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Research Paper

The urgency of legal regulations existence in case of COVID-19 vaccination refusal in Indonesia

Sunny Ummul Firdaus

Democracy and National Resilience Center Institute for Research and Community Service Sebelas Maret University, Ir. Sutami Number 36 Kentingan, Jebres, Surakarta City, Central Java, Indonesia

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ABSTRACT

This study investigated the problem of refusal of the COVID-19 vaccine. To solve this problem, it is necessary to develop regulations governing sanctions for refusing the COVID-19 vaccine and include these sanctions on informed consent documents. An informed consent document can be provided when health workers give a person a COVID-19 vaccine and be used as concrete evidence that a person refused to be vaccinated. This is very important considering that the COVID-19 vaccination program is expected to be able to accelerate COVID-19 management and prevention by achieving herd immunity. In this study, the researchers applied a socio-legal research method. This study investigated several aspects, the first is the issue of the refusal of the COVID-19 vaccine and the second are the legal considerations. The third aspect is a regulation model to deal with the issue of COVID-19 vaccine refusal.

1. Introduction

In 2019, a mysterious outbreak of pneumonia characterized by fever, dry cough, fatigue, and occasional gastrointestinal symptoms occurred at the Huanan Seafood in Jianghan District, Wuhan City, the capital of Hubei Province in Central China. On February 11, 2020, the Director-General of the World Health Organization (WHO) named the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) COVID-19, and on March 11, 2020, the disease spread throughout 114 countries, with over 118,000 cases and 4000 deaths, such that the WHO declared a pandemic status. The WHO declared a Public Health Emergency of International Concern, which means that COVID-19 is a major threat to the world. COVID-19 spread rapidly throughout the world, including in Indonesia, due to mobility. On March 2, 2020, Indonesian President Joko Widodo announced that the first cases of COVID-19 in the country were found in a dance instructor and her mother in Depok, West Java. Both of them had attended an event in Jakarta in which a Japanese national, who later tested positive for COVID-19 in Malaysia, was in attendance. After attending the event, both patients experienced fever, cough, and shortness of breath. Since these first cases occurred, the number of COVID-19 cases in Indonesia has been increasing daily. Data published by the COVID-19 National Task Force until July 26, 2021, showed 3,194,733 cases, 2,549,692 recovered patients, and 84,766 deaths.

Furthermore, the number of additional COVID-19 cases in Indonesia is very high, and the highest additional COVID-19 cases thus far occurred on July 15, 2021, with 56,757 new cases. This condition is exacerbated by the fact that the Ministry of Health until had discovered 463 sequences of the new COVID-19 variants by July 4, 2021.

With the broader spread of COVID-19, the government must accelerate COVID-19 management and prevention. One of the programs that must be accelerated is the COVID-19 vaccination program, whose main purpose is to reduce the transmission, morbidity, and mortality of COVID-19. The COVID-19 vaccination program also aims to achieve herd immunity and protect not only the health of the community but also its ability to remain productive socially and financially. The implementation of the vaccination program is mandated through Presidential Decree No. 50 of 2021, and Ministry of Health Regulation No. 19 of 2021. Broadly, Presidential Regulation No. 50 of 2021 covers vaccine procurement funding and activities, vaccination implementation and support, and facilities. Implementation of COVID-19 vaccine procurement as referred to in Article 3 of Presidential Regulation No. 99 of 2020 is carried out through assignment to state-owned enterprises, direct appointment of the provider business entity, and/or cooperation with international institutions/agencies. Furthermore, for implementation, the Ministry of Health determines the criteria of eligibility and prioritization of vaccine recipients, locations, stages of administration, and standards for vaccination services. To support the acceleration and
smooth functioning of the procurement and implementation of the vaccination, ministries and agencies of the central and local government need to provide support in accordance with laws and regulations.

Furthermore, the Ministry of Health Regulation No. 19 of 2021 regulates the planning for vaccination needs, the targets for vaccination implementation, the distribution of COVID-19 vaccines, the supporting equipment and logistics, the implementation of COVID-19 vaccination services, the cooperation in the implementation of COVID-19 vaccination, the monitoring and prevention of Post Immunization Adverse Events (AEFI), the communication strategies, the recording and reporting, the funding, the guidance and supervision, and the technical instructions for the implementation of COVID-19 vaccination. The two regulations, Presidential Regulation No. 50 of 2021 and Ministry of Health Regulation No. 19 of 2021, are the basic regulations for the implementation of COVID-19 vaccination in Indonesia, where presidential regulation controls vaccine procurement between countries, and the delegation and guarantee of vaccination implementation, and guarantees vaccination implementation. Meanwhile, the Minister of Health Regulation controls the technical implementation of the COVID-19 vaccination campaign so that these two regulations complement each other.

To date, the COVID-19 vaccination program in Indonesia has not run optimally. The first dose of vaccination reached only 21.35% of the population, and the second dose of vaccination reached only 8.60% of the population. These figures are still very far from the vaccination target set by the government, which is 70% or 181.5 million people. One of the causes of the non-optimality of this program is widespread refusal of the vaccine. Data from indicator.co.id (2021) show that as many as 41% of Indonesians refuse to be vaccinated. The reasons for this include unconfirmed side effects (54.2%), the unconfirmed effectiveness of the vaccine (27%), feeling healthy or no need to be vaccinated (23.8%), and suspicions of the business interests behind vaccines (17.3%).

Laws act as a means of social control and thus play an important role in supporting government programs. To address the problem of the COVID-19 vaccination program refusal, the government should develop a law. With a legal basis that is preventive and repressive, the COVID-19 vaccination program has implementation guidelines so that people understand their rights and obligations in this program. Moreover, a legal basis provides protection and legal certainty for health workers and recipients of the COVID-19 vaccine.

This study investigated several things. The first is the problem of the refusal of the COVID-19 vaccination program. The second is a legal perspective on the refusal of the COVID-19 vaccination program. The third is a recommended regulation model to deal with the problem of the COVID-19 vaccination program refusal.

2. Research methodology

This study is a socio-legal study, which is the study of law using both legal and social science approaches. There are two main characteristics of socio-legal studies. First, a socio-legal study conducts textual studies on articles in legislation and policies to critically analyse and explain their meanings and implications for legal subjects. Second, a socio-legal study develops new methods at the intersection of legal studies and the social sciences, such as socio-legal qualitative research and socio-legal ethnography. A socio-legal approach aims to explore a problem by studying related legal norms or doctrines and comprehensively examining the context of norms and their enforcement. The socio-legal method was applied to analyse the problem of COVID-19 vaccination refusal by examining the conditions of the community and conducting legal studies using quantitative and qualitative field data on COVID-19 vaccination refusal. In addition, the socio-legal approach in this study also involves different areas of knowledge, such as health sciences to analyse medical problems, sociology to determine appropriate community behaviour control, and civic education to analyse the implementation of the rights and obligations of citizens, and other disciplines.

Furthermore, field data and other data sources from the literature were used as the basis for making recommendations to optimize the implementation of COVID-19 vaccination programmes, both through socialization and legal formulations. The novel contribution of this study is the formulation of an ideal regulation model that regulates the obligation to obtain informed consent from vaccination candidates to provide protection and legal certainty for both the providers and recipients of the vaccine. Informed consent can enable the public to obtain information on medical actions and understand the procedures, side effects, benefits, and ingredients of the COVID-19 vaccine. Informed consent also contains the rights and obligations of both medical personnel and patients so that both can be realized effectively.

3. Research results

3.1. The problem of Covid-19 vaccination program refusal

The increasing number of COVID-19 cases in Indonesia has pushed the government to develop and implement COVID-19 management and prevention policies. These policies encourage people to follow health protocols, restrict public activities that can enable the wider spread of COVID-19, and implement a COVID-19 vaccination program to achieve herd immunity. Herd immunity is a product of several factors: the infectivity of the coronavirus, vaccine effectiveness, and the percentage of the population that has been vaccinated. The vaccine has to have at least 70% efficacy to prevent an epidemic and be taken by at least 80% of the population to extinguish an epidemic without taking any other measures (e.g., social distancing). For most countries, large-scale vaccination efforts have started since the first half of 2021. The needs of health workers, older adults, and emergency reserves for outbreak response or mitigation (e.g., severe localized outbreaks) take priority in the first stage. Indonesia responded well to the global call for vaccination against COVID-19. The COVID-19 vaccination programme in Indonesia officially began on January 13, 2021, with the President of Indonesia being the first recipient. The first phase of the vaccination program was conducted from January to April 2021 and covered 1.3 million health workers and 17.4 million public service workers.

The COVID-19 vaccination program is carried out based on the procedures established by the Ministry of Health that regulate the criteria, priority, schedule, stages, and standards of administering the vaccine. To accelerate and streamline vaccine procurement and implementation, it is necessary to obtain support from the ministries, agencies, and local governments stated in Presidential Regulation No. 99 of 2020. The ministries, agencies, and the local governments in question are the Ministry of Health, the Ministry of Finance, the Ministry of Foreign Affairs, the Ministry of State-Owned Enterprises, the Ministry of Home Affairs, the Head of the National Agency of Drug and Food Control, the Head of Government Goods/Services Procurement Policy Institute, the Head of Financial and Development Supervisory Agency, the Attorney General, the Head of National Police, the Commander of National Army, and the Governor and Regent/Mayor.

Below are the tasks of ministries and institutions in the COVID-19 vaccination implementation.

a. The Ministry of Health provides support as follows:
   1) Budgeting assignments, direct appointment, and/or cooperation with international institutions/agencies to provide COVID-19 vaccines and implement vaccinations;
   2) Accelerating the provision and authorization of ancillary equipment to implement COVID-19 vaccinations;
   3) Accelerating import approvals to provide ancillary equipment to implement COVID-19 vaccinations;
   4) Compiling standards for COVID-19 vaccination services; and
b. The Ministry of Finance provides support as follows:
   1) Allocating budget resources to provide COVID-19 vaccines and implement vaccinations; and
   2) Other necessary support.

c. The Ministry of Foreign Affairs provides support as follows:
   1) Facilitating international diplomacy to gain access to COVID-19 vaccines and acquire budgetary support for multilateral cooperation; and
   2) Other necessary support.

d. The Ministry of State-Owned Enterprises provides support as follows:
   1) Conducting corporate coaching and supervision on the implementation of assignments to state-owned enterprises;
   2) Coordinating other state-owned enterprises to support the assignments.

e. The Ministry of Home Affairs provides support by coordinating the provincial and district/city governments to implement the COVID-19 vaccination programme.

f. The Head of the National Agency for Drug and Food Control provides support as follows:
   1) Granting approvals for clinical trials;
   2) Granting approval for special entry lines for the raw materials or products needed for the development and use of the COVID-19 vaccine;
   3) Granting import approvals for the raw materials or products for the COVID-19 vaccine;
   4) Certifying drug manufacturing and distributing methods for vaccine production and distribution facilities, respectively;
   5) Granting emergency use authorization or issuing a marketing authorization number for the COVID-19 vaccine;
   6) Approving the passing test of each batch (i.e., lot release);
   7) Controlling product quality, safety, and integrity throughout the supply chain of the COVID-19 vaccine; and
   8) Other necessary support.

g. The Head of the Government Goods/Services Procurement Policy Institute provides support as follows:
   1) Providing guidance and assistance in the implementation of direct appointment of the COVID-19 vaccine provision;
   2) Other necessary support.

h. The Head of The Financial and Development Supervisory Agency provides support as follows:
   1) Providing guidance, assistance, and supervision in the implementation of the provision of the COVID-19 vaccine;
   2) Preparing supervision guidelines for the Government’s Internal Supervision Apparatus and the Development Finance Supervisory Agency in the implementation and procurement of the COVID-19 vaccine.

i. The Attorney General of the Republic of Indonesia provides support for legal assistance.

j. The Head of the National Police of the Republic of Indonesia provides support for the implementation of the COVID-19 vaccination campaign, including security services.

k. The Commander of the Indonesian National Armed Forces gives support for the implementation of the COVID-19 vaccination campaign.

l. The governor and regent/mayor provide support as follows:
   1) Supporting the implementation of the COVID-19 vaccination campaign, including budgetary support; and
   2) Other necessary support.

The implementation of the vaccination programme was regulated by the Ministry of Health Regulation No. 10 of 2021. The Ministry of Health made amendments to the regulation, resulting in the Ministry of Health Regulation No. 18 of 2021. According to Ministry of Health Regulation No. 10 of 2021, the implementation of the COVID-19 vaccination by the central government involving the provincial and district/city government as well as legal entities/business entities is carried out through vaccination programmes or cooperation schemes at no cost to recipients. According to Ministry of Health Regulation No. 18 of 2021, the COVID-19 vaccines to be used in the vaccination program that were obtained from grants, donations, or gifts from the public or other countries are prohibited from trade. To the scope of Ministry of Health Regulation No. 10 of 2021 covers the COVID-19 vaccination needs planning; the target of the COVID-19 vaccination implementation; the distribution of COVID-19 vaccines, supporting equipment, and logistics; the implementation of COVID-19 vaccination services; the cooperation in the implementation of COVID-19 vaccination; the monitoring and prevention of adverse events after COVID-19 vaccination; the communication strategy; the recording and reporting; the funding; and the guidance and supervision.

The COVID-19 vaccination programme in Indonesia has entered the third stage as written in Circular Letter No. HK.02.02/1/1727/2021 to Heads of Provincial Health Office and Heads of District/City Health Office throughout Indonesia concerning stage 3 vaccination for vulnerable communities, and the general public, and 12-17-year-old children. The circular letter details the stages of vaccination implementation. The following is the vaccination schedule:

a. Stage 1 (January–April 2021)

   Stage 1 vaccination is for health workers, assistants for health workers, and supporting personnel working in health care facilities.

b. Stage 2 (January–April 2021)

   Stage 2 vaccination is for the elderly and public service workers/officers.

c. Stage 3 (April 2021–May 2022)

   Stage 3 vaccination is for vulnerable people from geospatial, social, and economic aspects.

d. Stage 4 (April 2021–May 2022)

   Stage 4 vaccination is for other communities.

   Moreover, data from the Ministry of Health and the COVID-19 National Task Force stated as of 27 July 2021, stage 1 of vaccination had reached 45,278,549 people and that stage 2 vaccination had reached 18,666,343 people of the national target of 208,265,720 people. The data show that the COVID-19 vaccination campaign is still far from reaching the national target as the percentage of vaccinated people is only 30.7% of the target. This is an unpleasant fact. The national target must be achieved as soon as possible to create herd immunity.

   The slow vaccination rate is due to the refusal by society to be vaccinated. Unconfirmed side effects (54.2%), unconfirmed vaccine effectiveness (27%), feeling healthy or no need to be vaccinated (23.8%), and suspicions of the business interests behind vaccines (17.3%) are among the reasons for refusal. Lack of information and understanding among the public and feelings of anxiety due to being among the first to be vaccinated vaccination are factors that contribute to why people have refused to get vaccinated due to unconfirmed side effects. Moreover, the second most commonly cited reason is the unconfirmed effectiveness of the vaccine, which is due to the increase in COVID-19-positive cases along with the first stage of the vaccination programme. This is related to the belief among the public that if they feel healthy, then they feel that they do not need to be vaccinated.

   Furthermore, the least common reason is the paid vaccines due to a growing conspiracy that COVID-19 does not occur naturally, and that COVID-19 vaccines are a scam. The public believes this conspiracy because those such as the elderly and public employees were prioritized, thus indicating that only certain groups are eligible for COVID-19
treatment. Given the very limited number of vaccines available, incorrect information on paid vaccines became widespread.

A survey conducted by the Ministry of Health, the National Immunization Technical Advisory Group (NITAG), the United Nations International Children’s Emergency Fund (UNICEF), and the World Health Organization (WHO) showed that 7.6% of Indonesians refused all vaccines, and 27.6% of Indonesians did not know whether to refuse or to receive a vaccine. The most common reasons for refusal were concerns about vaccine safety (30%), uncertainty about the effectiveness of the vaccine (22%), lack of trust towards the vaccine (13%), fear of side effects such as fever and pain (12%), and religious beliefs (8%).

Data from a survey conducted by the Indonesian Survey Institute from 20 to 25 June 2021, showed that 82.6% of Indonesians had not been vaccinated, 36.4% of which were not willing to be vaccinated. The most commonly cited reasons were being afraid of the side effects of the COVID-19 vaccine (55.5%), believing that the vaccine is not effective (25.4%), thinking that they did not need it (19.0%), believing that the vaccine might not be halal (9.9%), being unwilling to pay for the vaccine (8.7%), feeling that they did not need to be vaccinated since so many other people had already been vaccinated (4.1%), believing that the vaccine was just a trick of pharmaceutical companies to make a profit (3.8%), and other reasons (9.3%).

Furthermore, there was encouragement to refuse the COVID-19 vaccine. Data from Saiful Mujani, Research, and Consulting (SMRC) showed that 8.4% of residents had received an invitation to refuse the COVID-19 vaccination program. Furthermore, 35% of residents who had ever received an invitation to refuse the COVID-19 vaccination program stated that they were willing to be vaccinated, and 47% of residents who had never received an invitation to refuse the COVID-19 vaccination program stated that they were willing to be vaccinated. The residents who were invited to refuse the COVID-19 vaccination program were mostly from Central and Eastern Indonesia (13%) and East Java (12%).

This invitation is made by spreading misinformation so that people who lack a clear understanding become influenced to refuse the vaccination and then even influence others to do the same. The invitation is done implicitly and explicitly, such as through intimidation, persuasion, and misinformation. Misinformation about COVID-19 is a threat to global public health. Misinformation, which mostly spread through social media, was prevalent in the first three months of the COVID-19 outbreak in Indonesia. As a result, the number of those who refused to be vaccinated was increasing. Continuous exposure to COVID-19 misinformation has negative effects, such as public doubt about the COVID-19 vaccine. This misinformation continues to develop along with various problems in managing and preventing COVID-19, such as the emergence of post immunization adverse events (AEFIs), the ineffective and inefficient implementation of vaccinations, and sudden changes in government policies, which have pros and cons.

There are several reasons why people refuse to be vaccinated. First, 25.6% of Indonesians believed that the vaccine was unsafe, where 0.9% strongly believed so. Second, 24.3% of Indonesians believed that the vaccine was not halal, where 1.5% strongly believed so. Third, people also refused to be vaccinated due to unclear information about the program. Data from a survey conducted by the Indonesian Political Indicators from February 1–3, 2021, showed that 7.2%, 49.9%, and 32.8% of Indonesians were extremely worried, very worried, and slightly worried, respectively, about false or misleading information related to the COVID-19 vaccine. Moreover, the Indonesian Survey Institute surveyed from 20 to 25 June 2021, to investigate people’s attitudes towards some misinformation about COVID-19. The survey found that 7.9% and 37.0% of people strongly agreed and somewhat agreed that the health authorities exaggerated the dangers of COVID-19, respectively. The survey also found that 10.5% and 15.2% of people strongly agreed and somewhat agreed that the COVID-19 vaccine was a way for the government to insert a chip into bodies was fake news, respectively. Moreover, religion is also a reason for COVID-19 vaccination refusal: 81.9% of people would receive the COVID-19 vaccine only if it is halal, and 31% of Muslims would not receive the COVID-19 vaccine. There is an ongoing debate about the halalness of the COVID-19 vaccine in Indonesian society. Furthermore, people are also questioning whether COVID-19 vaccines are effective and can prevent the spread of the virus. This is not the first time that the Muslim community has refused to be vaccinated. During a past measles pandemic, Muslim parents refused to vaccinate their children. As a result, 100 children in Indonesia’s eastern province of Papua died.

A measles outbreak also took place in the southern provinces of Thailand, which also has a Muslim population, and resulted in 14 deaths and more than 1500 cases of measles. Measles outbreaks were also reported among the Muslim population in Malaysia and the Philippines. Religious beliefs play a very important role in Indonesia, which has a Muslim majority population. The presence of religious and community leaders plays a role in instilling trust and willingness towards the COVID-19 vaccination. This rejection has been answered by Majelis Ulama Indonesia (MUI) in Fatwa Number 2 of 2021 regarding the COVID-19 vaccine product; in the fatwa, it is explained that based on the results of an audit of the object and process of making the vaccine, it is sacred and halal. This fatwa is of course the result of theoretical ijithad and the reality of production, which is reviewed directly by the MUI Fatwa Team. All these steps should strictly adhere to the Halal standards of Islam for the drug to be acceptable to Muslim consumers. The existence of this religious barrier is one of the reasons for the rejection of vaccines and why this obstacle takes a long time to overcome.

The existence of various considerations and reasons for the rejection of COVID-19 among the Indonesian population is certainly something that must be considered, considering that refusal can be an indication that public acceptance of vaccines has yet to be fully realized. Furthermore, the considerations and reasons for this refusal show that there still remain various obstacles to public health and information due to many forms of misinformation.
of COVID-19, the vaccine is mandatory for all Indonesian citizens, as also explained in Article 1 of the Regulation of the Ministry of Health No. 10 of 2021 that vaccination is the administration of a vaccine specifically given in the context of cause or to increase a person’s immunity actively against a disease so that if they are exposed to the disease, then they will not get sick or only experience mild illness and will not become a source of transmission. Consequently, to reduce transmission of the virus, sanctions can be imposed. In general, Indonesian criminal law adheres to the Ultimum Remedium mechanism, which means that the regulation of criminal sanctions is positioned as the last sanction. In a law, the first regulated sanctions are administrative sanctions or civil sanctions. Meanwhile, criminal sanctions are placed as a form of handling the final sanctions.26 Thus there no regulation more rigid than that regarding the rejection of COVID-19 vaccine.

The sanctions for those who refuse to be vaccinated have been stated in Presidential Decree No. 14 of 2021 Articles 13A and 13B concerning the amendment to Presidential Decree No. 99 of 2020 concerning vaccine procurement and vaccination implementation to handle the COVID-19 pandemic. The Presidential Decree is the only regulation that applies and governs the sanctions for those who refuse the COVID-19 vaccination program on the national level. Article 13A paragraph (2) states that everyone who has been designated as the target recipient of the COVID-19 vaccine based on the data collection as referred to in paragraph (1) must take the COVID-19 vaccine. Furthermore, paragraph (4) states that everyone who has been designated as the target recipient of the COVID-19 vaccine and who does not participate in the COVID-19 vaccination, as referred to in paragraph (2), may be subject to administrative sanctions in the form of: a) postponement or termination of the provision of social security or social assistance; b) suspension or termination of government administration services; or c) fines. Paragraph (5) states that the imposition of administrative sanctions, as referred to in paragraph (4), is carried out by the ministry, institution, regional government, or agency under their authority.

Article 13B states that anyone who has been designated as the target recipient of the COVID-19 vaccine, who does not participate in the COVID-19 vaccination as referred to in Article 13A paragraph (2), and obstructs measures to prevent the spread of COVID-19, in addition to being subject to sanctions as referred to in Article 13A paragraph (4), may also be subject to sanctions under the provisions of the law on infectious disease outbreaks. One of the sanctions as regulated in Article 14 paragraph (1) of Law No. 4 of 1984 concerning outbreaks of infectious diseases is that anyone who deliberately obstructs the implementation of epidemic control as regulated in this law faces a maximum imprisonment of one year and/or a maximum fine of one million rupiahs. In addition to law-level regulations, the rejection of COVID-19 vaccination is also governed at a lower level by regional regulations. The regional regulations that substantially have regulations regarding the rejection of the COVID-19 vaccination are more rigid than Presidential Decree No. 14 of 2022 with the provision of strict sanctions for those who refuse vaccination. Furthermore, the area that already has this regulation is DKI Jakarta through DKI Jakarta Regional Regulation No. 2 of 2020, where in article 30, "everyone who deliberately refuses to be treated and/or vaccinated against COVID-19 shall be punished with a maximum fine of five million rupiahs". However, the existence of these regional regulations only applies to DKI Jakarta Province and not on a national scale. Bearing in mind that based on the principle of the formation of laws and regulations in force in Indonesia, the level of regulations can accommodate the application of sanctions can only be regulated by laws and regional regulations. Therefore, if the rejection of the COVID-19 vaccination is applied nationally, then it must be regulated at the law level.

There are still some regulatory deficiencies in both laws and regulations. For things that have not been properly regulated in Presidential Regulation No. 50 of 2021, namely, the regulation regarding the clause "not following the COVID-19 vaccination", it does not directly refer to the rejection of the COVID-19 vaccination. This is different from the regulations applied by DKI Jakarta by using the clause "deliberately refusing to be vaccinated against COVID-19". The Presidential Decree does not concretely target the rejection of COVID-19, where the non-participation of the vaccination target has the potential to be caused by several factors other than direct rejection. For example, there are people who have serious or critical health conditions, and there are people who, due to work demands, are required to be out of town on the day of the COVID-19 vaccination; of course, they can be classified as part of those who can be subject to administrative sanctions or sanctions in the disease outbreak law. This, of course, cannot be classified as a refusal to vaccinate, so that it is not particularly targeted at setting sanctions, causing the implementation of this presidential regulation to not run effectively and maximally to encourage people to vaccinate against COVID-19.

Furthermore, the shortcomings in the presidential regulations and regional regulations above are that there is no concrete form of rejection of vaccinations that can be subject to sanctions. There must be concrete evidence of refusing to be vaccinated, considering that in order to apply sanctions or classify the form of refusal to vaccinate, the conditions must be stated in the informed consent form, which in this case, vaccination is also part of treatment or giving medical action. Meanwhile, the two regulations have not clearly regulated the confirmation of informed consent. Of course, if the consequences for refusing the vaccine are specified in the informed consent form, then the public will understand the concept and the consequences of rejection. The transparency of this implementation will support the COVID-19 vaccination programme to the maximum and the public will be given informed consent to make their own choices.

3.3. Informed consent in the COVID-19 vaccination

Informed consent is permission from a patient before conducting a healthcare intervention on him or her. A patient will be asked to consent after receiving information from the medical service provider about what treatment that he or she will receive and what consequences he or she may face.28 Fred Ameln explained that informed consent is a bond that must meet the conditions of consent in civil law because the doctor must provide complete information conveyed simply and understandable by the patient about health services he or she needs to receive, and the informed consent will be invalid and null if this information is lacking or unclear.29 An informed consent document is one of the documents that is stored as a medical record document. An informed consent document provides protection and certainty for providers of health services and patients. In the practice of health services, the execution of informed consent must be honesty-oriented.30

Obtaining informed consent is required from a patient or his or her family, but it is not needed if a patient is in an emergency that threatens the patient’s life and/or could cause disability. If health workers do not immediately treat the patient in an emergency, then they are acting against the law. A patient can give informed consent in writing or orally. Informed consent can be given implicitly (implied consent) or explicitly (expressed consent).

Ministry of Health Regulation No. 12 of 2017 concerning immunization implementation does not require health workers to obtain expressed consent before immunization. However, Article 32, Paragraph 3 states that the arrival of the community at the immunization service place both inside and outside the building after being explained, as referred to in paragraph (1) and paragraph (2), constitutes approval for immunization. Implied consent does not apply to COVID-19 vaccination because someone who receives the COVID-19 vaccine may experience a reaction after vaccination or an AEFI. Every medical treatment that contains a high risk must obtain expressed consent. An AEFI may occur because of product reactions, immunization process errors, product defects, or coincidental factors. The more comprehensive the coverage of the immunization program, the more frequently that AEFI problems occur. An increase in AEFI cases will increase anti-immunization
attitudes, reduce the coverage rate, and increase a second wave outbreak risk.\textsuperscript{31}

Furthermore, an informed consent document can be an effective tool to solve the problem of COVID-19 vaccination program refusal because it contains information about the consequences that people must accept if they refuse to be vaccinated. COVID-19 vaccination program refusal by society is a problem that is inevitable. Therefore, a legal instrument is needed to provide legal certainty and protection to improve, direct, and provide the basis for public health. Generally, health laws view this problem with three legal principles. The first is the legal principle of the right to health services in the form of treatment provided by health workers based on their abilities and skills to apply health science and technology.\textsuperscript{32} This principle means that all medical treatment procedures provided by health workers must comply with operational standards and have passed the clinical trial. Furthermore, every patient has the right to obtain proper health services. This principle is also stated in Law No. 36 of 2009 Article 4 and Article 5 paragraph (1) concerning health.

The second is the legal principle of the right to self-determination. This means that everyone freely determines his or her own will, including determining the health services needed for themselves. This principle is stated in Article 5 paragraph (3) of Law No. 36 of 2009: “everyone has the right to independently and responsibly determine the health services needed for him/herself.” This principle supports that a patient has a right to receive or refuse a health service for him/herself and prioritize individual interests. Furthermore, the third is the legal principle of the right to information, especially information about him/herself. This principle supports that everyone has a right to obtain information about health services that have been and will be received from health workers. This principle is stated in Article 52 of Law No. 29 of 2004 concerning medical practice that patients, in receiving services in medical practice, have the right to obtain a complete explanation of the medical action as referred to Article 45 paragraph (3); seek the opinion of another doctor or dentist; get services according to medical needs; refuse medical treatment; and obtain the contents of the medical record. Furthermore, Law No. 29 of 2004 also governs the obligations of a patient stated in Article 53 that patients, in receiving services in medical practice, have obligations to provide complete and honest information about their health problems, comply with the advice and instructions of a doctor or dentist, comply with applicable regulations in health care facilities, and provide compensation for services received.

Law No. 44 of 2009 Article 32 concerning hospitals also supports this right. The article states that every patient has the right to obtain information regarding the rules and regulations that apply in the hospital; to obtain information about the rights and obligations of patients; and to obtain information that includes diagnosis and procedures for medical action, the purpose of medical action, alternative actions, risks and complications that may occur, and the prognosis of the actions taken as well as the estimated cost of treatment. The implementation of COVID-19 management and prevention must adhere to the three legal principles. However, it is necessary to override individual rights for the common good. Moreover, the current health condition forces all people to have the same responsibilities to support government policies concerning COVID-19 management and prevention. The application of informed consent to the COVID-19 vaccination has also been carried out throughout the world as a form of standard approval and the basis for implementing health services for the world community.

Informed consent as part of a legal instrument containing the agreement of both parties to provide information and receive the implementation of health and medical services is certainly crucial to be implemented perfectly. Informed consent procedures for vaccine trials commonly include disclosure of very minor risks such as injection site reactions, rare risks from past, unrelated vaccines/viruses, such as Guillain–Barre syndrome for swine flu (interest in which is likely behind the interest in Astra Zeneca’s recent vaccine transverse myelitis event) and generic statements about the risk of idiosyncratic systemic adverse events and death. The existence of the meaning of consensus in informed consent will certainly have its own legal impact for the parties who have signed it, where all impacts and things that will arise will be adjusted to the things agreed upon. Therefore, the implementation of the law both das sollen and das sein on the application of informed consent is an absolute thing to be realized and optimized as part of the protection of patients and medical personnel.

3.4. A recommended regulation model to deal with the problem of the Covid-19 vaccination program refusal

Laws such as social control, social engineering, and social welfare play an important role in regulating people’s behaviour. Applying laws does not mean that the government wants to control people by force and to limit their freedom, but to protect people’s rights. To support the COVID-19 vaccination programme, there should be a legal basis to provide protection and legal certainty for providers and recipients of the vaccine. One of these is the obligation to obtain informed consent from a candidate for the vaccine. There are some reasons for this. First, informed consent can be a basis for vaccination after a candidate receives and completely understands the information about the vaccination from the health workers and after the health workers obtain the candidate’s medical record, which may contain information on congenital disease or the current status of compliance. Informed consent can also be a basis for treatment if there is an AEFI. If a candidate for the vaccine states in his or her informed consent document that he or she is not willing to receive any medical treatment if he or she experiences an AEFI, then the health workers responsible for the COVID-19 vaccination program cannot be sentenced. Moreover, informed consent can be evidence that health workers cannot be sentenced due to the side effects of the COVID-19 vaccine suffered by a vaccine recipient due to his or her dishonesty in conveying information on his or her health condition. For the vaccine recipient, informed consent can be a basis for the right to be vaccinated, and it can make the handling process easy if the vaccine recipient suffers an AEFI.

Second, informed consent makes the COVID-19 vaccination more effective because the informed consent contains information on what consequences candidates for the vaccine will face if they deliberately refuse to be vaccinated. The candidates get the information on the consequences after receiving the facts regarding the medical treatment. The candidates then have the choice to refuse with consequences. The consequences written on the informed consent document are based on the applicable legislation. With informed consent, the imposition of sanctions is carried out more clearly. In addition, informed consent can provide clear information that a candidate for the vaccine refuses to be vaccinated. Law enforcers can avoid bias in deciding whether a candidate for the vaccine deliberately refuses to be vaccinated or not.

The sanctions can be different in each region because each region may have different regulations governing the COVID-19 vaccination program. Regional regulations have advantages that are (1) only laws and regional regulations govern criminal sanctions and fines, and (2) a regional regulation is developed based on the culture that applies in the region, so it is more flexible. Local governments can impose sanctions that will give deterrent effects based on the culture applied in regions under their authority to support the implementation of the COVID-19 vaccination program. For example, if most people in a region were fishermen, the local government would impose sanctions such as a ban on getting fuel for their fishing boats, either at public or private service stations. Another example is if most people in a region were entrepreneurs, the local government would impose sanctions such as a ban on opening a business. In industrial areas, the local government requires all companies to separate workers who have been vaccinated from those who have not been vaccinated or refuse to be vaccinated so that COVID-19 does not spread wider inside the companies.

The sanctions for refusing to be vaccinated governed by regional regulations should be stated in the informed consent documents. The
sanctions in regional regulations should be synchronized with Presidential Decree No. 14 of 2021 and Law No. 4 of 1984. Moreover, it is necessary to open vaccination sites in various regions to support the imposition of the sanctions to reduce the number of people who refuse to be vaccinated. The government should work together with other parties to achieve the national vaccination target. COVID-19 management and prevention must beaccelerated effectively and efficiently to prevent a rise in COVID-19 cases in Indonesia.

4. Conclusion

The implementation of the COVID-19 vaccination programme in Indonesia must be based on informed consent, which contains information on vaccinations that will be given by doctors after receiving medical records containing pertinent information on congenital diseases, current perceived health conditions, and various preparations have taken place. Informed consent can be a means of measuring acceptance and rejection of the COVID-19 vaccine, where the presence of standards that must be met by patients becomes the basis for medical personnel to provide health services. Furthermore, the consequences of refusing the COVID-19 vaccine will be regulated by regional regulations in accordance with the conditions, habits, and customs of the region.

The application of sanctions in informed consent can be in the form of administrative sanctions and criminal sanctions adjusted to the study and observation of local governments. This informed consent will be a programme in order to achieve the target of establishing herd immunity, and observation of local governments. This informed consent will be a programme in order to achieve the target of establishing herd immunity, and encourage the community to care for each other, ultimately to accelerate the management and control of the spread of COVID-19 in Indonesia.

Disclosure statement

The research and preparation of this scientific article does not have a conflict of interest with the parties concerned.

Declaration of competing interest

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7