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Legal Protection for the Implementation of Immunization in Post-Immunization Adverse Incidents

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ABSTRACT – Immunization has been proven to be effective in reducing morbidity, disability and death. The government requires the public to undergo immunization, and regulations regarding rights and obligations in administering immunization have been regulated in Minister of Health Regulation Number 42 of 2013. Even though this regulation already exists, challenges arise, especially when Post-Immunization Adverse Events (AEFI) occur, which can haunt Immunization Implementers in carry out his duties. This study intends to explore legal protection and policies for Immunization Implementers based on these regulations in Indonesia. This study method uses a qualitative approach with a focus on normative juridical analysis. The results of the study show that the legal instruments for implementing immunization are adequate, but a lack of understanding of the law often raises concerns about the risk of Adverse Events Post-Immunization.

Keywords: right to access health services, legal protection, disability, health facilities, post-immunization, immunizations, health law.

A. INTRODUCTION

Early childhood is a golden period for a child, where his sensitivity to various stimuli begins to develop. Every child has a different level of sensitivity, according to their uniqueness and growth. Children's development during this period becomes an important foundation for their future lives, preparing them to face technological developments and changing times. Most abilities, both academic and non-academic, develop rapidly during childhood. Good attention to children's development during this period is an important key for parents, health workers and the government. This can be an important reference and note in prioritizing children's health before entering the curative period, so as to reduce morbidity and mortality rates in children.

Children have a higher risk of contracting infectious diseases because their immune systems are not yet perfect (Rytter et al., 2014). Currently, some germs around us are becoming increasingly resistant and difficult to treat. A very important prevention effort is providing vaccinations in accordance with government guidelines and health regulations.

Health is the main guard in starting daily activities and contributing to the development of a country. Health Services support the actions and efforts carried out by health workers with the aim of caring for, improving and restoring health (Newbrander et al., 2011; Darmawan et al., 2022; Khayru & Issalillah, 2022). Healthy children play an important role in forming intelligent and productive human resources who have the potential to compete in the business economy or health development. Prevention is better than cure, especially when it comes to children's health, because this creates a generation that has aspirations and makes positive contributions to the nation. A person is considered healthy when he can carry out normal activities without being disturbed physically or psychologically and creates productivity both for himself and his environment.

Law Number 17 of 2023 concerning Health confirms the right of every child to receive basic immunizations to prevent diseases that can be avoided through vaccination. Immunization aims to make a person immune to disease by stimulating the body's immune system through administering vaccines. By forming antibodies through immunization, children can reduce the risk of serious complications and even death if they are exposed to preventable diseases (Harmon & Faour, 2021). Adherence to the vaccination schedule is very important to ensure that children receive maximum protection according to their age. Vaccination is not only to reduce morbidity and mortality among children under five, but also has a

strategic role in national development and the nation's health economy. Ignoring vaccinations can result in reduced immunity in children, increase susceptibility to infectious diseases, and ultimately lead to the risk of death.

Based on the opinion of Cheng et al. (2015), in the implementation of immunization, there are Post-Immunization Adverse Events (AEFI) which consist of various effects, such as vaccine effects, toxicity side effects, sensitivity reactions, pharmacological effects, or program errors. Medical cases related to immunization and can harm the patient. This condition is a serious concern in the practices of health workers who provide immunization services.

The emergence of these cases shows an increase in legal awareness in society, which has resulted in demands for the right to damages due to alleged human error in carrying out duties (Iskander et al., 2004). Post-Immunization Adverse Events Patients are often supported by legal institutions, NGOs, or institutions that consider malpractice. Immunization officers often do not fully understand their legal rights and obligations, so they feel anxious about criminal threats and demands for compensation that may be imposed on them. There is a need for legal outreach and outreach efforts to health workers to overcome the uncertainty and fear that may arise.

Based on the Regulation of the Minister of Health of the Republic Number 42 of 2013 concerning the Implementation of Immunization, especially chapter V which regulates the Monitoring and Management of AEFI, every immunization implementer is required to carry out their duties in accordance with the applicable Implementation Guidelines. If a AEFI case occurs, the handling will be carried out by the AEFI Working Group at the district/city level, and the results will be reported to the Regional Committee for Post-Immunization Adverse Events at the provincial level for further explanation. For this reason, the concerns of immunization officers in carrying out their duties should be unfounded, because they are protected by law. However, it should be noted that problems often occur because some immunization officers do not keep post-mortem records in all their work, which can become a polemic and increase the risk of lawsuits. The government needs to pay special attention to ensuring that the implementation of operational guidelines has the force of law so that immunization implementers can carry out their duties with confidence and without excessive worry.

The operational guidelines, as the legal basis for immunization officers, are key in carrying out their duties. However, problems arise when some immunization officers do not make post-mortem records every time, they carry out work. This often becomes a point of dispute and lawsuits, considered a mistake in implementing operational guidelines. Post-mortem records have an important role as evidence and documentation that supports the implementation of immunization. Therefore, it is important for immunization officers to comply with the procedures and procedures described in the Juklak, including making post-mortem records as an integral part of their responsibilities (Malewezi et al., 2016).

Immunization is effective in reducing morbidity and mortality rates, every medical procedure has the potential for AEFI. In this case, legal protection for Immunization Implementers based on Law no. 42 of 2013 concerning immunization when post-immunization adverse events occur that are detrimental to the patient. For this reason, this study examines the legal responsibility of Immunization Implementers for patient losses in AEFI.

B. METHOD

This study is a normative juridical study which aims to find solutions to legal issues that arise in the legal protection of immunization implementation related to Post-Immunization Adverse Events (AEFI). The study approach uses a statutory approach to examine regulations and laws related to the legal issue being handled. The conceptual approach is also used with reference to views and doctrines in legal science. Sources of legal material used include related laws and regulations, such as Minister of Health Regulation Number 42 of 2013 concerning the Implementation of Immunization, as well as Law Number 17 of 2023 concerning Health. Apart from that, library literature such as books, papers and journals are also a source of secondary legal materials that are relevant for this study.

C. RESULTS AND DISCUSSION

Legal Protection for Immunization Implementers in Cases of Post-Immunization Adverse Events (AEFI)

Implementation of immunization is a very important activity in efforts to prevent the spread of infectious diseases (Quach et al., 2013). However, behind the benefits, there are

potential risks that can arise in the form of post-immunization adverse events. One of the concerns for immunization implementers is the possibility of legal action or compensation from the patient's family if there are post-immunization adverse events that result in serious impacts (Tanjaya et al., 2022). The value of the claims submitted can reach tens to hundreds of millions of rupiah, which is quite a fantastic amount for immunization implementers. In this situation, immunization implementers feel very limited in facing possible legal consequences. Surrendering to the Health Service is the last option, but often the Health Service itself does not have an adequate solution. As a result, immunization implementers and the Health Service were forced to negotiate peacefully with the patient's family so as not to take this matter to court. The negotiation process consists of various factors, such as medical explanations, policy considerations, and financial compensation.

In many cases, immunization implementers feel forced to assist in disbursing peace money as a form of settlement outside of court. This can be a financial burden for immunization implementers who are in a less favourable economic position. This difficulty creates a dilemma for immunization implementers, where they must find a balance between professional responsibility and legal uncertainty that may arise due to Post-Immunization Adverse Events. As time goes by, it is hoped that there will be improvements in the system for handling Post-Immunization Adverse Events and legal protection for immunization implementers to ensure the sustainability of the immunization program.

Patients who experience AEFI are actually still in the suspected category, as regulated in the Minister of Health Regulation (Permenkes) Number 42 of 2013 concerning the implementation of immunizations. In the Minister of Health regulations, in Chapter V it is explained that reports of suspected Adverse Events Post-Immunization will be handled by various institutions, including the Central National Commission for PP AEFI, the Provincial AEFI Komda, and the Regency/Municipal AEFI Working Group. This process is tiered and involves investigations to determine whether the Post-Immunization Adverse Event is truly the result of immunization or caused by other factors. This investigation stage involves various parties who have authority and power in assessing AEFI cases. Komnas PP AEFI Pusat, as the central institution, has an important role in coordinating investigations and assessing the case as a whole. Meanwhile, the Provincial AEFI Regional Commission and the Regency/City AEFI Working Group will be involved in the investigation.

The investigation process aims to determine whether Post-Immunization Adverse Events are truly related to immunization or whether there are other causes that are triggering factors. This approach is in line with efforts to ensure the safety and efficacy of immunization programs. The results of this investigation will be the basis for taking further steps, including preventive measures for similar cases in the future. It should be remembered that during the investigation process, the patient and his family remain in the status of suspected Post-Immunization Adverse Event. In many cases, the results of this investigation can reduce concerns and clarify whether Post-Immunization Adverse Events are truly related to immunization or not.

Immunization implementers should not need to worry too much if they have carried out immunization procedures in accordance with applicable standards and guidelines. The results of the investigation carried out by Komda AEFI will be an important basis for determining whether the alleged AEFI is proven to be the result of error or negligence by the immunization implementer or caused by other medical factors. If the results of the investigation state that the AEFI case was not caused by immunization causality, but by other medical factors, this should provide relief for immunization implementers. However, it is true that sometimes the patient or his family are not satisfied with the results and still want to pursue legal action. In this case, the patient's right to request a court is still recognized. Patients have the right to seek justice and provide an explanation from their perspective. The court process will be a forum where a variety of evidence and medical opinions can be presented to clarify responsibility and cause of the incident.

With strong evidence from the results of investigations carried out by Komda AEFI, and reported to the Minister of Health through Komnas AEFI, immunization implementers do have a strong legal basis. This factor will be important in proving that the immunization has been carried out in accordance with established standards and procedures, and that the AEFI

that occurred was not caused by negligence or error by the immunization implementer. The involvement of certified and legally protected medical professionals can provide additional legitimacy to the results of the investigation. During the legal process, documentation and evidence obtained from Komda AEFI investigations can become a strong basis for defending immunization implementers.

In addition, the re-investigation process carried out by the court will most likely refer to the same standards of Implementation Guidelines (Juklak) and Technical Instructions (Juknis) as used in the initial investigation. If there are no cover-ups or lies in the investigation report, it is likely that the results of a re-investigation by the court will confirm compliance with the initial findings. However, in the legal system, the final outcome cannot always be predicted. Therefore, maintain good communication with the Health Service, follow the legal process carefully, and ensure all relevant evidence and documentation is available for defense.

In dealing with legal issues related to the implementation of immunization, legal evidence plays an important role. Documentation of vaccine receipt, cold chain control, and patient medical records are important authentic evidence. Immunization implementers need to have documents showing that the vaccine was received in good condition, the cold chain is maintained, and the patient meets the requirements to receive the vaccine. In addition, documentation of immunization implementation according to regulations, including vaccine administration forms and certification of immunization implementers, can be supporting evidence. However, the immunization implementer's honest answers can also be used as valid evidence.

In the need for legal evidence that strengthens the professionalism of immunization implementers, the process of taking the vaccine becomes important. To ensure that this transaction complies with established rules, several steps can be taken as follows:

a. Immunization providers need to document the vaccine taking process completely and accurately. This consists of records about the vaccine storage temperature, packaging conditions, and clear proof of receipt. This documentation must be obtained from the vaccine storage manager and archived.
b. Verification of vaccine collection transactions can involve related parties in the vaccine distribution chain, such as storage officers and parties providing the vaccine. Documentation from the vaccine storage manager, including stock condition reports and approval for delivery, can be additional evidence.
c. The use of verified technology and monitoring tools can increase the validity of legal evidence. Automatic temperature recording at the time of vaccine collection and the use of electronic vaccine tracking systems can provide stronger, more easily verifiable evidence.
d. Including witnesses who can provide testimony about the process of taking the vaccine and its conditions can add evidence of thorough preparation.

By comprehensively documenting every step in the vaccine taking process, immunization implementers can have strong and valid legal evidence in dealing with cases of unexpected problems. This step is to protect their professionalism and ensure that immunization is carried out in accordance with established standards and in safe conditions.

The cold chain equipment factor for vaccine transportation is important and needs to be confirmed through legal evidence. Ensuring that the temperature and packaging of the vaccine remains in good condition during the journey to the immunization site can prevent the possibility of AEFI risks. Several steps that can be taken to strengthen legal evidence regarding vaccine transportation include:

a. Immunization implementers need to document the condition of cold chain equipment, including temperature records during transportation. This may consist of the use of automatic temperature monitoring devices that can keep records.
b. Involve related parties, such as the Head of Neighborhood Units or Cadres, to verify the condition of the vaccine upon arrival at the immunization site. Documentation from them as witnesses or temperature checkers can be additional evidence.
c. Providing written informed consent can be strong evidence that the patient has been informed and agrees to the immunization procedure that will be carried out.

Producing authentic evidence regarding vaccine administration procedures can be a strong layer of defense for immunization implementers. If all steps in the immunization process are documented accurately and in accordance with

applicable regulations, the possibility of errors or negligence by immunizers can be minimized. In AEFI, evidence stating that the vaccine was taken and given according to standards can provide legal protection for immunization implementers.

In addition, it is important to realize that although vaccines have been declared safe and have great benefits, it cannot be ignored that every medical product, including vaccines, has the potential to cause side effects. The involvement of immunization implementers in ensuring that vaccines taken from vaccine storage warehouses meet standards and are properly controlled to the vaccine administration site is a critical step. Documentation stating that the vaccine is in good condition and verified by the authorities is the right step to ensure its quality.

Furthermore, showing patients that the vaccine is in good condition according to the standards set by the government can build trust and provide a sense of security to the community. With these steps, immunization implementers have strong evidence that their duties have been carried out in accordance with the regulations, and if an AEFI occurs, this evidence can indicate that the error may lie in other factors outside the immunization implementer's control, such as poor quality of the vaccine. previous management.

Legal Responsibilities of Immunization Implementers when AEFI Occur

The application of disciplinary penalties to immunization implementers who do not carry out services in accordance with Minister of Health Regulation Number 42 of 2013 is an important step in maintaining quality and compliance with immunization standards. Disciplinary punishment, such as correcting and educating incompetent immunization implementers, aims to improve their qualifications and knowledge. A sense of responsibility towards professional duties will encourage immunization implementers to comply with the provisions of penalties that have been determined, so as to improve the quality of immunization services. Thus, the application of disciplinary sanctions is not only a corrective action, but also a preventive measure to maintain the sustainability and security of the immunization program in accordance with applicable regulations.

Legal liability in immunization services involves accountability from both the immunization implementer as the service provider and the patient as the service recipient. The lawsuit can originate from two legal bases. Based on the concept of default (Contractual liability) regulated in Article 1239 of the Civil Code, where immunization implementers have a contractual obligation to provide immunization services in accordance with applicable standards. If there is a discrepancy or negligence in the implementation of services that causes harm to the patient, the immunization provider can be held liable in accordance with the contractual agreement. Second, a lawsuit can also be filed based on an unlawful act (onrechtmatige daad) as regulated in Article 1365 of the Civil Code. This refers to the actions of immunizers which can be considered as violations of the patient's legal rights, so that patients have the right to demand legal responsibility for losses arising from these actions (Asmawati et al., 2022). Thus, legal responsibility in immunization services consists of contractual obligations and provisions for unlawful acts as the basis for lawsuits that can be filed by both immunization providers and patients.

Patients' lawsuits against health workers are often caused by default in the implementation of immunization. Default can occur if the immunizer does not fulfilled the promised standards or actions, including careless actions, negligence, or violations of procedures. Patient lawsuits arise when the actions of immunizers do not meet expectations, have the potential to cause harm or negative impacts on patients, and become the basis for demanding legal liability and compensation.

In a lawsuit based on breach of contract, the patient must prove the existence of a therapeutic contract through medical records, approval for medical treatment, or a medical card. The second element, namely the error or negligence of the immunizer, must be proven by the fact that the action is not in accordance with the therapeutic agreement. The third proof, that the actions of immunizers have a causal relationship with patient losses, is needed to strengthen the claim for tort (Anthonie et al., 2023).

In cases of immunization consent disputes, the first step is to examine medical records and consent documentation to seek clarity. Second, verbal clarification can be carried out to further understand whether consent has been expressly given by the patient. Finally, if disputes persist, mediation or consultation with

legal experts or health authorities can be undertaken to reach a resolution that is fair and in accordance with health regulations.

In cases like this, judges tend to avoid placing the burden of proof on one party because it is difficult to obtain concrete evidence. The judge will try to find as much information as possible from the patient and explanations at trial to make a decision. If an order on the burden of proof is required, the judge will consider that the position of the immunizer is more advantageous, especially if there are complete medical records, unless there is doubt about the validity of the records.

In criminal law, the handling of AEFI must be seen as a consequence of errors that may be made by the immunization implementer. The principle of "no crime without error" emphasizes that to impose criminal sanctions, there must be evidence that the immunization implementer carried out actions that caused AEFI to occur. The crime here consists of responsibility for the actions of the immunization implementer which can be identified as negligence or errors in the immunization process. Criminal law stipulates that immunization implementers can be held criminally responsible for actions that can be considered violations of immunization procedures that result in post-immunization adverse events.

The right to consent, which in health law is known as informed consent, involves explanation and notification before administering medical procedures. This consent arises after the patient receives information about the medical action to be taken, the purpose of the action, and the possible effects or results that may occur. All information provided must be clear and understandable to the patient, so that the patient can consciously give consent to receive immunization.

In compensation regulated in Law Number 17 of 2023 concerning Health, consent and medical records have an important role. Claims for compensation that are carried out directly without going through criminal procedures often face obstacles in obtaining evidence, both by the patient and his family. The criminal process to prove culpa late is also not easy. In this case, consent and medical records are important in accordance with criminal evidence law, as regulated in Article 184 of the Criminal Code concerning Evidence. Medical records and consent can provide information about the implementation of immunizations for patients, whether they comply with professional standards or not. By examining consent, the judge can determine whether the immunizer can be blamed. Making medical health records not only reflects professionalism but is also key in the judicial process, both in the civil and criminal realms. This reflects the importance of immunization service standards and professional standards to assess whether errors have occurred by immunization implementers.

D. CONCLUSIONS

Based on the results of the study, it was concluded that legal protection for immunization implementers is regulated in Minister of Health Regulation number 42 of 2013 concerning Immunization Implementation. Lack of understanding of the laws and regulations for implementing immunization, as well as the legal implementation of these regulations, makes immunization implementers feel unprotected. In Post-Immunization Adverse Events (AEFI), immunization implementers are forced to suffer losses through "peaceful" negotiations, even if they have strong evidence that the fault was not theirs.

Legal responsibility for immunizers who cause harm to patients can be judged according to the level of error committed. Immunizers can be caught in three levels of punishment, namely administrative penalties, civil penalties and criminal penalties, which are determined through a court process by considering evidence from both parties.

The suggestion from this study is the importance of disseminating information on Minister of Health Regulation number 42 of 2013 to all Community Health Centres to ensure good understanding regarding the implementation of immunization in accordance with applicable regulations. The Health Service should also urge immunization implementers to keep records that are verified by authorized officials and always provide informed consent.

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