



## The Right to Informed Consent for Communities That Is Injected with the Covid-19 Vaccine in Health Services in Ambon City

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### **Abstract**

The city of Ambon is included in another implementation of level 3 micro community activities (PPKM) because considering the spike in the number of positive Covid-19 confirmations, which is very high compared to the Maluku Province area. The government then set a mass vaccination program as a top priority, but this policy created pros and cons among the public because they were worried about post-vaccination follow-up events (AEFI). This study aims to examine the protection of the right to informed consent for people who are injected with the COVID-19 vaccine at health services in Ambon City. The research method used is empirical/sociolegal law, which is carried out through a review of regulations and literature, field observations and interviews with relevant sources. The results of this study found that doctors and health workers who carried out vaccinations had maximally carried out informed consent and sought optimal implementation procedures, only that vaccination services, especially those located in Merdeka Square, needed to make some improvements in their implementation, such as completing the doctor's identity data in the vaccination card. which has not been well documented, communication that can be carried out in an informative manner, and relatively little time used so that it needs to be added and the lack of comfort and safety from the risk of covid 19 for health workers and privacy for vaccine recipients must be considered.

**Keywords:** *Rights; Informed Consent; Vaccination; Covid 19; Health Services*

### **Introduction**

Vaccination is one of the government's efforts to overcome the spread of the Covid-19 outbreak with the aim of accelerating the creation of herd immunity for the community so it is hoped that with the vaccination, most of the population will have immunity to the virus in question. However, there are not a few problems that occur when this vaccination action is carried out, such as concerns among some people about the occurrence of post-vaccination side effects. The reaction of the community of participants receiving the covid 19 vaccine as referred to is humane and is part of their rights to health services (the right to health care) and the right to freedom to determine their own destiny (TROS).

According to Freddy Tengker, the right to self-determination in the health sector is the basis of rights (basisrecht) for other derivative rights in health services such as the right to information, the right to bodily integrity, the right to privacy, the right not to be treated and treated without consent, the right to

terminate therapeutic consent and others.<sup>1</sup> Danny Wiradharma and Dionisia Sri Hartati also mentioned that the right to self-determination (TROS) is a basic right or primary right in the health sector. These rights are individual basic rights and social basic rights. It was further stated that the right of self-determination (TROS) became the basis of other secondary rights such as the right to privacy and the right to one's own body. The right to privacy gives birth to the right to secret medical secrets, while the right to body itself gives birth to the right to consent from the patient to every medical action carried out by health workers, after the patient has been given an explanation regarding the medical action to be carried out.<sup>2</sup> These rights are better known as informed consent.

Informed Consent consists of two words, namely informed which means having received an explanation or information and consent which means approval or giving permission.<sup>3</sup>

According to Cocanour CS, although informed consent is part of the procedure, there are also legal aspects. Therefore, the informed consent must be considered

The important components are approval or refusal of the health services to be provided, clarity and details of the medical actions taken, and there should be no coercion when consent from a competent patient or family is given.<sup>4</sup>

Vaccination according to Danny Wiradharma is a form of medical action which is a variation of the object of a medical agreement with the aim of preventing (preventive efforts) for someone who has a risk of contracting a certain disease.<sup>5</sup>

Thus, for any medical action such as with the intention of introducing an attenuated virus in the form of a vaccine into the body of the vaccinator, the recipient must first obtain the approval of the vaccinator.

This consent is known as informed consent. Informed consent is the right of the vaccine recipient to know information about the vaccination procedure, the benefits of vaccination, the risks involved as a result of the vaccination that may occur and the form of treatment that will be carried out due to the risks that will be borne as well as other alternative therapies that can be carried out if needed by the recipient of the vaccine. In addition, the recipient of the vaccine is also entitled to information on the name of the vaccine product to be used, the injecting equipment and the safety of the vaccine storage area as well as on which part of the body the vaccine will be injected. The essence is that informed consent is an important condition that must be fulfilled so that medical action in the form of vaccination does not become an act that can be categorized as unlawful. Besides, apart from that, there must also be an indication of an outbreak medically and carried out according to standard procedures in medical science.

Informed consent has been regulated in article 5 of the Indonesian medical code of ethics, namely that the actions or advice of doctors that have the potential to cause a decrease in physical or psychological endurance, must obtain the consent of the patient or his family. Informed Consent functions, among others, as evidence in the event of a legal dispute in the future, besides that it can also function as a tool for analysis and evaluation of the quality of services provided by doctors or

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<sup>1</sup> Freddy Tengker, *Patient Rights*, (Bandung: Mandar Maju, 2007), p. 54

<sup>2</sup> Danny Wiradharma and Dionisia Sri Hartati, *Lecture Guides for Medical Law*, (Jakarta: Sagung Seto, 2010), page 36

<sup>3</sup> Nurrobikha, F. G. *Ethics in Midwifery Services*. (Yogyakarta: Deepublish, 2015).

<sup>4</sup> Cocanour CS. *Informed Consent-It's more than a Signature on a Piece of Paper*. *The American Journal of Surgery*. 2017 Dec 1;214(6):993-7

<sup>5</sup> Danny Wiradharma, *Medical Law Lecture Guide*, (Jakarta: Binarupa Aksara, 1996), p. 53

hospitals.<sup>6</sup>The legal aspect, informed consent has also been regulated in Law No. 29 of 2004 concerning medical practice, where it is stated that doctors and dentists in every action must obtain patient consent.

In Article 2 of the Regulation of the Minister of Health Number 290/Menkes/Per/III/2008 concerning Informed Consent, it is also stated that medical actions against patients of any nature must obtain written or verbal approval from the patient. The consent is given after the patient knows the diagnosis, procedure, purpose of action, risks and complications of the procedure, and prognosis disease with or without action. Informed consent in therapeutic transactions is included in the realm of state administration. Therefore, the informed consent agreement is a state administrative document as written evidence of the patient's approval of medical action, for further approval of the patient the doctor performs the medical action.<sup>7</sup>

Technical provisions that specifically regulate informed consent in carrying out the covid 19 vaccination have also been stipulated as stipulated in the Decree of the Director General of Disease Prevention and Control No: Hk. According to Sukanto Koesnoe, one of the inclusion criteria is the participant receiving an explanation and signing an approval letter after the explanation is given (informed consent).<sup>8</sup>However, in reality, there are still complaints to health workers who carry out vaccinations, such as in the case of the death of the Brimob Company Commander (Danki) Battalion A Unit Brimob Polda Maluku on April 4, 2021, after being vaccinated.<sup>9</sup> Several parties then responded by asking questions about the effectiveness of the vaccine and even the protection of the rights of vaccinating participants according to Health law, including the right to informed consent.

Several previous studies on informed consent have been carried out by several researchers such as Afendra Eka Saputra, but the research is only related to theoretical studies regarding the support of legal protection aspects through informed consent in immunization programs in general, not specifically as in the covid 19 vaccination program.<sup>10</sup> Helena Primadianti Sulistyningrum also conducted research on informed consent, but it was aimed only at covid 19 patients, not to covid 19 vaccination participants<sup>11</sup>. Tri Aktariyani et al, her research was on legal protection for residents in providing services to patients with the covid 19 outbreak. This research was only about informed consent from the side of interests law for health workers.<sup>12</sup> Meanwhile, Achmad Busro researched about informed consent, but what was discussed was only the legal aspects in health services, without mentioning the covid 19 vaccination service.<sup>13</sup>Thus, no one has ever researched the fulfillment of the right to informed consent for covid 19 vaccination participants. Based on this, the research conducted by the author has an element of novelty and is very urgent to do This study aims to explain several facts, especially at the Dr Leimena Referral Hospital and the mass vaccination service facilities at Merdeka Square and at the Sport Hall of Bank Indonesia in Ambon regarding the implementation of the fulfillment of the right to informed consent for vaccination participants at the three service facilities locations. The research method used is

<sup>6</sup> Oktavia, D. "Incomplete Analysis of Informed Consent Sheet for Surgical Patients at Tk. III dr. Reksodiwiryo Padang". Indonesian Journal of Health Information Management (JMIKI), 8(1), 24. 2020

<sup>7</sup> Arman Anwar et al, Professional Ethics & Health Law, (Bandung: Widina, 2020), page 192

<sup>8</sup> Sukanto Koesnoe, "Technical Implementation of Covid Vaccines and Anticipating AEFI", PB PAPDI Adult Immunization Task Force, <https://www.papdi.or.id/pdfs/1001/Dr%20Sukanto%20-%20Ws%20Vaksin%20Covid%20KIPI>. pdf, (accessed August 6, 2021)

<sup>9</sup> Rahmat Rahman Patty, "Sitting Case, Brimob Commander Dies After Vaccine Injected, Positive for Covid-19 and Enters Hospital 2 Times" in <https://regional.kompas.com/read/2021/04/05/061204278/sit-perkara-komandan-brimob-died-after-injection-vaccine-positive-covid?page=all>. (Diakses August 5, 2021)

<sup>10</sup> Afendra Eka Saputra, "Legal Protection Based on Informed Consent for the Implementation of the Immunization Program", Journal of Legal Studies Rechtsregel Vol 1, No 2 December 2018, p 235

<sup>11</sup>Helena Primadianti Sulistyningrum, "Informed Consent: Approval of Medical Actions in Health Services for Covid-19 Patients", Simbur Cahaya Journal, 2021, page 166

<sup>12</sup> Tri Aktariyani et al, "Resident Legal Protection in Handling Covid-19 Patients in Indonesia", Indonesian Health Policy Journal: JKKI, Volume 09 No. 04 December 2020, page 225

<sup>13</sup> Achmad Busro, "Legal Aspects of Medical Action Consent (Inform Consent) in Health Services", Law & Justice Journal, Vol 1, No 1 (2018): November 2018, page 1

empirical/sociolegal law. The type of research is qualitative to photograph the actions of health workers in implementing informed consent procedures at Covid-19 vaccination health care facilities in Ambon City with the research stages, namely reviewing regulations and literature, field observations and interviewing related sources.

### **Research Methods**

This study will describe some facts, especially at the Dr Leimena Referral Hospital and the mass vaccination service facilities at Merdeka Square and at the Bank Indonesia Sport Hall in Ambon regarding the implementation of the fulfillment of the right to informed consent for vaccinating participants in the three locations of these service facilities. The research method used is empirical law/sociolegal. The type of research is qualitative to photograph the actions of health workers in implementing informed consent procedures in Covid-19 vaccination health service facilities in Ambon City with research stages namely regulatory and literature review, field observations and interviews with relevant sources.

### **Result and Discussions**

Ambon City is the capital city and at the same time the largest city in Maluku Province with an area of 377 km<sup>2</sup> or 2/5 of the area of Ambon Island and is bordered by Central Maluku Regency. The total population in September 2020 was 347,288 people.<sup>14</sup>

Since the COVID-19 pandemic occurred, many Ambon City residents have been confirmed positive for COVID-19 with fluctuating numbers. A significant spike in the increase in COVID-19 cases began to occur in the last three months of 2021, namely in July. d. August 2021. The number of confirmed positive cases was recorded on August 8, as many as 2,439, adding to the number of confirmed cases, the total number of positive cases reaching 8,665 and 154 deaths, with the following details:

**Table 1. Recapitulation of the Development of Covid 19 Cases in Ambon City, August 8, 2021**

	2.439	0	2.439	
Covid in Ambon	(Suspect and Positive)	Suspect	Positive confirmation	
Positive Confirmation Case	8.665	2.439	6.072	154
	Total Positif care	Taking care	recover	Died

Source: Ambon City Covid 19 Acceleration Handling Task Force, 2021

Anticipating the spread of the covid 19 outbreak, the Ambon City Government has taken anticipatory steps, including starting by forming a Task Force for the Acceleration of Handling Covid 19 based on Presidential Decree No. 7 of 2020, and Mayor Regulation No. 25 of 2020 concerning the application of discipline and law enforcement of Health protocols. The Mayor has also issued a Circular Number 443/04/SE/2020 regarding the anticipation of the spread of covid 19 by detecting and collecting data on residents traveling from areas affected by Covid 19 and increasing vigilance by urging residents to strictly implement the Health protocol. This was followed by Circular Letter No. 3 of 2021 to extend

<sup>14</sup> BPS Ambon City, Ambon City in Figures 2021, page 6

the period of application of the Micro PPKM. In addition to circulars, the Mayor of Ambon has also issued Instruction No. 2 of 2021 concerning Micro PPKM at the sub-district level to the Neighborhood Association (RT). Then the validity period was extended by Instruction No. 6 of 2021 concerning PPKM Micro level 3 until August 8, 2021.

Head of Ambon City Office, dr. Wendy Pelupessy said that one of the prevention efforts from the increasing number of confirmed cases of covid 19 was to improve health protocols and vaccinations<sup>15</sup>. Therefore, vaccinations in Ambon City were carried out by involving the Maluku Police, Pattimura Military Command XVI, Ambon Lantamal IX, and Pattimura Air Base Ambon as well as SOEs such as banks and Bank Indonesia and the Maluku Financial Services Authority (OJK). Meanwhile, several places that are used as mass vaccination health service centers include Dr. RSUP. J. Leimena, Tribun Merdeka Ambon and Sport Hall Bank Indonesia and others.

### 1. Fulfillment of Hak atas Informed Consent at the Government General Hospital (RSUP) Dr. J. Leimena

Dr. J. Leimena Hospital was built by the Central Government located in Ambon City where one of the considerations is to facilitate access and reach of health services to communities in Eastern Indonesia.

Stipulated by Regulation of the Minister of Health of the Republic of Indonesia No. 34 of 2019 and an Operational Permit from the Governor of Maluku Number 01/DPMTSP/RS-B/2019 as the legal basis for the Dr. Central General Hospital. Leimena with accreditation as a Class B Hospital. Its service facilities consist of 5 polyclinics, namely the Pediatrics, Nerve, Eye, Heart, and Dental Clinic, equipped with 149 beds, RSUP Dr. J. Leimena is classified as having complete medical and health personnel, including the following:

**Table 2. Number of Medical and Health Workers at RSUP Dr. J. Leimena**

Medical personnel		Health workers			
Internal Medicine Specialist	Pediatrician	Docter	Dentist	Nurses	Health analysis
2	1	5	1	28	4

Source: RSUP Dr. J. Leimena, 2021

Since May 2020, RSUP Dr. J. Leimen has served COVID-19 patients. It is recorded that it has served 120 COVID-19 patients and 7 inpatients. RSUP Dr. J. Leimena on October 26, 2020, a simulation of the COVID-19 vaccine has also been carried out.<sup>16</sup>

According to the Public Relations of Dr. J. Leimena Hospital, the implementation of mass vaccination uses standard operating procedures (SOPs) and competency standards in accordance with Minister of Health Regulation No: 10 of 2021. Prior to vaccination, vaccination participants were first recorded for validation. For vaccination participants who have been validated, they will then go through a screening stage, namely to take anamnesis and check blood pressure. Then the doctor will provide an explanation related to the benefits of the vaccine and its side effects. After being vaccinated, participants

<sup>15</sup> Raudha Autana, High Confirmed Case, Ambon Threatened to Enter the Red Zone in <https://rri.co.id/ambon/1240-kesehatan/1094478/cases-confirmed-tinggi-amb-on-terancam-enter-zonamerah>, (accessed August 8, 2021)

<sup>16</sup> Widyawati, (Bureau of Communication and Community Services, Ministry of Health, Republic of Indonesia). Staff of Minister of Health Review Readiness of J Leimena Hospital and Covid-19 Vaccine Simulation, in <https://rsupleimena.co.id/article/article-detail/25>, (accessed August 8, 2021)

were given painkillers and fever to be taken home as a form of anticipation if there were post-vaccination side effects. Before the participants go home, the last step is to observe the vaccination participants for 30 minutes. If the participant is in good health and does not show any follow-up symptoms after the vaccination, they will be allowed to go home with a vaccine card given. During this process, there were no rejections or complaints from vaccinating participants.

If the anamnesis results are found that the participant has a history of severe disease such as heart disease, kidney disease, chronic gastritis and so on, so that it does not match the criteria as a participant who can be vaccinated, the vaccination will not be carried out even though the participant is willing to be vaccinated.

Generally, vaccination participants at Dr. J. Leimena came with his own will and consciousness without any coercion so that the process of requesting approval for medical treatment was not too formal. So that no significant obstacles were found.

Many of the vaccination participants were persuasive and cooperative during the vaccination, both stage 1 and stage 2. Even impressed very interactive with doctors and other health workers. Participants asked various questions about the prevention and impact of post-vaccination. The doctor was alert by providing explanations regarding certain types of drugs and herbal plants that can be consumed by the public. All questions submitted are answered by a doctor or health worker in a good and clear manner.

Nelvia Novita as one of the vaccination participants gave her appreciation because she was satisfied with the services of Dr. RSUP. J. Leimena who is friendly and highly respects the rights of participants for informed consent.<sup>17</sup>

## **2. Fulfillment of the Hak atas of Informed Consent at the Mass Vaccination Service at the Merdeka Square Tribune**

The Ambon Merdeka Field Tribune is one of the most visited mass vaccination services for the public. The number of people who have been vaccinated has reached 2,232 people. The high public interest means that there is a National Vaccination Assault program with a target of 1 million people per day according to the President's instructions to the TNI and Polri.<sup>18</sup>

Due to the crowd's enthusiasm, the vaccination service was temporarily suspended because there were health workers who were exposed to covid 19. The new vaccination service was resumed on June 24, 2021. However, it was only devoted to the second stage of the vaccination service. A.G Latuheru (Sekda of Ambon City) said that for the second stage of the vaccination, a stock of 1,000 vials of the vaccine has been provided, but the public is also advised to continue to comply with the PPKM provisions.<sup>19</sup>

Based on the monitoring, it can be seen that doctors and health workers have tried to apply the informed consent procedure to the maximum, but considering the blocked number of participants who come to be vaccinated causes doctors to have relatively little time to be able to provide explanations about vaccines. Likewise, the request for consent from participants to be vaccinated does not seem to be needed formally considering it is the participants themselves who hope to be vaccinated as soon as possible. The

<sup>17</sup> Interview with Nelvia Novita, June 23, 2021, at 15 WIT, where RSUP Dr. J. Leimena.

<sup>18</sup> Rahman Patty, "Our Vaccine Target in Ambon is 1,000 but those who participated on the first day are more than 2,000", <https://regional.kompas.com/read/2021/06/27/094953778/target-vaksin-kita-di-ambon-1000-but-who-follows-on-first-day-over?page=all>, (accessed August 8, 2021)

<sup>19</sup> Alvian, "Vaccination at Merdeka Square Starts Again, Only for Second Injection", <https://terasmaluku.com/vaccination-in-the-field-independence-start-again-only-for-second-injection/>, (accessed August 8, 2021)

impression of being rushed can also be seen from the lack of intense communication between participants and health workers.

Incomplete data entry on the vaccination card by a health worker who forgot to include the doctor's identity and contact number is evidence of this hasty impression.

All participants from the beginning came with their own will to be vaccinated so that the approval process for informed consent was no longer carried out formally. Nodding the head and giving the arm to be vaccinated have become common signs of agreeing to be vaccinated. According to Candra Istiningsih Dwi Wahyuni et al, that a nod of the head can be interpreted as a statement of approval, unless it is considered doubtful, the doctor can ask for written approval.<sup>20</sup>

The inconvenience factor for vaccinating participants was seen when some Muslim participants who wore hijabs seemed reluctant and showed an attitude of being forced to open their sleeves to be injected with vaccines while they were in an open public space so that this relatively did not guarantee their privacy rights.

### **3. Fulfillment of the Right to Informed Consent in Mass Vaccination Services Located at the Sport Hall of Bank Indonesia**

The implementation of the mass vaccination at the Sport Hall of Bank Indonesia on August 6-7, 2021, was carried out thanks to a collaboration between the Communication Forum for Regional Financial Services Institutions (FKLJKD) and the Regional Banking Consultative Body (BMPD) coordinated by the Maluku Province Financial Services Authority (OJK) and the Bank Indonesia Representative Office (BI) in Maluku and in collaboration with the Ambon City Health Office.

The target of the mass vaccination target is to employees of financial services institutions and their families and customers, including across the banking and multi-industry in Ambon, which is 1,433 people. The total vaccine prepared was 1,600 doses of vaccine. The rest is channeled in similar activities to other districts/cities in Maluku.

The aim is to increase and encourage vaccination for financial services sector players in Ambon so as to accelerate herd immunity. In this way, it is hoped that mobility and community interaction can recover quickly and the economic growth of the community can move up.

Roni Nazra (Head of OJK Maluku Province) said that his party was committed to supporting the government's mass vaccination program because he believed that mass vaccination was one of the keys to suppressing the spread of COVID-19 and bringing the economy back to normal. Therefore, the said activity carries the theme of maintaining the stability of the financial sector and encouraging the recovery of the national economy.

The mass vaccination received appreciation from Sadli Lie (Plt Sekda Maluku) who officially opened the said activity. According to him, the mass vaccination activity that has been carried out has helped the Maluku regional government, especially in its implementation, it still prioritizes health protocols.<sup>21</sup>

Arnezul Achmad Satriawan as one of the vaccination participants also gave the same appreciation to the organizers of mass vaccination activities because they have arranged for their orderly implementation, starting from collecting data and scheduling vaccinations until their implementation so

<sup>20</sup> Candra Istiningsih Dwi Wahyuni et al, (2020), "Informed Consent in Health Services: How Are the Patients' Rights Protected?" *Journal of Law & Legal Reform*, Volume 1(4) pp 598

<sup>21</sup> Sadli Lie (Plt Sekda Maluku), Address at the Opening Ceremony of Mass Vaccination in the Financial Services Sector August 6, 2021.

that participants who come do not have to queue for a long time to be served by health workers. Likewise, when the vaccine will be injected, the doctor will give an explanation first and then vaccinate. After all, his willingness to be vaccinated (informed consent) was a wish of his own so it did not become something that had to be done formally.<sup>22</sup>

Arnedi Rizki Adidharma is a 15 year old vaccination participant, one of the underage participants who came accompanied by his parents. Before being vaccinated, the parents were asked for their consent for medical treatment in the form of vaccinating their child. After being given an explanation by the doctor, the parents gave their consent verbally.<sup>23</sup>

Parental consent for children who are under 18 or have never been married is an absolute requirement that must be met before medical action is taken by a doctor. This provision is regulated in the Law on Medical Practice No. 29 of 2004 and Regulation of the Minister of Health No. 290/Menkes/PER/III/2008 concerning Approval of Medical Actions. This shows that the fulfillment of the right to informed consent for minors has been fulfilled by doctors.

In addition to the right to informed consent, the rights of privacy for Muslim women who wear the hijab are also fulfilled by the organizers of mass vaccination activities by providing a special room for Muslim women in hijab which is separate from the public space so that vaccinations carried out in addition to observing health protocols also pay attention to the privacy rights of vaccinated participants who are Muslim.

## **Conclusion**

The right to informed consent for vaccination participants at three mass vaccination health service locations, namely at Dr. RSUP. J. Leimena, Merdeka Square and Sport Hall of Bank Indonesia have been fully occupied by doctors and health workers. An important element of informed consent in the form of an explanation of the history, procedures, goals of action, and the risks and complications of the action has also been optimally sought by doctors and health workers. Likewise, vaccination participants have also given their consent response to medical actions in the form of a willingness to be vaccinated which is carried out verbally and impliedly. However, there are still some technical weaknesses in the implementation of informed consent, especially at the location of mass vaccination services in the Merdeka field, namely the identity data of doctors in vaccination cards that have not been well documented, the communication is less informative, and the time used is relatively small and the comfort and safety factors for health workers are still less guaranteed from the effects of vaccination for COVID-19 exposure and hijacking.

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<sup>22</sup> Interview with Arnezul Achmad Satriawan, August 7, 2021, 10 am, at the sports hall of Bank Indonesia.

<sup>23</sup> Interview with Nelvia Novita, August 7, 2021, at 11 am, at the Sport Hall of Bank Indonesia



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