et al.*, 2021; Wake, 2021; Osuji, 2018). An analysis of the importance of providing information related to vaccination that needs to be provided synergistically is illustrated in Figure 3.

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Conclusion

The problem of patient autonomy in providing COVID-19 vaccination lied in the lack of understanding of the importance of patient informed consent, which could be seen from the provision of information that was not yet optimal. Not all health facilities carried out adequate informed consent for COVID-19 vaccination. This condition is prone to medical conflicts in the future if there are side effects from administering the vaccine. This condition needs special attention from the management of health facilities and the government. The COVID-19 vaccination is indeed an obligation for citizens during this pandemic, but if the obligation is not accompanied by the provision of adequate information to provide a good understanding, it is considered a violation of respect for the autonomy of citizens. Thus, a strategy is needed so that within the limitations of health professionals in the implementation of the COVID-19 vaccination, information disclosure can still be carried out properly. Some strategies can be done by government. Information media can be used regularly during the implementation of the COVID-19 vaccination, either through print (pamphlets/brochures, banners), audio (recording explanations about vaccinations that are played during vaccination), or audio-visuals (showing videos explaining vaccinations). Government also can cooperate and coordinate with local government organizations (RT, RW, Kelurahan, Karang Taruna, PKK, etc.) or students (Student Executive Board of University) in the implementation of vaccination and use local cultural approaches and health belief behavior. The training of officers from the government/local organizations is related to providing vaccination information can also be carried out, so that information disclosure can be provided by these officers before signing the vaccination agreement. Finally, the government or health officer must carry out periodic supervision and procurement of SOPs (Standard Operational Procedures) for the implementation of informed consent for COVID-19 vaccination. This study has limitations because the location of the research was only local in Surabaya even though Surabaya is the second largest city in Indonesia. It is hoped that the findings of this study can become the initial research for further research, with research subjects and research locations from various places in Indonesia. Thus, the data obtained is more diverse and more representative so the recommended solutions are also expected to be applied more broadly in Indonesia.

Abbreviations

COVID-19: Corona Virus Disease of 2019; WHO: World Health Organization; UNICEF: United Nations International Children's Emergency Fund; BPJS: *Badan Penyelenggara Jaminan Sosial*; BLT: *Bantuan Langsung Tunai*; AEFI: Adverse Events Following Immunization; KIPI*: Kejadian Ikutan Pasca Imunisasi*; RT: *Rukun Tetangga*; RW: *Rukun Warga*; PKK: *Pembinaan Kesejahteraan Keluarga*.

Declarations

Ethics Approval and Consent Participant

This research has passed the ethics review from the Research Ethics Committee of the University of Surabaya with number 170/KE/VI/2021.

Conflict of Interest

We declare that we do not conflict with anyone’s interest.

Availability of Data and Materials

The availability of data and materials are provided on request.

Authors’ Contribution

EDAMD contributed to the conceptualization of the study, created the methodology and collected data, analyzed data, made a manuscript, and finally approved the version to be published. HC contributed to the analysis of government policies and their relevance to respondent data.

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