

Legal Review of Liability For Material Losses Resulting From Adverse Events Following Immunization (AEFI) in Non-Mandatory Immunizations

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Abstract

This research is motivated by the vulnerability of patients to material losses resulting from Adverse Events Following Immunization (AEFI), in circumstances where no automatic compensation scheme is available. This research aims to analyze hospital liability and legal protection for victims of AEFI. Employing a normative-empirical legal research method (socio-legal research) with statutory, conceptual, and case approaches, this research conducts observations at five healthcare facilities in the Bekasi region and analyzes relevant regulatory frameworks. The first part of the discussion demonstrates that, based on the principle of commutative justice and the doctrine of vicarious liability (Article 1367 of the Indonesian Civil Code), hospitals bear full responsibility for the negligence of their medical personnel; however, empirically, such liability is often reduced to mere administrative procedures. The second part of the discussion identifies defects in preventive legal protection, where healthcare facilities include exoneration clauses (disclaimers of liability) in informed consent forms that violate Article 18 of the Consumer Protection Law, as well as weaknesses in repressive legal protection, which is limited to patient referrals without the assumption of treatment costs. In conclusion, hospitals are obligated to provide restitution in integral, including full coverage of medical treatment costs for victims resulting from procedural errors. The author recommends that hospitals eliminate illegal standard clauses and establish healthcare cost guarantee schemes as a manifestation of product liability and professional responsibility.

Keywords: AEFI; optional immunization and hospital liability.

I. INTRODUCTION

Health is a human right and an element of well-being that must be realized in accordance with the ideals of the Indonesian nation (Ardiansah & Oktapani, 2020). In an effort to achieve the highest level of public health, immunization is one of the most cost-effective public health interventions in the world. Data from the World Health Organization (WHO) notes that immunization prevents 2 to 3 million deaths annually from infectious diseases. In Indonesia, public awareness of the importance of immunization shows a significant upward trend. While in the past, people relied solely on basic immunizations at Posyandu (Integrated Health Posts), currently there is a paradigm shift where the middle and upper classes are actively seeking additional health protection through optional immunizations (Widyakarya, 2025). Unlike mandatory immunizations (national programs), whose availability is guaranteed by the state, elective immunizations are entirely demand-based healthcare services. These services are provided based on the patient's awareness, preference, and willingness to pay. Because they are commercial in nature and not covered by the state, the legal relationship in elective immunizations shifts from public law to a civil relationship based on a therapeutic agreement between the patient and the healthcare facility (Ratman, 2021). In this context, the patient acts as a self-paying consumer of healthcare services, so their standards of responsibility follow general principles of medical practice and consumer protection. Despite its noble aims, immunization still carries the potential for medical risks in the form of Adverse Events Following Immunization (AEFI).

This risk triggers serious legal consequences when material losses occur, particularly with elective immunizations where there is no automatic compensation scheme from the state, unlike AEFI in program immunizations guaranteed by the government (Juanda, 2022). This legal issue is not merely a hypothesis but has become an empirical fact that is troubling the public, particularly in the Bekasi area, which serves as one

of the centers of private healthcare services supporting the capital. The urgency of consumer protection in private vaccination services (optional immunization) is clearly evident in the precedent-setting case at St. Elisabeth Hospital in Bekasi. This dispute not only resulted in a civil lawsuit demanding a total of Rp 50 billion in material and immaterial damages in the Bekasi District Court, but also established a precedent for dispute resolution through corporate liability. The hospital subsequently faced demonstrations and was pressured by the patient's family to agree to terms of liability, including demands for lifetime health insurance compensation and a refund of vaccination costs. The hospital subsequently agreed to these demands. Crucial points in the settlement include the hospital's obligation to provide full health coverage and health insurance for affected patients. Although the St. Elisabeth Hospital case started with the issue of vaccine authenticity, the core legal issue is very relevant to AEFI in selective immunization, namely adThere are only civil liability claims (material compensation) from patients against hospitals for losses arising from vaccination service transactions.

While in the case of counterfeit vaccines, losses arise from defective products, in cases of adverse events (AEFI) from elective immunizations, losses arise from the impact of the product or medical procedure (Setyawan & Purnamawati, 2023). The form of compensation, which includes health insurance and medical expense coverage, reflects the restoration of health care (*restitutio in integrum*) expected by healthcare consumers when paid medical services fail. From a civil law perspective, material losses experienced by patients due to Adverse Events (AEFI) in elective immunizations cannot be simply dismissed on the basis of medical risk alone. The construction of hospital liability can be constructed in layers, starting with Article 1365 of the Civil Code concerning Unlawful Acts (PMH) as the basis for the error, which is then extended to the corporate realm using Article 1367 of the Civil Code. Article 1367 adheres to the principle of vicarious liability, where the hospital is fully responsible for losses caused by healthcare workers working under its auspices. This means that if an AEFI arises due to procedural negligence—such as inaccurate initial screening, errors in the vaccine cold chain, or injection techniques—then the hospital is obliged to bear material compensation, without being able to shift this burden solely to the doctor personally. According to *lex specialis*, the patient's right to demanding compensation is expressly guaranteed in Article 327 of Law Number 17 of 2023 concerning Health, which states that every patient who is harmed due to the error or negligence of medical personnel has the right to request compensation.

This provision strongly overlaps with Article 19 paragraph (1) of Law Number 8 of 1999 concerning Consumer Protection, which requires business actors to provide compensation for damage or loss to consumers due to traded services. The position of patients in elective immunization is that of consumers who have the right to demand restoration of their condition if the service they purchased actually results in real economic losses, exceeding the limits of reasonable medical risks. A fundamental issue arises regarding the normative limits of hospital responsibility without necessarily escalating public disputes. Theoretically, a medical relationship is a contract of effort (*inspanningsverbintenis*). However, when patients who have paid high prices for elective immunizations suffer severe, costly adverse events (AEFI), they are often in a vulnerable position. Legal uncertainty arises in determining whether the AEFI is purely a medical risk that cannot be sued, or whether it is the result of negligence that requires compensation. Furthermore, proving the causality of an AEFI is often difficult if the impact is not immediately apparent (delayed reaction). This unclear line of responsibility underlies the urgency of a legal analysis of legal document practices, particularly Informed Consent forms and Standard Operating Procedures (SOPs) related to post-immunization complaint handling. This research focused on the Bekasi area, a location with a precedent of medical disputes related to immunizations using counterfeit vaccines.

Observations were conducted at private healthcare facilities representing different levels of service. Observations included MS Hospital, KB Hospital, DJ Clinic, DC Clinic, and BM Clinic. The urgency of this analysis is reinforced by the research's novelty. Although numerous legal studies have been conducted on compensation for the impacts of vaccination, the majority of the literature is limited to the context of COVID-19 vaccination or government immunization programs, where the state plays a dominant role. Conversely, literature specifically addressing elective immunization remains scarce. Yet, elective immunization has fundamentally different legal characteristics because it is based on a purely commercial

contractual relationship, not a state assignment. BerdBased on this background, the formulation of the research problem is divided into two, namely: (1) What is the responsibility of the hospital towards victims of KIPI in elective immunization? and (2) How is the protection of victims of KIPI (remembering that it is difficult to determine KIPI if the impact is not direct) for the losses they experience?

II. METHODS

1. Types of research

This research is a Normative-Empirical legal research or what is often classified as Socio-Legal Research (Fajar & Achmad, 2010). This method combines normative legal research that focuses on the inventory and study of norms, principles, and written legal rules, with empirical legal research that looks at how the law operates in the reality of community behavior (Soekanto, 2015). This approach is used to analyze the gap between statutory regulations (law in books) and the practice of law enforcement and medical responsibility that occurs in the field (law in action) (Waluyo, 2002). This type of research was chosen because the author not only examines the legal regulations (Health Law, Civil Code) textually, but also conducts field observations to observe the actual implementation of health facility responsibilities. The author will examine the correspondence between the legal regulations (*das sollen*) and actual practice (*das sein*), particularly regarding the Informed Consent form and the procedures for handling claims for compensation (KIPI) for elective immunizations in the Bekasi area.

2. Types of Approaches

To comprehensively address the research problem, this study utilizes several complementary legal research approaches. These include the legislative approach, the conceptual approach, and the case approach, each of which has a distinct yet integrated analytical function in explaining the responsibilities of healthcare facilities in medical procedures. A statutory approach was used to examine various legal provisions governing the responsibilities of healthcare facilities in administering medical procedures. The analysis focused on relevant legal norms, including Articles 1365 and 1367 of the Civil Code, which regulate unlawful acts and liability for the actions of others, Law Number 17 of 2023 concerning Health, and Law Number 8 of 1999 concerning Consumer Protection. Furthermore, this study also examined Minister of Health regulations relating to immunization and health services, as well as internal hospital regulations governing licensing for medical procedures and procedures for handling post-immunization adverse events (AEFI). Conceptual approachA conceptual approach is used to examine fundamental concepts in health law, such as informed consent, medical malpractice, negligence, and civil liability in health services.

This approach is based on the doctrines and views of experts, including Afandi's (2025) thoughts on the concept of informed consent and Philipus M. Hadjon's ideas on legal protection. Through this approach, the study seeks to understand how legal protection should be applied in elective immunization practices. Furthermore, a conceptual approach is also used to assess whether informed consent forms used in clinics or hospitals contain essential elements, such as an explanation of the benefits of medical procedures, the risks of adverse events (AEFI), available alternatives, and the limits of medical liability. A case-based approach was used to examine court decisions, reports of post-immunization adverse events, and malpractice cases related to vaccination or injections previously decided by courts in Indonesia. Through this approach, the study can understand the patterns of legal reasoning used by judges in assessing the causal relationship between medical procedures and resulting harm, the existence of negligence, and the form of responsibility imposed on hospitals or medical personnel.

3. Legal Materials

The primary legal materials used in this study include the 1945 Constitution of the Republic of Indonesia as the constitutional basis. The main laws and regulations analyzed in depth are Law Number 17 of 2023 concerning Health, which now serves as the sole legal umbrella for the responsibilities of hospitals and medical personnel, and Law Number 8 of 1999 concerning Consumer Protection to review the status of patients. Technical legal instruments are also specifically included, namely Government Regulation Number 47 of 2021 concerning the Implementation of the Hospital Sector, Minister of Health Regulation (PMK) Number 12 of 2017 concerning the Implementation of Immunization, PMK Number 24 of 2022 concerning

Medical Records, PMK Number 290/MENKES/PER/III/2008 concerning Approval of Medical Actions, and PMK Number 3 of 2020 concerning Hospital Classification and Licensing. In addition, this study refers to the Decree of the Minister of Health Number HK.01.07/MENKES/6424/2021 concerning vaccination techniques and the Guidelines for Post-Immunization Adverse Events (KIPI) Surveillance issued by the Ministry of Health and the National Committee for Post-Immunization Adverse Events (PP-KIPI).

The secondary legal materials used in this study include scientific journals on law and medicine that specifically examine the civil and criminal liability of hospitals, medical malpractice issues, and legal analyses of the risks of medical procedures such as AEFI. To strengthen the research's position and ensure originality, previous research findings, including undergraduate theses, dissertations, and research reports, were also used that are relevant to the legal liability of hospitals in high-risk medical procedures. Tertiary legal materials are used as supporting tools to provide guidance and clarification on terminology or concepts found in primary and secondary legal materials. These materials include the Indonesian Legal Dictionary and Black's Law Dictionary as international legal references, supplemented by the Great Indonesian Dictionary (KBBI) to ensure the accuracy of language definitions. Additionally, legal encyclopedias and professional codes of ethics, such as the Indonesian Medical Code of Ethics (KODEKI) and the Indonesian Hospital Code of Ethics (KODERSI), are utilized to provide additional normative perspectives. The integration of these three legal materials is expected to provide a comprehensive understanding of the limits of hospital responsibility in medical services.

4. Data collection technique

Data collection was conducted through literature review and field observations. The literature review was conducted by reviewing various laws and regulations, court decisions, academic journals, scientific books, and official documents related to elective immunization, informed consent, and hospital responsibilities. Furthermore, researchers conducted field observations by visiting several clinics and hospitals to gain a firsthand understanding of elective immunization procedures. Observations were conducted to observe how health facilities provide explanations to patients or parents prior to immunization, examine the format of the informed consent form used, and understand the handling process in the event of an adverse event (AEFI). These observations also helped illustrate how health facilities manage risks in paid immunization services. However, observations do not transform this research into an empirical one, as field data is used only as a complement to normative interpretation.

5. Data Analysis Techniques

All legal materials were analyzed qualitatively using descriptive, interpretive, and argumentative techniques. Descriptive analysis was used to describe legal provisions governing informed consent, medical service standards, and hospital responsibilities in the event of an Adverse Event (AEFI). Interpretive techniques were used to interpret the relationship between norms, health law doctrine, and selected immunization practices in the field. Furthermore, argumentative techniques were used to construct legal arguments regarding whether hospitals can be held responsible for AEFI, and under what conditions patients are entitled to compensation if proven negligence or malpractice occurred under the Medical Practice Law and the Health Law. The research focuses on two theoretical foundations. The first theoretical foundation is the theory of justice, which will be used to assess hospital liability. The second theoretical foundation is the theory of legal protection, which seeks to answer how victims of adverse event (AEFI) are protected, particularly in cases of alleged malpractice. Using these analytical techniques, the research is expected to provide a comprehensive overview of the legal aspects of hospital liability in providing elective immunization services, as well as legal protection for patients who experience material losses due to AEFI.

III. RESULT AND DISCUSSION

A. Responsibility Hospitals against KIPI Victims in Selected Immunizations

An analysis of hospital responsibility for victims of Post-Immunization Adverse Events (AEFI) in elective immunization services needs to be placed within the perspective of the Theory of Justice, specifically commutative and distributive justice. In the context of elective immunization, the relationship between patients and hospitals is contractual-transactional, where patients are positioned as consumers who

pay for services to obtain safe health services. Based on the principle of commutative justice, which emphasizes equality of performance and counter-performance, hospitals are obliged to provide the highest safety standards in return for the costs paid by patients (Notohamidjojo, 2011). If losses occur due to AEFI caused by negligence in the management of vaccines or medical procedures, then justice demands restoration of the situation (*restitutio in integrum*). This is in line with Law Number 8 of 1999 concerning Consumer Protection, which expressly stipulates that business actors are responsible for providing compensation for damage or loss experienced by consumers due to consuming goods and/or services produced or traded.

Therefore, from a fair perspective, it cannot be justified if the hospital releases its full risk responsibility to the patient through a standard clause, while the hospital enjoys economic benefits from the service (Nasution, 2015). Legally, hospital responsibility is not only attached to individual medical personnel, but also to the healthcare institution through the doctrine of Vicarious Liability or superior responsibility. This provision is stipulated in Article 1367 of the Civil Code (KUHPerdata), which states that a person is not only responsible for losses caused by their own actions, but also for losses caused by those they are dependent on or under their supervision. In the context of elective immunization in hospitals, if medical personnel (nurses or doctors) make errors in initial screening, injection, or cold chain management of vaccines that result in serious AEFI, then the hospital as the employer is obliged to be civilly responsible (Fuady, 2014). This is reinforced by Law Number 17 of 2023 concerning Health, which serves as the main legal umbrella, under which healthcare facilities are required to guarantee the safety, quality, and standards of service. Failure to implement standard operational procedures—as stipulated in the Minister of Health Regulation Number 12 of 2017 concerning the Implementation of Immunization—which results in harm to patients, absolutely shifts the burden of responsibility from the realm of pure medical risk to the realm of unlawful acts (Article 1365 of the Civil Code) (Isfandyarie, 2006).

However, empirical reviews (law in action) show a disparity between the norms of justice in the law and actual practice. Based on observations of the implementation of procedures in healthcare facilities, hospital responsibility is often reduced to administrative and procedural responsibilities, rather than material ones. Although Minister of Health Regulation Number 24 of 2022 concerning Medical Records and Minister of Health Regulation Number 290/MENKES/PER/III/2008 concerning Approval of Medical Actions require clear documentation, healthcare facilities often use informed consent to interpret Adverse Events (AEFI) solely as a biological risk to the patient that cannot be contested. However, according to the principle of distributive justice, the burden of risk must be distributed proportionally. It is unfair for patients to bear the physical and financial burden of an AEFI, while hospitals are exempt from the obligation to rehabilitate simply because administrative procedures have been followed (Rawls, 1999). Therefore, the hospital's responsibility should be interpreted broadly to include responsibility for the quality of facilities, infrastructure, human resource competency, and handling of any adverse effects that arise, in order to provide substantive legal protection for patients receiving elective immunizations.

The ideal form of responsibility that should be implemented by hospitals in cases of adverse events (AEFI) for elective immunization is comprehensive responsibility that includes medical recovery and rehabilitation of material losses (product and professional liability). Referring to Article 19 paragraphs (1) and (2) of the Consumer Protection Law in conjunction with Article 1365 of the Civil Code, hospitals may not only act as referral facilitators, but must also bear all medical expenses arising from AEFI until the patient recovers (Shofie, 2011). In this ideal legal construction, if AEFI is proven to occur due to a deviation from service quality standards (in accordance with Law No. 17 of 2023), then the hospital is obliged to provide compensation without burdening the patient with personal insurance or BPJS bureaucracy. This accountability model reflects the principle of *ubi commodum ibi incommodum*—where there is profit, there is responsibility, thus creating real justice between the rights and obligations of the hospital or clinic providing elective vaccination.

B. Protection of KIPI Victims for the Losses They Experience and Possible Malpractice Lawsuits

An analysis of legal protection for victims of Post-Immunization Adverse Events (AEFI) at selected immunization services in the Bekasi area was dissected using the analytical knife of Philipus M. Hadjon's

Legal Protection Theory, which dichotomizes legal protection into preventive and repressive means. Preventive legal protection in medical services aims to prevent disputes by providing clear limits of obligations and standards before actions are taken (Hadjon, 1987). Based on empirical observations at five health facilities, namely MS Hospital, KB Hospital, DJ Clinic, DC Clinic, and BM Clinic, it turns out that clinical preventive efforts have been implemented through screening procedures, specialist doctor consultations, and pre-action observations to minimize risks. However, there is a fundamental legal flaw in the preventive protection instrument in the form of an Informed Consent document. The findings show that all five facilities include an exoneration clause that requires patients to waive the right to sue if adverse effects occur after immunization. This practice strictly violates Article 18 paragraph (1) letter a of Law Number 8 of 1999 concerning Consumer Protection, which prohibits business actors from including standard clauses that transfer responsibility. From a legal perspective, this clause is null and void and has no binding force, so that the function of informed consent as a means of risk education and medical approval is reduced to a unilateral effort by the hospital to avoid legal liability (Guwandi, 2005).

Furthermore, according to Hadjon, repressive legal protection functions to resolve disputes and restore victims' rights if losses have occurred (Hadjon, 1987). In reality, the form of repressive protection provided by health facilities in Bekasi is still very limited and administrative-procedural in nature, namely limited to minor medical treatment or referrals to higher-level hospitals without any cost coverage. This practice of "washing hands" after providing a referral contradicts the legal construction of Law Number 17 of 2023 concerning Health. This law implicitly stipulates that health care facilities are responsible for losses suffered by patients due to the negligence of their medical personnel. When an Adverse Event (AEFI) occurs not due to pure anaphylaxis (an unexpected allergic reaction), but rather due to procedural errors—such as poor vaccine storage (cold chain failure) or incorrect dosage—then the pretext of "medical risk" is dropped and turns into malpractice (Komalawati, 2002). The absence of a material compensation scheme from clinics or hospitals forces patients to bear the burden of recovery costs through personal insurance or BPJS, which violates the sense of justice and the principle of product liability in paid healthcare services.

Regarding the possibility of malpractice lawsuits, victims of Adverse Events Following Optional Immunization (AEFI) have strong legal standing to file a civil lawsuit based on Unlawful Acts (PMH) as stipulated in Article 1365 of the Civil Code. Although proving causality in AEFI cases is often complicated due to the sometimes delayed onset of reactions, victims can use medical records and medical audits as indicative evidence. The element of "fault" (*schuld*) in Article 1365 is fulfilled if the medical personnel is proven to have violated professional standards or standard operating procedures mandated by Law No. 17 of 2023. In addition to suing medical personnel individually, victims can also sue hospitals or clinics as defendants under Article 1367 of the Civil Code, which adheres to the doctrine of Vicarious Liability. This article emphasizes that employers (hospitals) are responsible for losses incurred by their subordinates (medical personnel) within the scope of their employment. Thus, even though health facilities attempt to hide behind standard clauses in informed consent, Indonesian positive law still provides a repressive path through civil lawsuits to demand compensation for material (medical costs and economic losses) and immaterial (pain and trauma) due to negligence in immunization services.

IV. CONCLUSION

The hospital's responsibility towards AEFI victims in elective immunization is normatively based on the principle of commutative justice and the doctrine of Vicarious Liability (Article 1367 of the Civil Code), where the hospital as the employer and service provider is fully responsible for losses due to negligence of medical personnel or failure of quality management. However, empirically, the implementation of this responsibility does not reflect justice due to the practice of transferring risk to patients through the inclusion of an exoneration clause in informed consent, which is contrary to Law Number 8 of 1999 concerning Consumer Protection. Therefore, the ideal form of accountability that must be implemented is not merely providing an administrative referral, but rather restoration of the condition (*restitutio in integrum*) in the form of covering all medical care costs and compensation for material losses in accordance with the principle of *ubi commodum ibi incommodum*. Legal protection for victims of KIPPI reviewed from the legal protection theory

of Philipus M. Hadjon shows legal flaws in preventive protection facilities and weaknesses in repressive facilities. Preventive protection through informed consent is considered null and void because it contains a clause on the transfer of responsibility which is prohibited by law, while the repressive protection currently available is limited to initial medical treatment without guarantee of further funding.

Nevertheless, victims of KIPi have a strong legal standing to take repressive legal action through a civil malpractice lawsuit based on Unlawful Acts (Article 1365 in conjunction with Article 1367 of the Civil Code), as long as it can be proven that there is an element of procedural error or violation of professional standards that causes the loss. To the manager Hospitals and healthcare facilities providing selected immunizations are advised to immediately revise their informed consent forms by removing the standard clause containing a release of liability (exoneration clause) as it is contrary to positive law in Indonesia. Hospitals need to establish progressive internal policies regarding the management of Adverse Events (AEFI), namely by providing a full cost guarantee scheme for patients who experience serious side effects due to medical procedures, as a form of implementing product and professional liability and maintaining consumer trust in the quality of healthcare services. The Health Department and related professional organizations are advised to increase monitoring and regular audits of medical legal documents used in private healthcare facilities to ensure there are no violations of consumer rights in consent documents. Furthermore, legal education is needed to educate the public about their rights as patients. Therefore, if disputes arise due to alleged medical negligence, they can pursue appropriate dispute resolution channels, either through complaints to the disciplinary panel or civil lawsuits, to ensure legal certainty and improve the quality of national healthcare services.

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